

Produce Safety

- Establishes science-based standards for growing, harvesting, packing, & holding of produce on domestic and foreign farms
- Initial Rule Published January 2013/AFBF Filed Comments November 2013
- Supplemental Rule Published September 2014
 - Rule Available at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- AFBF filed comments December 2014
- Final Rule Expected October 31, 2015

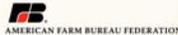
7



Produce Safety

- Rule set FDA's standards of growing, harvesting, packing and holding produce on farms and routes of possible microbial contamination including:
 - Agricultural Water
 - Biological Soil Amendments of Animal Origin
 - Health and Hygiene
 - Animals in growing area
 - Equipment
- AFBF raised multiple concerns about the FDA's approach in each of these areas.
- FDA is responsive and outcome will likely be very similar to a Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audit

8



Produce Safety

- GAP/GHP Audits
 - Voluntary audits that focus on best agricultural practices to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial food safety hazards.
 - Includes principles related to water, worker health & hygiene, sanitary facilities, field sanitation, packing sanitation, etc.
 - In 2014 USDA performed over 3,800 GAP & GHP audits in 46 states and Canada, covering over 90 commodities.

9



Produce Safety

- Covered Farms/Mixed Type Facility
 - Establishment under one ownership in *one general physical location*
 - Devoted to the growing and harvesting of crops, the raising of animals, or both
 - Includes establishments that:
 - Pack or hold RACS
 - Pack or hold processed food if consumed on farm or another farm under same ownership
 - A farm no longer would be required to register as a food facility because it packs or holds RAC grown on another farm

10



Produce Safety

- Covered Farms/Mixed Type Facility
 - Exemptions are classified by "produce" sales – not all food sales. (*We want this to be "covered produce"*)
 - Farms with an average annual monetary value of PRODUCE sales of \$25,000 or less will not be covered
 - "Very small business" and "small business" exemptions also defined by only PRODUCE sales, which gives those farms longer to comply.
 - Note: There remains a statutory exemption from the rule for farms who directly locally market their produce (consumer, retail, or restaurants in the same state or within 275 miles from the farm) and have FOOD sales of less than \$500,000
 - "in one general physical location" could impact exemptions*

11



Produce Safety

- Covered Produce (unchanged in supplemental)
 - Food that is produce and that is a RAC is covered by the produce rule

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

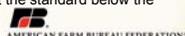
Produce does NOT include food grains (meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.
 - Unless:
 - Rarely consumed raw
 - Produced for individual consumption
 - Covered produce that receives commercial processing

12



Produce Safety

- **Water Quality**
- Continues to only be concerned with generic E. Coli & utilizes the 2012 EPA Recreational Water Quality Standard
- BUT Creates more flexibility:
 - No single maximum level of generic E.Coli, rather testing of multiple samples and using Statistical Threshold Value (STV) and Geometric Means (GM)
 - STV = 410 CFU per 100 mL/GM = 126 CFU per 100 mL
 - **Last irrigation and harvest:** If water doesn't meet that threshold, still can use but must provide a time interval (in days) applying a microbial die-off rate of 0.5 log per day to get the standard below the SVU/GM requirement
 - Can utilize a different standard if you have adequate scientific data to support
 - **Harvest and end of storage:** If water doesn't meet that threshold, still can apply water but must apply a time interval in days use an "appropriate" microbial die-off rate and/or appropriate rates during activities such as washing between to get the standard below the SVU/GM requirement¹³



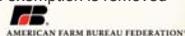
Produce Safety

- **Water Testing**
- Eliminates the requirement to test every 7 days for a tiered approach
- Must test as close to harvest as "practical" – no set time frame to test prior to harvest
- Direct Surface Water Application – 2 step process:
 1. Conduct a baseline survey to develop WQ profile by taking 20 samples in a 2 year period. This must be done every 10 years.
 2. Conduct an annual survey to verify WQ by taking 5 samples/year. If it does not meet baseline, conduct a new baseline profile
- Surface Water not used directly for growing – sprout irrigation, washing, etc.
 1. Test with an adequate frequency to provide reasonable assurances
- Ground Water
 1. Test WQ 4 times during growing season over a period of 1 year
 2. If WQ is met, 1 test annually. If WQ is not met any year thereafter, resume 4 times in the period of 1 year standard.¹⁴



Produce Safety

- **Biological Soil Amendments**
- Removes 9 month minimum application interval
- FDA will conduct a risk assessment & work with USDA to see if other standard should apply
- Eliminates the 45 days minimum compost application period
- This was important as the original requirement did not comply with USDA organic standards. Our comments ensure that our organic farmer members would not be limited by the rulemaking and conflict with USDA standards.
- **Animals**
- Clarifies that it does not authorize a taking of endangered species
- **Withdrawal of Qualified Exemptions**
- Adds clarification to the process when an exemption is removed¹⁵



Produce Safety

- **COMPLIANCE DEADLINES:**
- Very small businesses, those with more than \$25,000 but no more than \$250,000 in annual produce sales, would have four years after the rule's effective date to comply with most provisions.
- Small businesses, those with more than \$250,000 but no more than \$500,000 in produce sales, would have three years after the rule's effective date to comply with most provisions.
- All other farms would have two years after the effective date to comply with most provisions.
- The compliance dates for water quality standards, and related testing and recordkeeping provisions would be an additional two years beyond the compliance dates for the rest of the final rule¹⁶



Produce Safety

- **Exemptions Recap:**
- Farms with an average annual monetary value of PRODUCE sales of \$25,000 or less will not be covered
- A statutory exemption for farms who locally market their produce (in the same state or within 275 miles from the farm) and have FOOD sales of less than \$500,000
 - Food is broader than produce
- Size affects compliance deadlines



Preventative Controls for Human Food

- Focuses on preventing problems that can cause foodborne illness and applies to domestic and foreign facilities that manufacture, process, pack or hold human food
- Establishes **Current Good Manufacturing Practices and Hazard Analysis & Risk Based Preventative Controls**
- Initial Rule Published January 2013/AFBF Filed Comments November 2013
- Supplemental Rule Published September 2014
 - Rule Available at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>
- AFBF filed comments December 2014



Preventative Controls for Human Food

Per FDA, FARMS ARE EXEMPT FROM CURRENT GOOD MANUFACTURING PRACTICES

Per Congress, FARMS ARE NOT FACILITIES AND NOT SUBJECT TO THE HAZARD ANALYSIS & RISK BASED PREVENTATIVE CONTROLS

- Potential Overlap between Produce Safety/Preventative Controls
- Definition of Farm/Covered Facility:
 - A farm no longer would be required to register as a food facility because it packs or holds RAC grown on another farm
 - On-farm packing and holding of produce is subject to the proposed produce safety rule, not preventative controls of human food
 - Farms that conduct additional processing or manufacturing may be subject to preventative controls for those activities

19



Preventative Controls for Human Food

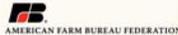
- Exemptions:
 - Statutory exemption for facilities selling to qualified end users (consumers in the same state or 275 miles of your farm mixed-type facility) and less than \$500,000 of annual value of food sales.

Exempt From Hazard Analysis and Preventative Controls

On farm low-risk manufacturing/processing activities conducted by:

- “Small” Facilities with <500 employees
- “Very Small” Facilities with <\$1,000,000 in annual sales of human food

20



Preventative Controls for Animal Feed

- Establishes preventative controls for improved safety of domestic and imported animal food, including pet food, animal feed, & raw materials & ingredients.
- Establishes Current Good Manufacturing Practices and Hazard Analysis & Risk Based Preventative Controls
- Initial Rule Published October 2013/AFBF Filed Comments March 2014
- Supplemental Rule Published September 2014
 - Rule Available at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm>
 - AFBF filed comments in December

21



Preventative Controls for Animal Feed

- Definition of Farm/Covered Facility:
 - Cites back to proposed Preventative Controls for Human Food
 - Reminder: A farm no longer would be required to register as a food facility because it packs or holds RAC grown on another farm
 - Same “in one general physical location” concern
- **GENERALLY FARMS NOT REQUIRED TO REGISTER UNDER THIS SECTION**

22



Preventative Controls for Animal Feed

FDA believes that with the broadened definition of holding and packing most grain elevators and silos would not be required to register as a facility. Also, some facilities that conduct broader activities like packaging and selling seed for crops, but seed leftover for animal food may also qualify.

23



Preventative Controls for Animal Feed

- Cow Happy Hour -
 - Human food safety requirements would not also need to implement additional preventative control or CGMP when supplying a by-product for animal food
- Exemptions:
 - “Very small business” <\$2.5 million in total annual sales of animal food, adjusted for inflation
 - Affects compliance dates & some requirements of Hazard Analysis & Risk Based Preventative Controls

24



Foreign Supplier Verification Programs

- Establishes standards for importers to ensure food imported in to the US is produced safely
- Initial Rule Published July 2013/AFBF Filed Comments January 2014
- Supplemental Rule Published September 2014
 - Rule Available at:
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>
 - AFBF filed comments December 2014

25



Foreign Supplier Verification Programs

- Hazard Analysis - requires importers to conduct a compliance status review of each food to be imported and foreign supplier being considered and they must analyze hazards in each food
- Supplier Verification – verification would be based upon food and supplier risk. Could consist of annual audits for high risk to a lesser standard if adequate assurances are given that the hazard is controlled
- Exemptions consistent with other FSMA Rules
 - “Very Small Importer” and “Very Small Foreign Supplier” = no more than \$1 million in annual food sales
 - AFBF has concerns about exemption levels because they will exclude many foreign suppliers placing US farms at a competitive disadvantage.

26



IMPLEMENTATION

- NASDA/FDA Partnership
- Education/Training Funding
 - USDA and FDA
- Private Ventures:
 - 3rd Party Verification Niche
 - AFBF Webinars/Educational Meetings

27



Questions?

Kristi Boswell, Director of Congressional Relations
 American Farm Bureau Federation
kristib@fb.org
 202-406-3675

28

