

# Stateline Midwest

Vol. 25, No. 11 • November 2016

THE MIDWESTERN OFFICE OF THE COUNCIL OF STATE GOVERNMENTS

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Stateline Midwest is published 12 times a year by the **Midwestern Office of The Council of State Governments.**

Annual subscription rate: \$60.  
To order, call 630.925.1922.



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# States face decisions on their piece of food-safety system

## New FDA standards and rules impact farmers, food processors

by *Carolyy Orr (corr@agandrurallleaders.org)*

**B**etween 2003 and 2009, a string of high-profile food-borne illnesses hit consumers across the United States.

There were salmonella outbreaks from produce, Hepatitis A infections from raw or undercooked green onions, and cases of pet foods contaminated with melamine. And nine people died and more than 700 people got sick from eating salmonella-tainted peanut butter traced back to a single processing plant in Georgia.

In the wake of these deaths and illnesses, federal food-safety legislation that had been many decades in the making finally got signed into law.

The bipartisan Food Safety Modernization Act of 2010 marks the most sweeping change in government regulation of food production and processing in more than 70 years.

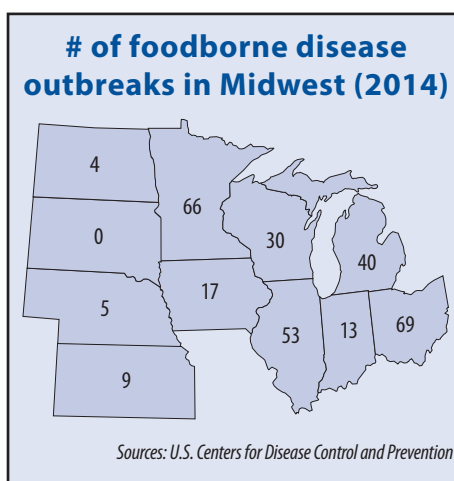
It is just now beginning to be implemented.

The law's goal is to reduce the prevalence of foodborne illnesses by focusing more on prevention, rather than responding to outbreaks once they occur. (According to the U.S. Centers for Disease Control and Prevention, close to 48 million Americans get sick every year from pathogens transmitted through food; nearly 128,000 people are hospitalized and more than 3,000 die.)

To meet this objective, the U.S. Food and Drug Administration's authority to regulate fruit and vegetable production has been greatly expanded. (The FSMA does not apply to meat, poultry and egg production; those industries are covered by other rules.)

The 2010 law and subsequent FDA rules also impacts food processors and transporters, as well as the animal-feed industry. From the farmer to the distributor, new accountability measures are in place.

And for states, decisions will have to be made on whether to harmonize their own regulations on food safety with the FSMA, as well as how involved they want to be in areas



Annual value of food production in Midwest*		
State	\$ (cash receipts)	U.S. rank
Illinois	\$19.6 billion	6
Indiana	\$12.1 billion	9
Iowa	\$32.0 billion	2
Kansas	\$16.2 billion	7
Michigan	\$8.3 billion	18
Minnesota	\$20.6 billion	5
Nebraska	\$24.5 billion	3
North Dakota	\$8.7 billion	17
Ohio	\$10.1 billion	11
South Dakota	\$10.0 billion	12
Wisconsin	\$12.1 billion	8

\* Combined, the 11-state Midwest accounts for 44.1 percent of the nation's total value of food production  
 Source: U.S. Department of Agriculture (2015)

such as producer education, inspection and compliance.

"The role for states [is] to help their businesses compete and be successful," Jamie Clover Adams, director of the Michigan Department of Agriculture & Rural Development, said in July during a presentation to state lawmakers at the Midwestern Legislative Conference Annual Meeting. (CSG Midwest provides staffing services to the MLC.)

### 'Preventive controls' a must

For the first time in the nation's history, as a part of a set of new "preventive controls" being put in place, the FDA has established science-based, minimum standards for how fruits and vegetables

(those typically eaten raw) are produced on the farm.

These standards specify everything from the use of biological soil amendments to animal contamination in the fields, and require documentation of every aspect of production.

For example, water that comes in

▶ PLEASE TURN TO PAGE 6



*Final rules for the Food Safety Modernization Act are now in place. Designed to reduce the prevalence of foodborne disease outbreaks, the new law sets new standards for fruit and vegetable farmers and food processors, among others. It also requires inspections of facilities. States must decide how involved they want to be in implementing the act and helping the food industry adapt to it.*

▶ CONTINUED FROM PAGE 1

## States in Midwest partnering with FDA to implement new food-safety rules

contact with food sources will have to be tested for microbiological contamination. The frequency of this testing mandate varies — at least five samples per year when surface water is used and annual testing for those farms that rely on groundwater.

New science-based standards will be in place, too, on the use of manure in order to “minimize the potential for contact with produce during and after application.” In addition, farm workers must be trained on the importance of food hygiene and safety.

Some fruit-and-vegetable farms will be exempt from these new FDA rules and standards — for example, if their sales are less than \$25,000 a year. However, commercial produce buyers such as grocery stores may still require some of these “exempt” farms to follow the new federal rules.

### Safety plans required of food processors

The federal government also is changing how it regulates the facilities that process and manufacture food for human and animal consumption. (Farms that are “mixed-type” may also be covered under these new regulations for processors — for example, a dairy farm that processes its own milk or an apple grower that makes dried apple slices.)

Under the Food Safety Modernization Act, the first step for any of these processing facilities is to register with the FDA. They must then have a written plan that identifies food-safety hazards, details how to prevent contamination and documents the use of these preventive measures. Facilities must also specify the corrective actions taken when a problem occurs.

The new FDA rules require some food manufacturers and processors to test their products and facilities for bacteria contamination. They all must ensure that their employees are properly trained in any tasks related to food safety.

Similarly, food safety plans (known as Current Good Manufacturing Practices) will be required of

### The Food Safety Modernization Act: What states should know

✓ **Historic new federal rules in place** — Seven new rules/regulations (to be enforced by the U.S. Food and Drug Administration) related to food safety have been finalized:

- science-based, minimum standards on how farms produce raw fruits and vegetables (see sidebar article on page 7 for details),
- requirements that food processors and manufacturers implement and document “risk-based preventive controls” to keep the food supply safe from contamination,
- a verification program for foreign suppliers of U.S.-consumed food,
- accreditation for third parties to conduct food-safety audits of foreign facilities where food is imported to the United States;
- requirements that animal-feed manufacturers implement “preventive controls,”
- standards on the safe transport of food (proper refrigeration and regular cleaning of vehicles, for example), and
- mitigation strategies to prevent intentional, wide-scale harm to public health



✓ **Widespread impact on states’ producers** — These new FDA regulations will effect a majority of states’ fruit and vegetable farmers, feed mills, and food processors — either directly through new requirements and inspections, or indirectly through the demands of the buyers of their produce. The bottom-line expectations for producers is to “say what they do, do what they say, and then validate what they do and say” in developing procedures and written plans to comply with the new FDA rules.

✓ **Need for outreach and education** — A state can help its entire food-production industry adjust to the new law by providing information and outreach about the new FDA rules.

✓ **Possible new inspections role for states** — The new federal law requires inspections of food-production facilities; states can leave this to the FDA or do the inspections themselves (through contracts with the federal government).

the nation’s manufacturers of animal feed. Under the FSMA, the frequency of facility inspections will depend on a facility’s risks to food safety. The law also directs the FDA to inspect at least 600 foreign facilities and to double those inspections every year for the next five years. (The federal law requires importers to verify that their food has been produced under the same standards required of domestic producers.)

### Decisions for states on food safety

Under the Food Safety Modernization Act, states still have the authority to set stronger, more protective regulations on food safety. States, too, can determine how involved they want to be (if at all) in carrying out the FSMA and the related new rules.

Michigan’s Jamie Clover Adams, a member of a National State Department of Agriculture Association working group on food safety, says states have three policy options.

The first is to not adopt any part of the FSMA into state statutes or rules. A second option would be for a state to adopt only a portion of the new FSMA. Under these two scenarios, the states could take a hands-off approach and leave it to the FDA to conduct outreach and educational activities, as well as the mandatory inspections. (In some cases, a state agency could do the inspections under contract with the FDA.)

The problem with these two options, Clover Adams says, is that producers and processors would have to meet the new FSMA regulations without the benefit of state assistance.

She suggests a third option: full adoption of the FSMA rules related to human food, animal feed and produce safety. This could require legislative action, by changing existing laws or giving state agencies statutory authority to implement the FSMA through administrative rulemaking

With this third option, a state would take responsibility for helping farmers and other parts of the food industry comply with the FSMA. It also could carry out the inspection of facilities.

Leah Wilkinson, vice president of the Animal Feed Industry Association, says many farmers, and feed mills in particular, would prefer that state personnel do the mandatory inspections. (The FDA is explicitly authorized in the law to rely on state or local inspectors.)

In fact, some cooperative arrangements between the FDA and states are already in place. The federal agency recently announced funding for 42 states (seven in the Midwest; see table on this page) to implement the new standards on produce safety for fruit and vegetable growers.

Under these new cooperative agreements, states will use the federal dollars to develop a system of inspections, compliance and oversight as well as provide education and technical assistance to farmers.

According to Mike Naig, Iowa’s deputy secretary of agriculture, his state expects to continue its current practice of performing feed inspections under contract with the FDA. It will do so by incorporating the FSMA standards into future state-led inspections. (Iowa has more feed mills than any other Midwestern state, but fewer produce farms.)

Iowa officials are less certain about the state’s

### 7 Midwest states among 42 nationwide receiving federal dollars to implement new produce safety rule\*

State	Implementing state agency	\$ awarded (FY 2016-2017)
Iowa	Department of Agriculture and Land Stewardship	\$218,000
Indiana	Department of Health	\$500,000
Kansas	Department of Agriculture	\$299,000
Michigan	Department of Agriculture	\$700,000
Minnesota	Department of Agriculture	\$679,000
Nebraska	Department of Agriculture	\$120,000
Ohio	Department of Agriculture	\$377,000
Wisconsin	Department of Agriculture, Trade and Consumer Protection	\$700,000

\* Funding was made available to all states that wanted to begin planning and developing a produce-safety program under the U.S. Food Safety Modernization Act.

Source: U.S. Food and Drug Administration

role in implementing the FDA's new produce-safety rules.

The Department of Agriculture and Iowa State University Extension have been educating producers about the FSMA and its new standards. But no final determination has been made on inspections — whether to simply leave them to the FDA or not.

### Inspections often a shared responsibility

Organizations such as the National Association of State Departments of Agriculture, meanwhile, are trying to help states prepare for the FSMA.

According to senior policy advisor Bob Ehart, his association is developing model legislation for states that choose to fully incorporate the FSMA. Likewise, the feed industry is developing state legislation related to the new animal-feed rules.

Option three — the one in which a state decides to take an active role in implementing the FSMA and providing assistance to its farmers and processors — appears to be a likely choice in the Midwest's states where food production is high. This will likely mean, too, that states take on the role of performing the mandatory inspections of farms, food processors and animal feed producers.

In some ways, this role for states is nothing new — they already cooperate with federal agencies on food safety (see table below).

For example, state, local and tribal agencies have had the primary responsibility for regulating the retail food and food service industry, inspecting more than 1 million food establishments.

In addition, most Midwestern states have already been inspecting food processors that engage in interstate meat sales, and the region's four largest egg-producing states (Iowa, Indiana, Michigan and Ohio) contract with the FDA and inspect egg farms in an effort to prevent salmonella contamination.

With the FSMA now in place, state legislators and agencies must consider whether and how to expand the scope of their food-safety responsibilities.

Michael Taylor, the FDA's commissioner for foods, says the success of the Food Safety and Modernization Act in reducing food-borne illnesses will depend in part in how well it coordinates and collaborates with state government. And for state legislatures, this is the time to work with state agencies in order to ease the transition for food producers and processors as they adjust to the largest changes to the food and feed industry in at least 70 years. ★

## FDA's new produce-safety rule covers six areas of farm operations, with exemptions for certain fruit and vegetable growers

### Six areas covered

- ✓ **Water** — Must meet microbial quality with respect to E. Coli
- ✓ **Biological soil amendments** — Final rule deferred until more research is done
- ✓ **Sprouts** — Must be tested for Listeria
- ✓ **Animals** — New standards in place to prevent contamination of produce by domestic or wild animals
- ✓ **Workers** — Food-safety training required; hygienic practices must be followed when handling produce
- ✓ **Equipment** — New standards for appropriate storage, maintenance and cleaning of facilities, tools and buildings



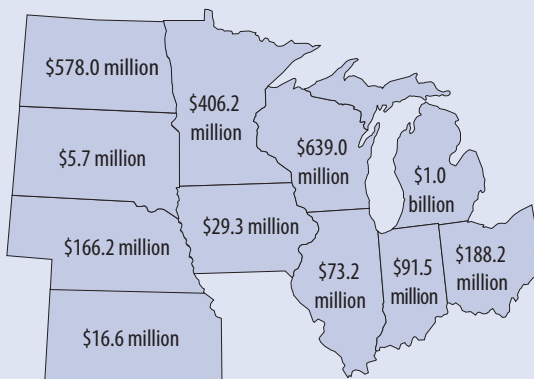
### Farms exempt from new rule

- ✓ Any farm selling less than \$25,000 in produce
- ✓ Any farm that only sells produce normally cooked before eating (sweet corn, beans, potatoes, etc)
- ✓ Any farm that sells less than \$500,000 and mostly to "end users" in the same state or within 275 miles

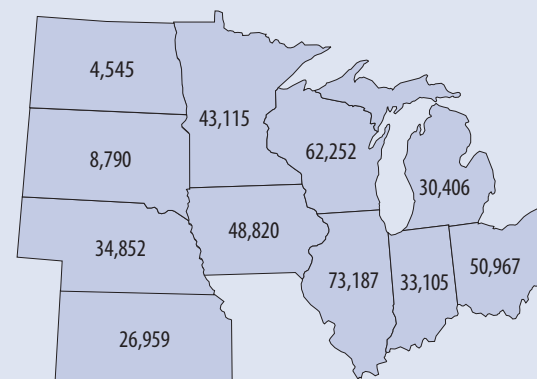
*Note: The distributors of a farm's products may require it to meet the new federal regulations, regardless of the farm's size.*



### Total farm cash receipts from production of vegetables, melons, fruits and nuts (2015)



### # of people employed in food manufacturing industry (2012)



Sources: U.S. Department of Agriculture and U.S. Census Bureau

## Other state-federal partnerships on food safety and inspections of food operations

Program	Midwest states involved	Year it began	Details	Funding source
Federal-State Meat and Poultry Inspection Program	Illinois, Indiana, Iowa, Kansas, Minnesota, North Dakota, Ohio, South Dakota (meat only) and Wisconsin,	1967	Under agreement with U.S. Department of Agriculture, states inspect meat processors to enforce requirements "at least equal" to federal regulation (meat cannot be shipped across state lines)	States run inspection program with 50% of funding from USDA; state funding typically comes from general fund revenue
Cooperative Interstate Shipment of State Inspected Meats Program	Indiana, North Dakota, Ohio and Wisconsin	Part of 2008 farm bill	Allows meat products inspected under state inspection programs to be shipped across state lines; state inspections are overseen by a federal coordinator and must be "the same as" federal inspections	Federal government pays for coordinator as well as 60 percent of state costs; state funding typically comes from general fund revenue
Egg Safety Inspection Program	Iowa, Indiana, Michigan and Ohio	2010	Goal is to prevent salmonella; states inspect shell egg producers with 3,000 or more hens	U.S. Food and Drug Administration negotiates with each state on specific number of inspections
Inspection of animal feed mills (under Food, Drug and Cosmetic Act)	Illinois, Iowa, Kansas, Minnesota, Nebraska, North Dakota, Ohio, South Dakota and, Wisconsin	1965	States conduct inspections under their own authority, but state employees also inspect feed mills for the U.S. Food and Drug Administration, particularly manufacturing processes for medicated feeds (75% of FDA's feed inspections are performed by state agencies)	75% of FDA's feed inspections are performed by state agencies (the FDA contracts with states for the reimbursement of costs); states with their own inspection requirements also charge feed mills a registration fee, generally based on tonnage