Requirements for Additional Traceability Records for Certain Foods Under the Food Safety Modernization Act (FSMA) Produce Rule

The Food and Drug Administration is proposing a new rule on produce traceability under FSMA. This new rule will impact most wholesale fruit and vegetable growers in New Jersey and some retail growers. There is a 120-day (until January 21, 2021) comment period to respond to the proposed rule. Take the time to review the rule and make comments, it will affect your operation, so your input is important!

What is in the Proposed Rule?

- Those who manufacture, process, pack, or hold a food on the FOOD TRACEBILITY LIST would be required to establish and maintain records associated with specific Critical Tracking Events (CTEs), including growing, receiving, transforming, creating, and shipping.
- For each CTE, entities would be required to establish and maintain records containing Key Data Elements (KDEs), such as the traceability lot code, the date the product was received, the date the product was shipped, and a product description.
- In addition, those subject to the rule would also be required to create and maintain records related to their internal traceability program.
- The proposed rule would require records to be maintained as either electronic, original paper records, or true copies.
- In addition, the proposal states that in the event of a foodborne illness outbreak, a product recall, or other threat to public health, the FDA could require that firms submit, within 24 hours, an electronic sortable spreadsheet containing relevant traceability information for specific foods and date ranges.

Following is the tentative list of foods for which additional traceability records would be required under the proposed rule

Tentative Food Traceability List

Food Traceability List	Description
Cheeses, other than hard cheeses	Includes all soft ripened or semi-soft cheeses, and fresh soft cheeses that are made with pasteurized or unpasteurized milk
Shell eggs	Shell egg means the egg of the domesticated chicken
Nut butter	Includes all types of tree nut and peanut butters; does not include soy or seed butters
Cucumbers	Includes all varieties of cucumbers
Herbs (fresh)	Includes all types of herbs, such as parsley, cilantro, basil
Leafy greens, including fresh-cut leafy greens	Includes all types of leafy greens, such as lettuce, (e.g., iceberg, leaf and Romaine lettuces), kale, chicory, watercress, chard, arugula, spinach, pak choi, sorrel, collards, and endive
Melons	Includes all types of melons, such as cantaloupe, honeydew, and watermelon
Peppers	Includes all varieties of peppers
Sprouts	Includes all varieties of sprouts
Tomatoes	Includes all varieties of tomatoes
Tropical tree fruits	Includes all types of tropical tree fruit, such as mango, papaya, mamey, guava, lychee, jackfruit, and starfruit
Fruits and Vegetables (fresh-cut)	Includes all types of fresh-cut fruits and vegetables

Finfish, including smoked finfish	Includes all finfish species, such as cod, haddock, Alaska pollack, tuna, mahi mahi, mackerel, grouper, barracuda, and salmon; except does not include siluriformes fish, such as catfish
Crustaceans	Includes all crustacean species, such as shrimp, crab, lobster, and crayfish
Mollusks, bivalves	Includes all species of bivalve mollusks, such as oysters, clams, and mussels; does not include scallop adductor muscle
Ready-to-eat deli salads	Includes all types of ready-to-eat deli salads, such as egg salad, potato salad, pasta salad, and seafood salad; does not include meat salads

Exemptions:

There are some exemptions (full or partial). Full exemptions include small retail food establishments, small farms (less than $25,000 in sales), farms selling food directly to consumers, certain food produced and packaged on a farm, food that receives certain types of processing and transporters of food. Partial exemptions would apply to certain commingled raw agricultural commodities (not including fruits and vegetables subject to the produce safety regulations), fishing vessels, retail food establishments that receive a listed food directly form a farm and farm to school and farm to institutions programs.

How to Submit a Comment:

SUMMARY: The Food and Drug Administration is proposing to establish additional traceability recordkeeping requirements for persons that manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The proposed rule would require these entities to establish and maintain records containing information on critical tracking events in the supply chain for these designated foods, such as growing, shipping, receiving, creating, and transforming the foods. The proposed requirements are intended to 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 proposed rule in accordance with the FDA Food Safety Modernization Act (FSMA).
Submit either electronic or written comments on the proposed rule by January 21, 2021.
The proposed rule was published in the Federal Register on September 23, 2020 (pages 59984-60038)

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 21, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions
Submit electronic comments in the following way: Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions
Submit written/paper submissions as follows:
Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-N-0053 for "Requirements for Additional Traceability Records for Certain Foods." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Virtual Meetings

The Food and Drug Administration is scheduling three day-long virtual meetings on its proposed rule to increase traceability requirements on fresh produce and other foods.

The enhanced requirements will be in a public comment period until Jan. 21.

The online seminars are:

- Nov. 6: 8:30 a.m. to 4:30 p.m. Eastern;
- Nov. 18: 9:30 a.m. to 5:30 p.m. Eastern; and
- Dec. 2: 11:30 a.m. to 7:30 p.m. Eastern.

Although they are all virtual meetings, space is limited and registration is required. More information and links to register for each meeting are on the FDA's website. The times are staggered to give people in different time zones the opportunity to comment, according to the FDA's notice on the meetings.