



GAPs & Food Safety Update

National Organic Program Accredited Certifying Agents Annual Training Event

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Presentation Topics

- Working Relationship & Activity with FDA
- FDA's Rulemaking Highlights, i.e., Food Safety Modernization Act (FSMA)
 - Relative to NOP regulations
- Produce Safety Alliance
 - And other Technical Assistance
- USDA Good Agricultural Practices (GAPs) Program
- Q&A



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Agricultural Marketing Service (AMS) - Mission and Vision

Mission: To facilitate the competitive and efficient marketing of agricultural products.

Vision: We envision a marketing system that quickly and efficiently moves wholesome, affordable agricultural products from the farm to the consumer.



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USDA & FDA Working Relationship

- FDA's Mission
- Memoranda of Understanding
- Interagency Agreement
- Federal Gov't Review Process led by the Office of Management & Budget
- *USDA Teams* working with FDA on a variety of issues



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USDA Team working with FDA

- USDA FSMA Workgroup
 - Re-open comment period for:
 1. Ag water
 2. Biological Soil Amendments of Animal Origin
i.e., manure, compost
 3. Farm/Facility issues
 4. Withdrawal of exemption – material conditions
 - Workgroup members



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USDA Team working with FDA

- Preliminary Regulatory Impact Analysis
i.e., economic impact
 - Specific to manure & compost
- Participants
 - AMS NOP
 - AMS Fruit & Vegetable Program Economists
- Primarily sharing info & identifying data sources



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USDA Team working with FDA

- Cooperating Agency Request for the *Draft* Environmental Impact Analysis Statement (EIS)
 - Scoping activity
 - Co-management (conservation & food safety)
- Other Cooperating Agency partners
 - Fish & Wildlife Service at Dept. of Interior
 - Environmental Protection Agency



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USDA Team working with FDA on:

- Produce Safety Alliance (PSA)
 - Cooperative agreement (USDA & FDA & Cornell U.)
 - reaching out to all land-grant universities
 - Development of standardized **farmer** training curriculum & train-the-trainer curriculum
- Members from
 - farmers/growers, packers across diverse operations, cooperative extension, researchers, consultants, land-grants
 - FDA, USDA's Natural Resource Conservation Service, Ag. Research Service & Ag Marketing Service



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FDA's Rulemaking Highlights

- *Food Safety Modernization Act* – 01/04/11
- Suite of proposed rules
 - Environmental Impact Statement Scoping activity
- Related activities
 - Education & Outreach
 - Research
 - Implementation & Compliance
 - Communications Strategy
- Guidance docs



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FSMA – *Proposed* Produce Safety Rule

- Consider risks posed by practices, commodities, conditions
- Science and risk based
 - Identified routes of contamination
 - Excludes certain produce rarely consumed raw
 - Excludes commercially processed with “kill-step”
- Flexible
 - Additional time for small farms to comply
 - Alternatives and variances provisions



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FSMA – *Proposed* Produce Safety Rule

- Considers diversity of operations, size, practices, crops
 - Qualitative Assessment of Risk
- Draws on FDA's past experiences with
 - current Good Manufacturing Practices, Hazard Analysis & Critical control Point programs, and the Shell egg regulation
- Coverage – farms, domestic & imports
- Exemptions – size, qualified exemption



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FDA's Rulemaking Highlights Relative to USDA Organic Regulations

- Coverage: food safety -- organic integrity
- NOP Compliance – requirement differences, e.g.,
 - Manure & Compost
- Recordkeeping Requirements
 - If NOP records contain required info no need to duplicate for FSMA



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FDA's Rulemaking Highlights

- *Technical Assistance*
- FSMA Operational Teams
- Comment Periods
 - Re-proposal for specific provisions
 - EIS comment period
- Court-ordered timeframes
- Effective dates & Compliance dates



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FSMA – Technical Assistance by FDA

- Updated Good Ag Practices Guidance
 - update 1998 guide
- Implementation & Compliance Guide
- National Technical Assistance Network
- Information Center
- Website postings
- Produce Safety Alliance



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USDA's Good Ag Practices (GAP) Program

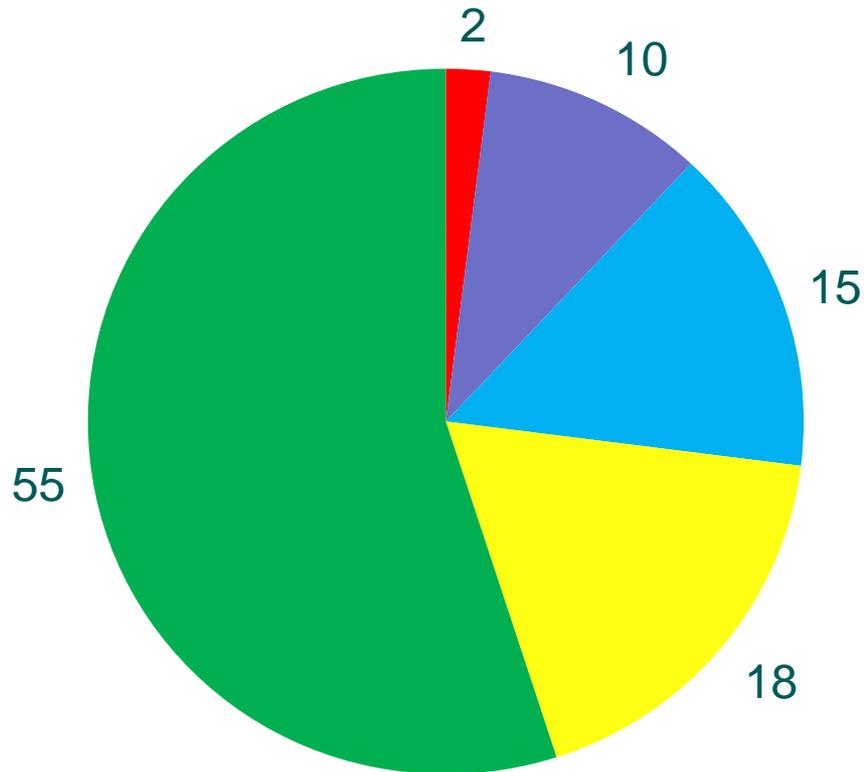
- Brief history
- Standard used
- Oversight mechanism
 - Federal State Partners
- Auditor qualifications
- Status of Global Food Safety Initiative (GFSI) recognition efforts
- Services offered & Services NOT offered



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Compliance Example Hypothetical Leveraging



- **FDA Staff**
- **FDA State Partners**
- **USDA GAPs**
- **Private Industry**
- **Education**

Q & A

- Recap and Q&A



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