



# Food Safety on the Farm: Federal Programs and Selected Proposals

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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, 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 have been implicated in several 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, if any, 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 likely to arise as Congress debates new food safety bills.

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.

Legislative action on food safety could occur in the 111<sup>th</sup> Congress, where a number of comprehensive bills have been introduced that could affect farmers and ranchers. They include H.R. 759, H.R. 1332, and S. 510, all of which contain provisions requiring FDA to regulate production and harvesting practices for fruits and vegetables, and H.R. 875, in which a more broadly cast provision mandates regulation of all "food production facilities" (essentially, farms and ranches) for food safety. Provisions in these as well as other bills that focus primarily on post-harvest food safety measures also might indirectly lead to changes in on-farm practices, particularly if handlers and processors of agricultural products place new demands on their suppliers in order to comply.

## **Contents**

Introduction .....	1
Food Safety Hazards on the Farm.....	2
Federal Food Safety Programs.....	2
Food and Drug Administration .....	2
Food Safety and Inspection Service.....	5
Other Programs Affecting Producers .....	6
Regulation of Animal Drugs and Feeds .....	6
Regulation of Pesticides .....	6
Animal Health Programs .....	6
Federal Marketing Programs .....	7
Selected Proposals in Congress .....	8
Proposals for On-Farm Regulation .....	8
DeLauro Bill (H.R. 875) .....	8
Dingell Bill (H.R. 759).....	9
Costa Bill (H.R. 1332) .....	9
Durbin Bill (S. 510) .....	10
Other Proposals Affecting On-Farm Practices.....	10
Concerns of Small and Organic Farm Interests .....	11
Food Safety Compensation Proposals.....	12

## **Contacts**

Author Contact Information .....	13
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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 major illness outbreaks recently 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.<sup>1</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.

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

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<sup>1</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*, 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.<sup>2</sup>

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>3</sup>

The FFDCA specifically exempts farms (and restaurants) from requirements to maintain records for up to two years for purposes of identifying “... immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals,” and to permit officials access to these records if a food is suspected of being adulterated and presenting a serious health threat.<sup>4</sup> Such requirements pertain to anyone who “manufactures, processes, packs, distributes, receives, holds, or imports.” Furthermore, farms are among those exempted from a requirement that food facilities be registered with FDA, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.<sup>5</sup>

FDA’s general approach has been not to impose mandatory on-farm safety standards or inspections of agricultural facilities.<sup>6</sup> Rather, the agency relies 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.<sup>7</sup> The

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<sup>2</sup> 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*.

<sup>3</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.”

<sup>4</sup> 21 U.S.C. 350c and 21 U.S.C. § 374. FDA has observed that produce farms generally do pack and hold food for introduction into interstate commerce, so it can and does inspect them periodically, usually in areas associated with illness outbreaks or to conduct surveillance sampling. Source: U.S. Congress, House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Appropriations for 2008, Hearings, Part 5, p. 479.

<sup>5</sup> P.L. 107-188; 21 U.S.C. 350(d).

<sup>6</sup> 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.

<sup>7</sup> Sources: FDA, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, October 26, 1998, (continued...)

agency's agricultural guidance documents<sup>8</sup> 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 launched in 2006 a "Leafy Greens Initiative" to address recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce, the majority of which had been traced to California. 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. The initiative is to support a 2004 "Produce Safety Action Plan."<sup>9</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>10</sup>

In a rare instance of proposed on-farm regulatory activity, FDA had proposed rules to require shell egg producers to implement specific safety measures to prevent on-farm contamination of eggs by *Salmonella enteritidis* (SE). However, a final SE rule, although reportedly completed by FDA, was postponed in late 2008 due to concerns raised during the Office of Management and Budget's (OMB's) pre-publication review. Egg producers reportedly criticized the rule as too restrictive and lacking incentives for them to vaccinate their flocks against SE.<sup>11</sup>

The preamble to the proposed rule had observed that SE-contaminated eggs have been a major source of foodborne illness and that on-farm prevention measures could be "very important" in reducing SE infections from eggs.<sup>12</sup> The proposal would require SE testing in poultry houses, with follow-up tests on eggs if environmental testing is positive for the bacteria. Other proposed measures in the rule address the procurement of chicks and pullets, a biosecurity program, disinfection of poultry houses where SE is found, and on-farm refrigeration of eggs.<sup>13</sup> The

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at <http://www.cfsan.fda.gov/~dms/prodguid.html>; and *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, at <http://www.cfsan.fda.gov/~dms/prodgui4.html>.

<sup>8</sup> FDA, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, October 26, 1998, at <http://www.cfsan.fda.gov/~dms/prodguid.html>; and *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, at <http://www.cfsan.fda.gov/~dms/prodgui4.html>. On September 2, 2008, FDA asked for public comments and scientific data to assist it in improving its 1998 guidance; comments were due by December 31, 2008.

<sup>9</sup> FDA, "Lettuce Safety Initiative," August 23, 2006, which notes that regulatory action would be considered if deemed appropriate to prevent contamination. Also, "Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption." Both documents accessed August 2008 at <http://www.foodsafety.gov/~dms/fs-toc.html#prod>.

<sup>10</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>11</sup> See for example, "FDA withdraws Salmonella Enteritidis shell egg rule from OMB review," *Food Chemical News*, December 1, 2008; "FDA Withdraws Egg Safety Rule; Vows to Reintroduce It Soon," *FDA Week*, November 28, 2008. A final rule did not appear by the end of the Bush Administration.

<sup>12</sup> 69 *Federal Register*, p. 56825.

<sup>13</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...)

preamble argued that voluntary quality assurance programs “have led to meaningful reductions in SE illnesses already. However, these programs are not always uniformly administered or uniformly comprehensive in their prevention measures.”

One such program is the National Poultry Improvement Program (NPIP), a longstanding voluntary cooperative effort between USDA’s Animal and Plant Health Inspection Service (APHIS), the states, and industry. The effort has involved the promotion of detailed on-farm sanitation procedures, yearly inspections, and regular testing for producer-participants, all aimed at eradicating bacterial diseases that can cause heavy losses in poultry flocks. SE is one of the avian diseases NPIP has sought to control.<sup>14</sup>

## **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 of catfish, 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.<sup>15</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.

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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.

<sup>14</sup> See also “Animal Health Programs.”

<sup>15</sup> *Ensuring Safe Food from Production to Consumption*, National Academies Press, Washington, D.C., 1998.

## 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>16</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>17</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 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>18</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

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<sup>16</sup> See the FDA website at <http://www.fda.gov/cvm/bsetoc.html>.

<sup>17</sup> Source: CRS Report RL31921, *Pesticide Law: A Summary of the Statutes*, by Linda-Jo Schierow.

<sup>18</sup> *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology*.

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.)

### **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 that can include quality (and possibly, safety) standards. AMS in October 2007 invited comments on whether to create such a federal marketing program that specifically would require handlers (packers, processors, shippers) of leafy greens, including lettuce and spinach, to meet prescribed safety standards.<sup>19</sup> Further action on this order had not occurred as of early 2009.

However, a similar state order was adopted in California in 2007. 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>20</sup>

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>21</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 commercial agreements in the trade or to provide consumers with more information about their prospective purchases.

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<sup>19</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>20</sup> California Leafy Green Products Handler Marketing Agreement website, at <http://www.caleafygreens.ca.gov/>.

<sup>21</sup> Detailed information about these programs can be accessed through the AMS website at <http://www.ams.usda.gov>.

## Selected Proposals in Congress

In 2007 and 2008, a series of widely quoted reports by congressional agencies and committees, the Administration, and outside advocacy groups raised questions about shortcomings in the federal food safety system. Several dozen bills addressed one or more aspects of the issue, and numerous hearings were held. A number of proposals could have influenced on-farm practices. New proposals have emerged in the 111<sup>th</sup> Congress.

### Proposals for On-Farm Regulation<sup>22</sup>

Several bills that seek to regulate agricultural producers directly are now before the 111<sup>th</sup> Congress. H.R. 759 (Dingell), H.R. 1332 (Costa), and S. 510 (Durbin) all focus on safety standards for fresh fruits and vegetables; H.R. 875 (DeLauro) would more broadly cover all food production facilities, as defined below. The DeLauro bill would combine all federal food safety responsibilities under a single new Food Safety Administration, and would impose various new record-keeping, risk reduction, and certification requirements on both the domestic and imported food systems. With regard to farms, the bill first defines a “food production facility” to be “any farm, ranch, orchard, vineyard, aquaculture facility, or confined animal feeding operation.”

#### DeLauro Bill (H.R. 875)

Section 206 of the DeLauro bill provides explicit authority to a new Food Safety Administrator to visit both domestic and foreign food production facilities to determine if they are abiding by food safety laws, to review food safety records, to set “good practice standards” to protect public and animal health, to conduct monitoring and surveillance as appropriate, and to “collect and maintain information relevant to public health and farm practices.” Section 206 requires a food production facility to permit the Administrator access to (and ability to copy) all records necessary to determine whether a food is contaminated, adulterated, or otherwise out of compliance with food safety law, and to track food in commerce.

Also, Section 206 requires the Administrator, in consultation with the Secretary of Agriculture and representatives of state departments of agriculture, to promulgate regulations for “science-based minimum standards for the safe production of food by food production facilities.” The regulations are to:

- consider all relevant hazards, whether intentionally or unintentionally introduced, including naturally occurring ones;
- require each facility to have a written food safety plan that describes likely hazards and preventive controls in place to address them; and
- include minimum standards for fertilizer use, nutrition, hygiene, packaging, temperature controls, animal encroachment, and water; and, for food animals, minimum food safety-related standards for animal health, feed, and environment.

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<sup>22</sup> See also CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress*, by Geoffrey S. Becker.

The regulations also are to provide for a reasonable compliance period, especially for small businesses; for coordination of educational and enforcement activities by state and local officials; and for a system of “variances” from the standards. Such variances could be requested, in writing, by states and foreign countries and would have to describe why a variance is being requested, as well as what procedures and practices would be in place to prevent food adulteration. The Administrator would review each request to determine if it provides equivalent protections before approving a variance. Under the required Section 206 regulations, the Administrator could coordinate with state authorities to perform compliance activities. Finally, the Administrator would have to promulgate regulations to ensure that raw agricultural commodities and minimally processed imports of produce can meet safety, labeling, and consumer protection standards that are “at least equal to” U.S. standards.<sup>23</sup>

### **Dingell Bill (H.R. 759)**

In the Dingell bill (H.R. 759), Section 104 would require the HHS Secretary to propose regulations setting “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 Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.” Such regulations are to include:

- any necessary procedures, processes, and practices aimed at preventing the “introduction of known or reasonably foreseeable biological, chemical, and physical hazards,” including those that may be natural, intentionally or unintentionally introduced;
- minimum safety standards for growing, harvesting, packing, sorting, and storage operations; and
- standards addressing manure use, water quality, employee hygiene, sanitation and animal control, temperature controls, and nutrients.

H.R. 759 further requires the Secretary to prioritize implementation for specific fruits and vegetables that have been associated with foodborne illness outbreaks; for enforcement purposes, it permits coordination with the Secretary of Agriculture and requires coordination and contracts with state authorities. Failure by a producer to adhere to the new regulatory standards would become one of the “prohibited acts” under Section 301 of the FFDC (21 U.S.C. 331).

As does the DeLauro bill, the Dingell bill requires that regulations provide for a reasonable compliance period, especially for small businesses, and for coordination of educational and enforcement activities by state and local officials. Among other Dingell produce provisions, the Secretary would have to update good agricultural practices and guidance for specific types of produce.

### **Costa Bill (H.R. 1332)**

The bill introduced by Representative Costa (H.R. 1332) requires regulations, in consultation with USDA and state agriculture departments, for the safe production, harvesting, handling, and

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<sup>23</sup> “Raw agricultural commodity” is defined in footnote 3.

packing of fruits and vegetables (that are raw agricultural products)<sup>24</sup> for which the HHS Secretary has determined that such standards are needed to “minimize the risk of serious adverse health consequences.” Final rules are to take into account the needs of small businesses and provide for coordination of enforcement and education activities with USDA, states, and appropriate foreign government agencies. Required contents of the regulations do not appear to be as prescriptive as the Dingell or DeLauro bills. The bill requires “to the maximum extent practicable,” use of USDA and state agricultural agencies when enforcing standards; enforcement may be in the form of audit-based verification systems or other inspection methods.

The Costa bill also includes variance language for states and foreign governments, but it differs somewhat from the DeLauro bill. The relevant section of the bill specifies timelines for rulemaking, requires updated guidance for good agricultural practices in coordination with USDA and state agriculture departments, and specifically excludes activities involving further processing or in retail establishments. Not being in compliance with this section would be a prohibited act under the FFDCA.

### **Durbin Bill (S. 510)**

The bill offered by Senator Durbin (S. 510) requires, within one year, in consultation with USDA and state agriculture departments, 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 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, and storage operations, minimum standards related to soil amendments, hygiene, packaging, temperature controls, animal encroachment, and water; and to “consider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism.”

Under the Durbin bill, final rules are 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 requires 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 that differs somewhat from that in the DeLauro and Costa bills.

### **Other Proposals Affecting On-Farm Practices**

Agricultural producers also likely would be affected by other proposed food safety changes emerging in the 111<sup>th</sup> Congress. For example, a number of bills would require the establishment of so-called traceability systems aimed at improving regulators’ ability to more quickly find the source of adulterated products in order to remove them from commerce. Most proposed systems entail new recordkeeping requirements for the food industry, often including agricultural

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<sup>24</sup> The bill uses the term “raw agricultural products” in lieu of “raw agricultural commodities.”

producers. The DeLauro bill (in Section 210) would require the new Food Safety Administrator to establish standards pertaining to the information, format, and time frame that food establishments, as well as “food production facilities,” would have to follow; any required records would have to be made available for the Administrator’s inspection.

Section 107 of the Dingell bill includes a traceability program that, among other things, would remove the current exemption that both farms and restaurants now have from the more general recordkeeping requirements of the current FFDCA (in 21 U.S.C. 350). Furthermore, Section 107 of the Dingell bill would consider as misbranded any shipment of a raw agricultural product if it does not contain information enabling the HHS Secretary to identify the grower of the product, the lot on which it was produced, its harvesting and packing dates, and “any other information determined appropriate by the Secretary to facilitate identification of the source of raw agricultural products.”<sup>25</sup>

The Costa and Durbin bills generally parallel each other on traceability, requiring the Secretary, in consultation with USDA and state departments of agriculture, to improve the capacity to effectively and rapidly track and trace, in the event of an outbreak, fruits and vegetables that are raw agricultural commodities. They would require proposed rules within 24 months of enactment for standards on the type of information, format, and time frame for persons to submit records to aid in such tracebacks, and also mandate a pilot project, in coordination with the produce industry, to evaluate new methods for more effectively conducting such tracebacks.

A traceability bill (H.R. 814) introduced by Representative DeGette would amend the FFDCA and the meat and poultry inspection acts (FMIA and PPIA, respectively) to require traceability systems; for the FMIA and PPIA, this would have to include the ability to trace live food animals (i.e., those subject to inspection under the acts) to any premise or location where they were held. Presumably, the traceability of FDA-regulated products also could extend back to the farm. Most of the implementation details of these new systems would be left to the respective Secretaries of HHS and Agriculture. H.R. 815 (also DeGette) contains notification requirements regarding potentially unsafe foods that would likely be applicable to both animal and crop producers. A bill by Senator Brown (S. 425) is somewhat similar to the combined provisions of H.R. 814 and H.R. 815. Both the Dingell and DeLauro bills also contain broad notification requirements likely applicable to farms.

## **Concerns of Small and Organic Farm Interests**

Some videos and emails have circulated on the Internet asserting that pending food safety legislation, and particularly H.R. 875, would undermine or even destroy the nation’s small and organic farms, to the benefit of industrialized agriculture. In fact, none of the bills’ farm-related provisions appear to explicitly exempt such operations, other than directing that the needs of small businesses be considered during implementation.

In a posting on her 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

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<sup>25</sup> H.R. 759, Section 107(c). Also, Section 107(d) would require FDA to complete, within two years, a study on the effectiveness of technologies for determining the source of raw agricultural products.

farming, and has the support of all major consumer and food safety groups, she asserted.<sup>26</sup> One consumer advocacy organization acknowledged that some of the bills contain 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.”<sup>27</sup>

## **Food Safety Compensation Proposals**

In the 110<sup>th</sup> Congress, some agricultural producers had sought public compensation for losses they said they unfairly shouldered as a result of the government’s food safety response. H.R. 6581, introduced July 23, 2008, would have required USDA to make available \$100 million for payments to growers and handlers of fresh tomatoes that experienced crop or market losses, or both, as a result of the FDA Public Health Advisory issued in early June 2008 (and long since lifted) to avoid certain types of raw tomatoes. H.R. 912, introduced February 8, 2007, would have authorized USDA payments to growers and handlers unable to market spinach crops as a result of an FDA Public Health Advisory in September 2006 not to eat bagged spinach (also long since lifted). The spinach was in fact contaminated and believed to have been the vehicle of interest, while the relationship between some tomatoes and the outbreak was not clarified.

The concept of indemnity payments is not new. For example, in 1960 and 1961, USDA, using its standing Section 32 authority, made more than \$9 million in direct payments to cranberry producers, after federal officials recommended—just before Thanksgiving 1959—a halt in all cranberry product sales due to possible pesticide contamination.<sup>28</sup> Under the Dairy Indemnity Program (7 U.S.C. 4501), USDA makes payments to dairy producers whenever a public regulatory agency directs them to remove their raw milk from the commercial market because it has been contaminated by pesticides, nuclear radiation or fallout, or toxic substances and chemical residues other than pesticides. Since the program’s inception in 1965 through FY2007, a total of approximately \$20 million in payments were made.<sup>29</sup> However, this dairy program compensates farmers for milk they are *required* to remove from the market, not for imputed market losses.

In considering compensation bills, numerous policy questions likely arise, such as the need, if any, for such indemnities, and whether market losses can be calculated with some accuracy and equity. What might be the cost of payments to taxpayers, and what types of food safety incentives or disincentives do they telegraph to producers? Should payments only be provided in the event of agency error—for example, misidentification of the food vehicle? If so, how might that be determined?

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<sup>26</sup> “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](http://delauro.house.gov/files/HR875_Myths_Facts1.pdf).

<sup>27</sup> 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>.

<sup>28</sup> Source: USDA, Agricultural Marketing Service. *History of Section 32*, February 2007. Also see CRS Report RL34081, *Farm and Food Support Under USDA’s Section 32 Program*, by Geoffrey S. Becker.

<sup>29</sup> Source: *2009 USDA Budget Explanatory Notes for Committee on Appropriations*.

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