APAC Agricultural Policy Analysis Center
The University of Tennessee

PolicyPennings by Daryll E. Ray & Harwood D. Schaffer

FDA's newly proposed food safety regs

On January 4, 2013, two years to the day after President Obama signed the Food Safety Modernization Act into law the US Food and Drug Administration (FDA) issued two proposed regulations that they said will "help prevent foodborne illness." According to the US Centers for Disease Control and Prevention (CDC), "roughly one in six Americans gets sick…128,000 are hospitalized, and 3,000 die of foodborne diseases" http://www.cdc.gov/foodborneburden/.

In recent years, major outbreaks of foodborne illness have included products from spinach and melons, to peanut butter and ground beef. About 80 percent of food products fall under the aegis of the FDA while the remaining—most meat, poultry, and processed egg products—are the responsibility of the US Department of Agriculture, Food Safety and Inspection Service. Food safety for fish is the responsibility of the FDA. In addition, responsibility for restaurant food safety falls to state and local health departments.

The FMSA framework for food safety included, human food, produce safety, imports, and animal food. The first two of these are the subjects of the January 4 proposed regulations. Together these two proposed rules run over 1,250 typed pages. Both proposed rules are subject to a 120-day comment period after which the FDA will take the comments into consideration in preparation of the final rule. Proposed rules for imports and animal food will be forthcoming.

The first of these proposed rules, titled, "Current good manufacturing practice and hazard analysis and risk-based preventative controls for human food," (https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-00125.pdf) would "revise FDA's current good manufacturing practice (CGMP) regulations regarding the manufacturing, processing, packing, or holding of human food in…fundamental ways."

The proposed rule "would add new preventive controls provisions as required by the FDA Food Safety Modernization Act (FSMA). In general, with some exceptions the new preventive controls provisions would apply to facilities that are required to register with FDA under FDA's current food facility registration regulations.

"These preventive controls would include requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Facilities would also be required to monitor their controls, verify that they were effective, take any appropriate corrective actions, and maintain records documenting these actions."

"In addition, this proposed rule would clarify the scope of the exemption for "farms" in FDA's current food facility registration regulations and make corresponding clarifications to FDA's current regulations for the establishment, maintenance, and availability of records. These clarifications would affect who would be subject to the current regulations for registration and recordkeeping as well as the new preventive controls requirements that would be established by this proposed rule."

Because some food facilities are located on farms, the FDA developed a document entitled "Draft qualitative risk assessment of risk of activity/food combinations for activities (outside the farm definition) conducted in a facility co-located on a farm" (draft RA) (http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM334110.pdf) to "to provide a science-based risk analysis of those activity/food combinations that would be considered low risk."

The FDA used "the results of the draft RA to propose to exempt food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/food combinations from the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for hazard analysis and risk-based preventive controls."

The second proposed rule is titled, "Standards for the growing, harvesting, packing, and holding of produce for human consumption" and can be found at https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-00123.pdf.

"To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA) is proposing to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables [not grains and oilseeds] grown for human consumption. FDA is proposing these standards as part of our implementation of the…FSMA.

"These standards would not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance would be eligible for exemption from the requirements of this rule."

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We will be using future columns to identify some of the major issues in these proposed rules that have significance for either producers or consumers.

Daryll E. Ray holds the Blasingame Chair of Excellence in Agricultural Policy, Institute of Agriculture, University of Tennessee, and is the Director of UT's Agricultural Policy Analysis Center (APAC). Harwood D. Schaffer is a Research Assistant Professor at APAC. (865) 974-7407; Fax: (865) 974-7298; dray@utk.edu and hdschaffer@utk.edu; http://www.agpolicy.org.