

# Challenges Regarding Compliance with FSMA Regulations

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**USDA** UNITED STATES DEPARTMENT OF AGRICULTURE

Form AD-425-C (Revised 9/2006)

# Objectives

- Understand FDA's perspective on compost in the Produce Rule.
- Become familiar with several key components that may require grower action.
- Compare what FDA wants with what's actually happening on-farm.



# The Past as Prelude

- 2008 Spinach outbreak
- 2009 Congress proposes FSMA
- 2011 FSMA passed
- 2013 Produce Safety Rule released
- 2016 Produce Safety Rule enforcement clock started
- 2018 First inspections started



# The Past as Prelude

## PRODUCE

Fruit, vegetables,  
peanuts, tree nuts,  
herbs, and mushrooms  
and the plants they  
come from

VS

## FOOD

All other consumables in  
addition to Produce,  
including candy, jams, iced  
cream, canned goods,  
meats, grains for  
meat/dairy production, etc.



# Excluded Under FSMA

- Asparagus
- Dry Beans (black, northern, pinto, navy, kidney, and lima)
- Beets, roots, and tops
- Cashews
- Sour Cherries
- Chickpeas
- Collard Greens
- Dill
- Eggplant
- Figs
- Lentils
- Okra
- Ginger
- Hazelnuts, Pecans, & Peanuts
- Horseradish
- Cranberries
- Dates
- Coffee Beans
- Peppermint
- Potatoes
- Water Chestnuts
- Sugar beet
- Sweet Potatoes
- Pumpkins and Winter Squash



# Excluded

- Average < \$25k in **PRODUCE** sales in three years
  - Covered and uncovered **produce**



# First Exemption

## Qualified Exempt

- Average <\$500k in **FOOD** sales in three years

## AND

- Average >50% of **FOOD** sales to **qualified end users** within 275 miles of farm or the consumer of the food.
  - Restaurants
  - Retailers





# Second Exemption

## Processing Exemption

- Your **PRODUCE** is processed
  - Cucumbers of pickling
  - Carrots for baby food
  - Mint for oil
  - Red beets for dye

“Not processed to adequately reduce the presence of microorganisms of public health significance;” [112.3(b)(2)].

~~Annual written assurance from the buyer saying the food, “has been commercially processed in a manner that adequately reduces the presence of microorganisms of public health concern prior to entering commerce.” [112.2(b)(3)(ii)(B)(1)].~~



# Labeling: FSMA Modified Requirements for Growers Who are Qualified Exempt



*“Must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard...”*



# Packhouses



- Where is the packhouse?
  - On-farm = Produce Rule
  - On its own = more info needed
- Who owns the product?
  - >50% on-farm = Produce Rule
  - <50% on-farm = Preventive Controls Rule



# The Future of FSMA

- Determine if you're Exempt.
- **IF** you're exempt, fill out an Annual Review of FSMA Exemption by 2018 at the earliest.
- If you're **NOT** exempt, begin complying and be aware of your full compliance date.



# FSMA Implementation

- January 2018 for firms over \$500,000
- January 2019 for firms over \$250,000
- January 2020 for firms above \$25,000
- All farms above \$25,000 in **PRODUCE** sales are subject to the rule. Farms below \$500,000 in **FOOD** sales MAY be qualified exempt.



# Comparison of Audits and Inspections

## Audit

- Usually points based
- Annual
- Crop-specific
- Consequence of failure is loss of sales

## Inspection

- NOT points based
- Intermittent, not annual
- Covers whole farm
- Consequences of failure may be a fine or closure



# Poop by any other name...

## BSAAO Definition

*“A biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste alone or in combination.”*



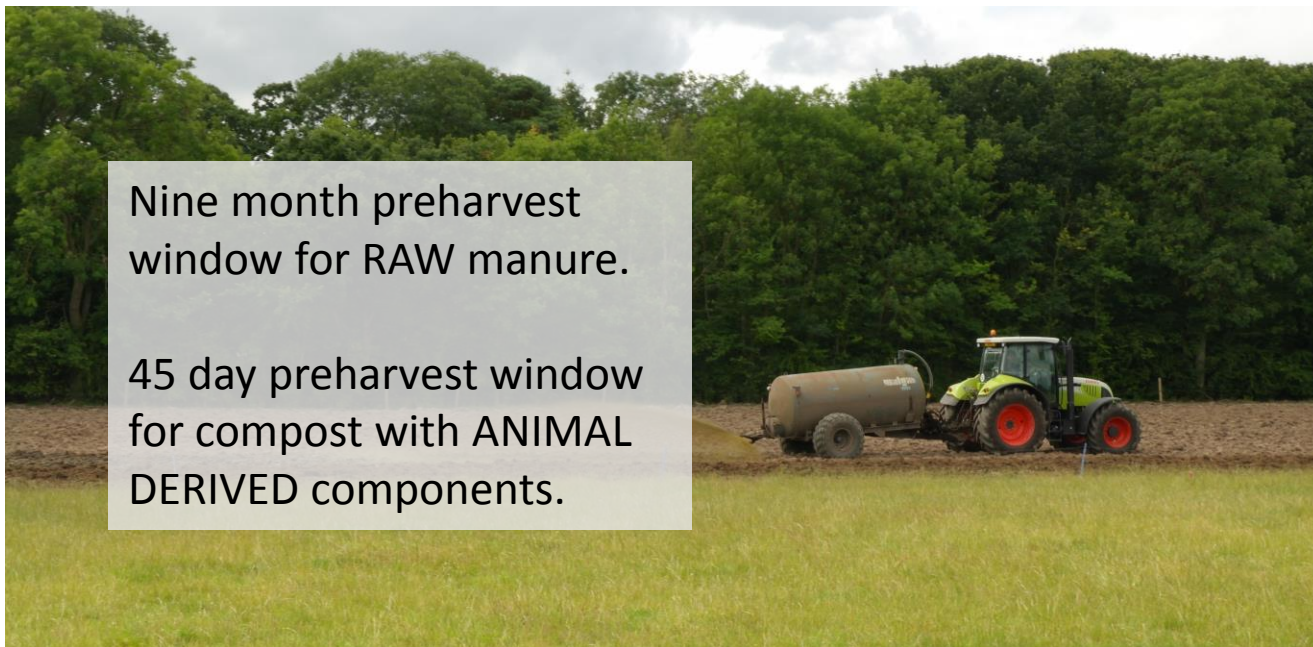
Photo Credit:

<https://www.noble.org/globalassets/images/news/ag-news-and-views/2013/10/manure2.jpg>



# Evolution of Manure Policy

## First Draft



Nine month preharvest window for RAW manure.

45 day preharvest window for compost with ANIMAL DERIVED components.

Photo Credit: Adrian Plaxton[CC-BY-SA-3.0 (<http://creativecommons.org/licenses/by-sa/3.0>)], via Wikimedia Commons





# Evolution of Manure Policy

## Second Draft



FDA will defer a ruling and research a viable wait time

Will not stand in the way of 120 day post harvest interval in National Organic Program and Good Agricultural Practices

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# What is Animal Derived?

Manure

Mortalities

Fish Emulsion

Blood Meal

Bone Meal

Table Scraps

Bed Pack

“Aged” Animal Materials



# Approved Composting Process

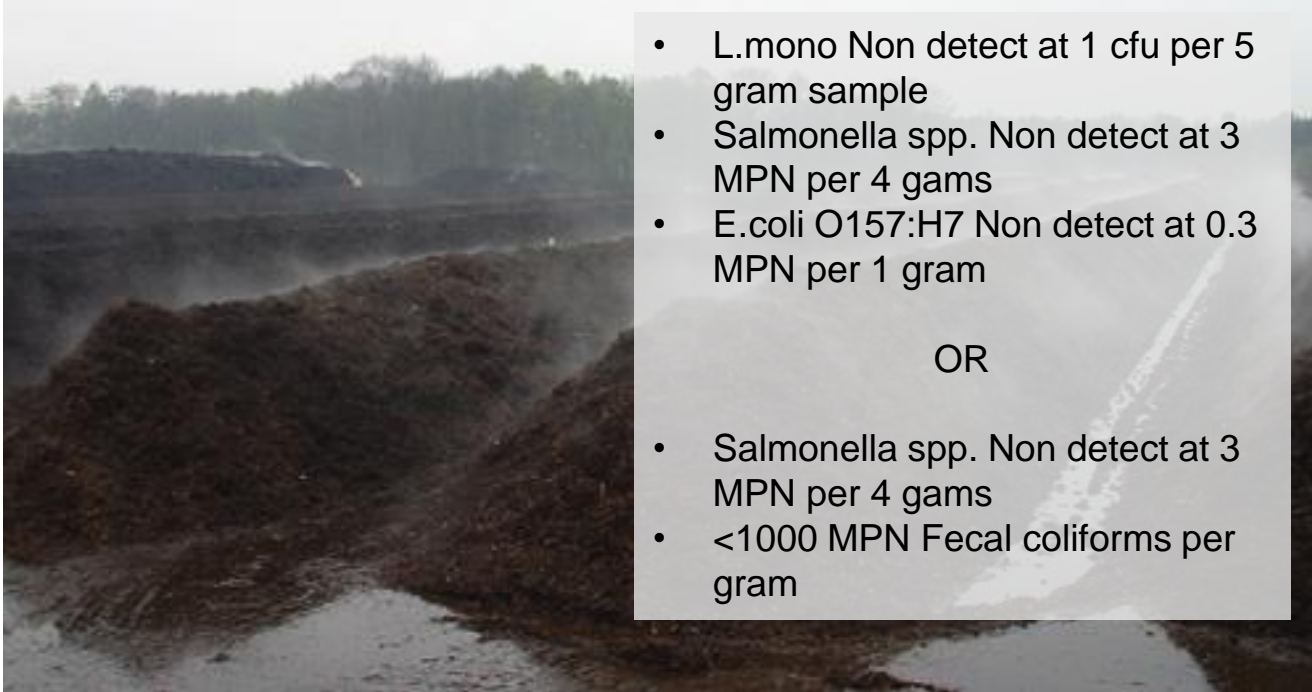


Photo Credit: <https://www.flickr.com/photos/evefox/2777640169/>

- Static Compost: minimum of 131 F for 3 days, then “adequate curing, which includes proper insulation”
- Turned Compost: minimum of 131 F for 15 days, “adequate curing, which includes proper insulation”



# Equivalency Test



- L.mono Non detect at 1 cfu per 5 gram sample
- Salmonella spp. Non detect at 3 MPN per 4 gams
- E.coli O157:H7 Non detect at 0.3 MPN per 1 gram

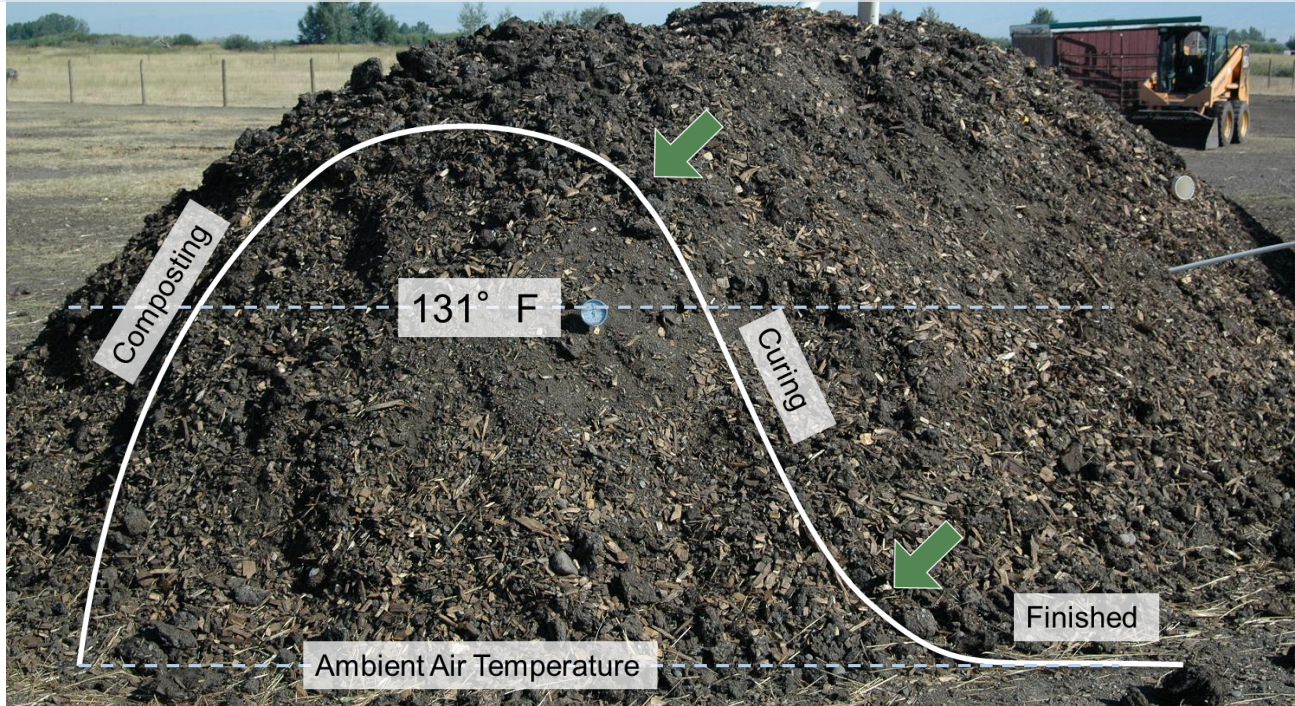
OR

- Salmonella spp. Non detect at 3 MPN per 4 gams
- <1000 MPN Fecal coliforms per gram

<https://www.flickr.com/photos/evefox/2777640169/>



# Doings Inside the Poo Pile



# Agricultural Teas

- FDA assumed all agricultural teas would be soil applied.
- They view a foliar application as a pesticidal activity requiring a label.



[http://www.tuttleridgefarms.com/\\_Media/pasted-file\\_med\\_med.jpeg](http://www.tuttleridgefarms.com/_Media/pasted-file_med_med.jpeg)



# Agricultural Tea No-Nos

- Adding anything that would stimulate microbial growth.
  - Molasses
  - Sugar
  - Yeast extract
  - Algal powder



<http://www.motherearthnews.com/-/media/Images/MEN/Editorial/Blogs/Green-Homes/Compost-Tea/ingredients-use-jpg?la=en&hash=D709453868C9EA1A99B08779297AE61D91B841D1>



# Key Issues with Melons

## Growth on the Ground

- Avoid application of risky amendments on melon ground.
- Using new plastic is less risky than reusing plastic.



<http://www.civiggardencenter.org/compost-cincy-puts-organic-waste-to-good-use/>





# Safe(er) Handling Practices



- How can pathogens be re-introduced into a “clean” soil amendment?
- How should that inform how you manage the product?



# Record Keeping Requirements



## DIY Compost

- Needs the following records:
  - A record outlining the scientific validity of the process used to make the compost [112.54]
  - Time, temp, and turning records showing the process was followed on the farm [112.60(b)(2)]



# Record Keeping Requirements



## Purchased Compost

- Needs a Certificate of Compliance
- Assurance that the process is scientifically validated  
[112.60(b)(1)(i)]
- Assurance that the compost wasn't contaminated from making it to its arrival on-farm  
[112.60(b)(1)(ii)]



# Record Retention



- Records must be on-site for at least 6 months
- After 6 months, records must be stored so as to be accessible on-site within 24 hours
- Records must be retained for 2 years
- Can be maintained via hard copy or digitally

