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Two Years to Comply with New Food Safety Rules: Get Started NOW

(Hint: There are a LOT of Requirements)

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Food producers and shippers can't say that the U.S. Food and Drug Administration didn't warn them.

Food Safety News has reported that the FDA will provide up to two years to comply with strict new Food Traceability rules, set to be published on November 7 in the *Federal Register.* The rules will apply to "high risk foods" such as fresh fruits and vegetables, ready-to-eat salads, and fish, as well as soft cheeses. The rules are being implemented to improve the impression and speed of a food recall in case of contamination of the food, thereby reducing the number of cases of food-borne illness. The rules will apply to those who manufacture, process, pack, transport or hold foods on the Food Traceability List.

The rule would become effective 60 days after it is published.

But why the long lead time? The answer is that because the new rules are so complex and the amount of data required so extensive, the FDA has proposed that total compliance for all entities that fall under the rule would be two years after the effective date of the final regulation. Among the new requirements: where the product was produced, a detailed description of the producer's coding system, who received the product from the producer, who transported it, where it was stored, how often it was shipped, and who received it, among other items. The new rules will greatly increase the amount of data required to be maintained on each product.

It might seem that two years for full compliance is an unusually long time. In my opinion, and—interestingly in FDA's opinion—it is not. The following is a quote from FDA's website: "Because an effective traceability system requires all entities in a supply chain to maintain traceability records, we believe all persons subject to the rule should come into compliance by the same date. We propose that the compliance date for all persons subject to the recordkeeping requirements would be 2 years after the effective date of the final regulation."

The new rules will greatly increase the amount of data required, called Key Data Elements or KEDs, to be maintained on each product. Below is a list of some of the KEDs that will be required in the traceability lot codes. In the spirit of brevity it is not close to the entire list.

- If you're a grower of fruits and vegetables, you must include the coordinates of the growing area
- If you're a producer of sprouts, a not-close-to-comprehensive list of what must be provided includes:
    - Location identifier and location description of the grower of seeds for sprouting, and the associated seed lot code assigned by the seed grower, and date of seed harvesting
    - Description of the seeds, including type or taxonomic name, growing specifications, volume, type of packaging, and antimicrobial treatment
    - Location identifier and location description of the seed packinghouse (including any re-packers), associated seed lot codes, and date of packing/repacking
- If you're a receiver of the food on the traceability list, again, not a comprehensive list of what must be provided includes:
    - Location identifier and location description for the immediate previous source (other than a transporter) of the food
    - Entry number assigned to the food (if imported)
    - Location identifier and location description of where the food was received, and the date and time the food was received
    - The quantity and unit of measure of the food (e.g., 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds)

There are similar requirements for shippers, transformers (cutting, cooking, commingling, repacking foods on the list), and creators (producing a food that is on the traceability list from ingredients that are not on the list, such as producers of soft cheese).

So, given the amount of data required and the intricacy with which the data has to be coordinated throughout the supply chain, my advice to our clients, and anyone who falls under the FDA's new Food Traceability rules: Get to work soon on figuring out these compliance complexities.

Two years might seem like a long time—but not when you're working with the Food and Drug Administration.

Mark Newbold is a chemist and former head cheesemaker at an award-winning artisanal creamery in Upstate New York, where he developed new goat milk products, maintained food quality and safety plans for all manufacturing operations, and supervised all production, packaging, and shipping efforts. He previously served as a research support specialist for the Department of Food Science at Cornell University. Active at the Northeast Dairy Foods Research Center at Cornell, Mark works with AlterEcho clients on a range of product safety and regulatory initiatives.