

# Bridging the GAPs and Beyond in Food Safety

Michigan Good Food Summit

October 28, 2016



## Session Outline

- Why care about food safety
- Basic areas of consideration for food safety
- What is FSMA and what are the key areas
- On Farm Readiness Tool
- GroupGAP
- Questions and Discussion



## An Important Distinction

**Stuff that MIGHT be  
bad for you...**

- GMO's
- rBST
- Antibiotics

**Stuff that WE KNOW  
IS bad for you...**

- Listeria
- Salmonella
- E. coli
- Gasoline



# Every Year...

- One in Six will get sick
- 47.8 Million episodes annually
- 127,839 Hospitalizations
- 3,037 Deaths



Inspiration from Chapman, info from Scallan et al. 2011

# What Specific Foods Cause Illness?

## What people thought:

- 1: Chicken
- 2: Meats
- 3: Ground meats
- 4: Fin fish
- 5: Shellfish

## Actual causes of illness:

- 1: Produce
- 2: Poultry
- 3: Beef
- 4: Eggs
- 5: Seafood

Environics, 2005

CDC, 2009

## Produce Farm Food Safety Means

- Protecting water and soil
- Separating animals from crops
- Maintaining clean equipment
- Having a plan to address potential contaminating products and situations
- Keeping a healthy workforce
- Following recommended handling practices
- Being able to prove compliance with food safety practices



# On-farm Food Safety Spectrum



# Food Safety Modernization Act

Michigan Good Food Summit



*Michigan Department of Agriculture & Rural Development*

Tim Slawinski

Food and Dairy Division

*October 28, 2016*





# Food Safety Modernization Act

- Signed into Law January 4, 2011
- 41 Sections
- Focus on **Prevention**
- Ensure the US Food Supply is Safe





# Produce Safety

- First food safety regulation specific to growing and harvesting
- Prior regulations cover adulteration
- Addresses Microbiological Risks





# Produce Safety

- Who's Covered?
  - Produce that is typically eaten raw.
- Who's Not Covered?
  - RAC's Not typically eaten raw
  - RAC's destined for Commercial processing
  - On-farm consumption
  - Farms with <\$25,000 Annual Food Sales
  - "Qualified Facilities" have modified requirements
    - <\$500K & 50% of sales local (in-state or within 275 mi.)



# Produce Safety

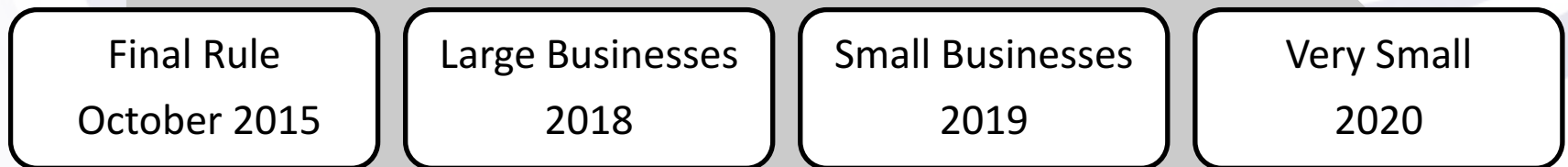
- What's Covered?
  - Agricultural Water
  - Biological Soil Amendments of Animal Origin
  - Equipment, Tools and Buildings
  - Animals in the Growing Area
  - Health and Hygiene





# Produce Safety

- Compliance Dates



- Large Business: > \$500K in Annual Sales
- Small Business: \$500K-\$250K in Annual Sales
- Very Small Business: \$250K-\$25K Annual Sales
- Exempt: <\$25K in Annual Sales



# Agricultural Water

- What is Agricultural Water?
  - Water that contacts the harvestable portion of produce or food-contact surfaces.
    - Irrigation (direct applied)
    - Crop sprays
    - Frost protection
    - Washing
    - Cooling





# Agricultural Water

- What's Required?
  - Inspect water source(s)
  - Testing for E.coli
    - Different standards for pre and post harvest
  - Respond to unacceptable results





# Water Testing

- Ground Water:
  - 4 samples in year 1 (initial survey)
  - 1 annual sample after year 1
- Surface Water:
  - 20 samples over a 2 – 4 year period (initial survey)
  - 5 annual samples after initial survey
- Treated or Public Water Supply
  - No annual testing





# Soil Amendments

- **Treated:**
  - Processed to adequately reduce microorganisms.
  - Physical and Chemical processes or combination.
  - Composting (Specific Time/Temp requirements)
- **Untreated:**
  - Not fully processed or contaminated
  - Treated combined with untreated
  - Contains Agricultural Tea Additive





# Equipment, Tools and Buildings

- Equipment that contacts produce
  - Can be adequately cleaned
  - Inspect, maintain, clean and sanitize
- Fully or partially enclosed buildings
  - Adequate size, construction and design
  - Cleaned and Maintained
  - Prevent pest harborage





# Animals in the Growing Area

- **Domestic Animals:**
  - Grazing when contamination is likely
    - Waiting period before harvest
  - Working Animals:
    - Prevent the introduction of contamination.
- **Animal Intrusion:**
  - Monitor for evidence of animal intrusion
  - Do not harvest contaminated produce



# Health and Hygiene

- Exclude ill employees
  - Observation, acknowledgment or medical
- Hand washing
  - Before starting work
  - After using toilet
  - After break
  - After touching animals





# Training

- Food Safety Training:
  - Equivalent to standardized curriculum
    - Produce Safety Alliance
    - 7 hour standard training
  - Required for at least one supervisor or responsible party



# Training

- Training for personnel must include:
  - Food hygiene and food safety
  - Health and personal hygiene
  - FDA standards
  - Produce that should not be harvested
  - Inspection of harvest containers
  - Correcting Problems



# Packinghouses

- Manufacturing vs. Farm activity
  - Farm = Produce Safety Rule
  - Manufacturing = Preventive Controls Rule
- Similar operations fall under different rules
  - Performed by farmer = farm activity
  - Not performed by farmer = Manufacturing activity





## Resources

- MDARD: 1-800-292-3939
  - [www.michigan.gov/MDARD](http://www.michigan.gov/MDARD)
- FDA FSMA page
  - <http://www.fda.gov/FSMA>
- USDA GAP
  - <http://www.ams.usda.gov/AMSV1.0/gapgph>
- Food Safety Risk Assessment
  - <http://www.mifarmfoodsafety.org>





# Questions?

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# Preparing for FSMA: On-Farm Readiness Review



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# Objectives

- Offer a voluntary pre-inspectional readiness review for covered farms.
- Promote coordination between farmers, regulators, and educators.
- Educate regulators about on-farm conditions.
- Identify educational needs.
- Familiarize non-qualified farms with the regulation



# On-Farm Readiness Review

- **Education before Regulation**
- **Value gained by learning industry/regulatory practices in a spirit of partnership**



## On-Farm Readiness Review

- Driven by National Association of State Departments of Agriculture (NASDA)



- State Departments of Agriculture
  - Oregon, North Carolina, Florida, Vermont



# On-Farm Readiness Review Partners

- FDA
  - Produce Safety, Office of Regulatory Affairs, inspector
- USDA
  - FDA liaison, GAP auditor
- Extension
  - Michigan, New Jersey, Florida, North Carolina
  - Produce Safety Alliance



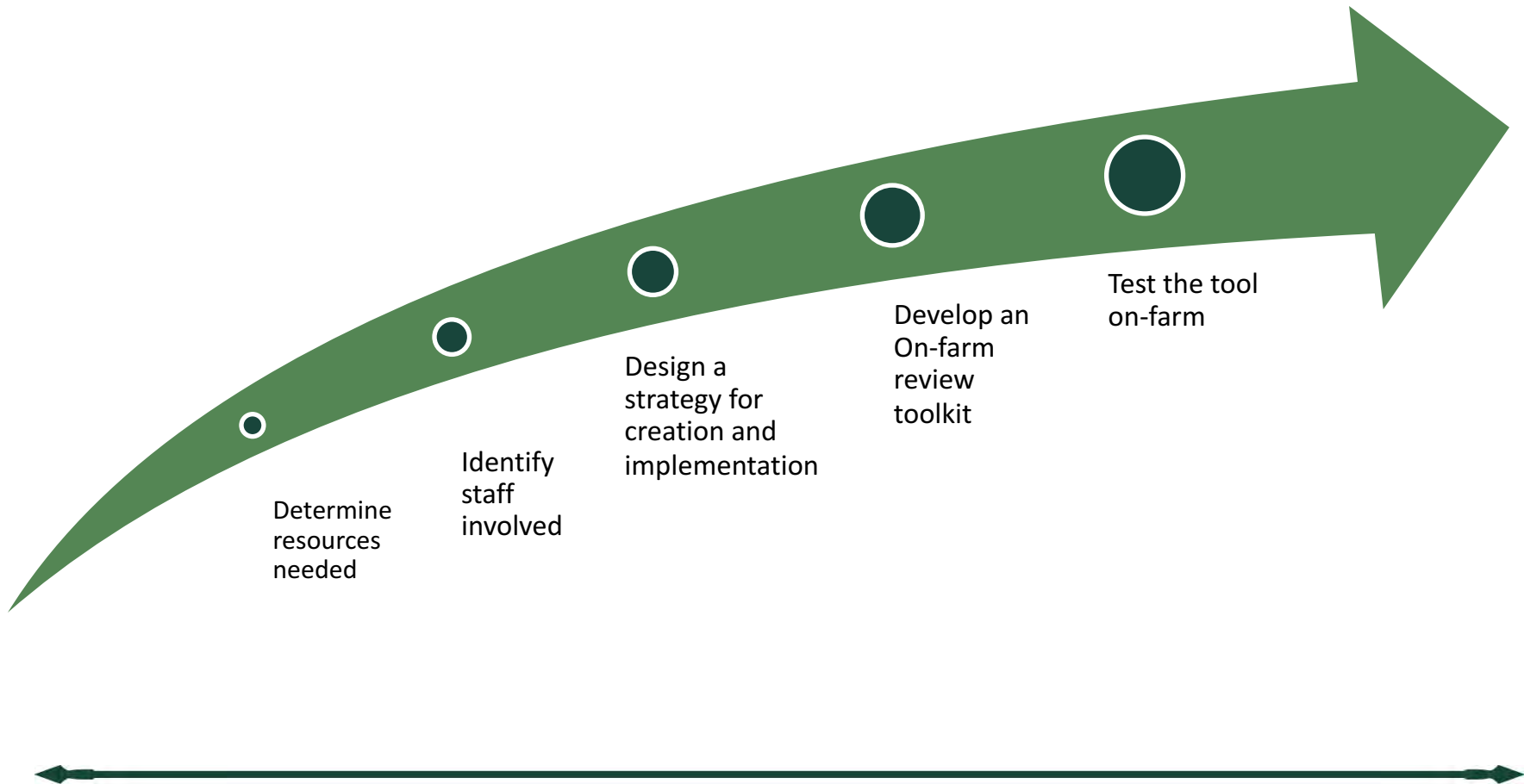
## NASDA Perceived Benefits

- Learning opportunity for both industry and regulators
- Industry exposure to the regulatory process
- Provides regulators an opportunity to build knowledge and skills necessary to uniformly and consistently regulate the fresh produce industry
- Builds awareness of critical food safety practices for farmers
- Provides farmers an opportunity to assess their operations against regulatory provisions
- Assists in building consensus among industry, academia and regulatory stakeholders





# How We Got to Now



## OFRR toolkit modules\*

- Preharvest water
- Preharvest sanitation
- Preharvest worker training
- Preharvest wildlife
- Preharvest soil amendments



- Harvest water
- Harvest sanitation
- Harvest worker training
- Harvest wildlife



- Postharvest water
- Postharvest sanitation
- Postharvest worker training



Regulation	Recommendation	Document (D) Policy (P) Record (R) Observation (O)
Text of the Regulation	Possible activities that may lead to compliance with the regulation.	Method of verification
<p>§ 112.12(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.</p>	<p>Any alternative used must be specified in § 112.49. The list of alternatives includes:</p> <ul style="list-style-type: none"> <li>a) microbial quality criterion using an appropriate indicator of fecal contamination</li> <li>b) pre-harvest microbial die-off rate and accompanying maximum time interval</li> <li>c) minimum number of samples used in the initial survey of an untreated surface water source</li> <li>d) minimum number of samples used in the annual survey of an untreated surface water source</li> </ul>	
<p>§ 112.12(b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.</p>	<p>Support the alternative (see § 112.12(a) and § 112.49) with scientific data or other information.</p> <p>The support must include evidence that</p> <ul style="list-style-type: none"> <li>• the alternative provides the same level of public health protection as use of the relevant value in the codified Rule.</li> <li>• the alternative does not increase the likelihood of adulteration compared to the relevant value in the codified Rule in light of practices and conditions on the farm.</li> </ul>	
<p>§ 112.12(c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from tem's test results for generic E. coli in the farm files. See § 112.50(a) for gen</p>	<p>Keep documents or other records to support the validity of the alternative and appropriate use of the alternative.</p> <p>Keep the supporting documentation for the alternative in the farm records, or ensure that it is available in the scientific literature or available via a third party. Documentation should be kept along with other farm records as required in § 112.50(b)(8) (see § 112.50 for general requirements for records, detailed in subpart O)</p>	
<p>§ 112.41 What requirements apply to the quality of agricultural water? N/A: title statement</p>		

Regulation	Recommendation	Document (D) Policy (P) Record (R) Observation (O)
<p><b>§ 112.41</b> All agricultural water must be safe and of adequate sanitary quality for its intended use.</p>	<p>Take measures necessary to ensure that agricultural water does not contaminate produce), food contact surfaces, or hand wash water. Pending guidance, regulatory evaluation cannot be defined.</p>	
<p>§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?</p>		
<p><b>§ 112.42(a)</b> At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:</p>	<p>Inspect your water system at least once per year and keep a signed and dated inspection record on file. It should include any hazards you identified and any steps you took to minimize risks. It may help to create a map or diagram of your water distribution system, but this is not required.</p> <p>Keep the inspection record and other documentation described under subheadings of provision § 112.42(a) in the farm record as required by § 112.50(b)(1).</p>	

# Pilot

- First pilot test, Grand Rapids, 8/16-18
  - 2 farms
    - Celery and blueberries



# Celery farm

- **200 acres (of ~1,700 in MI)**
- **Mechanically harvested**
- **Packinghouse only packs from this farm on two lines**
- **10 years experience with 3<sup>rd</sup> party audits**



## Blueberry farm

- **Hand harvest early season, mechanical late season**
- **Packinghouse only packs from this farm on one line**
- **3<sup>rd</sup> party audits**
- **Marketing contract**



# Pilot

- First pilot test, Grand Rapids, 8/16-18
  - Day 1 – Extension team visits farms
    - Rutgers, UF/IFAS, NCSU, MSU, PSA
    - 2-3 hours per farm
    - Farm overview, tour, intro to OFRR
    - What to expect, role of partners (FDA)





# Pilot

- First pilot test, Grand Rapids, 8/16-18
  - Day 1 PM – Organizational pre-meeting
    - Reduce time of OFRR pilot to ~1 hr
    - Define roles of extension, federal, and state partners
    - Ground rules
      - Extension team leads pilot process
      - No sidebar conversations
      - Primary goal: test and refine the tool, not audit or inspection



# Pilot

- First pilot test, Grand Rapids, 8/16-18
  - Day 2 – Full team travels to farms
  - Divide into 2 groups of ~10
    - Preharvest (Celery AM / Blueberries PM)
      - Preharvest water, worker training
    - Postharvest (Blueberries AM / Celery PM)
      - Postharvest water, sanitation



# Pilot

- First pilot test, Grand Rapids, 8/16-18
  - Day 3 – Post-visit meeting at Ottawa County extension ~ 2 hours
  - Including all extension, PSA, federal and state regulatory partners, growers, and local extension



## Post Pilot

- **Challenges with tool (extension perspective):**
  - **Bulky**
  - **Can't interpret rule/provide guidance**
- **Waiting for FDA guidance**
  - **Avoiding a “gotcha” list**



## Post-Pilot

- Regulators
  - Surprised by how extension used the tool.



## Post-Pilot

- Farm feedback:
  - PSR is a new approach (non-prescriptive)
  - 3<sup>rd</sup> party audit alignment (one food safety manual)
  - Improve efficiency of tool (weed out N/A questions)
    - Want to be able to easily explain to an inspector which sections of the rule/tool aren't applicable to a given operation rather than being put on defensive



## On-Farm Readiness Review Summary

- Final tool should be used by extension as educational tool or for growers and packers under the Produce Safety Rule to use for self-assessment
  - Other possible uses?
- Utility of the tool can improve after FDA releases guidance



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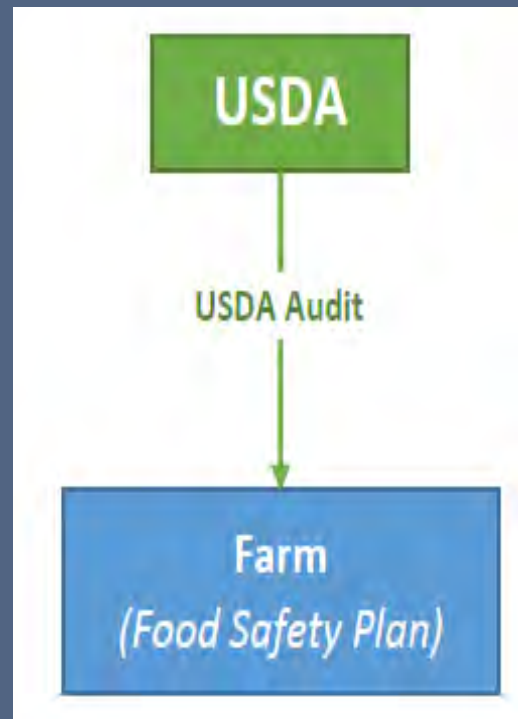
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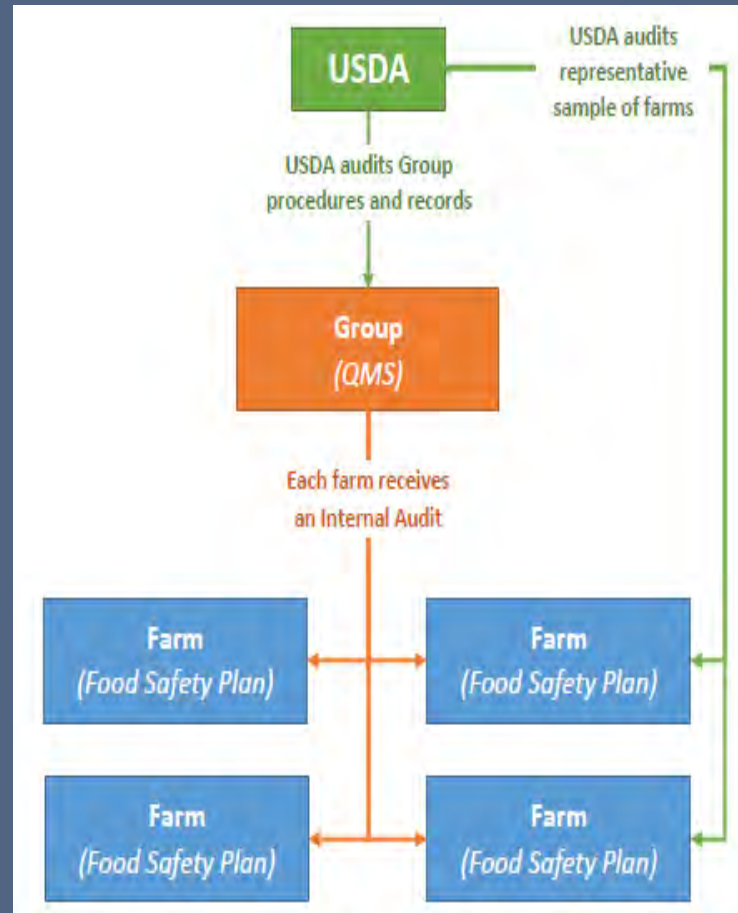




# GroupGAP



# GroupGAP



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