



# Food Safety on the Farm

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## Summary

Foodborne illness-causing bacteria on farms can enter the food supply unless preventive measures are in place to reduce them, either prior to or after harvest. Also of potential risk to the food supply are pesticide residues, animal drugs, and certain naturally occurring contaminants.

There is interest in examining on-farm practices, given continued major outbreaks of foodborne illness involving both domestically produced and imported foods. An example is the case in April-July 2008, when more than 1,000 persons in more than 40 states and Canada were found to be infected with the same unusual strain of bacteria (*Salmonella* Saintpaul), which was later traced back to fresh peppers from a farm in Mexico. In May 2010, a large-scale recall of more than 550 million shell eggs from two farms in Iowa was linked to concerns about a nationwide increase in *Salmonella* Enteritidis (SE) infections. Most recently, in November 2010 through January 2011, more than 100 people in 18 states were sickened from *Salmonella*-contaminated sprouts linked to an Illinois organic farm.

Food safety experts agree that an effective, comprehensive food safety system should include consideration of potential hazards at the farm level. However, opinions differ on the need for more stringent, government-enforced safety standards for farms, as exist for processors and others in the food chain. This question and others, such as the potential cost of new interventions to producers, taxpayers, and consumers, are at issue as Congress debates food safety legislation.

The lead federal food safety agencies are the Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA), which regulates major species of meat and poultry and some egg products, and the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services (HHS), which regulates virtually all other foods. Generally, these agencies' regulatory oversight of foods begins after the farm gate, at slaughter establishments and food handling and manufacturing facilities. However, various activities of these and other federal agencies involved in assuring the safety of the food supply can, and do, have an impact on how farms and ranches raise food commodities.

In December 2010, the 111<sup>th</sup> Congress passed comprehensive food safety legislation (FDA Food Safety Modernization Act (FSMA), P.L. 111-353). This newly enacted law is focused on foods regulated by FDA and amended FDA's existing structure and authorities, in particular the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§ 301 *et seq.*). FSMA is the largest expansion of FDA's food safety authorities since the 1930s; it does not directly address meat and poultry products under the jurisdiction of USDA. The provisions in the law that could have the most direct effect on on-farm activity, especially for produce growers, could be the establishment of new standards for produce safety. Other requirements that could affect on-farm activity are facility registration requirements, records access and/or inspection requirements, food traceability requirements, hazard analysis and risk-based preventive controls, and targeting of inspection resources. The 112<sup>th</sup> Congress will likely provide oversight over how the law is implemented, including FDA's coordination with other federal agencies. Implementation of the law will depend largely on discretionary appropriations, and some have questioned whether funding is available in the current budgetary climate.

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## Introduction

In recent years, major outbreaks of foodborne illnesses, product recalls, and reports about unsafe food imports have caused some to question the adequacy of the U.S. food safety system. Stakeholders appear to agree that an optimal system should encompass a comprehensive, preventive approach to food safety, focusing on those foods and points in the food system that pose the greatest public health risks, starting at the point of production—that is, on farms and ranches.

Here, viewpoints diverge. Should farmers and ranchers be subject to mandatory safety standards, enforced through certification of their practices, periodic inspections, and penalties for noncompliance? Or, should public policy continue to encourage voluntary strategies for producing safe foods on farms and ranches, through education, cooperation, and market-based incentives? Historically, the federal and state governments have relied on the latter “carrot” approach that, in the view of some critics, is no longer effective. Further complicating matters is that consumers increasingly rely on distant, often foreign, sources of production for a significant portion of their food.

It also could be argued that numerous laws and regulations already impose restrictions, both direct and indirect, on producers of food commodities, which effectively meet food safety objectives—and also involve significant compliance costs. These restrictions include requirements on the use of animal drugs, feed additives, and pesticides. Voluntary and market-based incentives also effectively regulate safety, it could be argued. For example, major food marketing chains and food service providers generally set quality and safety standards that suppliers must meet, which often extend back to the farm.

A number of high-profile illness outbreaks have placed on-farm practices under the policy microscope. Examples include the following:

- After more than 1,300 persons in 43 states, the District of Columbia, and Canada were found to be infected with the same unusual strain of bacteria (*Salmonella* Saintpaul) in April-July 2008, officials first suspected fresh tomatoes as the vehicle and later expanded their concerns to fresh jalapeño and serrano peppers. By late July, genetic tests confirmed the pathogen on samples of a serrano pepper and irrigation water from a farm in Tamaulipas, Mexico, the same strain found on a pepper provided by one of the ill persons.
- In the fall of 2006, more than 200 confirmed illnesses and three deaths were linked to the consumption of packaged spinach that apparently had been contaminated by *E. coli* O157:H7 in California fields, possibly due to the presence of wild pigs, the proximity of irrigation wells used to grow the produce, or surface waterways exposed to feces from cattle and wildlife.
- Numerous recent recalls and illness outbreaks have been linked to *E. coli* O157:H7 in raw or undercooked beef products. The bacteria is endemic in the live U.S. cattle population and can become a greater hazard if measures are not taken to control its spread on ranches and feedlots and in processing plants. (Proper cooking kills *E. coli* O157:H7.)
- In July 2010, CDC noticed a spike in cases of infection with *Salmonella* Enteritidis, a strain commonly associated with shell eggs, which are regulated by

FDA.<sup>1</sup> In August, FDA found the same pathogen on two egg farms in Iowa, leading to the nationwide recall by the companies of more than 500 million eggs packaged under several brand names.<sup>2</sup> FDA samples collected at the facilities matching the DNA fingerprint of the outbreak strain have been detected from manure and traffic areas in and around the facility (walkways, equipment, other surfaces), and from the mill providing finished feed to pullets raised at and distributed at both facilities.<sup>3</sup>

- In November 2010 through January 2011, an estimated more than 100 people in 16 states and Washington, DC, were sickened from *Salmonella*-contaminated sprouts linked to an Illinois organic farm.<sup>4</sup>

## Food Safety Hazards on the Farm

Pathogens—bacteria, viruses and other biological hazards—are the leading cause of foodborne illnesses. Pathogens are found in foods of all kinds, although those of animal origin, including raw meat and poultry, eggs, unpasteurized milk, and seafood, are most likely to be contaminated. Fruits and vegetables also are of growing concern, particularly because a considerable portion is consumed raw. Often these pathogens are first acquired at the farm (or harvest) level; processing and cooking does not always kill them.<sup>5</sup>

Also complicating an understanding of on-farm food safety is “the range of pathogens on the farm and the range of organisms associated with each food product,” the American Society for Microbiology report notes. Foodborne pathogens include the following. Viruses such as hepatitis A often originate from human feces, which can contaminate produce either when handled by infected humans or exposed to unsafe irrigation or washing water. Parasites such as *Cryptosporidium*, *Cyclospora*, and *Giardia* can be acquired from human and other animal fecal material directly or through water or soil; such waste can be generated by both domesticated and wild animals. Bacteria including *Salmonella* Enteritidis, *E. coli* O157, *Campylobacter*, *Vibrio*, and *Yersinia* are ubiquitous and can proliferate on the farm; the degree to which they are a problem depends on such variables as animal density and housing, feeding practices, water and wastewater treatment and disposal methods, human handling practices, interactions between animals, and the proximity of animals to crop-producing fields and orchards. Some hazards are naturally occurring, such as aflatoxin, a fungus that can infect crops, including peanuts and grains.

<sup>1</sup> USDA regulates processed eggs, and grades shell eggs for quality (such as grade and size), but does not oversee the safety of shell eggs. According to the CDC, this is the largest such outbreak reported since the start of its outbreak surveillance in the early 1970s (see: FDA press release, “FDA: Don’t Eat Certain Lots of Tiny Greens Brand Alfalfa Sprouts or Spicy Sprouts,” December 27, 2010).

<sup>2</sup> FDA, “Salmonella Enteritidis Outbreak in Shell Eggs,” November 30, 2010.

<sup>3</sup> FDA, “Recall of Shell Eggs,” October 18, 2010.

<sup>4</sup> FDA press release, “FDA: Don’t Eat Certain Lots of Tiny Greens Brand Alfalfa Sprouts or Spicy Sprouts,” December 27, 2010.; and M. Rothschild, “Sprouts Outbreak Toll Now at 112 in 18 States,” *Food Safety News*, January 7, 2011.

<sup>5</sup> Sources include various background materials and reports from the U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC); also, Isaacson, Richard E., and others, “Preharvest Food Safety and Security,” a 2004 report by the American Society for Microbiology. Although these sources include discussions of seafood-borne food safety risks, this CRS report focuses primarily on land-based agricultural operations. See also CRS Report RS22797, *Seafood Safety: Background and Issues*.

Pre-harvest controls are only effective if additional safety problems are avoided further down the food production and marketing chain. There is not always a clear relationship between food safety measures taken—or not taken—prior to harvest, and their impacts on the incidence of foodborne illnesses.

Also of potential risk to the food supply are numerous nonbiological contaminants. Fruits, vegetables, and other crops can contain higher than acceptable levels of pesticides if they are improperly applied prior to harvest to control weeds and kill insect pests, or after harvest to control fungus, insects, or rodents during food storage. Foods of animal origin potentially can contain excess residues of drugs administered to control or eliminate diseases or promote more efficient growth.

## Federal Food Safety Programs

### Food and Drug Administration

The Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services (HHS) is responsible for ensuring that all domestic and imported foods—excepting major species of meat and poultry and some egg products—are safe, wholesome, and accurately labeled. FDA's primary governing statutes are the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended (21 U.S.C. §§ 301 *et seq.*) and the Public Health Service Act (PHSA) as amended (42 U.S.C. §§ 201 *et seq.*). The FDA Food Safety Modernization Act (FSMA) (P.L. 111-353), enacted in December 2010, amended and added several new food-related provisions to the FFDCA. New food-related provisions were also added to the FFDCA in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). FDA divides responsibilities for the safety of eggs with the U.S. Department of Agriculture (USDA), under the Egg Products Inspection Act as amended (21 U.S.C. §§ 1031 *et seq.*). FDA appears to have the authority to regulate at least some on-farm activities, although it rarely does so.<sup>6</sup>

Historically, FDA has focused its oversight and enforcement activities on periodic inspections of food processing and handling facilities, on sampling and testing foods for the presence of adulterants, and on cooperation with firms seeking approval of specific food or feed additives or packages. FDA has promulgated “current good manufacturing practice” (CGMP) requirements (21 C.F.R. Part 110). Failure to comply with these requirements, which apply to manufacturing, packing, or holding human food, can result in enforcement actions and penalties, including an FDA declaration that a food is adulterated. Excluded from these requirements are establishments engaged solely in harvesting, storing, or distributing raw agricultural commodities. FDA rules do state that the agency “will issue special regulations if it is necessary to cover these excluded operations.”<sup>7</sup>

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<sup>6</sup> A more detailed legal analysis is in CRS Report RS22939, *FDA Authority to Regulate On-Farm Activity*. FDA's own arguments in support of its on-farm authority can be found in a final rule to regulate egg production to control *Salmonella enteritidis*, 74 *Federal Register* 33030, July 9, 2009 (p. 33049), <http://edocket.access.gpo.gov/2009/pdf/E9-16119.pdf>. See also CRS Report RS22600, *The Federal Food Safety System: A Primer*.

<sup>7</sup> 21 C.F.R. 110.19(b). The FFDCA at 21 U.S.C. § 321(r) defines a “raw agricultural commodity” as “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.”

Many of the FFDCA requirements specifically exclude farms. For example, FFDCA § 414 (21 USC §350c) sets forth record-keeping requirements and the circumstances for making these records available for inspection by the HHS Secretary.<sup>8</sup> Other parts of FFDCA § 414 delineate the types of such records, and authorize the promulgation of regulations on record-keeping requirements. The FSMA further amended FFDCA § 414 to establish additional recordkeeping requirements for certain “high risk” foods. FFDCA § 414 states, in part:

If the Secretary has a reasonable belief that an article of food is adulterated or presents a threat of serious adverse health consequences or death to humans or animals, *each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports* such article shall, at the request of an officer or employee duly designated by the [HHS] Secretary, permit such officer or employee, upon presentation of appropriate credentials and with a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records related to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. (emphasis added)

FFDCA § 415 requires food facilities to register with the FDA (21 USC § 350d).

FFDCA § 415(a) requires that “any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the [HHS] Secretary,” among other language. The FSMA further amended FFDCA § 415 to establish additional recordkeeping requirements for certain “high risk” foods. It defines a “facility” as follows:

The term ‘facility’ includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. *Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer...* (emphasis added)

Both FFDCA § 414 and § 415 exempt farms but do not define the term “farm.” The term does not appear to be defined elsewhere in the FFDCA. However, FDA’s implementing regulations for these two provisions of the bioterrorism act do provide more guidance on how farms are to be treated. A portion of the regulations (at 21 CFR 1.226) on the facility registration requirements (i.e., of FFDCA § 415) lists farms among the exempted entities, and (at 21 CFR 1.227) defines a farm as:

a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. The term “farm” includes: (1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

The FDA regulations implementing the record-keeping and access requirements of FFDCA § 414 also exempt farms (at 21 CFR 1.327), and (at 21 CFR 1.328) also define a farm as noted above.<sup>9</sup>

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<sup>8</sup> For practical purposes, this is done by the department’s Food and Drug Administration.

<sup>9</sup> During the rulemaking process, the FDA received extensive comments on how to define a farm, and in its October 10, 2003, final rule on facility registration, it responded in detail. See 68 *Federal Register* pp. 58893–58974.

FDA's general approach has been not to impose mandatory on-farm safety standards or inspections of agricultural facilities.<sup>10</sup> Rather, the agency tends to rely on farmers' adoption of so-called good agricultural practices to reduce hazards prior to harvest. Such practices are issued as FDA guidance, not regulations.<sup>11</sup> The agency's agricultural guidance documents have focused on the safety of fresh fruit and vegetables in recent years, which are more likely to be consumed in uncooked forms than are other regulated foods (cooking can kill many pathogens). FDA's recommendations cover, for example, the use and testing of water that will come in contact with crops, proper application of animal manure, and sanitation for field workers.

FDA in recent years has sought to address recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce. For example, the agency launched in 2006 a "Leafy Greens Initiative." Among the key features of this cooperative and voluntary initiative are visits, in cooperation with state agricultural officials, to farms (as well as produce packers and processors) to assess industry efforts to improve lettuce safety and, if appropriate, "stimulate" further needed efforts.<sup>12</sup> In 2007, FDA issued a "Tomato Safety Initiative" modeled after the lettuce initiative and operated in cooperation with Florida officials. FDA stated at the time that 12 different outbreaks of foodborne illness (including from *Salmonella*) had been linked to fresh tomatoes, a majority of which were grown in Florida.<sup>13</sup> In July 2009, FDA published three guidance documents for tomatoes, melons, and leafy greens.<sup>14</sup>

More recent actions by FDA indicated that the agency may be moving toward a potentially more hands-on regulatory approach to produce safety. In July 2009, the FDA published a final rule to require shell egg producers to implement specific safety measures to prevent on-farm contamination of eggs by *Salmonella* Enteritidis (SE).<sup>15</sup> The rule observes that SE-contaminated eggs have been a major source of foodborne illness and that on-farm prevention measures are needed to reduce SE infections from eggs.<sup>16</sup> The rule requires SE testing in poultry houses, with follow-up tests on eggs if environmental testing is positive for the bacteria. Other measures in the rule address the procurement of chicks and pullets, pest control and biosecurity programs, disinfection of poultry houses where SE is found, and on-farm refrigeration of eggs.<sup>17</sup> The rule

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<sup>10</sup> The FDA advisory panel acknowledged that "[t]he Agency conducts no inspections of retail food establishments or of food-producing farms." *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007, p. 21.

<sup>11</sup> Most FDA guidance documents include the following: "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required." Sources: FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens*, Draft Guidance, July 2009; and FDA, *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008.

<sup>12</sup> FDA, "Lettuce Safety Initiative," August 23, 2006, at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/ucm115906.htm>, which notes that regulatory action would be considered if deemed appropriate to prevent contamination.

<sup>13</sup> "FDA Implementing Initiative to Reduce Tomato-Related Foodborne Illnesses," June 12, 2007. Florida was cleared as the source in the more recent (April-July 2008) *Salmonella*-linked outbreak in which tomatoes were first suspected.

<sup>14</sup> *Ibid.* Available at FDA's website, Produce and Plant Products Guidance for Industry, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm>.

<sup>15</sup> 74 *Federal Register* 21928-21929.

<sup>16</sup> 74 *Federal Register* 33030-33101. As already noted, since May 2010, a large-scale recall of more than 550 million shell eggs has been linked to concerns about a nationwide increase of SE infections.

<sup>17</sup> "Biosecurity" refers to agricultural practices intended to reduce or prevent the introduction of infectious diseases on a farm or other production facility and includes practices such as limiting access by personnel and vehicles; reviewing (continued...)



applies to farms with 3,000 or more laying hens, unless they sell directly to consumers or do not produce shell eggs for table use, although those with less than 50,000 layers have until July 9, 2012, to comply. FDA published a guidance document on April 13, 2010, to help small producers comply with the new rule.<sup>18</sup>

In another recent instance of on-farm regulatory activity, in February 2010, FDA announced,

While USDA's Agricultural Marketing Service (AMS) is in the midst of evaluating a proposed marketing agreement for the leafy green industry, the FDA is currently developing a proposed produce safety regulation. It is our expectation that these products will take into account the diverse nature of farming operations and that any marketing agreement would conform to any regulations that may be promulgated by FDA.<sup>19</sup>

Newly enacted provisions in the FSMA regarding hazard analysis and risk-based preventive controls (§ 103), safety standards for produce (§ 105), and traceability requirements focused in part on produce (§ 204). The FSMA provisions are discussed in greater detail in "Treatment of Farms."

## Food Safety and Inspection Service

USDA's Food Safety and Inspection Service (FSIS) regulates the safety, wholesomeness, and proper labeling of most domestic and imported meat and poultry and their products (and, beginning soon, of catfish products), under authority of the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. 601 *et seq.*), and the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. 451 *et seq.*). Agency officials periodically have stated that these laws provide no direct authority to regulate on-farm activity. Under both statutes, agency oversight begins when animals arrive at slaughter facilities. These laws direct the Secretary of Agriculture to prevent adulterated meat and poultry from entering commerce by examining all animals just before slaughter (*ante-mortem*), with additional provisions requiring post-mortem inspections of all carcasses and of food products made from these carcasses (21 U.S.C. § 455 and §§ 603-606).

Farmers and ranchers do not appear to be among the persons, establishments, and other firms subject to the provisions of these acts, including record-keeping requirements and penalties for noncompliance. Neither act "speaks to how livestock are produced, maintained, or managed,"

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(...continued)

and screening introduced items such as seed, feed, and new animals; and controlling vermin. More recently, biosecurity programs have incorporated elements to protect against terrorism, vandalism, and other intentional acts that could compromise disease control, whether or not they were the primary aim of the illicit acts.

<sup>18</sup> *Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Transportation, and Storage; Small Entity Compliance Guide*, April 2010, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/SmallBusinessesSmallEntityComplianceGuides/ucm207507.htm>.

<sup>19</sup> "USDA and FDA Coordinating Efforts to Ensure Safety of Produce: FDA Invites Public Comments to Inform Future Rulemaking," February 18, 2010, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm200965.htm>. The FDA's docket notice inviting public comments was published in the February 23, 2010, *Federal Register*. The AMS leafy greens marketing agreement is described in the "Leafy Greens Marketing Agreement" section of this CRS report.

according to a 1998 report issued by the Institute of Medicine of the National Academy of Sciences.<sup>20</sup>

FSIS and livestock industry officials have asserted that agricultural producers are indirectly regulated under these laws. For example, slaughter establishments are not to accept unhealthy or mistreated animals that may harbor diseases and pathogens dangerous to humans. Such animals can spread contamination in plants, as well as result in rejection or other enforcement actions by inspectors and/or costly (if ostensibly voluntary) product recalls, it is argued. Moreover, FSIS has worked with animal industry organizations to encourage producers to adopt voluntarily “best practices” aimed at reducing the spread of pathogens like *E. coli* O157:H7 among live animals.

## Other Programs Affecting Producers

### Regulation of Animal Drugs and Feeds

Under the FFDCFA, FDA’s Center for Veterinary Medicine regulates the manufacture and distribution of drugs and feeds for animals. Drugs are used in food-producing animals to treat and prevent animal diseases and to improve growth rates, such as with antibiotics. If unapproved or used improperly, they can compromise human food safety. Another regulatory example affecting producers is FDA’s rule prohibiting the use, in animal feeds, of materials of ruminant origin. This rule is aimed at preventing the spread of bovine spongiform encephalopathy (BSE, or “mad cow disease”); though rare, a human form of BSE can be contracted if infected tissues are consumed.<sup>21</sup>

In addition to drug approvals and oversight of feed manufacturers, FDA also works with FSIS, which tests for violative residues of antibiotics and other drugs in meat and poultry and reports them to FDA. FDA can conduct follow-up inspections (often done through state agencies) of livestock producers and others. Another cooperative effort between FDA and state milk control officials is the National Drug Residue Milk Monitoring Program, which routinely tests raw milk for certain drug residues.

### Regulation of Pesticides

The Environmental Protection Agency (EPA) regulates the sale and use of pesticides, including those used to control insects, weeds, mold, and other pests affecting food crops, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; P.L. 92-516). It is a violation of FIFRA to use a pesticide that is inconsistent with its approved label instructions. Under the FFDCFA, EPA sets allowable residue levels, called tolerances, for pesticides used in food production. Tolerances are set to ensure that harm to health is prevented with “a reasonable certainty.” Foods with residues that exceed tolerances, or that contain a residue that lacks an established tolerance, are considered adulterated under the FFDCFA. Generally, the FDA monitors and enforces residue limits, while EPA and the states enforce FIFRA’s provisions.<sup>22</sup>

The FDA Science Board, in its November 2007 report, argued that these programs have their limitations: “These [FDA and EPA] conditions are meant to prevent the presence of dangerous

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<sup>20</sup> *Ensuring Safe Food from Production to Consumption*, National Academies Press, Washington, D.C., 1998.

<sup>21</sup> FDA’s website: <http://www.fda.gov/cvm/bsetoc.html>.

<sup>22</sup> See CRS Report RL31921, *Pesticide Law: A Summary of the Statutes*.

amounts of those chemicals in food. However, monitoring of compliance with approved usage is poorly funded and episodic. State and local authorities have more to say about on-farm practices, but their monitoring capabilities are severely limited.”<sup>23</sup>

### **Animal Health Programs**

Under the Animal Health Protection Act (7 U.S.C. § 8301 *et seq.*), USDA’s Animal and Plant Health Inspection Service (APHIS) is to protect U.S. livestock and poultry from domestic and foreign diseases and pests. Some of these diseases, including BSE, avian influenza (AI), and bovine tuberculosis, also have public health implications. *Salmonella* Enteritidis, an infection found among poultry (see previous discussion), is a major cause of foodborne illness in humans. Although the APHIS programs often are cooperative, voluntary efforts between APHIS, states, and industry, APHIS does have the authority to impose quarantine, eradication, and other regulatory requirements on producers. These requirements relate to the control animal diseases, however, not food contamination.

Under another program, USDA is proposing a new approach that will allow individual states (and tribal nations) to chose their own degree of within-state animal identification (ID) and traceability for livestock populations. This voluntary program is intended to improve the ability to pinpoint and control animal diseases.<sup>24</sup> Some policymakers believe animal ID, which seeks to document the movements of individual animals, or herds or flocks, from place of birth to slaughter, can contribute to food safety, particularly if it can be linked to a farm-to-retail food traceability system. (Other policymakers counter that animal ID should be limited to animal disease control.)

### **Federal Marketing Programs**

USDA’s Agricultural Marketing Service (AMS) oversees a number of programs intended to assure that various agricultural products meet specified quality and grade standards, sometimes involving safety attributes. For example, under the Agricultural Marketing Agreement Act of 1937 (7 U.S.C. § 601 *et seq.*), producers and handlers can organize themselves under legally binding marketing orders and agreements that can include quality (and possibly, safety) standards.

Under the Agricultural Marketing Act of 1946 (7 U.S.C. § 1621 *note*), AMS has implemented a wide range of voluntary testing and process verification programs. Funded by industry user fees, these AMS services use independent, third-party audits and other standardized procedures to help producers certify that their products meet buyer specifications.<sup>25</sup> Although some of these programs can be, and are, designed to ensure the safety of certain food commodities from a public health standpoint, they are not regulatory by nature. Rather, they are intended to facilitate

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<sup>23</sup> FDA Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007.

<sup>24</sup> For more information, see CRS Report R40832, *Animal Identification and Traceability: Overview and Issues*.

<sup>25</sup> More detailed information about this programs was presented in May 14, 2009, testimony before the House Agriculture Subcommittee on Horticulture and Organic Agriculture by AMS Acting Administrator David Shipman, <http://agriculture.house.gov/testimony/111/h051409/Shipman.pdf>. Detailed information is available at the AMS website, <http://www.ams.usda.gov>.

commercial agreements in the trade or to provide consumers with more information about their prospective purchases.<sup>26</sup>

## **Leafy Greens Marketing Agreement**

In October 2007, AMS invited comments on whether to create a federal marketing program that specifically would commit handlers (packers, processors, shippers) of leafy greens, including lettuce and spinach, to meet prescribed safety standards.<sup>27</sup> In June 2009, a group of agricultural associations formally requested that AMS begin the steps toward establishment of a national marketing agreement for leafy greens.<sup>28</sup> The key difference between an agreement and an order is that an agreement is legally binding only on those who voluntarily join it, whereas an order is binding on all handlers. Nonetheless, sponsors of the request for a national agreement (including major produce industry associations) anticipate broad participation.

A similar state order was adopted in California in 2007 and by Arizona later that year. Under the California Leafy Green Products Handler Marketing Agreement (LGMA), nearly 120 handlers (essentially, those who first handle the product as it leaves the farm), representing 99% of the volume of California-grown leafy greens, have committed to selling products grown in compliance with the food safety practices accepted by the LGMA board. Members submit to mandatory third-party audits to verify compliance.<sup>29</sup> Reportedly, California and Arizona represent approximately 90% of leafy greens production, and a national agreement would seek to cover the nation's remaining 10%.<sup>30</sup>

Such audits would be to ensure that the good agricultural production, handling, and related practices the agreement stipulates—referred to as “metrics”—are being followed. These practices are aimed at enhancing the safety aspects of produce quality. Some food safety advocacy organizations have expressed concern that AMS, an agency whose primary mandate is providing quality and grading services to industry, essentially would be conducting safety inspections, which is within the purview of FDA.<sup>31</sup> The metrics themselves are not regulatory FDA standards under the FFDCA; however, the agreement's drafters expect that any violations of FDA law will be reported to the FDA by agricultural inspectors.<sup>32</sup>

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<sup>26</sup> For a more detailed analysis of USDA's on-farm authorities with respect to food safety, see CRS Report R40577, *USDA Authority to Regulate On-Farm Activity*.

<sup>27</sup> An advance notice of proposed rulemaking appeared in 72 *Federal Register* pp. 56678-80. A provision in the House-passed farm bill in 2007 (H.R. 2419) would have expressly authorized the implementation of quality-related food safety programs under marketing orders for specialty crops. The provision was deleted from the final version in 2008 (P.L. 110-246).

<sup>28</sup> See, for example, letter from various produce groups to USDA's AMS Administrator Rayne Pegg, July 31, 2009, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5081064>.

<sup>29</sup> California Leafy Green Products Handler Marketing Agreement website, <http://www.caleafygreens.ca.gov/>.

<sup>30</sup> “Produce industry petitions USDA for leafy greens marketing agreement,” *Food Chemical News*, June 15, 2009.

<sup>31</sup> Concerns about the use of marketing agreements as food safety instruments were aired at a July 29, 2009 hearing before the House Committee on Oversight and Government Reform's Subcommittee on Domestic Policy.

<sup>32</sup> National Leafy Greens Marketing Agreement, “Frequently Asked Questions,” <http://www.nlgma.org/faqs.php>. The greens to be covered by the national agreement would be arugula, cabbage (red, green, and savoy), chard, cilantro, endive, escarole, kale, lettuce (iceberg, leaf, butterhead, and romaine), parsley, raddichio, spinach, spring mix (baby leaf items including but not limited to cress, dandelion, endigia, mache, mizuna, tat soi, winterpurslane), or any other leafy green recommended by the committee and approved by USDA.

Currently, the USDA (AMS) role in a national agreement is to publish a notification regarding the request and to conduct public hearings. In fall 2009, USDA held public hearings on a proposed marketing agreement covering leafy green vegetables and products under the Agricultural Marketing Agreement Act.<sup>33</sup> If adopted, the agreement would be managed by an industry committee and would provide for AMS inspectors, or inspectors designated by AMS, to audit producers who supply the participating handlers. These inspections would be conducted on a fee-for-service basis, although AMS asked Congress to provide it with \$2.3 million to write and initiate an agreement. In March 2010, FDA announced that it would issue a proposed rule to establish safety standards for the production and packing of fresh produce by the end of 2010.<sup>34</sup> Many produce groups supporting the establishment of a national marketing agreement further want Congress to consider viewing the LGMA as “an instructive example for how to proceed” with the development of new food safety rules and regulations.<sup>35</sup>

## FDA Food Safety Modernization Act

The 111<sup>th</sup> Congress passed comprehensive food safety legislation in December 2010 (FDA Food Safety Modernization Act (FSMA), P.L. 111-353).<sup>36</sup> Although numerous agencies share responsibility for regulating food safety, this newly enacted legislation focused on foods regulated by the Food and Drug Administration (FDA) and amended FDA’s existing structure and authorities, in particular the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§ 301 *et seq.*). The 112<sup>th</sup> Congress will likely provide oversight and scrutiny over how the law is implemented, including FDA’s coordination with other federal agencies, such as those in the U.S. Department of Agriculture (USDA) and the Department of Homeland Security (DHS). Implementation of FSMA will depend largely on discretionary appropriations, and some have questioned whether funding is available in the current budgetary climate.

Several of the FSMA requirements could potentially affect farms, especially produce growers. The provision that could have the most direct effect on on-farm activity is the establishment of new standards for produce safety. Other requirements that could affect on-farm activity include facility registration requirements, records access and inspection requirements, food traceability requirements, hazard analysis and risk-based preventive controls, and targeting of inspection resources. The enacted law, however, reflects compromise language intended to address concerns about the potential economic and regulatory effects to small businesses.

Throughout the food safety debate, Congress continued to modify provisions to address the potential effects of the proposed food safety requirements on small farms and food processors, as well as organic, direct-to-market, and sustainable farming operations. For example, although the House Energy and Commerce Committee amended and approved its version of the bill (H.R. 2749) to address small-farm concerns, the version passed by the full House in June 2010

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<sup>33</sup> 74 *Federal Register*, 45565-45574, September 3, 2009, <http://www.gpo.gov/fdsys/pkg/FR-2009-09-03/pdf/E9-21295.pdf>. Information on the hearings is at AMS website.

<sup>34</sup> FDA, “Preventive Controls for Fresh Produce” (FDA-2010-N-0085), March 12, 2009, <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/ucm202945.htm>.

<sup>35</sup> Comments to FDA on preventive controls for fresh produce safety (Docket No. FDA-2010-N-0085) from Scott Horsfall and the Leafy Green Products Handler Marketing Agreement, July 23, 2010.

<sup>36</sup> For more detailed information see CRS Report R40443, *Food Safety in the 111<sup>th</sup> Congress: H.R. 2749 and S. 510*, coordinated by Renée Johnson.

contained additional changes addressing agricultural interests. Similarly, the Senate version of the bill (S. 510) reported by the Senate Health, Education, Labor, and Pensions Committee in December 2009 was further modified to address small-farm concerns as part of a substitute manager’s amendment agreed to by Senate leaders that was released in August 2010. Despite these changes, some farm groups are continuing to push for additional changes to further address these concerns. The FSMA includes provisions that will exclude certain small businesses—both farms and food processors—from some of the food safety requirements. For a more detailed timeline of these events, see **Appendix**.

## **Treatment of Farms**

The FSMA provisions that could have the most direct effect on on-farm activity, especially for produce growers, will be the establishment of new standards for produce safety. These provisions will require that producers follow new minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities. These provisions, among other provisions, could potentially affect agricultural producers. In summary, these are:

- new on-farm safety standards, especially for produce (§ 105);
- facility registration requirements (§ 102);
- records access and/or inspection requirements (§§ 101 and 204);
- food traceability requirements (§ 204);
- hazard analysis and risk-based preventive controls (§ 103); and
- targeting of inspection resources (§ 201).

Although these provisions contain requirements that might affect small business and farming operations, the law takes into account the needs of small businesses and provides for coordination of enforcement and education activities with others such as USDA and state authorities.

The full extent to which these other provisions might actually affect small business and farming operations remains unclear, since the specific business requirements under these provisions would be subject to agency rulemaking, as well as the discretion of the HHS Secretary. It is not possible to estimate what share of all food processing operations might be exempt from the new HACCP-like requirements, how many farms might be exempt from the new produce standards, or how other small business considerations might possibly mitigate the effects of these and other requirements in the proposal. In part, this is because the definition of small and very small business would be determined by HHS in future agency rulemaking and subject to other requirements specified in the measures. Even though farms would continue to be exempt from the proposed facility registration requirements, there are farms that also engage in food processing that might be affected. Data are not available to determine what share of farms also engage in food processing. In addition, regarding foods that are sold locally and/or to certain qualified end-users, data are also not available to determine what share of grower-processors might qualify for such an exemption. Such a determination would likely be made on a case-by-case basis.

## **Standards for Produce Safety**

FSMA § 105 establishes a new FFDCA § 419, regarding safety standards for produce. It would require within one year—in consultation with USDA and state agriculture departments (including

with regard to the national organic foods program), and in consultation with the Department of Homeland Security—the publication of a notice of proposed rulemaking for “science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the [HHS] Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.” The law provides that any proposed rules include, with respect to growing, harvesting, sorting, packing, and storage operations, minimum standards related to soil amendments, hygiene, packaging, temperature controls, animal encroachment, and water; and they are to “consider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism.”

The FSMA also provides that proposed rulemaking shall “provide sufficient flexibility to be applicable to various types of entities ... including small businesses and entities that sell directly to consumers and be appropriate to the scale and diversity” of production and harvesting, as well as take into consideration, consistent with public health protection, “conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies.” It also requires that for certified organic production, the rules shall “not include any requirements that conflict with or duplicate the requirements of” the national organic foods program, while providing the same level of protection as required under this act. Priority is to be given to those raw fruits and vegetables that have been associated with foodborne illness outbreaks. The FSMA also includes provisions for public input, timelines for implementation of rules, and a system for granting variances for states and foreign governments.

The FSMA contains provisions for consideration of small businesses. As noted above, small and very small businesses may be exempted from regulation if the Secretary has determined these “are low risk and do not present a risk of serious adverse health consequences or death.” In addition, there are extended implementation deadlines for small and very small businesses: small businesses (as defined by the Secretary) are given one year after final regulations are promulgated, and very small businesses (as defined by the Secretary) two years after final regulations. In addition, the HHS Secretary is required to issue a “small entity compliance policy guide” to assist small entities in complying with the registration requirements and other activities (no later than 180 days after the issuance of the regulations under this section). The Secretary must also ensure that any updated guidance complies with the Paperwork Reduction Act (PRA) and minimizes regulatory burden and unnecessary paperwork and the number of separate standards on the facility, among other clarifications regarding acknowledgment of risk differences and compliance burden.

The FSMA exempts certain farms from the new produce standards. Farms that would be exempt from the produce standards under Section 105 also include those with a three-year average monetary value of the food they sold of less than \$500,000, provided that the food is sold directly to the similarly defined “qualified end users” and if the farm provides similar notification to consumers. The exemption for both facilities and farms may be revoked in the event that a foodborne illness outbreak is directly linked to an exempted facility or farm, or based on a determination by the HHS Secretary.

## **Inspection of Records**

FSMA § 101 amends FFDC § 414 and modifies the circumstances under which the HHS Secretary could access the records of facilities (see above definitions for what is or is not

considered a facility). However, it does not appear to change the definition of a facility; thus farms would not be newly impacted by this provision, at least directly.<sup>37</sup> However, farms that fall within the definition of “facility” (e.g., those that process some or all of their production for sale) would be affected.

### **Registration of Food Facilities**

FSMA § 102 amends FFDC § 415 to require biennial facility registration, with an abbreviated process for registrants whose information has not changed. It would require all food facilities to register biennially, and there is new language regarding what information should be provided and regarding terms for suspending registrations. However, this provision would not alter the definition of “facility” in the current FFDC § 415; farms are not affected unless they process food for sale. In addition, the FSMA does not set a registration fee.<sup>38</sup> However, it does provide consideration of small businesses, including a requirement that the Secretary issue a “small entity compliance policy guide” no later than 180 days after issuing regulations.

The FSMA contains a provision that would clarify the types of businesses that should be considered to be “retail food establishments” and therefore generally not subject to the facility registration requirements. It specifies that roadside stands, farmers’ markets, and foods sold through a community-supported agriculture (CSA) program would also not be subject to the requirements.

### **Hazard Analysis and Risk-Based Preventive Controls**

FSMA § 103 establishes a new FFDC § 418, requiring the owner, operator, or agent in charge of a facility to develop, implement, and keep records on preventive controls for food safety. It references the current definition of “facility” under FFDC § 415. Therefore, farms are not affected unless they process food for sale. The law explicitly permits the Secretary to exempt or modify compliance requirements for those facilities “solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.”

As with other provisions, there is consideration of small businesses, including a requirement that the Secretary issue a “small entity compliance policy guide” no later than 180 days after issuing regulations. It provides for extended implementation deadlines for small and very small businesses: small businesses (as defined by the Secretary) are to have two years after final regulations are promulgated, and very small businesses (as defined by the Secretary) three years after final regulations. The bill also contains clarifying language regarding the promulgation of FDA regulations, including consideration for various types of businesses and activities (on-farm and at processing facilities).

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<sup>37</sup> It could be argued that this provision—and other provisions of S. 510 not readily applicable to farms—might indirectly affect farms if, for example, the buyers of their products were to require a farm supplier to meet new contractual terms to help the buyer meet any newly enacted food safety requirements.

<sup>38</sup> The House-passed food safety bill (H.R. 2749) would have imposed a \$500 per facility registration fee. This proposal was not adopted in the enacted law.



The FSMA further exempts certain food processing operations from the new HACCP-like requirements under § 103 if they are either a “very small business” as defined by FDA in rulemaking, or if the facility’s “average annual monetary value” of all food sold during the previous three-year period was less than \$500,000, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments located in the same state where the facility sold the food or within 275 miles of the facility. Such a facility would need to demonstrate that it either has “identified potential hazards associated with the food being produced,” and is implementing and monitoring these preventive controls, or that it is “in compliance with State, local, county, or other applicable non-Federal food safety law.” Foods produced from such a facility would also need to provide the facility’s name and address on a food packaging label or at the point of purchase.

### **Targeting of Inspection Resources**

FSMA § 201 specifically requires the HHS Secretary to inspect food facilities (as defined under FFDCFA § 415) and to allocate inspection resources according to the risk profiles of the facilities. Generally, those determined to be of lower risk must be inspected at least once every four years; those of higher risk within two years of enactment and then every year thereafter. Again, farms that process food for sale would be subject to these inspections; others would not because they are excluded under current law from the definition of a “facility.”

### **Enhancing Traceback and Record-Keeping**

FSMA § 204 requires the Secretary, in consultation with USDA and state officials, to improve the capacity of FDA to effectively and rapidly track and trace foods in the event of an outbreak. Within 270 days of enactment, the Secretary is required to establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated or misbranded. Participants are to include one or more projects with the processed food sector and one or more projects coordinating processors or distributors of fruits and vegetables that are “raw agricultural commodities,” reflecting the diversity of the food supply. The projects must include at least three different types of foods that have been the subject of significant outbreaks during the five-year period preceding enactment, among other criteria for project selection intended to inform future rule promulgation.

The Secretary shall publish a notice of proposed rulemaking to establish additional record-keeping requirements for high-risk foods, subject to certain specified conditions, no later than two years after enactment. The Secretary shall designate such high-risk foods within one year after enactment based on criteria specified in the provision, and shall publish the list of the foods designated as high-risk, which may be subject to updates and revision. The record-keeping requirements address information protection; public input; and rules on retention of records. They allow for the consideration of less restrictive requirements (as specified) for farm-to-school or farm-to-institution programs of USDA and other related programs; food produced through the use of a fishing vessel; producers of commingled raw agricultural commodities; grocery stores; direct farm sales to consumers or grocery stores; and “identity-preserved labels” on farm sales of food produced and packaged on a farm, among others. The Secretary may modify requirements, or exempt a food or facility from them, if product tracing requirements are not needed to protect public health. The law also specifies the information the Secretary may request from U.S. farms,

subject to certain limitations, but specifies that the Secretary is not authorized to impose any limitations on commingled foods. With the exception of farms, failure to comply with record-keeping provisions under this section is prohibited.

There is also consideration of small businesses, including the requirement that the Secretary issue a "small entity compliance policy guide" and provide delayed implementation timelines for small and very small operations to comply with the requirements. Small businesses (as defined by the Secretary) will have one year after final regulations are promulgated, and very small businesses (as defined by the Secretary) two years after final regulations to comply.

## Mitigating Effects on Small Business and Farms

Concerns among farm and rural groups about the potential effects of new food safety requirements on farms and food processors surfaced early in the debate over how to reform U.S. food safety laws (see **Appendix**). Most vocal were small farms and processors; organizations representing small, organic, direct-to-market, and sustainable farming operations; and small livestock operations.<sup>39</sup> At issue is whether numerous proposed requirements would be more costly and burdensome to small farms and other small businesses than could be justified by the potential public health protections such requirements are intended to provide.

Considerations for small business could take many forms, including waiving certain requirements, providing additional time for compliance, providing grants and/or technical assistance to aid in compliance, and exempting certain types of businesses from meeting the requirements. Currently the FFDCFA exempts some types of businesses from certain food safety requirements. For example, farms, restaurants, other retail food establishments, and certain nonprofit food establishments and fishing vessels are exempt from facility registration requirements under FFDCFA § 415.

Various approaches might be used to define whether a farm or food processor is a "small" business. Often, a definition is based on a particular threshold value for a financial or business measure, such as annual income or value of sales, numbers of employees, or other measures.

With respect to farming operations, USDA typically relies on measures of *gross cash income* as a measure of the size of a farm business. Gross cash income refers to the sum of all receipts from the sale of crops, livestock, and farm-related goods and services, including any direct payments from the government. For purposes of classifying farms, USDA defines a "small commercial farm" as an operation with gross cash income of \$10,000 to less than \$250,000 annually; "large farms" are defined as farms with gross cash income of \$250,000 to less than \$1 million.<sup>40</sup> USDA defines farms with gross cash income of less than \$10,000 annually as very small, non-commercial farms. Under these definitions, USDA data indicate that about one-third of all crop and livestock producers are considered "small commercial" farms (**Table 1**). The share of small commercial farms will vary depending on commodity. For example, among fruit and vegetable

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<sup>39</sup> See CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Legislative Action*.

<sup>40</sup> Hoppe, R.A., "U.S. Farm Structure: Declining—But Persistent—Small Commercial Farms," *Amber Waves*, USDA, September 2010; and Hoppe, R.A., *Small Farms in the United States: Persistence Under Pressure*, EIB-63, USDA, February 2010. Based on 2007 survey data.

producers who might be affected by requirements under the House and Senate food safety measures, the share of small commercial farms is roughly 10% of all growers in this category.<sup>41</sup>

The size threshold used and the type of income counted to define a small business varies in legislation and by agency. For example, the Small Business Administration (SBA) has set different thresholds for defining a small business that vary considerably from USDA: among most crop and livestock producers, SBA defines as a small business those who make no more than \$750,000 in sales per year.<sup>42</sup> In some cases, however, USDA uses SBA's definition for defining a small business. Specifically, SBA's threshold of \$750,000 in annual sales is used by USDA to determine small and very small meat and poultry plants as part of FSIS's outreach and oversight activities under its HACCP implementation and laboratory testing programs.<sup>43</sup> Under SBA's business size standards, more facilities would be considered small businesses, with up to one-half of all commercial crop and livestock producers defined as small.<sup>44</sup>

Elsewhere in farm legislation, such as in the periodic omnibus farm bill,<sup>45</sup> *adjusted gross income (AGI)* is an alternative income measure that is generally used to differentiate farm size. AGI is a common measure of income for tax purposes, combining income from all sources. Business income contributes to AGI on a net basis, that is, after business expenses. Thus, it is comparable to profit: sales minus expenses and also taxable deductions. In the farm bill, an AGI limit is used to differentiate wealthier farm households as a means test for the maximum amount of income that an individual can earn and still remain eligible for commodity program benefits, including any direct payments from the government. The 2008 farm bill tightened these limits by reducing the AGI limit to \$500,000 of non-farm AGI and \$750,000 of farm AGI.<sup>46</sup> Given that most business information is proprietary, data are limited on the share of commodity producers (farms and food processors) that have an annual AGI of less than \$500,000. Information for U.S. farms indicates that farms with less than \$500,000 AGI account for more than 95% of all farms.<sup>47</sup>

Data are not available indicating what share of all farms also engage in food processing. Such operations might include fruit and vegetable producers that pack or further process the produce they grow by making products such as jams, jellies, or juices, or other processed fruit and vegetable products; other examples might include dairies that are also producer-handlers that bottle their own milk. Also, only limited data are available that generally characterize the market and producer channels for so-called locally or sustainably produced foods, or other direct-to-market foods.<sup>48</sup>

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<sup>41</sup> Ibid., Figure 3.

<sup>42</sup> Small Business Size Regulations, Title 13 C.F.R. Part 121.

<sup>43</sup> Correspondence between CRS personnel and askFSIS (<http://www.fsis.usda.gov/>).

<sup>44</sup> Based on data on farms that make up to \$1 million. USDA survey data are not published for farms that generate between \$500,000 and \$750,000 in annual sales.

<sup>45</sup> The most recent farm bill was the Food, Conservation, and Energy Act of 2008, P.L. 110-246. For more information, see CRS Report RL34594, *Farm Commodity Programs in the 2008 Farm Bill*.

<sup>46</sup> Ibid.

<sup>47</sup> The White House, "Strengthening the Rural Economy—Improving America's Support of Agriculture," <http://www.whitehouse.gov/administration/eop/cea/factsheets-reports/strengthening-the-rural-economy/improving-americas-support-of-agriculture>. Based on USDA data from the Agricultural Resource Management Survey.

<sup>48</sup> See for example Martinez, S. et al., *Local Food Systems, Concepts, Impacts, and Issues*, ERR-97, USDA, May 2010, <http://www.ers.usda.gov/Publications/ERR97/ERR97.pdf>; and Hoppe, R.A. et al., *Small Farms in the United States, Persistence Under Pressure*, EIB-63, USDA, February 2010, <http://www.ers.usda.gov/Publications/EIB63/EIB63.pdf>.

**Table I. U.S. Farms and Food Manufacturers, 2007**

(by size based on average annual sales receipts)

<b>Farms and Food Manufacturing Establishments</b>	<b>Number</b>	<b>Percent</b>
<b>All Farms, Total</b>	<b>2,204,792</b>	<b>100.0%</b>
Less than \$10,000 (defined by USDA as “very small, non-commercial” farms)	1,271,735	57.7%
Between \$10,000-\$249,000 (defined by USDA as “small commercial” farms)	715,947	32.5%
Between \$250,000-\$499,000	96,251	4.4%
More than \$500,000	120,859	5.5%
<b>All Food Manufacturing, Total<sup>a</sup></b>		
Total, All Food Manufacturers	<b>25,796</b>	<b>100.0%</b>
Less than \$500,000	8,906	34.5%
<b>Selected Food Manufacturing Sectors<sup>b</sup></b>		
Grain and Oilseed Milling, Total	830	100.0%
Less than \$500,000	71	8.6%
Fruit/Vegetable Manufacturing, Total	1,668	100.0%
Less than \$500,000	203	12.2%
Dairy Product Manufacturing, Total	1,612	100.0%
Less than \$500,000	174	10.8%
Animal Slaughtering and Processing, Total	3,817	100.0%
Less than \$500,000	784	20.5%
Seafood Preparation/Packaging, Total	685	100.0%
Less than \$500,000	114	16.6%
Bakeries/Tortilla Manufacturing, Total	10,269	100.0%
Less than \$500,000	5,835	56.8%
Other Food Manufacturing, Total	3,310	100.0%
Less than \$500,000	671	20.3%

**Source:** Data for farms are from USDA, *2007 Census of Agriculture*, Table 58, December 2009. Data for manufacturing establishments are from the U.S. Census Bureau’s *2007 County Business Patterns* based on annual survey data for all food manufacturers on the number of establishments by “enterprise receipt size,” <http://www.census.gov/econ/sub/>.

**Notes:** “Average annual sales” includes market value of agricultural products sold and government payments. Farm size designations are those described by USDA in *Small Farms in the United States: Persistence Under Pressure*, EIB-63, February 2010, <http://www.ers.usda.gov/publications/eib63/>. For manufacturing, industry classification is based on 2002 North American Industry Classification System (NAICS) codes.

- a. Included in this total, but not shown separately are data for sugar and confectionery and animal food manufacturing.
- b. Ranked in order by NAICS code but including sugar and confectionery and animal food manufacturing.

For food processors and manufacturers, often different business measures are used to define small businesses. SBA definitions of small food processors are based on the number of employees at a business. Given that most farms do not employ large numbers of workers, size standards based on the number of employees are generally not applicable to farming operations. Among most food processors, a small business is defined by the SBA as a business with no more than 500 employees.<sup>49</sup> By this definition, nearly all (97%) of all food processors would be considered small businesses based on U.S. Census Bureau data.<sup>50</sup> The U.S. Census Bureau also tabulates data for manufacturing facilities based on annual sales receipts (**Table 1**).

FDA regulations also define certain small food processing businesses, but they are case by case and not inclusive. For example, FDA's current HACCP regulations exempt "small" juice processors as those "employing fewer than 500 persons."<sup>51</sup> Accordingly, available data indicate that as many as 84% of businesses that make juice are not covered by the HACCP requirements.<sup>52</sup> Very small businesses are also exempt, and so defined by FDA if they meet one of the following three criteria: "annual sales of less than \$500,000, total annual sales greater than \$500,000 but total food sales less than \$50,000, or operations that employ fewer than an average of 100 full-time equivalent employees and sell fewer than 100,000 units of juice in the United States."<sup>53</sup> Available data indicate that about 12% of all fruit and vegetable manufacturers have annual sales less than \$500,000 (**Table 1**). Producers of "raw agricultural ingredients of juice," such as fruit and vegetable growers, are not covered by the HACCP requirements.

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<sup>49</sup> Small Business Size Regulations, Title 13 C.F.R. Part 121.

<sup>50</sup> Based on annual survey data for all food manufacturers on the number of firms broken out by employment size of the enterprise. U.S. Census Bureau, *2007 County Business Patterns*, <http://www.census.gov/econ/susb/>.

<sup>51</sup> Hazard Analysis And Critical Control Point (HACCP) Systems, Title 21 C.F.R. Part 120.

<sup>52</sup> U.S. Census Bureau, *2007 County Business Pattern*. Data for "Frozen Fruit, Juice, and Vegetable Manufacturing."

<sup>53</sup> Hazard Analysis And Critical Control Point (HACCP) Systems, Title 21 C.F.R. Part 120.

## Appendix. Farm Interest Concerns

In the 110<sup>th</sup> and 111<sup>th</sup> Congress, comprehensive food safety legislation was actively debated, and the largest expansion of FDA's food safety authorities since the 1930s was enacted (FDA Food Safety Modernization Act (FSMA), P.L. 111-353). Concerns among farm and rural groups about the potential economic and regulatory effects on farms and food processors of provisions in the proposed legislation calling for new food safety requirements surfaced early in the debate. Most vocal were small farms and food processors; organizations representing small, organic, direct-to-market, and sustainable farming operations; and also small livestock operations. Below is an accounting of selected events during the 111<sup>th</sup> Congress's food safety debate.

### House Debate

Early on in the food safety debate, concerns among farm and rural groups arose following the introduction by Representative Rosa DeLauro of a comprehensive food safety bill (H.R. 875), among other congressional bills. In part, these concerns arose in the wake of a series of Internet videos and postings asserting that the proposed food safety bills would undermine or even destroy the nation's small and organic farms, to the benefit of industrialized agriculture.<sup>54</sup> Concerns were directed at the fact that none of the original bills' farm-related provisions appeared to explicitly exempt such operations, other than directing that the needs of small businesses be considered during implementation. Some groups, such as the Organic Consumers Association (OCA) and La Vida Locavore, sought on the one hand to challenge what they viewed as the "hysteria" and unsubstantiated facts that were circulating (about H.R. 875 in particular), and on the other hand to criticize sharply the bill's language.<sup>55</sup> Most concerns centered on potential ambiguity in the definition of a "food production facility" and fears that organic producers as well as "individuals beyond large farms (i.e., backyard gardeners) could be penalized and subject to review by the government."<sup>56</sup>

In a posting on her own website, Representative DeLauro sought to challenge the "myths" about her bill, H.R. 875, arguing that its focus was to ensure the safety of food in interstate commerce, not to regulate or penalize backyard gardens or farmers markets. She also asserted it would not interfere with organic farming, and had the support of major consumer and food safety groups.<sup>57</sup>

One consumer advocacy organization acknowledged that some of the bills contained provisions that could prove problematic for small farms and processors and that "one-size-fits-all regulation only tends to work for one size of agriculture—the largest industrialized operations." However, it urged affected interests essentially to seek improvements in the bills rather than to defeat "any

<sup>54</sup> See, for example, <http://www.youtube.com/watch?v=eDl6RjYaOt4> (video) and articles; <http://educate-yourself.org/cn/HR875andS425organicfarmingban13mar09.shtml>.

<sup>55</sup> See, for example, OCA, "H.R. 2749 The Food Safety Enhancement Act," *Action Alert*, <http://capwiz.com/grassrootsnetroots/issues/alert/?alertid=13799941>; and Jane Richardson, "HR 875 Rumors Will Destroy Our Credibility," March 23, 2009, <http://www.lavidalocavore.org/showDiary.do?diaryId=1266>.

<sup>56</sup> Alexandra Gross, "Food Fight: The Food Safety Bill Is Cause for Concern, Not Panic," *E Magazine*, March/April 2009, <http://www.emagazine.com/view/?4629&src=QSA062>.

<sup>57</sup> "Myths and Facts, H.R. 875—The Food Safety Modernization Act," [http://delauero.house.gov/files/HR875\\_Myths\\_Facts1.pdf](http://delauero.house.gov/files/HR875_Myths_Facts1.pdf).

attempt to fix our broken food safety system.”<sup>58</sup> At a conference in early April 2009, Carol Tucker Foreman, of Consumer Federation of America’s Food Policy Institute, agreed that Congress might want to consider tailoring some requirements based on different types of operations or phasing in requirements for some operations. Foreman suggested, for example, possibly exempting direct-to-market farms (e.g., those serving farmers markets).<sup>59</sup>

Around this time, H.R. 2749 had overtaken the DeLauro bill (H.R. 875) as the House food safety vehicle, and it had been altered several times in response to criticisms by agricultural interests. H.R. 2749 was modified during committee action to exempt direct-to-market farms from some of the new traceability provisions. However, some small farm advocates have continued to express their opposition to this and other major sections of the bill. For example, although the bill’s new facility registration requirements continued to exempt farms, there were concerns that the requirements could be applied by FDA to a farm that does any processing, even of its own food, such as washing and packaging fruits and vegetables before selling them. These and other provisions appeared to create a regulatory framework that would heavily burden small farms and local food processors, which some claim are “the very people who provide a safe, healthy alternative to the industrial food supply.”<sup>60</sup>

#### One mainstream agricultural publication observed

small farms and organic growers are objecting to any requirement that they register their facilities and be subject to possible inspection by federal authorities. Apparently they are as pure as the driven snow and claim that food borne diseases only come from ‘some multinational food corporation’ (e.g., ignore CDC data on outbreaks at fairs, festivals, *campylobacter* from small local dairy farms, etc.).<sup>61</sup>

As H.R. 2749 was being readied for consideration by the full House, some of the more traditional agricultural groups weighed in with their own concerns. For example, in separate letters to the House Energy and Commerce Committee and the House Agriculture Committee, a group of agriculture interests asserted that H.R. 2749 would create new on-farm regulatory authorities that would be redundant with USDA oversight.<sup>62</sup> They argued that such new requirements could affect agricultural practices that the FDA neither has the funding nor expertise to regulate, and that the bill would impose significant costs on small farms and food producers while doing little to improve safety. This, they argued, would violate U.S. trade commitments, inviting retaliation by trading partners against U.S. agricultural exports.

The House-passed bill contains additional provisions that are intended to address potential effects of the food safety requirements on small, organic, direct-to-market, and sustainable farming

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<sup>58</sup> Food & Water Watch, “Background on H.R. 875,” <http://www.foodandwaterwatch.org/food/foodsafety/background-on-h-r-875?searchterm=h.r.+875>.

<sup>59</sup> Remarks at the Farm Foundation Forum, “The Future of Food Safety Regulation,” available by audio link at [http://www.farmfoundation.org/news/articlefiles/363-20090407\\_pv\\_farm\\_foundation.mp3](http://www.farmfoundation.org/news/articlefiles/363-20090407_pv_farm_foundation.mp3).

<sup>60</sup> Farm-to-Consumer Legal Defense Fund, “H.R. 2749’s Real Impacts: a Response to Consumers’ Union,” <http://www.farmtoconsumer.org/HR2749-response.htm>.

<sup>61</sup> Gary Blumenthal, “Policy Roundup,” *World Perspectives*, March 11, 2009.

<sup>62</sup> The June 26, 2009, letters were signed by the American Farm Bureau Federation and several other commodity associations such as the National Association of Wheat Growers and the National Milk Producers Federation (<http://www.ncga.com/files/pdf/foodsafety-ecc090625.pdf>; <http://www.ncga.com/files/pdf/foodsafety-ag09.0625.pdf>). Farm-related concerns also were explored at a July 16, 2009, hearing before the House Agriculture Committee.

operations, among other related provisions. For example, H.R. 2749 would exempt from the facility registration requirements most commodity producers that sell directly to consumers, including an “operation that sells food directly to consumers if the annual monetary value of sales of the food products from the farm or by an agent of the farm to consumers exceeds the annual monetary value of sales of the food products to all other buyers” (Section 101(b)(1)). H.R. 2749 also would require that any regulations governing performance standards “take into consideration, consistent with ensuring enforceable public health protection, the impact on small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts, and organic production methods” (§ 104(b)).

## Senate Debate

Following passage of the House bill, and modifications to address farm interest concerns with H.R. 2749, agriculture groups continued to urge Congress to mitigate any potential effects of the food safety requirements on small, organic, direct-to-market, and sustainable farming operations.

S. 510 was first modified by the Senate HELP Committee to require that the HHS Secretary “provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities” (§§ 103 and 105, among others). Other committee modifications required consideration of federal conservation and environmental standards and policies including wildlife conservation, and assurances that these provisions will not conflict with or duplicate those of the national Organic Foods Production Act (§ 105). These provisions were retained in the Senate’s August 2010 manager’s amendment to S. 510.

The Senate manager’s amendment of August 2010 included additional modifications to address the potential effects of the food safety requirements on small businesses and other farming operations. These included allowances for HHS to exempt or limit compliance requirements for certain types of farming operations and food processors, along with provisions that would allow the HHS Secretary the discretion to exclude certain operations, if it is determined that these are low risk and/or do not present a risk of “serious adverse health consequences or death.” Also included were assurances that any new regulations would not conflict with or duplicate other federal policies and standards, and that they would minimize regulatory burden and unnecessary paperwork and the number of separate standards imposed on the facility (for example, the registration, HACCP, produce standards, and traceability requirements in §§ 101, 103, 105, and 204). In addition, HHS would be required to publish “small entity compliance policy guides” to assist small entities in complying with some proposed requirements, such as those regarding registration, HACCP, produce standards, and traceability. Implementation would be delayed for small and very small businesses (as defined by the Secretary) for the HACCP and produce standards requirements, and there would be assurances of “sufficient flexibility” for producers, including small businesses and entities that sell directly to consumers, for the HACCP, produce standards, and traceability provisions.

Despite these additional modifications, Senator Jon Tester continued to push for further amendments to address small farm interests. Senator Tester had first announced in spring 2010 that he planned to introduce two amendments to the Senate committee-reported bill, S. 510.<sup>63</sup>

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<sup>63</sup> Senator Tester press release, “Tester to Introduce ‘Common Sense’ Amendments to Food Safety Bill,” April 14, (continued...)



Under one amendment, certain commodity producers would face limited traceback and record-keeping requirements if the “average annual adjusted gross income [AGI] of such facility for the previous 3-year period is less than \$500,000”; another amendment would have exempted producers who sell directly to market if “the annual value of sales of food directly to consumers, hotels, restaurants, or institutions exceeds the annual value of sales of food to all other buyers.”<sup>64</sup> These amendments were not included in the Senate manager’s amendment of August 2010.

In September 2010, Senator Tester, along with Senator Kay Hagan, announced an updated version of this amendment.<sup>65</sup> The modified Tester-Hagan amendment would establish “modified requirements for qualified facilities” for so-called “very small” businesses, among other provisions for both small and very small businesses (to be defined by HHS in regulation). Under this proposed amendment, certain qualified facilities would not be subject to certain food safety requirements; instead they would be required to submit to HHS relevant documentation showing that they have implemented preventive food safety controls and evidence that they are in compliance with state, local, county, or other applicable non-federal food safety laws, among other documentation. Such modified requirements would apply to producers considered “very small” and would include operations that have annual sales of less than \$500,000 (defined not as AGI, but as the three-year average “annual monetary value of sales,” adjusted for inflation) and whose value of sales directly to “qualified end-users” *exceeds* all other sales. Qualified end-users would include consumers or a restaurant or retail food establishment that is located in the same state or less than 400 miles<sup>66</sup> from the qualified facility, or that is buying food for sale directly to consumers. Implementation deadlines would also be delayed for small and very small businesses, following promulgation of any applicable regulations under the newly enacted law. The provision also would require that HHS conduct a study of the food processing sector, in conjunction with USDA.

During the Senate floor debate in November 2010, a modified version of this amendment was adopted as part of the substitute Senate amendment (S.Amdt. 4715) to S. 510. This version was passed off the Senate floor on November 30, 2010. Consequently, the Senate-passed bill would exempt certain food processing operations from the proposed HACCP requirements and also would exempt certain farms from the new produce standards. Food facilities would qualify for an exemption from the HACCP requirements in the bill, if they are either a “very small business” as defined by FDA in rulemaking, or if the facility’s “average annual monetary value” of all food sold during the previous three-year period was less than \$500,000, provided that the food is sold directly to “qualified end users” such as consumers, restaurants, or retail food establishments located in the same state where the facility sold the food or within 275 miles of the facility. Such a facility would need to demonstrate that it either has “identified potential hazards associated with the food being produced,” and is implementing and monitoring these preventive controls, or that it is “in compliance with State, local, county, or other applicable non-Federal food safety law.”

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(...continued)

2010, [http://tester.senate.gov/Newsroom/pr\\_041410\\_foodsafety.cfm](http://tester.senate.gov/Newsroom/pr_041410_foodsafety.cfm) (bill language is posted at website).

<sup>64</sup> Ibid.

<sup>65</sup> Press release, Senator Tester, “Updated Food Safety Amendment Protects Small Producers,” September 24, 2010, [http://tester.senate.gov/Newsroom/pr\\_092410\\_foodsafety.cfm](http://tester.senate.gov/Newsroom/pr_092410_foodsafety.cfm). Bill language is available at <http://tester.senate.gov/Legislation/upload/Tester-Food-Safety-Amendment.pdf>.

<sup>66</sup> The 400-mile designation is similar to the distance specified in a provision of the Food, Conservation, and Energy Act of 2008 (P.L. 110-246, Section 6015). That provision defines a “Locally or Regionally Produced Agricultural Food Product” as any agricultural food product that is grown, produced, and distributed near where it is marketed such that “the total distance that the product is transported is less than 400 miles from the origin of the product.”

Foods produced from such a facility would also need to provide the facility's name and address on a food packaging label or at the point of purchase.

Farms that would be exempt from the produce standards in the bill also include those with a three-year average monetary value of the food they sold of less than \$500,000, provided that the food is sold directly to the similarly defined "qualified end users" and if the farm provides similar notification to consumers. The exemption for both facilities and farms may be revoked in the event that a foodborne illness outbreak is directly linked to an exempted facility or farm, or based on a determination by the HHS Secretary. This version of the Tester-Hagan amendment was ultimately included in the enacted law.

Throughout this debate, many farm groups have expressed support for the Tester-Hagan amendment.<sup>67</sup> However, one of the leading produce industry groups, United Fresh Produce Association (UFPA), opposed the amendment and urged the Senate not to add "exemptions based on the size of the operation, production practices, or geographic location for food being sold in the commercial market" to its food safety proposal.<sup>68</sup> In November during the floor debate, a letter circulated from UFPA and 19 other producer associations again urging the Senate not to adopt the amendment.<sup>69</sup> In addition to broader industry concerns about the need to preserve consumer confidence in the safety of all marketed produce, another industry concern is whether small foreign producers might also be exempt, if small U.S. producers were to be exempt (given prevailing U.S. equivalency standards).<sup>70</sup>

Meanwhile, some public health and consumer groups expressed concern that the Tester-Hagan amendment would create "too great a loophole" in the food safety requirements, among other concerns.<sup>71</sup> In October 2010, a coalition of these groups expressed its opposition to the modified version of the Tester-Hagan amendment.<sup>72</sup> The groups cited concern that the exemption was based only on sales volume and could result in certain high-risk foods being exempted from food safety protections, and concern about whether labeling requirements were needed for such foods. They argued that it is unclear how many facilities would be exempted under the proposed sales threshold, and that FDA should conduct market analyses to determine appropriate thresholds for exemption in both the produce and processed food sectors. They also questioned the appropriateness of the then 400-mile designation and other aspects of what would constitute a

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<sup>67</sup> See, for example, letter from more than 100 farm groups under the Small Holder Alliance, "Support Fresh, Safe Local Food in the Food Safety Bill," April 15, 2010, [http://smallholdersalliance.com/Amend-S510-April-15%20\(2\).pdf](http://smallholdersalliance.com/Amend-S510-April-15%20(2).pdf); and articles in *Food Safety News* (<http://www.foodsafetynews.com/>) by Helena Bottemiller, "Tester Amendment Picks Up Cosponsor," May 3, 2010, and "Farmers Gain in Senate Food Safety Battle," April 15, 2010.

<sup>68</sup> United Fresh Produce Association, 2010 Issues Brief, [http://www.unitedfresh.org/assets/Issue\\_Brief\\_United\\_Fresh\\_Produce\\_Association\\_2010.pdf](http://www.unitedfresh.org/assets/Issue_Brief_United_Fresh_Produce_Association_2010.pdf).

<sup>69</sup> Letter to Senators Reid, McConnell, Harkin, and Enzi from United Fresh Produce Association, Produce Marketing Association, Northwest Horticultural Council, and other national and state groups, November 18, 2010, available at <http://www.unitedfresh.org/>.

<sup>70</sup> *Ibid.*, comments by industry representatives at the UFPA's 2010 Washington Public Policy Conference, September 15, 2010; and Helena Bottemiller, "Group Breaks Ranks on Small Farm Exemptions," *Food Safety News*, September 10, 2010.

<sup>71</sup> Letter to Senator Tester from the Consumers Union regarding Amendments to S. 510, the FDA Food Safety Modernization Act, April 20, 2010, <http://www.consumersunion.org/campaigns//notinmyfood/016345indiv.html>; and articles in *Food Safety News* (<http://www.foodsafetynews.com/>); Helena Bottemiller, "Public Health Opposition to Tester Amendment," April 28, 2010; Helena Bottemiller, "Farmers Gain in Senate Food Safety Battle," April 15, 2010; and Alex Ferguson, "What's Wrong with the Tester Amendments," May 4, 2010.

<sup>72</sup> Make Our Food Safe coalition, October 19, 2010, <http://www.makeourfoodsafesafe.org/>. The coalition's white paper on the Tester-Hagan amendment is at <https://ssl.capwiz.com/pew/attachments/TesterResponsefactsheetfinal.pdf>.

“direct sale” under the proposed amendment, such as whether grocery stores and restaurants should be included.

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