Food Safety on the Farm: Federal Programs and Selected Proposals

Geoffrey S. Becker
Specialist in Agricultural Policy

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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 naturally occurring contaminants such as aflatoxin.

Interest in on-farm practices was renewed 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 2008, genetic tests confirmed the pathogen on samples of a serrano pepper and irrigation water from a farm in Tamaulipas, Mexico. Agricultural operations in the United States also have been implicated in past outbreaks of foodborne illness.

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 the 111th Congress, comprehensive bills are progressing that could affect farmers and ranchers. On June 10, 2009, a House Energy and Commerce Subcommittee marked up and approved H.R. 2749, which is based largely on provisions of an earlier version (H.R. 759) by the same sponsor. H.R. 2749 would require the establishment of new standards for the production of some fruits, vegetables, nuts, and fungi. Other provisions of H.R. 2749 that focus more broadly on food safety, such as requiring a new food tracing system, and expanding authority for access to records, also could impact on-farm practices. The full Energy and Commerce Committee further amended and approved H.R. 2749 on June 17, 2009, and the full House passed the measure—with additional changes made by the bill's sponsors to address agricultural interests' concerns—on July 30, 2009.

The Senate Health, Education, Labor, and Pensions Committee marked up its food safety measure (S. 510) on November 18, 2009, reporting it on December 18, 2009. Provisions in this bill also would affect on-farm production, including but not limited to a section requiring produce safety standards. As of this writing, interests representing smaller producers were seeking additional changes in the bill to address their concerns about its impact on their operations; such changes, if accepted by the bill's managers, conceivably could be proposed as part of a so-called manager's amendment when the bill is considered on the Senate floor, where action was anticipated (but not necessarily certain) in spring 2010.

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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.)

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.[1]

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.

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

[1] 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*, by Geoffrey S. Becker and Harold F. Upton.

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.*). 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.[2]

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."[3]

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) added several new food-related provisions to the FFDCA. Notably, FFDCA § 414 now sets forth record-keeping requirements and the circumstances for making these records available for inspection by the Secretary of Health and Human Services (for practical purposes, by the department's Food and Drug Administration). Also, FFDCA § 415 requires food facilities to register with the FDA. Both provisions exempt farms but do not define the term "farm."

More specifically, 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)

Other parts of FFDCA § 414 delineate the types of such records, and authorize the promulgation of regulations on record-keeping requirements.

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,"

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[2] A more detailed legal analysis appears in CRS Report RS22939, *FDA Authority to Regulate On-Farm Activity*, by Vanessa K. Burrows. FDA's own arguments in support of its on-farm authority can be found in a proposed rule to regulate egg production to control *Salmonella enteritidis*, at 69 Federal Register pp. 56842-45. See also CRS Report RS22600, *The Federal Food Safety System: A Primer*.

[3] 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."

among other language. FFDCA § 415(b) states (in part) that for purposes of this section, a 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; or fishing vessels" (emphasis added).

As noted, neither § 414 nor § 415 provides a definition of "farm." (The term also 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.[4]

More generally in its exercise of FFDCA authority, FDA's traditional approach has been not to impose mandatory on-farm safety standards or inspections of agricultural facilities.[5] Rather, the agency has relied on farmers' adoption of so-called good agricultural practices to reduce hazards prior to harvest. Such practices are issued as FDA guidance, not regulations; they are advisory and not legally enforceable responsibilities.[6] The agency's agricultural guidance documents[7] 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."

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[4] 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.

[5] An FDA advisory panel acknowledged that the agency "conducts only limited inspections of food-producing farms, except in emergencies." FDA Science Board, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*, November 2007.

[6] Sources: FDA, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, October 26, 1998, at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm; and *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm.

[7] FDA, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, October 26, 1998, at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm; and *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* (see above footnote for link). On September 2, 2008, FDA asked for public comments and scientific data to assist it in improving its 1998 guidance.

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.[8] 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.[9]

In July 2009, FDA published three guidance documents targeted at specific produce types: *Guide to Minimize Microbial Food Safety Hazards of Tomatoes*, *Guide to Minimize Microbial Food Safety Hazards of Melons*, and *Guide to Minimize Microbial Food Safety Hazards of Leafy Greens*.[10] However, the agency now appears to be moving toward a potentially more hands-on regulatory approach to produce safety. On February 18, 2010, it 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."[11]

In another recent instance of on-farm regulatory activity, the FDA on July 9, 2009, published final rules to require shell egg producers to implement specific safety measures to prevent on-farm contamination of eggs by *Salmonella enteritidis* (SE).[12] The final 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.[13] 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.[14] The rule 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

[8] 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.

[9] "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.

[10] These documents were accessed February 25, 2010 at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm.

[11] "USDA and FDA Coordinating Efforts to Ensure Safety of Produce: FDA Invites Public Comments to Inform Future Rulemaking," accessed February 25, 2010, at 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.

[12] 74 *Federal Register* pp. 21928-21929.

[13] The final rule is at 74 *Federal Register* pp. 33030-33101.

[14] "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 and screening introduced items such a 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.

July 9, 2012, to comply. FDA published a guidance document on April 13, 2010, to help small producers comply with the new rule.[15]

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," according to a 1998 report issued by the Institute of Medicine of the National Academy of Sciences.[16]

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 FFDCA, 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.[17]

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[15] *Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Transportation, and Storage; Small Entity Compliance Guide*, accessed April 21, 2010, at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/SmallBusinessesSmallEntityComplianceGuides/ucm207507.htm.

[16] *Ensuring Safe Food from Production to Consumption*, National Academies Press, Washington, D.C., 1998.

[17] See the FDA website at http://www.fda.gov/cvm/bsetoc.html.

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 FFDCA, 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 FFDCA. Generally, the FDA monitors and enforces residue limits, while EPA and the states enforce FIFRA's provisions.[18]

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 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."[19]

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.

Another APHIS cooperative program is the national animal identification (ID) program, which the agency is implementing nationally (on a voluntary basis) to improve the ability to pinpoint and control animal diseases. 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.)

[18] Source: CRS Report RL31921, *Pesticide Law: A Summary of the Statutes*, by Linda-Jo Schierow.

[19] *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*.

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.[20] 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 commercial agreements in the trade or to provide consumers with more information about their prospective purchases.[21]

Leafy Greens Marketing Agreement

AMS in October 2007 had invited comments on whether to create such a federal marketing program that specifically would commit handlers (packers, processors, shippers) of leafy greens, including lettuce and spinach, to meet prescribed safety standards.[22] On June 8, 2009, a group of agricultural associations formally requested that AMS begin the steps toward establishment of a national marketing agreement for leafy greens. 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.[23] Reportedly, California and Arizona represent approximately 90% of leafy greens production, and a national agreement would seek to cover the nation's remaining 10%.[24]

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[20] 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. It can be accessed at http://agriculture.house.gov/testimony/111/h051409/Shipman.pdf. Detailed information about these programs can be accessed through the AMS website at http://www.ams.usda.gov.

[21] 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*, by Cynthia Brougher.

[22] 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).

[23] California Leafy Green Products Handler Marketing Agreement website, at http://www.caleafygreens.ca.gov/.

[24] "Produce industry petitions USDA for leafy greens marketing agreement," *Food Chemical News*, June 15, 2009.

The USDA (AMS) role in a national agreement is to publish a notification regarding the request and to conduct public hearings; these hearings were conducted in fall 2009.[25] If adopted (possibly in 2010), 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.

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.[26] 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.[27]

Selected Proposals in Congress[28]

In the 111th Congress, bills that seek to regulate agricultural producers directly have included H.R. 759 (Dingell), which was reintroduced as H.R. 2749; H.R. 1332 (Costa); H.R. 875 (DeLauro); and S. 510 (Durbin). The Costa and Durbin bills focus on safety standards for fresh fruits and vegetables; the Dingell bill originally covered other types of food production (except animal-based commodities), as described below, but has since been scaled back. The DeLauro bill would have combined all federal food safety responsibilities under a single new Food Safety Administration, and imposed various new record-keeping, risk reduction, and certification requirements on both the domestic and imported food systems. With regard to farms, the DeLauro bill first would have defined a "food production facility" to be "any farm, ranch, orchard, vineyard, aquaculture facility, or confined animal feeding operation."

However, the Dingell bill (H.R. 2749) became the House legislative vehicle for food safety changes. It was amended and approved by a House Energy and Commerce subcommittee on June 10, 2007, and further amended and approved by the full Energy and Commerce Committee on June 17, 2009. In the Senate, the Durbin bill (S. 510) was modified and approved by the Senate Health, Education, Labor, and Pensions (HELP) Committee on November 18, 2009, and reported on December 18, 2009. The following discussion thus focuses on H.R. 2749 and S. 510.

[25] Information on the hearings was available on the AMS website.

[26] 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, http://domesticpolicy.oversight.house.gov/story.asp?ID=2557.

[27] National Leafy Greens Marketing Agreement, "Frequently Asked Questions," at http://www.nlgma.org/faqs.php (accessed June 19, 2009). 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.

[28] See also CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111th Congress*, by Geoffrey S. Becker.

Dingell Bill Overview (H.R. 2749)

Section 104 of the Dingell bill, as amended and approved by the House Energy and Commerce Committee, and as modified prior to final House action, creates a new section 419A of the FFDCA. It would require the HHS Secretary to publish within 18 months of enactment a notice of proposed rulemaking, and within three years after such date, final rules, establishing scientific and risk-based food safety standards for the growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities that are a fruit, vegetable, nut, or fungus, and for which the Secretary has determined such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals.

The Secretary is authorized to include in these regulations procedures and practices that the Secretary determines to be reasonable to prevent known or reasonably foreseeable biological, chemical, and physical hazards, including natural ones, that may be intentionally or unintentionally introduced. The regulations may also include minimum safety standards, and address manure use, water quality, employee hygiene, sanitation and animal control, and temperature controls, as the Secretary determines to be reasonably necessary. They could provide for coordination of education and enforcement activities and must provide a reasonable time for compliance, taking into account the needs of small businesses for additional time, among other permitted activities. In developing these regulations, the Secretary would be *required* to take into consideration (consistent with public health) "the impact on small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts, and organic production methods."

A food would be adulterated under terms of the FFDCA if it is grown, harvested, packed, sorted, transported, or held under conditions that do not meet these requirements, if applicable. The Dingell bill also would require the Secretary to update the 1998 FDA guidance for minimizing hazards in fresh fruits and vegetables.

Other provisions in the Dingell bill also would, or at least could, have impacts on agricultural producers. These include the registration requirements under section 101, the records access requirements under section 106, the food traceability system to be established under section 107, and a change in the reportable food registry under section 112. These provisions are discussed at length in the next section of this CRS report, "Farm Interest Concerns with H.R. 2749."

Farm Interest Concerns with H.R. 2749[29]

Some videos and emails have circulated on the Internet asserting that pending food safety legislation would undermine or even destroy the nation's small and organic farms, to the benefit of industrialized agriculture.[30] In fact, none of the original bills' farm-related provisions appear to explicitly exempt such operations, other than directing that the needs of small businesses be considered during implementation.

[29] Renée Johnson, Specialist in Agricultural Policy (7-9588), contributed to this section of the report.

[30] See, for example: http://www.youtube.com/watch?v=eDl6RjYaOt4 (video) and articles; http://educate-yourself.org/cn/HR875andS425organicfarmingban13mar09.shtml; and http://www.opednews.com/articles/FOOD-SAFETY-REGULATIONS—by-Linn-Cohen-Cole-090108-947.html.

The Organic Consumers Association (OCA) sought on the one hand to challenge what it viewed as the "hysteria" and unsubstantiated facts that circulated about H.R. 875 in particular, and on the other hand to criticize sharply the bill's language. It posted an article on its website that commented:

> It's really a fight about government control. The loose terms and definitions of what H.R. 875 would actually do—enact more stringent and much-needed safety regulations—left room for organic and biodynamic growers to become fearful of government intervention. Section 206 of the bill, which defines a "food production facility," is so ambiguous that individuals beyond large farms (i.e. backyard gardeners) could be penalized and subject to review by the government.[31]

In a posting on her own website, Representative DeLauro sought to challenge the "myths" about her bill, arguing that its focus was to ensure the safety of food in interstate commerce, not to regulate or penalize backyard gardens or farmers markets. H.R. 875 would not interfere with organic farming, and has the support of all major consumer and food safety groups, she asserted.[32]

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 attempt to fix our broken food safety system."[33] At a conference in early April 2009, Carol Tucker Foreman, of Consumer Federation of America's Food Policy Institute, agreed that Congress may want to consider tailoring some requirements based on different types of operations or to phase in requirements for some operations. Foreman had suggested, for example, possibly considering exempting direct-to-market farms (e.g., those serving farmers markets).[34]

The Dingell bill (H.R. 2749) has since overtaken the DeLauro bill (H.R. 875) as the House food safety vehicle, and it has been altered several times in response to various criticisms by agricultural interests. H.R. 2749 was modified during committee action to exempt farms that market directly from some of the new traceability provisions. However, some small farm advocates 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, could they 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 in the measure appeared to create a regulatory framework that would heavily burden small farms and local food processors, "the very people who provide a safe, healthy alternative to the industrial food supply."[35]

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[31] Alexandra Gross, "Food Fight: The Food Safety Bill Is Cause for Concern, Not Panic," *E Magazine*, March/April 2009, at http://www.organicconsumers.org/articles/article_17492.cfm.

[32] "Myths and Facts, H.R. 875—The Food Safety Modernization Act," accessed April 6, 2009, at http://delauro.house.gov/files/HR875_Myths_Facts1.pdf.

[33] Food & Water Watch, "Background on H.R. 875, accessed March 19, 2009 at http://www.foodandwaterwatch.org/food/foodsafety/background-on-h-r-875?searchterm=h.r.+875.

[34] These remarks were made at the Farm Foundation Forum, "The Future of Food Safety Regulation." The remarks came near the end of the program during the question and answer segment. An audio link is at http://www.farmfoundation.org/news/articlefiles/363-20090407_pv_farm_foundation.mp3.

[35] Farm-to-Consumer Legal Defense Fund, "H.R. 2749's Real Impacts: a Response to Consumers' Union," accessed on the Internet July 22, 2009, at http://www.farmtoconsumer.org/HR2749-response.htm.

One mainstream agricultural publication had observed, "[S]mall 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.)"[36]

Later, as the Dingell bill (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. In a June 26, 2009, letter to the House Energy and Commerce Committee, 13 groups asserted that H.R. 2749 would create new on-farm regulatory authorities that would be redundant with USDA oversight, affecting agricultural practices that the FDA does not have the funding or expertise to regulate, and that the bill would impose significant costs on small farms and food producers while doing little to improve safety, and would violate U.S. trade commitments, inviting retaliation by trading partners against U.S. agricultural exports.[37]

Farm-Related Modifications in H.R. 2749

After reaching further compromises with farm interests, sponsors brought to the House floor an amended bill with additional changes regarding the treatment of farms, including the following.

On-Farm Standards

The committee-approved bill would have authorized the imposition of on-farm standards for any plant or fungus (in other words, all crops but not animal-based food commodities) for which the HHS Secretary determined such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals. The final House bill limits this standards authority to a fruit, vegetable, nut, or fungus (section 104).

Facility Registration Requirements

The committee-approved bill would not require farms (or retail food establishments) to begin registering—which for facilities is to become an annual requirement to include a $500 annual fee. To clarify this continuing exemption, the final House bill added extensive new language defining the meaning of a farm, which is intended to ensure that those farms marketing directly to consumers, among other specified activities, will not be newly subjected to such registration requirements. For example, a farm means "an operation in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both." It includes an operation that packs, holds, manufactures, or processes food, so long as it is produced and consumed on the farm; an operation that sells food directly to consumers if the sales value from such consumer sales exceeds the value of food products sold to all other buyers; and operations that manufacture grains or other feed stuffs grown there and only distributed directly to another farm for its consumption there (Section 101).

[36] Gary Blumenthal, "Policy Roundup," World Perspectives, Inc., daily news for March 11, 2009.

[37] The letter was signed by the American Farm Bureau Federation, the Pet Food Institute, and 11 commodity associations such as the National Association of Wheat Growers and the National Milk Producers Federation. Farm-related concerns also were explored at a July 16, 2009, hearing before the House Agriculture Committee.

Records Access

The committee-approved bill, which broadens the HHS Secretary's authority to access records, would also have subjected farms to such records access (and record-keeping) provisions. The final House bill continues to exempt farms from records access requirements, except where the article of food is a fruit, vegetable, or fungus that has a standard, or is the subject of an active foodborne illness investigation and is not a grain or similarly handled commodity—wheat, corn, grain sorghum, barley, oats, rice, wild rice, rye, soybeans, legumes, sugar cane, sugar beets, sunflower seed, canola, safflower, flaxseed, mustard seed, crambe, seasame seed, camelina, cottonseed, cocoa beans, grass hay, and honey, and any other commodity determined by the HHS Secretary in coordination with the Secretary of Agriculture. Also, any record-keeping regulations affecting farms must be promulgated in consultation the Secretary of Agriculture (section 106).

Food Traceability

The committee-approved bill would require the HHS Secretary to establish a tracing system able "to identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food in as short a timeframe as practicable but no longer than 2 business days." This also would entail new record-keeping requirements for those in each segment of the food industry. The committee bill would exempt foods produced on a farm and sold directly to consumers, restaurants or grocery stores, except for a requirement that they keep records for at least 6 months on which restaurants or grocery stores received their foods. The committee bill also authorized the Secretary to partially exempt farms (or foods, facilities, restaurants) if he/she determines that traceability is not necessary to protect the public health.

Additional language was added to the final House bill to satisfy agricultural interests that would also require the HHS Secretary to coordinate with the Secretary of Agriculture in both conducting pilot projects on traceability (a prerequisite to traceability regulations) and issuing such regulations; the nature of the impact of the regulations on farms also must be taken into account. Furthermore, the final House bill contains extensive new language intended to limit the system's applicability regarding farms that grow and store grain or similarly handled commodities (see "Records Access," above, for specific commodities) (section 107).

Reportable Food Registry

The Administration is now implementing a provision of the FDA Amendments Act of 2007 (P.L. 110-85) which requires food facilities to report foods for which there is a reasonable probability of serious adverse health consequences or death to humans or animals. The committee-approved bill would extend this reporting requirement to farms (and restaurants and retail food establishments). Under a change in the final House bill, farms (and restaurants, retail food establishments) that are unable to provide such information through a new electronic portal must be given an alternative means for reporting (section 112).

Other Farm-Related Modifications

The committee-reported bill would exempt foods and facilities regulated by USDA under the meat, poultry products, or egg inspection acts; it also would exempt farms to the extent they raise animals sourced for such USDA-regulated foods. The final House bill adds language to ensure

that the animals themselves are also exempt and that USA-approved, state-inspected meat and poultry facilities are exempt as well (section 5).

Durbin Bill Overview (S. 510)

Section 105 of the bill offered by Senator Durbin (S. 510), as modified by the HELP Committee, would create a new FFDCA Section 419. It would require, within one year, in consultation with USDA and state agriculture departments (including with regard to the national organic foods program), 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 proposed rules are to 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."

Under S. 510, final rules would have to spell out "practices as the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into fruits and vegetables that are raw agricultural commodities and to provide reasonable assurances that the produce is not adulterated" under the FFDCA. S. 510 would require the Secretary to prioritize regulations for specific fruits and vegetables that are raw agricultural commodities that have been associated with foodborne illness outbreaks. It also includes provisions for public input, timelines for implementation of rules, and a system for granting variances for states and foreign governments.

The HELP Committee added language to the original bill that requires the proposed rules to "provide sufficient flexibility 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." Committee-added language also requires consideration (consistent with public health protection) of federal policies and standards regarding natural resources conservation, wildlife conservation, and environmental practices. Moreover, new regulations are not to include "any requirements that conflict with or duplicate the requirements" of the national organic foods program (consistent with public health protection).

Treatment of Farms Under Other S. 510 Provisions

Inspection of Records

In S. 510, § 101 amends 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.[38] 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

Under § 102, S. 510 would require all food facilities to register bienially, 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 FFDCA; farms are not affected unless they process food for sale. In addition, S. 510 does not set a registration fee, unlike the House-passed food safety bill (H.R. 2749).

Hazard Analysis and Risk-Based Preventive Controls

This provision (§ 103) establishes a new FFDCA § 418, requiring the owner, operator, or agent in charge of a facility to develop, implement, and keep records on preventive controls for food safety. Section 103 references the current definition of "facility" under FFDCA § 415. Therefore, farms are not affected unless they process food for sale. This section of the bill, as modified by the committee, 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."

Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report

This section (§ 201) specifically requires the Secretary to inspect food facilities (as defined under FFDCA § 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

This provision (§ 204) requires the Secretary, in consultation with USDA and state officials, to improve the capacity of FDA to effectively and rapidly track and trace fruits and vegetables that are raw agricultural commodities in the event of an outbreak. It would require proposed rules within three years of enactment for standards on the type of information, format, and time frame for persons to submit records to aid in such tracebacks. Also, within nine months of enactment, the Secretary is required to establish at least three pilot projects in coordination with the produce industry to test and evaluate methods for rapidly and effectively tracking and tracing fruits and vegetables in the event of a foodborne illness outbreak. If, as it appears, this provision would not

[38] It could be argued that this provision—and other provisions of S. 510 not readily applicable to farms—might be indirectly affected 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.

require the establishment of a traceability system, then neither facilities nor farms would be subjected to newly legislated traceback rules.

The HELP Committee added language to this section of the bill requiring the Secretary to consider the impact of the standards regulations on farms and small businesses, the findings of the pilot projects, and existing trade obligations. Furthermore, those subject to the new produce standards that are not facilities under the FFDCA could not be required by the Secretary to submit records other than distribution records kept in the normal course of business, among other committee modifications.

Concluding Observations on the Bills' Provisions

The farm-related provisions of the original House and Senate bills generally made no explicit distinctions between agricultural producers of different sizes or of varying production practices. Concerns raised by groups representing organic producers, smaller-scale farmers, and others have since led sponsors of both versions to add new language aimed at recognizing any special circumstances faced by, for example, smaller farms, those that market directly to consumers, and so forth. At issue is whether these changes will satisfy farm interests, what, if any additional modifications should be made, and their potential impact on food safety.

The House-passed and pending Senate food safety bills have numerous elements that appear to be similar to each other, including new record-keeping and records access provisions, changes in food registration, and a mandate for preventive food safety plans for food facilities and for produce, for example. However, these seemingly similar provisions appear to be somewhat more prescriptive under the House version and/or could have a greater potential impact on producers, regardless of size, production, and/or marketing practices. That is a key reason that H.R. 2749 appears to contain more specific language than existed in S. 510 in order to limit the applicability of the bill—or a number of its specific provisions—to farms generally. For example, H.R. 2749 specifically exempts all foods and facilities regulated by USDA under the meat and poultry inspection laws, as well as the animals used in these products and the farms that raise them. Again, although neither bill initially distinguished between farms of different sizes or operating practices, provisions have since been added to both that direct the Secretary to take such distinctions into account. For example, the on-farm produce standards that must be issued under § 104 of the House bill require the HHS Secretary to take into account "the impact on small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts, and organic production methods." The Senate HELP Committee added language with similar intentions to its produce safety section (§ 105).

Some small-farm interests have continued to seek changes in the Senate bill. The National Sustainable Agriculture Coalition (NSAC) has asserted that the measure would subject farm-based facilities with value-added processing or that commingle products with neighboring farms to extensive FDA regulation regardless of their risk or scale. NSAC has called for amendments to address this concern, including authority to exempt from regulation farms with relatively low risks or sales and adoption of language in a freestanding Senate bill (S. 2758) that would create a USDA competitive grants program to provide food safety training and technical assistance to smaller-sized producers, processors, and produce wholesalers.[39] Such proposals conceivably

[39] Possible changes in the Senate bill being sought by small farm advocates were discussed at some length by NSAC on its website at http://sustainableagriculture.net/blog/senate-food-safety-bill-includes-improvements-for-farmers/.

could be offered either as part of a manager's amendment package of changes, or as separate floor amendments, when the bill reaches the full Senate (such action was anticipated but not necessarily assured in spring 2010).

If and when S. 510 passes through the Senate and reaches a conference with the House, it is possible, if not likely, that further modifications affecting the agricultural sector could be made.

Author Contact Information

Geoffrey S. Becker
Specialist in Agricultural Policy
gbecker@crs.loc.gov, 7-7287