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PolicyPennings by Daryll E. Ray & Harwood D. Schaffer

Hazard analysis and risk-based control points (HACCP) not just for meat

In the weeks since the Food and Drug Administration (FDA) issued 2 proposed regulations to implement the Food Safety and Modernization Act (FMSA), the agency has reported 10 food recall notices, 8 of them for undeclared ingredients and two for pathogenic contamination by either Shiga-Toxin producing E. coli or Listeria monocytogenes. The ongoing recalls illustrate the importance of the FDA and other agencies in ensuring the safety of the US food supply.

In our previous column we looked at the proposed rule (Standards for the growing, harvesting, packing, and holding of produce for human consumption) that primarily involves the farm-level production of fruits and vegetables. This column is focused on the other proposed rule which amends FDA's "regulation for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human food (GCMPs) to modernize it and add requirements for domestic and foreign facilities that are required to register" with the FDA.

Under this regulation, covered facilities must "establish and implement hazard analysis and risk-based preventative controls for human food" that are similar to the hazard analysis and critical control points (HACCP) rules that are in effect for meat slaughter and processing plants whose activities are regulated by the USDA's Food Safety and Inspection Service (FSIS).

In the past FSIS was criticized for being slow to implement traceback to the source of E. coli—the packing facility—when contamination was found at a downstream processing firm that did not slaughter animals. In response to outbreaks of foodborne illness and pressure from food safety advocates, the USDA has since instituted traceback procedures.

The FDA specifically writes that "depending on the circumstances…[a] multidisciplinary investigation…[of an outbreak of foodborne illnesses] may involve a traceback investigation (i.e., an investigation to determine and document the production chain and the source(s) of contaminated or potentially contaminated food); a traceforward operation (i.e., an operation to determine the distribution of contaminated or potentially contaminated food); regulatory inspections; and, in some cases, root cause investigations (to try and determine the specific causes of contamination and contributing factors)."

The overall goal of the FSMA is to enable the FDA to better protect public health by helping ensure the safety and security of the food supply. The "FSMA enables [the FDA] to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur….In addition, the law gives [the FDA] important new tools to better ensure the safety of imported foods" which constitute about 15 percent of the US food supply including "80 percent of our seafood, 50 percent of our fresh fruit, and 20 percent of our vegetables."

In the space of this column, it is impossible to cover this regulation in any detail, so we encourage both farmers and consumers to consider downloading the rule and reading it. While it contains its share of technical detail, many will find information that is of interest.

Of particular interest to farmers, especially those who engage in on-farm processing of agricultural products is the discussion in the rule of which on-farm facilities fall under the regulation (covered facilities) and which are exempt. In making that decision the Department of Health and Human Services conducted a science-based risk analysis to determine which on-farm facilities to exempt from the requirements in the proposed rule.

Farmers engaged in on-farm processing of agricultural products will want to read the rule (https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-00125.pdf) carefully and take the opportunity to comment on the rule within the 120 day comment period.

Likewise, consumers will find it an informative slog to make their way through the lengthy rule. Like with farmers, they may want to afford themselves of the opportunity to submit comments within the 120 day comment period. Procedures for submitting comments can be found within the rules.

While none of us welcomes increasing complexity in our lives and businesses, these regulations lay out a path by which we can reduce the frequency and severity of outbreaks of foodborne illnesses. To the extent that they achieve this goal, all of us will breathe a little easier when we sit down at the family table.

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