FDA Proposes New Food Safety Regulations to Prevent Illness

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In response to several high-profile instances of foodborne illness, Congress enacted the Food Safety Modernization Act (FSMA) of 2010. Just months later, a listeria outbreak, which was traced back to cantaloupes from a Colorado farm, caused 147 illnesses and 33 deaths. According to the U.S. Food and Drug Administration (FDA), this multistate outbreak was the deadliest since 1924. In 2006, E. coli-contaminated spinach from a California farm was linked to three deaths and 31 instances of kidney failure. Just this past month, a listeria outbreak from caramel apples from a California distributor caused 32 cases of infection and three deaths.

The FSMA requires the FDA to create regulations aimed at preventing, detecting and responding to food safety issues, and improving the safety of imported foods. The FSMA is the first food safety regulatory overhaul in over 70 years and many felt it was long overdue given the frequency and devastating effects of outbreaks. The Centers for Disease Control and Prevention estimate that each year approximately one in six Americans get sick, 128,000 are hospitalized and 3,000 die from foodborne illnesses. A visit this week to the federal website recalls.gov shows an overwhelming number of food recalls. In addition to the human toll, the federal government estimates that the economic losses to the food industry total over $75 billion per year.

Pursuant to the FSMA, the FDA issued four key proposed rules in 2013 governing produce safety (the produce safety rule), preventive controls for human food (the preventive controls rule), preventive controls for animal food, and the foreign supplier verification programs. Additionally, the FDA has issued three more proposed rules on accreditation of third-party auditors, focused mitigation strategies to protect food from intentional adulteration, and sanitary transportation of human and animal food.

In response to vast numbers of public comments, the FDA issued proposed supplemental rules in September 2014, which made significant revisions to the produce rule and the preventive controls rule. In these revisions, the FDA has provided additional flexibility regarding treatment of different-sized farms, clarified definitions to allow for more efficient and uniform application, and properly followed a risk-based approach. This article discusses the ways in which the revised two key rules, the produce rule, which affects farms, and the preventive controls rule, which applies to food facilities, were modified to prevent foodborne illness while still allowing the continued resurgence of the local food movement.

Part of the difficulty in crafting protective food safety regulations is the large spectrum of food producers, from large-scale industrial farm operations to small, diversified family farms that direct market to consumers. These wide varieties in production size result in inherent differences in production methods and the potential risk of foodborne illness. Among these differences are distance between producer and consumer, length of time from harvest to consumption, number of potential contamination points, and degrees of mechanization. Considering these factors, the

FDA recognized that uniform application of food safety standards would unduly burden small farmers.

The produce rule applies to all farms, with certain exemptions, that grow fresh fruits and vegetables usually consumed raw, such as apples, leafy greens and tomatoes. The rule sets specific standards for growing, harvesting, packing and holding produce. Most of the proposed changes to the rule create additional flexibility by reducing the regulatory burden on certain smaller producers. For example, the FDA initially proposed exempting any farm with annual total food sales of less than $25,000. This exemption when applied to diversified farms, common in the local food movement, would mean that a farm would not be exempt if it had total food sales (including meat, dairy and grain) above $25,000, but much smaller sales (under $25,000) of raw fruits and vegetables.

In its September revised rule, the FDA expanded this exemption so that only produce sales are included toward the $25,000 threshold. This revision greatly improves the ability of small farms to diversify their food products in an economically efficient and ecologically sustainable way without concern that they will now be burdened by the regulatory requirements of the produce rule. Additionally, the FDA now proposes counting only produce sales when determining whether a farm is a "small business" (average annual produce sales of under $500,000) or a "very small business" (average annual produce sales of under $250,000). Small businesses and very small businesses still must comply with the produce rule, but are given extended compliance dates.

In another win for local food, an amendment to the FSMA (the so-called Tester-Hagan Amendment) includes an additional, qualified exemption. This qualified exemption excludes a farm or facility from the majority of the produce rule and the preventive controls rule requirements if its total food sales are under $500,000 on average per year and more than half of these sales are directly to consumers and/or to local restaurants or retailers (in the same state or within a 275-mile radius). Unfortunately, because this language is in an amendment to the FSMA, the FDA must use that same language basing the $500,000 threshold on total food sales instead of just produce sales for farms under the produce rule.

Qualified exempt farms still must follow labeling requirements, which include signage with the producer's name and address, and are still prohibited from (and subject to enforcement for) selling adulterated food. The FDA also has broad discretion to withdraw qualified exempt status from any farm or facility that has a foodborne illness outbreak linked to it or whenever necessary to protect public health. The revised rules added additional due process protection requiring the FDA to follow specific procedures when withdrawing a farm or facility from exemption. Notice must first be given to the farm prior to issuing a withdrawal order and reinstatement of qualified exemption status is possible under the revised rule. These additional safeguards provide the necessary opportunities for back-and-forth between the alleged violator and the agency and will hopefully prevent abuse of discretion.

The revised produce rule also includes requirements and standards for irrigation water testing and specifications for manure and compost applications. The FDA, recognizing that different water sources have different contamination risks, has applied a risk-based approach in its

revisions to the water testing requirements. This tiered approach, which includes modified testing frequencies and varying implementation dates, is intended to reduce the burden on farmers while still protecting human health.

Additional requirements of the produce rule include specified waiting periods between grazing animals and crop harvest on the same land if there is reasonable probability of contamination and monitoring for wild animal intrusion and not harvesting crops that are visibly contaminated with animal feces. The produce rule also contains detailed specifications for worker hygiene practices, equipment and facilities, and required worker training. There are, of course, recordkeeping requirements to track adherence to these various standards.

The preventive controls rule applies to facilities that process food. Under the rule, a food facility is one that manufactures, processes, packs, or holds human food. If a farm conducts certain activities, it may be considered a "facility" for the purposes of the preventive controls rule and be subject to both rules. For example, farms that chop up their own raw vegetables for sale would be considered a "facility" as they are transforming the product through processing. There is still some question as to whether the definition of "farm" is broad enough to encompass today's diversified and innovative new ways of producing and marketing food without inadvertently classifying these new farming operations as "facilities" subject to additional regulatory requirements under the preventive controls rule.

In its revised rules, the FDA clarifies the definition of "farm" to exclude certain activities that are typically conducted on a modern, diversified farm such as packing or holding raw produce grown on another farm for distribution, such as at a community-supported agriculture pickup where a neighboring farm's goods are also distributed or offered for sale. The FDA has properly determined that these activities should not impose the same regulatory burdens of a "facility" under the rule.

The preventive controls rule includes requirements for hazard analysis and risk-based preventive controls (HARPC) and revisions to existing good manufacturing practices (GMP). Facilities that manufacture products, such as juice, seafood and dietary supplements, which are covered by preexisting regulations, are exempt, along with facilities that are solely engaged in storing agricultural commodities. Additionally, small and very small on-farm businesses that conduct low-risk processing activities are exempt from the HARPC requirements and have delayed compliance deadlines for applicable requirements.

The "modified requirements" for facilities are those that can be classified as "very small businesses" or are under the $500,000 threshold. Under the preventive controls rule, any "very small business" (annual sales of human food, excluding animal feed, under $1 million) or facility with total food sales under $500,000 on average per year with more than half of these sales from direct-to-consumer platforms qualifies for modified requirements. The revisions streamlined the qualification process by redefining "very small business," which allows for a much simpler determination of application and eliminates the need to track the end customers. Due to the typically large size of food processing facilities, not many facilities will qualify for the "very small business" exemption.

In addition to registering with the FDA, facilities must maintain a written food safety plan and keep records of compliance with each element of the plan. The revised rule also adds a supplier approval and verification program, as well as environmental monitoring and product testing, to the requirements of the food safety plan.

Through these revisions, the FDA has properly recognized that different supply chains and scales of production and consumption pose varying health risks. Taking this into account, the FDA has differentiated between different-size farms and facilities in the revised regulations. Local food proponents argue that the close link between farmer and eater, along with the ability to trace the product back to a farm if there is a problem, results in a reduced need for stringent regulations. Indeed, the FDA has taken a risk-based approach and has allowed for flexibility in the application of this regulatory scheme.

One disappointing element missing from the proposed rules, despite the efforts of sustainable food advocates, is any acknowledgment or requirements relating to longer-term food safety concerns such as the use of antibiotics and pesticides in food production. As far as Congress and the FDA are concerned, the only food safety issues that warrant action are those that cause immediate and acute pathogenic illness.

The public comment period on the revised rules closed in December. Pursuant to court-ordered deadlines, the FDA must issue the final preventive controls rule by Aug. 30 and the final produce rule by Oct. 31.

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