

Food Safety, What's Next?

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FOOD SAFETY, WHAT'S NEXT?

The food industry is regulated by the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA). The FSIS is responsible for ensuring the safety of the meat, poultry and processed egg supply, and the FDA has responsibility for all other foods. The FSIS introduced the Hazard Analysis Critical Control Point (HACCP) system in 1996 to their regulatory framework (61 Fed. Reg. 38806). FSIS is continuing to expand a more risk-based approach to inspection and has begun to employ a more data-driven approach. The FDA is now (in 2013) responding with preventive controls for the remainder of the food industry.

FOOD SAFETY AND INSPECTION SERVICE EXPECTATIONS FOR 2013

With the second term of the Administration, it is clear that FSIS will be powering forward with their issuance of regulations that have been on hold for some period of time. In addition, it should be expected that the Agency will work to continue to modernize the inspection system and make all efforts to ensure the system is preventive rather than reactive. The FSIS implemented the Public Health Inspection System (PHIS) which is a data driven system, and will continue to become more reliant on data to enhance their policies moving forward. FDA is reviewing their critical technology infrastructure as well.

Some specific actions expected within the FSIS in the next year include:

Finalization of validation compliance guidelines – FSIS has been working with the industry to ensure the validation of food safety systems. It should be expected that FSIS will be more focused on the validation of the design of food safety systems during food safety assessments (FSAs).

Salmonella initiatives – The Agency's testing data and Centers for Disease Control Public Health data suggest that *Salmonella* is an organism for which FSIS (and FDA) could provide more regulatory focus. FSIS has already indicated that producers of raw, not ready-to-eat com-

minuted poultry must reassess their food safety systems. In addition, FSIS has changed sample size for *Salmonella* from 25 grams to 325 grams for all species. The change first initiated with poultry June 2013; the change for other species will take place throughout 2013. We also expect FSIS to evaluate the current sampling programs for *Salmonella* and initiate changes within these programs to make them more risk-based in nature. *Salmonella* is a pathogen of concern in not only poultry, but in ground beef as well.

Poultry Slaughter Modernization – The modernization of the poultry slaughter inspection system has been proposed by FSIS (77 Fed. Reg. 24873) to, among other things, assign responsibility to the establishments to sort birds, thereby reducing the number of inspectors at poultry slaughter plants, while leaving one inspector on the line to meet the statutory requirement of bird-by-bird inspection. This would provide additional FSIS resources to conduct more public health activities across the Agency. As part of the proposal, establishments would be required to initiate sampling to demonstrate the on-going safety of their food safety system. The Agency is evaluating comments and could issue a final rule later this year.

Non-O157 testing – The FSIS has issued a survey to all beef establishments to collect data to assist in determining the next steps for their non-O157 policies. In addition, the Agency is continuing to send all of the samples that are positive for the "stx" and "eae" genes but negative for all of the six non-O157 STEC and *E. coli* O157:H7 to USDA, ARS for further analysis. FSIS is updating the *Risk Profile for Pathogenic Non-O157 Shiga Toxin Producing Escherichia coli* published in May 2012 based on data collected to date. All of these inputs will assist FSIS in determining future policies.

Residues – Residue control remains a "hot topic" and one that has been receiving high-level attention from both regulatory Agencies. FSIS has continued to make changes to their National Residue Program to make it more efficient and effective. The FDA has issued "judicious use guidance" materials for veterinarians and producers (77 Fed. Reg. 22327 and 77 Fed. Reg. 22328). It is anticipated that chemical residues will continue to receive high priority attention in 2013.

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FOOD AND DRUG ADMINISTRATION EXPECTATIONS FOR 2013

The FDA issued the first two of what is expected to be a significant number of proposed regulations to implement the Food Safety Modernization Act (FSMA) ((21 U.S.C. 301 et. seq.). These two proposed regulations are very broad in nature—the “Produce Safety Standards” (78 Fed. Reg. 3504) and the “Preventive Controls for Human Food” (78 Fed. Reg. 3646). The next proposed rules anticipated include, “Foreign Supplier Verification Program” and “Preventive Controls for Animal Food.”

The FDA is working to move the remainder of the food industry under HACCP-type preventive control systems. The “Preventive Controls” proposal would require that each facility implement a written food safety plan that focuses on preventing hazards in foods. The proposed preventive control regulations also would require significantly increased recordkeeping compared to what has been maintained by FDA-regulated plants. In a dual jurisdiction plant, one that produces products inspected by both FSIS and FDA, the proposal includes some discrepancies between the FDA and FSIS regulated commodities. The proposed preventive controls would require a validated food safety system (similar to FSIS), however, in addition to recordkeeping requirements to the monitoring and verification activities, the proposed preventive con-

trols includes these same documentation requirements for what is considered to be “pre-requisite programs” under FSIS HACCP as well. The comment period could serve to resolve this concern.

In the proposed rule for produce, FDA considers the risk posed by practices and commodities associated with growing, harvesting, packing and holding produce as well as how produce will be used and consumed after it leaves the farm. The Produce Safety Standards would set standards for the produce industry associated with identified routes of microbial contamination of produce. The standards would be set for areas such as the agricultural water; biological soil amendments of animal origin; health and hygiene; animals in the growing area, and equipment, tools and buildings.

SUMMARY

For both FSIS and FDA, the Obama Administration has been committed to a more preventive food safety system that works together to better protect public health. FSIS continues to finalize and implement more risk-based initiatives. FDA has issued the initial proposed regulations to implement the Food Safety Modernization Act. These activities provide a hopeful expectation that the Agencies’ are aligning their expectations and requiring similar paths for ensuring the production of safe food.