

# Food Safety Regulations and Soil Amendments: What's Coming

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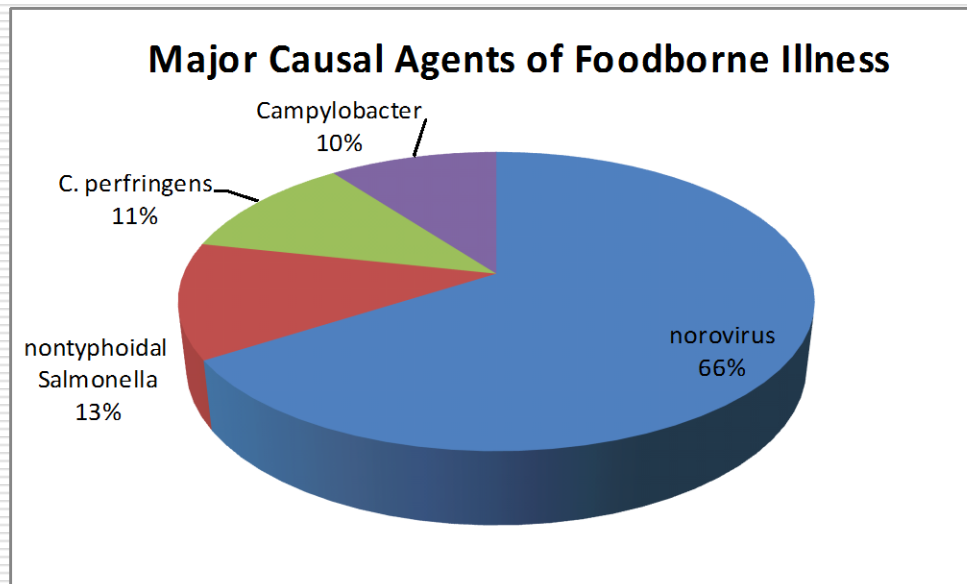
**US Composting Council Conference**

**San Jose, CA Jan 24-27, 2011**

# Preventable Foodborne Illnesses in US

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31 major US pathogens caused 37.2M illnesses, 9.4M foodborne illnesses, 55,961 hospitalizations, and **1,351 deaths**, mainly from nontyphoidal *Salmonella* (28%), *T. gondii* (24%), *L. monocytogenes* (19%), and norovirus (11%). [ *Scallan et al. 2011. www.cdcgov/EID/content/17/1/7.htm* ]



# Historical Events

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- Jan 4, 2011 the Amended S. 510 Food Safety Modernization Act was signed into law
  - First major overhaul of US food safety regulations since the Federal Food, Drug and Cosmetic Act in 1938.
- Authorizes Food and Drug Administration (FDA) to:
  - Increase risk-based inspections
  - Require mandatory recalls of tainted food
  - More effectively trace foodborne illness outbreaks to their source

# Five Major Elements of the FMA

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- **Preventive Controls**
- **Inspection and Compliance**
- **Imported Food Safety**
- **Response**
- **Enhanced Partnerships**

# Major Element 1: Preventive Controls

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- For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply.
- Food companies to write/ implement new safety protocols to mitigate potential hazards.
- Processors of all food types required to have HACCPs & implement/monitor effective measures to prevent contamination, and take necessary corrective action
- FDA to establish science-based standards for safe production and harvesting of fruits and vegetables to minimize risk of serious illnesses or death, and set standards for safe transportation of food.

# Major Element 2: Inspection and Compliance

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- **Requires FDA to conduct more frequent inspections, including required annual inspections of high-risk facilities**
- **Law specifies how often FDA should inspect food producers, 3-5 yrs**
- **FDA to set forth requirements for mandatory testing**
- **Establish standards and regulations, and issue guidance documents to ensure firms are aware of these standards**
- **HHS will require registration and payment of a fee by any "person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports an article of food."**

## **Major Element 3: Imported Food Safety**

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- FDA to require importers to verify that their foreign suppliers have adequate preventive controls in place to ensure safety**
  - FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards**
  - Imported food products may be denied entry into the United States under certain circumstances if they do not demonstrate adherence to US food safety standards.**
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# Major Element 4: Response

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- **FDA will have mandatory recall authority for all food products after allowing responsible parties the opportunity to cease distribution voluntarily**
  - **Shut down facilities that consistently violate safety regs**
  - **Produce more comprehensive tracking and data collection methods**
  - **Access records to determine the source of an outbreak**
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# Major Element 5: Enhanced Partnerships

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- **FDA to strengthen existing collaboration among all food safety agencies—U.S. federal, state, local, territorial, tribal and foreign to provide improved training of state, local, territorial and tribal food safety officials**
  - **FDA authorized to provide grants for training, conducting inspections, building capacity of labs and food safety programs, and other food safety activities**
  - **Help state, local and tribal governments stay prepared to handle agriculture and food emergencies**
  - **FDA and USDA coordination including organic farming**
  - **FDA and USEPA coordination on environmental matters**
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# Funding Implementation of S. 510 FMA

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- **FMA is estimated to cost \$1.4 billion over five years according to the CBO**
    - [www.cbo.gov/ft-p-docs/117xx/doc11794/s510.pdf](http://www.cbo.gov/ft-p-docs/117xx/doc11794/s510.pdf)
  - **It faces an uphill battle for funding in the budget-conscious 112th Congress**
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# Amendments

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- **Sanders:** FDA authorized to exempt farms engaged in low/no risk processing or co-mingling activities from new regulatory requirements or to modify particular regulatory requirements for such farming operations.
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# Amendments: Tester-Hagen

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**FDA to provide a size appropriate and less costly alternative to preventative control plans and produce standards for farmers who:**

- Direct market more than 50% of their products to consumers, stores or restaurants**
  - Have gross sales (direct and non-direct combined) of less than \$500,000 over the past 3 yrs**
  - Sell to consumers, stores, or restaurants that are in-state or within 275 miles, and**
  - Provide customers with their name, address, and contact data**
    - Records kept on immediate suppliers and immediate subsequent recipients of such farm**
    - Farms must still must comply with state rules**
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# Amendments

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- **Stabenow** – provides a USDA-administered competitive grants program for food safety training for farmers, small processors, wholesalers, with priority on small and mid-size farms
  - **Boxer** – eliminate wildlife-threatening enforcement against animal encroachment on farms; requires FDA to apply science to any requirements that may impact wildlife and habitat
  - **Brown** - Exempts farmers from extensive/expensive traceability and recordkeeping requirements, if selling food directly to consumers or grocers, to allow labeling that keeps the farm identity through to consumer to meet traceability requirements, and to limit farm recordkeeping to the first point of sale when the product leaves the farm.
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# **Soil Amendments: Manure and Compost Use on Fresh Produce – USDA - National Organics Program**

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**Raw manure application: NOT within 120 days of harvest where edible portions have soil contact**

**- NOT within 90 days of harvest where edible portions do not have soil contact**

**Composting (no testing of final compost required)**

- Initial C:N ratio of 25:1 to 40:1 in "pile" mixture; and**
  - Temperatures: 131° F - 170° F, sustained for 3 days using in-vessel or static aerated pile system; or**
  - Temperatures: 131° F - 170° F sustained for 15 days using a windrow composting system, during which period the materials must be turned a minimum of five times**
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# **Soil Amendments: Manure and Compost Use on Fresh Produce – USDA – Agricultural Marketing Service**

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## **Proposed Marketing Agreement for Leafy Greens - Sept. 3, 2009**

**Multistate Open Hearings held in Oct. 2009 and Docket of responses**

**<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&page=LeafyGreensCABriefs>**

**Decision is pending FDA rules – need consistency**

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# Soil Amendments: Manure and Compost Use on Fresh Produce – Western Growers Assoc.

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Raw manure application: NOT within 1 yr of harvest where edible portions have soil contact

Composting (testing of final compost required)

- Testing for fecal coliforms, *E. coli* O157:H7, *Salmonella*
  - Temperatures:  $\geq 131^{\circ}$  F, 3 days for in-vessel or static aerated pile system; 15 days for windrows with five turnings.
  - Record keeping and tracibility of products sold
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# Soil Amendments: Manure and Compost Use on Fresh Produce – FDA *rules in development*

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Raw Manure – likely to follow LGMA

Composting – likely to follow EPA 503

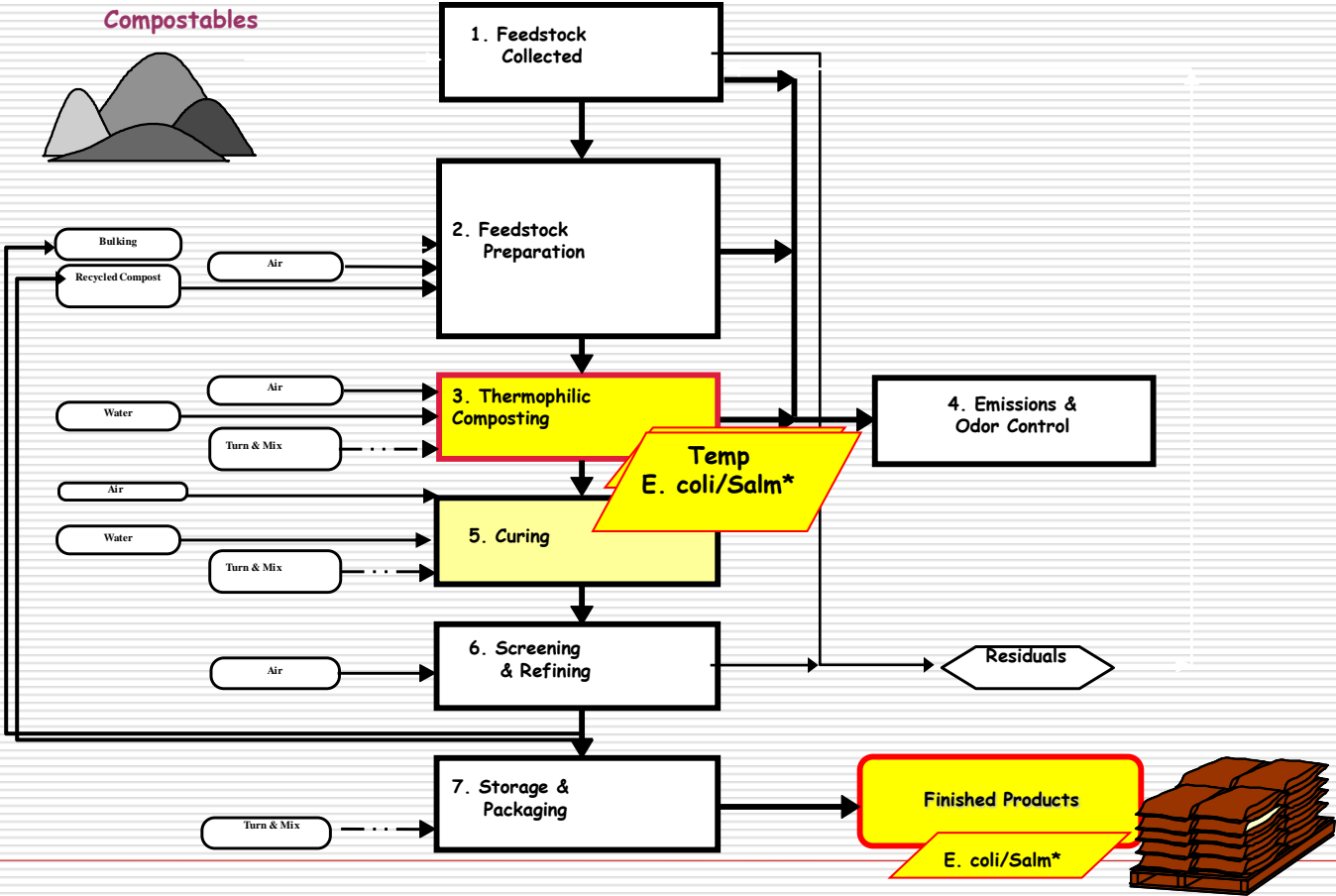
Monitoring & Documentation – expect as much as for biosolids and possibly additional especially for storage, bagging, and blending operations; SOPs to control cross-contamination of finished product.

Testing – Expect more than EPA testing for biosolids, especially for toxigenic/enterohemorrhagic *E. coli*, maybe even for serotypes or virulence factors; as tests are developed new methods may be used.

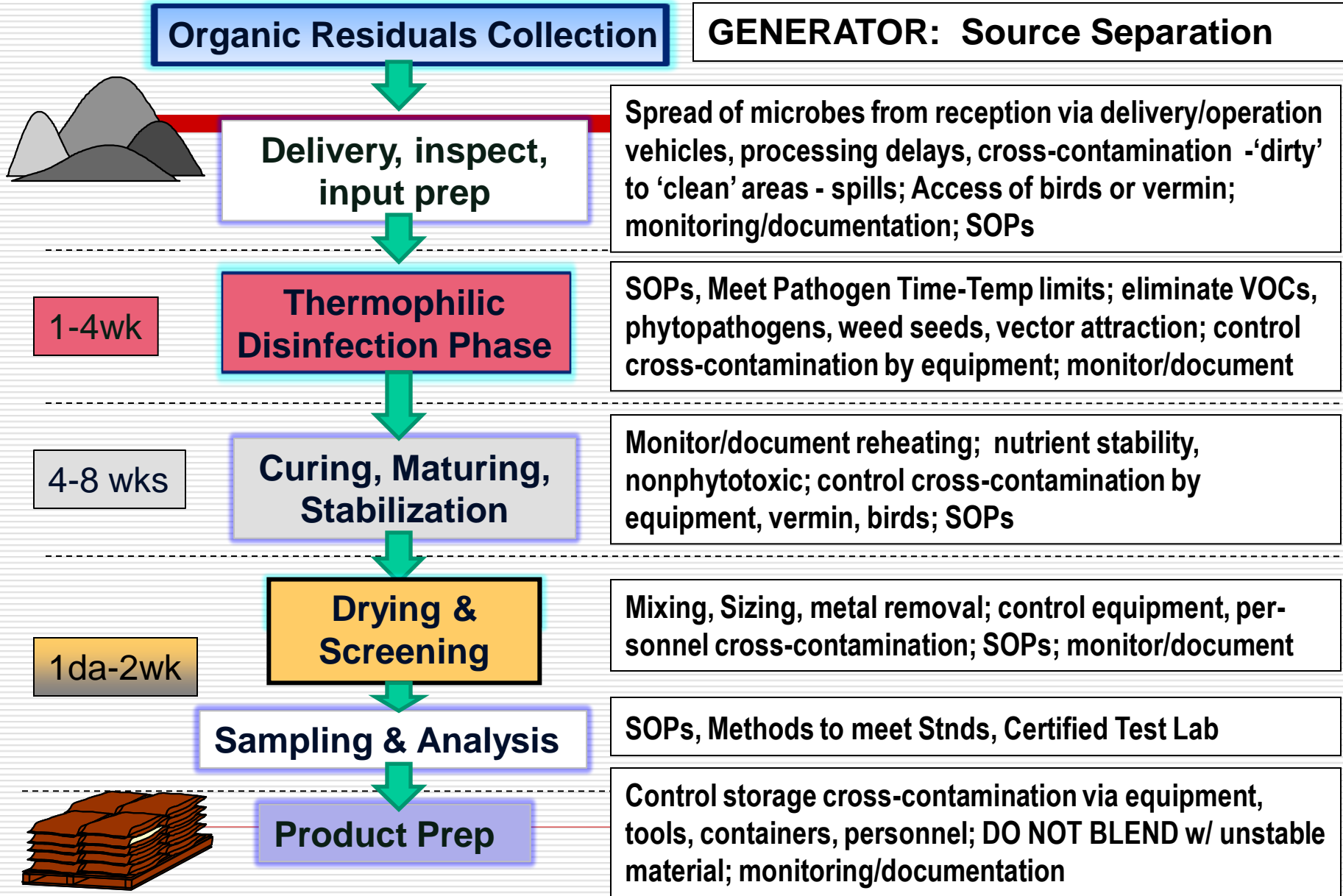
Third-party audits – likely to be required for compost used in production of fresh fruits and vegetables

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**Fig. A-1. Critical Control Points for Process Control, Monitoring and Sampling**



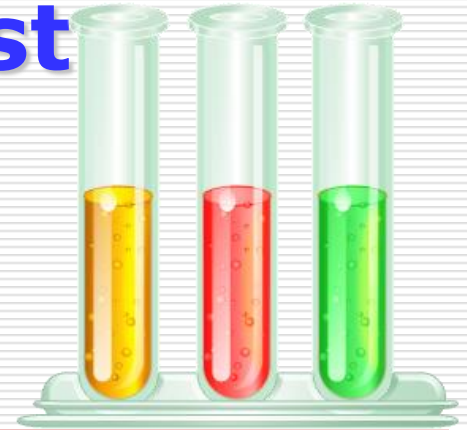
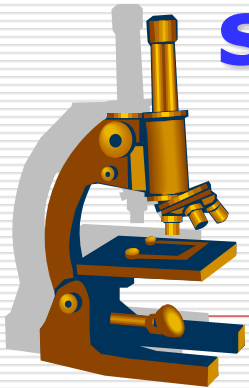
# Major Microbial Issues & Composting Critical Control Points



# Compost Analytical Testing

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**Establish a quality assurance plan for each microbial target assay, include appropriate controls and lab performance standards for compost samples.**



# QUESTIONS?



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# **USDA Agricultural Marketing Service Farmer's Market Promotion Program (FMPP)**

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**Jan. 19, USDA-AMS issued proposed rules for FMPP**

- A competitive grants program for projects to establish, expand, and promote farmers markets, roadside stands, community-supported agriculture, internet sales, agritourism activities, and other direct producer-to-consumer marketing opportunities.**
  - For farm coops, farmer associations and networks, local gov't, non-profit orgs, public benefit and economic development corps, farmers' markets, and tribes (2/3 of grants have been to non-profits)**
  - Grants are to expand/improve existing markets or develop new ones.**
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