

# Interaction of Federal Agencies with Food Safety Missions

Responsibility for food safety is shared by a number of federal, state and local agencies. The individual responsibilities of the key food safety agencies at the federal level have already been discussed in the background pieces on the Department of Agriculture (USDA), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Because of overlapping mandates and the complex nature of interaction among all the federal agencies working on food safety, we present a separate overview on how the entire food safety system is organized and what this implies for inter-agency coordination.

In 2007 the General Accountability Office placed the fragmented federal oversight system for food safety on its list of High Risk government operations because of inconsistent oversight, ineffective coordination, and inefficient use of resources. In response to GAO recommendations, the President reconvened the Council on Food Safety and established the Food Safety Working Group in 2009 to coordinate federal efforts. However, the food safety program remains on the High Risk list because a government-wide performance plan for food safety that includes results-oriented goals and performance measures and information about resources has not yet been developed. Without a government-wide plan, decision makers do not have a comprehensive picture of the government’s performance on food safety.<sup>1,2</sup>

## Structure and Organization of the Food Safety Agencies

A detailed discussion of these interacting services is provided in an article from the *Seton Hall Law Review* entitled “Organizing Federal Safety Regulations”.<sup>3</sup> The following table from that article shows the division of responsibilities by food type and agency and gives a description of each agency's focus. Although extensive, the table is not all inclusive as it leaves out activities such as the monitoring of foodborne illnesses carried out by the CDC, the USDA role in fruit and vegetable safety that goes beyond pesticide concerns, as well as some of the enforcement of food advertising and labeling functions that are carried out by other agencies such as the Federal Trade Commission (FTC).<sup>4,5,6</sup>

Food	Regulator(s)*	Comments
Alcoholic beverages	ATF, FDA	ATF licenses and inspects breweries. FDA oversees wine coolers
Eggs	FDA, AMS, FSIS, APHIS	FDA has lead jurisdiction over shell eggs. FSIS continuously inspects egg products. AMS operates a voluntary grading program. APHIS monitors animal health

Fruits & vegetables (including GE varieties)	FDA, EPA, USDA	EPA and USDA share pesticide regulation responsibilities. FDA enforces standards for pesticide residues on processed food.
Grain	FDA, GIPSA, EPA	GIPSA establishes and enforces identity standards through inspection. FDA enforces standards for pesticide residues on processed food.
Meat & poultry	FSIS, FDA	FSIS inspects meat during processing. FDA holds regulatory authority once meat leaves the slaughtering or manufacturing plant.
Processed Foods	FDA	FDA is responsible for most non-meat products.
Seafood	FDA, NMFS	FDA oversees seafood safety generally. NMFS runs a voluntary inspection service.
Water	FDA, EPA	EPA regulates tap water, FDA bottled water.
*Acronyms include ATF (Bureau of Alcohol, Tobacco, and Firearms); AMS (USDA Agricultural Marketing Service), FSIS (USDA Food Safety and Inspection Service), APHIS (Animal Plant Health Inspection Service), GIPSA (USDA Grain Inspection, Packers and Stockyards Administration), NMFS (National Marine Fisheries Service), ATF (Bureau of Alcohol, Tobacco and Firearms).		

In addition to this mix of agencies and responsibilities there is also a mix of underlying legislation. A recent Government Accounting Office (GAO) study on Federal Food Safety Oversight includes a four-page appendix table providing information on the underlying legislation for 15 agencies involved in food safety. This table lists each agency, identifies the programs and products under the agency’s jurisdiction, notes the types of responsibilities they have (e.g., regulation, inspection, enforcement, research, administration of grants and cooperative agreements) and identifies the many authorizing statutes relevant to each agency.<sup>7</sup>

The summary table above and the one in the GAO report illustrate the complexity of the food safety structure, which renders decision making more complicated. The system is continuously evolving as the agencies update and change their roles in an effort to become more efficient and comply with changes in legislation.

## USDA Role in Food Safety

The safety of meat, poultry and egg products is a major responsibility of the USDA Food Safety Inspection Service. The Federal Meat Inspection Act of 1906 Act authorized the Secretary of Agriculture to inspect and condemn any meat product found unfit for human consumption. The law requires mandatory inspection of livestock (cattle, sheep, goats, equines and swine) before slaughter, postmortem inspection of every carcass, sanitary standards for slaughterhouses and meat processing plants with ongoing monitoring and inspection of slaughter and processing operations for any meat that crosses state lines. The act requires all labels on any type of food to be accurate (although not all ingredients were provided on the label).<sup>8</sup>

The pilot for a new meat inspection program for hogs<sup>9</sup> was set up in 1997 to allow five processing plants to accelerate their processing lines and use company employees, instead of

some USDA inspectors to check that the meat was safe. The USDA inspector general reported in the spring of 2013 that the evaluation of the pilot had not been completed even though a number of safety violations were reported from three of the five plants. A GAO study said it would be difficult to recommend that the experimental procedures be extended across the 608 processing plants subject to inspection, but the USDA has said it plans to complete the evaluation report by March 2014 and to roll out the program to save millions of dollars in inspection costs. These same procedures are authorized by the USDA for foreign meat.<sup>10</sup>

Dozens of chicken processing plants are subject to the same procedures in a pilot program for proposed new regulations. The 49-page proposed USDA regulations for chicken processing would allow poultry processing plants to speed up their slaughter lines to 175 birds per minute while reducing the number of federal health inspectors 40%. This combination means that companies will rely more upon chemicals to keep the poultry free of contaminants. The proposed rule allows the use of chemicals on “air chilled” birds and use of the chemicals along the processing line, not just at the end. The FDA provides the chemical review and approval process, but relies upon data provided by the chemical manufacturers in its evaluation of the possible health risks that the chemicals could pose to consumers. USDA officials say that research into the effects of the chemical sprays on its inspectors or private employees is the job of another agency, but discomfort and even deaths attributed to the chemical spraying have been reported.<sup>11</sup>

Through the Agricultural Marketing Service, Fruit and Vegetable Program, Specialty Crops Inspection (SCI) Division Audit Programs, voluntary independent audits of produce suppliers throughout the production and supply chain are available. While these programs are voluntary, any farmer who desires to market to a major supplier must achieve certification through a SCI Division Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audit. These audits focus on best agricultural practices to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial food safety hazards. SCI Division GAP & GHP audits verify adherence to the recommendations made in the U.S. Food and Drug Administration’s *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*<sup>12</sup> and industry recognized food safety practices. Over 90 fruit and vegetable crops may be audited for GAP certification.<sup>13</sup>

The farmer incurs a cost for the GAP audit to become certified and to successfully pass an audit must have comprehensive records and a multitude of plans for all aspects of the production and management of the crop. This includes such things as a contingency plan if a deer should enter his field, the disposal of crop residue, and records of all chemical applications to the crop. Procedures such as hand washing by drivers who might enter a storage facility and care of oil leaks from machinery must be in place.

## Food Safety Modernization Act (FSMA)

A recent effort to improve food safety monitoring is the Food Safety Modernization Act (FSMA) of 2011, which calls for the FDA to prevent rather than simply respond to food contamination. FDA describes this Act as the most significant change in U.S. food safety legislation in 70

years.<sup>14</sup> Before describing some of the key provisions of FSMA, it is important to note that it does not address:

*... food safety risks from genetically engineered crops, pesticide use, or antibiotic resistance nor does it change food safety regulations for meat, poultry, and egg products, which are under the U.S. Department of Agriculture's jurisdiction.*<sup>15</sup>

Given the sharp rise in the share of US foods that are imported (now about 15% of all foods consumed in the U.S.) FSMA calls for the development of a new system for import oversight that requires importers to ensure that their foreign suppliers have adequate preventive controls in place.<sup>16</sup> This new approach should address some of the concerns noted in the FDA discussion about the small share of imports (about 2%) that FDA is able to physically inspect.

While the FSMA gave the FDA authority to address food safety issues more fully than previously, the Act did not include the specifics of the regulations to be applied. FDA is now in the process of consulting with stakeholders with the intent of:

*... [making] these new regulations scale-appropriate, conservation-friendly, and accessible to certified organic producers and value-added producers. The regulations focus on addressing food safety risks from microbial pathogen contamination (e.g., Salmonella, E. coli O157:H7, and Shigella).*<sup>17</sup>

*... developing a proposed rule that will establish science-based minimum standards for the safe production and harvesting of fruits and vegetables and will address soil amendments, worker health and hygiene, packaging, temperature controls, water, and other issues. Food facilities will be required to implement a written preventive control plan, provide for the monitoring of the performance of those controls, and specify the corrective actions the facility will take when necessary.*<sup>18</sup>

Although the implementing regulations for the Food Safety Modernization Act are supposed to take into account the size and nature of the operation being regulated, the National Sustainable Agriculture Coalition and the Farmers Market Coalition are concerned that the regulatory burden of rules proposed in 2013 and currently undergoing public comment is still too onerous for small-scale producers and processors.<sup>19,20</sup>

## Current Issues

Among the key issues of interest concerning food safety programs in the U.S. are (1) the current division of responsibilities among agencies, (2) agency differences in approaches to inspection and enforcement, and (3) the adequacy of funding for the different food safety missions.

Over the years there has been a great deal of discussion about reforming the structure and organization of the food safety system and whether consolidation of monitoring responsibilities into a single agency would improve performance; the two recommended readings present different points of view on how to reform the system.

Different approaches to inspection are illustrated by comparing USDA, which has statutory authority to conduct continuous inspections, with FDA, which has authority for periodic inspections. Another difference is that FDA has authority for on-farm inspection but not USDA. In terms of responsibilities, USDA has responsibility for a limited number of similar food products (which would be expected to facilitate inspections) while FDA has responsibility for a very diverse array of food and non-food products (which would complicate inspections and demand a greater range of expertise). Over time, there seems to be a general trend toward fewer facility inspections. Annual inspections declined from more than 15,000 during the 1970s to a range of 5,000 to 10,000 during the 1980s and 1990s (with most years closer to 5,000 than 10,000). Since 2000 there has been a small uptick, with the range between 7,500 and 10,000 per year.<sup>21</sup>

Actual food safety budgets and personnel do not always appear to be well calibrated with responsibilities. USDA, for example, has 7800 inspectors for 6800 facilities while FDA has 2000 inspectors for more than 130,000 facilities. Part of the reason for this disparity is the USDA mandate to inspect virtually all meat products while FDA uses much smaller samples for products under its responsibility. In 1972 the FDA drug and food budgets were about equal, yet in 2011, the Drug Center staff was more than 3 times greater than that of the Food Center staff (3097 vs. 871 people). The latest challenge is the estimated cost for the FSMA of 1.4 billion over 5 years, coupled with a Congressional authorization of only a \$50 million boost in the 2012 FDA appropriation.<sup>22</sup>

## Recommended Readings

GAO (Government Accountability Office), Federal Food Safety Oversight: Food Safety Working Group Is a Positive First Step but Government wide Planning Is Needed to Address Fragmentation. GAO Report to Congressional Offices No. 11-289, March 2011, <http://www.gao.gov/new.items/d11289.pdf>, accessed 10/28/13.

Merrill, Richard and Jeffrey Francer, "Organizing Federal Food Safety Regulations," *Seton Hall Law Review*, Volume 31, Issue 1, Article 8, (11/10/2011), <http://erepository.law.shu.edu/cgi/viewcontent.cgi?article=1334&context=shlr>, accessed 10/28/13.

Although this article was published in 2011, the research seems to have been completed by 2000, as there are no references cited with a more recent date.

<sup>1</sup> General Accountability Office, High-Risk Series: An Update, GAO-13-283, February 2013, <http://www.gao.gov/assets/660/652133.pdf>, pp. 196-201, accessed 10/28/13.

<sup>2</sup> Federal Food Safety Working Group Progress Report, [http://www.whitehouse.gov/sites/default/files/fswg\\_report\\_final.pdf](http://www.whitehouse.gov/sites/default/files/fswg_report_final.pdf), December 2011, accessed 10/28/13.

<sup>3</sup> Merrill, Richard and Jeffrey Francer, "Organizing Federal Food Safety Regulations," *Seton Hall Law Review*, Volume 31, Issue 1, Article 8 (11/10/2011), <http://erepository.law.shu.edu/cgi/viewcontent.cgi?article=1334&context=shlr>, accessed 10/28/13.

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<sup>4</sup> "A Brief Review of the FTC's Environmental and Food Advertising Enforcement Programs" FTC Commissioner Roscoe B. Starek, October 13, 1995, <http://www.ftc.gov/public-statements/1995/10/brief-review-ftcs-environmental-and-food-advertising-enforcement-programs>, accessed 10/28/13.

<sup>5</sup> Through its Bureau of Consumer Protection, and pursuant to its authority under the Fair Packaging and Labeling Act, FTC food-related enforcement actions include false claims such as food supplements that cure ADHD or the health benefits of POM Wonderful 100% pomegranate juice; see, for example, FTC rules POM ads were false and deceptive By Lesley Fair, January 16, 2013 - 12:47pm at <http://www.business.ftc.gov/blog/2013/01/ftc-rules-pom-ads-were-false-and-deceptive>, accessed 10/28/13.

<sup>6</sup> Examples of FTC food-related advisory opinions, testimony, and reports include meat and poultry labeling (USDA); what constitutes a qualified health claim (FDA); labeling of trans fats and weight loss foods (FDA); and marketing to children and adolescents; see, for example, "A Review of Food Marketing to Children and Adolescents—Follow-Up Report" December 2012, <http://www.ftc.gov/os/2012/12/121221foodmarketingreport.pdf>, accessed 10/28/13.

<sup>7</sup> GAO (Government Accountability Office), Appendix II: Federal Agencies with Food Safety Responsibilities in Federal Food Safety Oversight: Food Safety Working Group Is a Positive First Step but Governmentwide Planning Is Needed to Address Fragmentation. GAO Report to Congressional Offices No. 11-289, March 2011 (21-24), <http://www.gao.gov/new.items/d11289.pdf>, accessed 10/28/13.

<sup>8</sup> U.S. Food and Drug Administration (FDA), 21 C.F.R. § 12, <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148693.htm> -- When was this accessed?

<sup>9</sup> Hazard Analysis and Critical Control Point-based Inspection Models Project (HIMP)

<sup>10</sup> Kimberly Kindy, "USDA pilot program fails to stop contaminated meat," Washington Post, September 8, 2013, [http://www.washingtonpost.com/politics/usda-pilot-program-fails-to-stop-contaminated-meat/2013/09/08/60f8bb94-0f58-11e3-85b6-d27422650fd5\\_story.html](http://www.washingtonpost.com/politics/usda-pilot-program-fails-to-stop-contaminated-meat/2013/09/08/60f8bb94-0f58-11e3-85b6-d27422650fd5_story.html), accessed 11/14/13.

<sup>11</sup> Kimberly Kindy, "At chicken plants, chemicals blamed for health ailments are poised to proliferate," Washington Post, April 25, 2013, page 1. [http://www.washingtonpost.com/politics/at-chicken-plants-chemicals-blamed-for-health-ailments-are-poised-to-proliferate/2013/04/25/d2a65ec8-97b1-11e2-97cd-3d8c1afe4f0f\\_story.html](http://www.washingtonpost.com/politics/at-chicken-plants-chemicals-blamed-for-health-ailments-are-poised-to-proliferate/2013/04/25/d2a65ec8-97b1-11e2-97cd-3d8c1afe4f0f_story.html), accessed 11/14/13.

<sup>12</sup> *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, FDA, <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf>, accessed 11/14/13.

<sup>13</sup> <http://www.ams.usda.gov/gap> is a search for a sample of GAP certifications.

<sup>14</sup> Food and Drug Administration, FDA Food Safety and Modernization Act (FSMA), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>, accessed 10/28/13.

<sup>15</sup> Quoted from National Sustainable Agriculture Coalition, "What is the Food Safety Modernization Act (FSMA)?", <http://sustainableagriculture.net/fsma/overview-and-background/>, accessed 10/28/13.

<sup>16</sup> Food and Drug Administration, Background on the Food Safety and Modernization Act (FSMA), Imports Section, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm>, accessed 10/28/13.

<sup>17</sup> Quoted from National Sustainable Agriculture Coalition, "What is the Food Safety Modernization Act (FSMA)?", <http://sustainableagriculture.net/fsma/overview-and-background/>, accessed 10/28/13.

<sup>18</sup> This paragraph is quoted from the Food and Drug Administration, Frequently Asked Questions (General Section), Food Safety Modernization Act, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#general>, accessed 10/28/13.

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<sup>19</sup> See National Sustainable Agriculture Coalition, “NSAC Statement on FDA Release of Food Safety Rules” NSAC press release January 4, 2013, <http://sustainableagriculture.net/blog/for-immediate-release-nsac-statement-on-fda-release-of-food-safety-rules/>, accessed 10/28/13.

<sup>20</sup> Farmers’ Market Coalition, “The New Safety Rules Are Bad for Farms and Food”, October 4, 2013, <http://farmersmarketcoalition.org/the-proposed-food-safety-rules-are-bad-for-farms-and-food>, accessed 10/28/13.

<sup>21</sup> These comparisons were made by Robert E. Brackett “Policy, Politics, and Progress in Protecting Our Food Supply”. Presentation to the League of Women Voters of Illinois Annual Issues Briefing, January 28, 2012.

<sup>22</sup> Illustrations from Robert E. Brackett, op. cit.