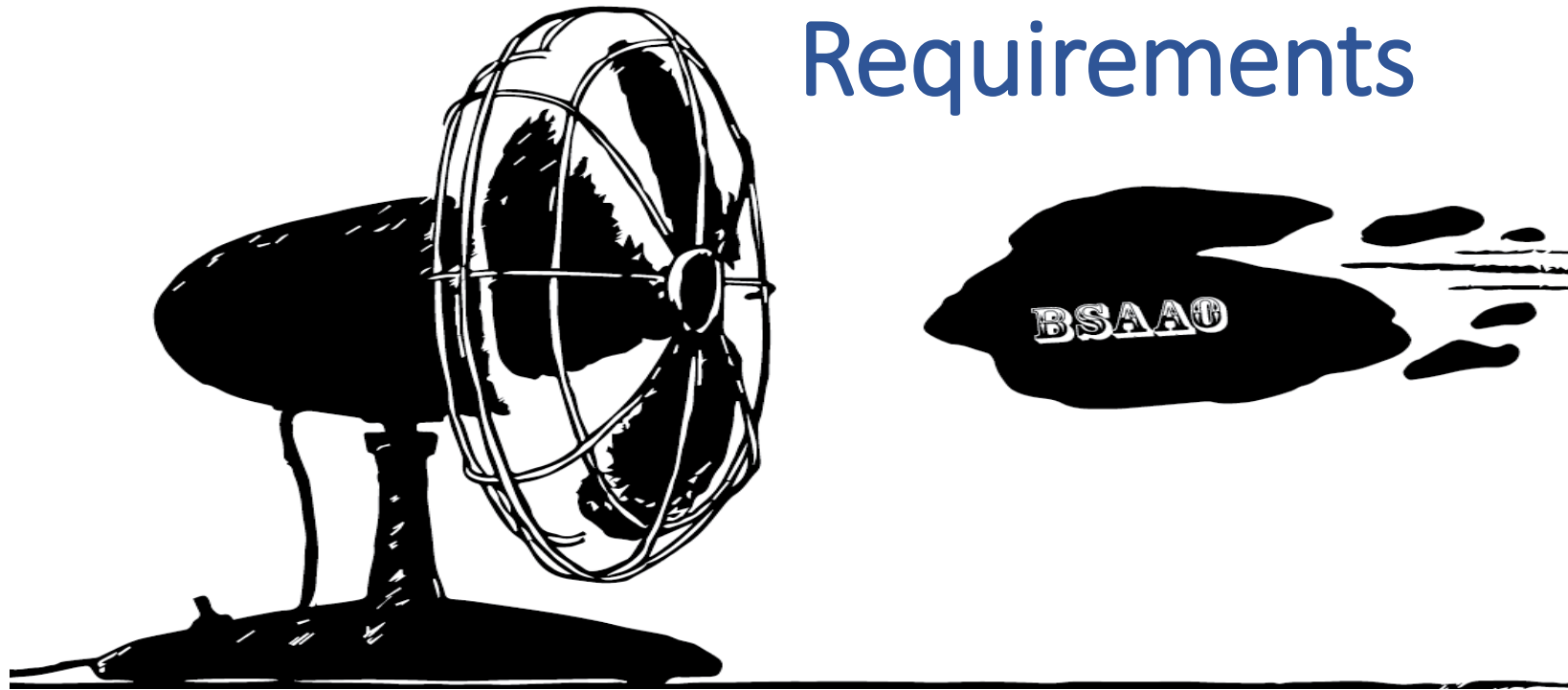


# ***LAO-IICA-DPS Partnership***

***April 11, 2024***



## Food Safety Modernization Act: Produce Safety Rule Standards for Soil Amendments: Clarification on Requirements



**David T. Ingram, Ph.D.**  
Fresh Branch, Division of Produce Safety

**FDA FOOD SAFETY  
MODERNIZATION ACT**

**THE FUTURE IS NOW**

1. Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption, the Produce Safety Rule
2. Preventive Controls for Human Foods
3. Preventive Controls for Animal Foods
4. Foreign Supplier Verification Programs (FSVP)
5. Mitigation Strategies to Protect Food Against Intentional Adulteration
6. Sanitary Transport of Human and Animal Food
7. Accredited 3<sup>rd</sup> party certification

## FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW



# FSMA: Produce Safety Rule

Conditions and practices identified as potential contributing factors for microbial contamination:

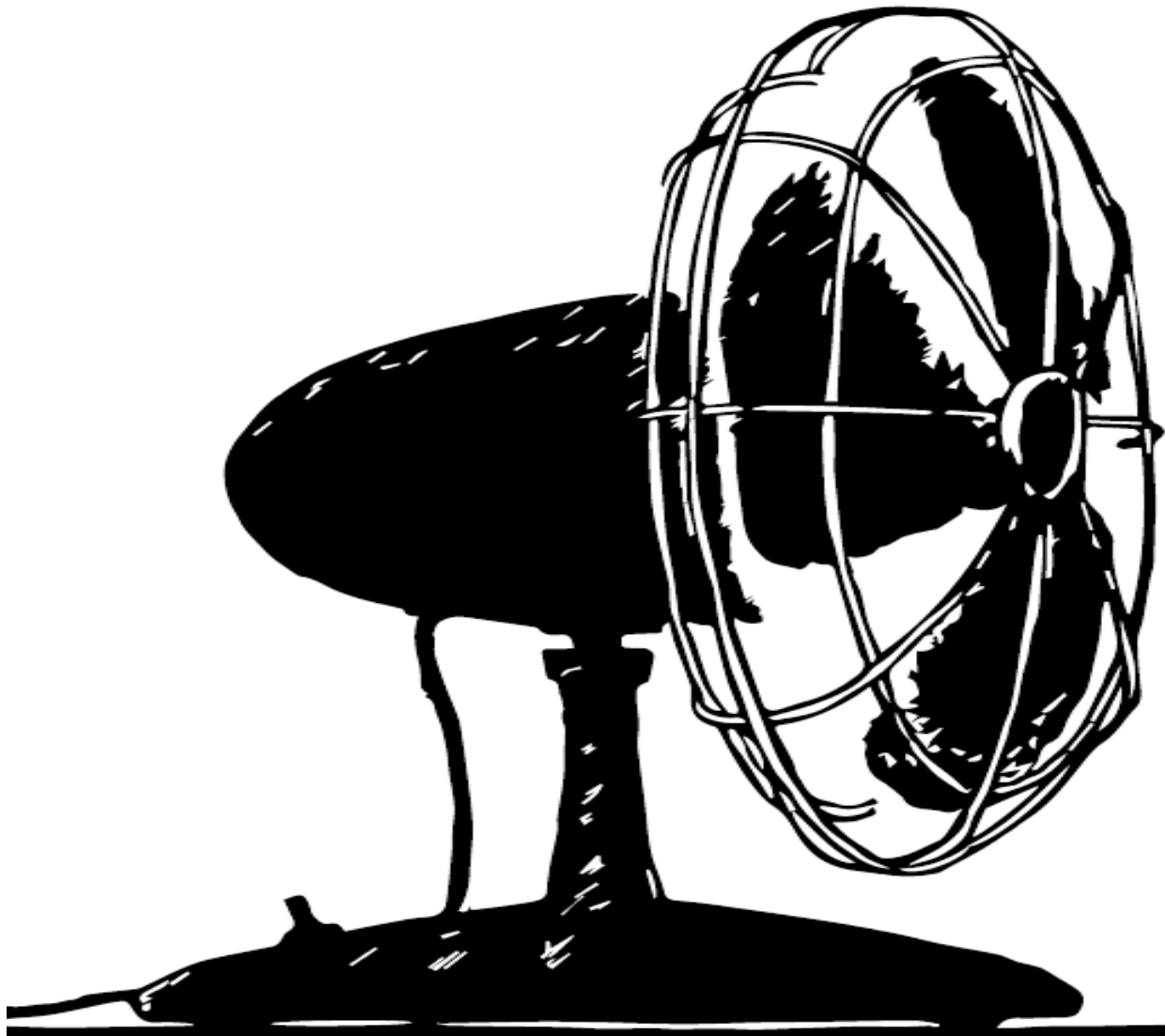
- ❖ Agricultural water
- ❖ **Biological soil amendments of animal origin**
- ❖ Worker health and hygiene
- ❖ Equipment, tools, buildings and sanitation
- ❖ Domesticated and wild animals
- ❖ Growing, harvesting, packing and holding activities
- ❖ Sprouts requirements



# Resources: PSR and Guidance Documents

- Produce Safety Rule
  - Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption
    - Preamble and codified
- DRAFT Produce Safety Rule Compliance and Implementation Guidance
- Produce Small Entity Compliance Guide

# What is not Regulated under PSR?



# Soil Amendments - Framework



<b>Type</b>	<b>Non-Biological (e.g., elemental)</b>	<b>Non-Animal Origin</b>	<b>Animal Origin</b>	<b>Human Waste</b>
-------------	---	------------------------------	----------------------	--------------------

And where contamination is known to exist, the likelihood of contamination is a function of the following factors:

<b>Treatment</b>	Pasteurized (heat, chemical, physical)	Composted	Untreated/Raw; Partially treated; Re-contaminated
<b>Application timing</b>	Further from harvest		Close to harvest
<b>Application method</b>	No contact with harvestable portion	Effort made to minimize contact	Contact with harvestable portion

Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce

<https://www.fda.gov/media/116766/download>

# Soil Amendments - Framework



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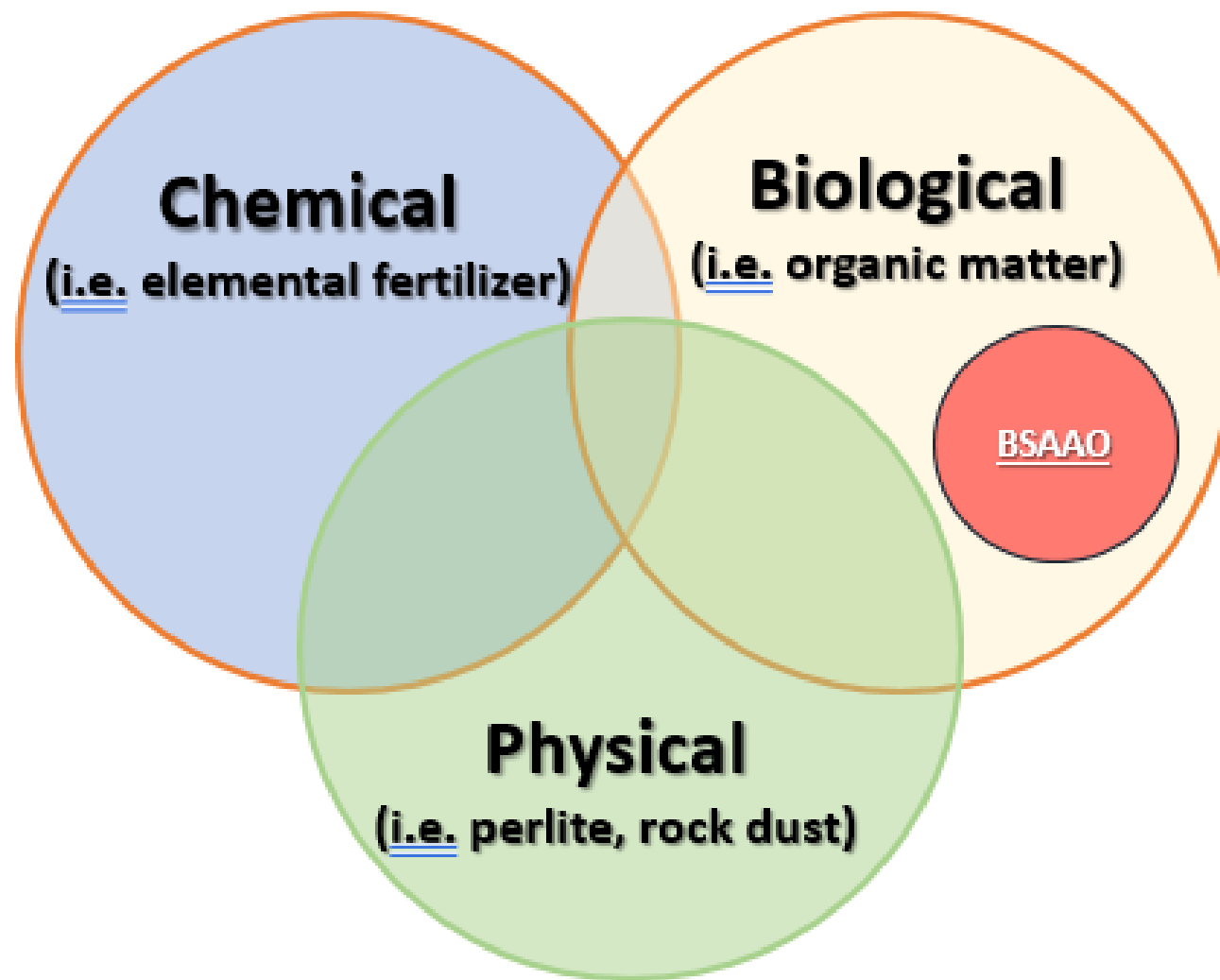
Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce

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# Soil Amendments

## Defined terms:

- Soil Amendment
- Biological Soil Amendment
- Agricultural Tea
- Curing
- Non-fecal animal by-products
- Table waste
- Yard trimmings



# DRAFT Produce Safety Rule Compliance and Implementation Guidance: Chapter 4



## Chapter 4: Biological Soil Amendments of Animal Origin and Human Waste Overview

1. Determine Whether your Soil Amendment is a BSAAO
2. Determine Whether your BSAAO is “Treated” or “Untreated”
- ★ 3. Determine level of treatment and associated Microbial Standard for **the Treatment Process**
4. Determine How to Apply your BSAAO
5. Determine the Requirements for Handling, Transporting, and Storing your BSAAO
6. Determine What Records to Keep for your Treated BSAAO

# Subpart F: Biological Soil Amendments of Animal Origin (BSAAO) Decision Tree

Understanding how to characterize and utilize your BSAAO in compliance with the Produce Safety Rule

Do I need to comply with this Subpart?

Proper handling, transporting and storing requirements §112.52(a)

**START HERE**  
Your Soil Amendment is, contains components of or has become contaminated with BSAAO or human waste 21 CFR §112.3

**Not subject to Subpart F**

Is my BSAAO Treated or Untreated?

Processed to Completion per § 112.54 or per 40 CFR part 503, Subpart D (for Class A Biosolids) ?

Used as component of an Agricultural Tea that contains or is prepared with one or more of the following:  
1) Untreated Surface Water  
2) Water containing ≥1 cfu or MPN *E. coli* /100ml?  
3) Agricultural tea additives § 112.3

**TREATED**

**UNTREATED**  
("Class B" or Untreated Human Waste is Prohibited §112.53)

How may I use my BSAAO?

Handled, Transported and Stored per § 112.52(b) and (c)

Validated Treatment process to meet § 112.54(a) & .55(a)

Records kept per § 112.60

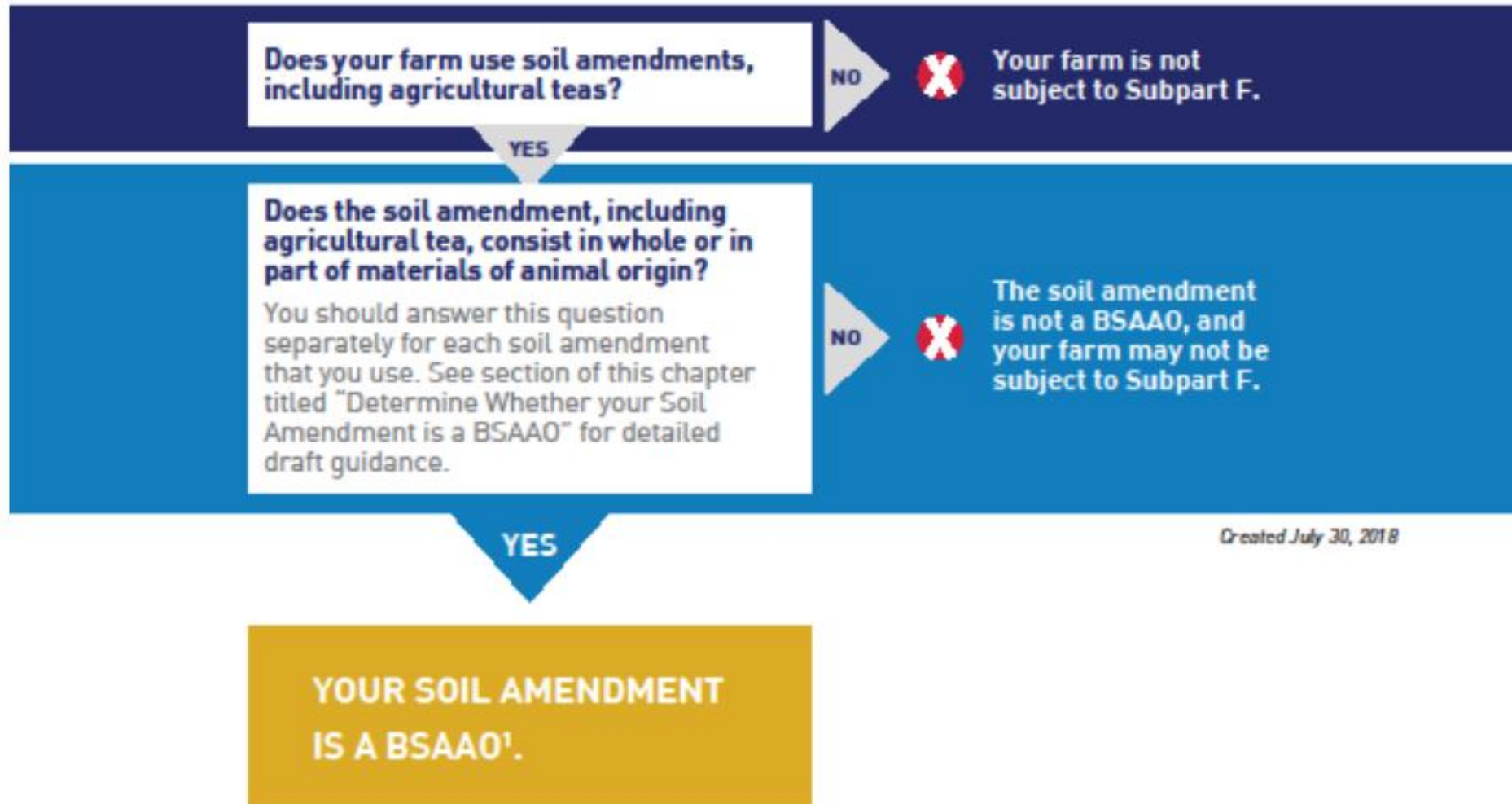
Validated Treatment process to meet § 112.54(b) & .55(b)

Records kept per § 112.60

Requirements related to CONTACT with harvestable portion of covered produce

	DURING application	AFTER application	Days-to-Harvest	Codified
YES	No Restriction	No Restriction	Zero Days	§ 112.56(a)(3)
NO	MINIMIZES	MINIMIZES	Zero Days	§ 112.56(a)(2)
(Untreated BSAAO except for Human Waste per §112.53)				
	NO CONTACT	NO CONTACT	Zero Days	§ 112.56(a)(1)(ii)
	NO CONTACT	MINIMIZES	[RESERVED]	§ 112.56(a)(1)(i)

# 1. Determine Whether Your Soil Amendment is a BSAAO



<sup>1</sup> You must handle, convey and store your BSAAO in accordance with the requirements of 21 CFR 112.52. See section "Determine the Requirements for Handling, Conveying, and Storing your BSAAO" for detailed draft guidance.



## 2. Determine Whether Your BSAAO is “Treated” or “Untreated”



- **Treated** BSAAO

- Compost, Heat Treated Poultry Pellets, Fish Emulsion, Meals (bone, blood, feather, fish, meat, etc.), “Class A” Biosolids, etc.
- Agricultural Teas that are BSAAOs
- The rule does not require you or your supplier to conduct microbiological testing
- TREATMENT PROCESS must be scientifically validated

- **Untreated** BSAAO

- **Examples**
- Options for management



## 2. Determine Whether Your BSAAO is “Treated” or “Untreated”



**Agricultural Tea** may be considered “**treated**” if:

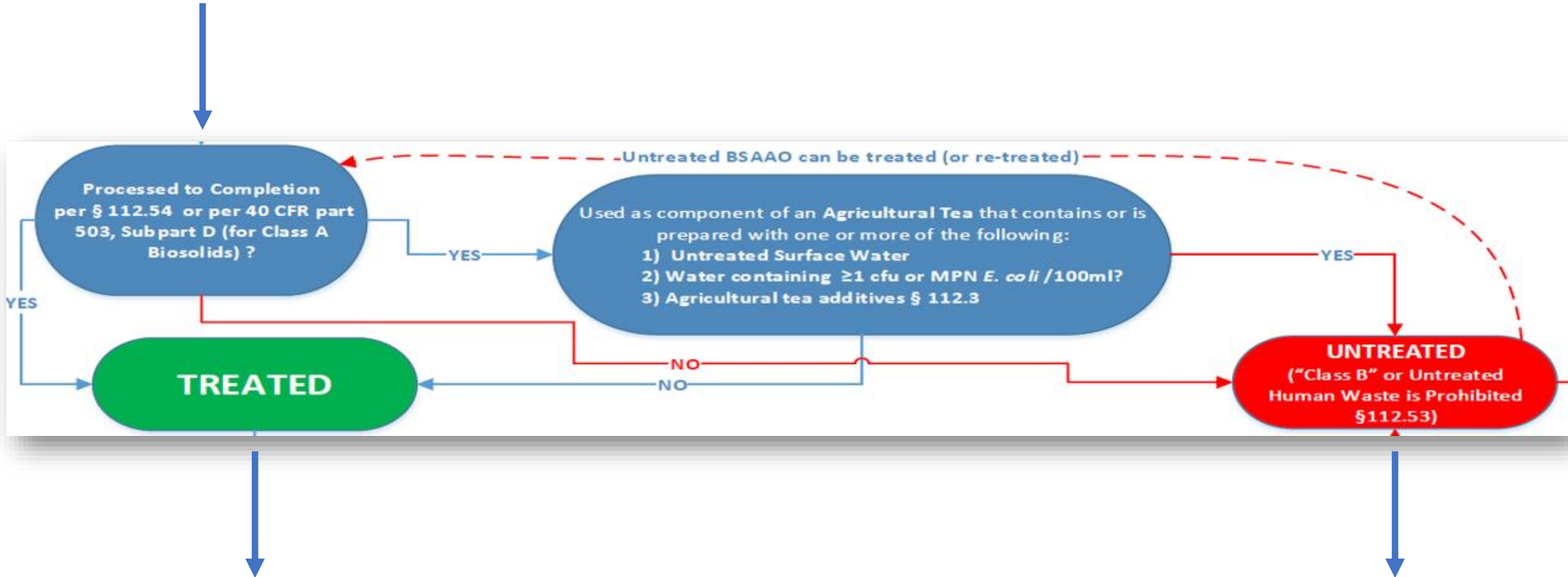
- “treated” BSAAO feedstock is used
- No untreated surface water is used
- Water has NO detectable *E. coli* per 100ml
- No agricultural tea additives are used



**§ 112.3(a) “....  
Agricultural teas are held  
for longer than one hour  
before application”**



# 2. Determine Whether Your BSAAO is “Treated” or “Untreated”





### 3. Determine the Appropriate Treatment Level and Associated Microbial Standard

#### ❖ BSAAO Treatment Levels and associated microbiological standards

- § 112.54 / § 112.55 - Treatment processes validated to meet the relevant microbial standard

#### ❖ Recommendations to process your BSAAO to completion

- Establish procedures to deliver the scientifically valid, controlled process throughout the BSAAO;
- Administer the treatment process in a controlled manner to ensure treatment parameters are achieved throughout the BSAAO material;
- Ensure that the treatment parameters are achieved in areas of the material where delivery of the process could be more challenging to achieve

# § 112.54 – BSAAO Treatment Levels

**Flexibility:** any chemical, physical and/or biological treatment process that is scientifically validated to meet one of two treatment levels and associated microbiological standard.

➤ **Treatment A** aka ‘nuclear bomb approach’

➤ § 112.54(a)

➤ **Treatment B**

➤ § 112.54(b)(1) **Static Composting**

▪ 131°F / 55°C for 3 consecutive days + adequate curing

➤ §112.54(b)(2) **Turned Composting**

▪ 131°F / 55°C for 15 days + adequate curing

# Treatment A: § 112.54 / § 112.55 – BSAAO Treatment Levels and associated microbiological standards



Treatment A (21 CFR § 112.55(a))	The microbial standard is -
<i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.
<i>Salmonella species</i>	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
<i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

# Treatment B: § 112.54 / § 112.55 – BSAAO Treatment Levels and associated microbiological standards



<b>Treatment B (21 CFR § 112.55 (b))</b>	<b>The microbial standard is -</b>
<b><i>Salmonella</i> species</b>	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
<b>Fecal coliforms</b>	Less than 1,000 most probable numbers (MPN) per gram (or mL, if liquid is being sampled) of total solids.



## **Guidance**

# **Processed Animal Manures in Organic Crop Production**

Links Update: August 31, 2018

### **1. Purpose**

This guidance explains the policy for the use of heat processed animal manures in crop production operations certified as organic under the National Organic Program (NOP). This policy does not supersede requirements of other Federal and State laws and regulations. However, written procedures and records prepared by producers to meet NOP requirements may be the same as those prepared to meet other regulatory requirements.

### **2. Scope**

This guidance applies to all organic crop producers. This guidance does not apply to compost teas or other products that may contain raw or composted manure.



## Guidance

### Processed Animal Manures in Organic Crop Production

Processed manure products must be treated so that all portions of the product, without causing combustion, reach a minimum temperature of either 150° F (66° C) for at least one hour or 165° F (74° C), and are dried to a maximum moisture level of 12%; or an equivalent heating and drying process could be used. In determining the acceptability of an equivalent process, processed manure products should not contain more than  $1 \times 10^3$  (1,000) MPN (Most Probable Number) fecal coliform per gram of processed manure sampled and not contain more than 3 MPN Salmonella per 4 gram sample of processed manure.

and records prepared by producers to meet NOP requirements may be the same as those prepared to meet other regulatory requirements.

## 2. Scope

This guidance applies to all organic crop producers. This guidance does not apply to compost teas or other products that may contain raw or composted manure.

# DRAFT Produce Safety Rule Compliance and Implementation Guidance: Chapter 4



## Chapter 4: Biological Soil Amendments of Animal Origin and Human Waste Overview

1. Determine Whether your Soil Amendment is a BSAAO
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3. Determine level of treatment and associated Microbial Standard for **the Treatment Process**
4. Determine How to Apply your BSAAO
5. Determine the Requirements for Handling, Transporting, and Storing your BSAAO
6. Determine What Records to Keep for your Treated BSAAO

## 4. Determine How to Apply Your BSAAO

- **Factors to Consider**

- ✓ **Treatment Status, Level of Treatment (A or B) and *Application Restrictions***
- ✓ The application methods that you could use and the likelihood of contact between the BSAAO and the harvestable or harvested part of the crop
- ✓ The type of covered produce and maturity at the time of application
- ✓ Location of the growing area and environmental conditions

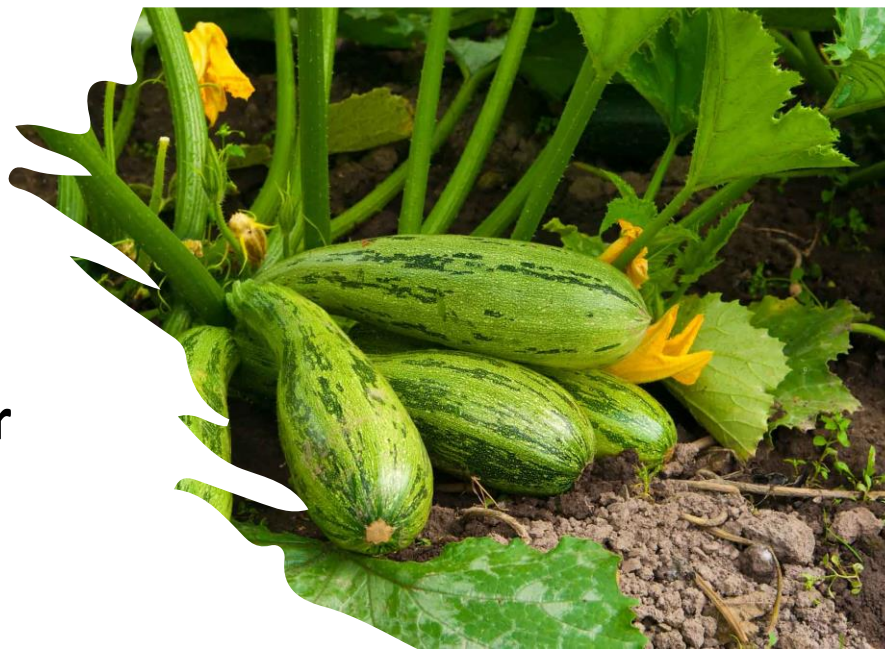
- **Application Methods**

- Direct contact *with covered produce*
- Minimizes potential for contact *with covered produce*
- No contact *with covered produce*



**“We do not object to growers’ use of a 90 or 120 day application interval for untreated BSAAOs...”**

- **§205.203(c)(1)) “The [90-120 Day Rule](#)”**
- **If the edible portion is exposed to splash with raw manure-amended soil from irrigation, precipitation or manure application**
- **You may not apply raw, un-composted livestock manure to food crops unless it is:**
  - Incorporated into the soil a minimum of 120 days prior to harvest when edible portion of the crop has contact with soil or soil particles**





# §112.56 – Application Requirements



	Contact <u>During Application</u>	Contact <u>After Application</u>	Minimum Application Interval
<b>Untreated</b> <b>BSAAO</b>	MUST be applied in a manner that does <b>not contact</b> covered produce <i>during application</i>	<i>and minimizes potential</i> for contact with covered produce <i>after application</i>	<b>[Reserved]</b> harvest interval
		<i>and No contact after application</i>	<b>Zero days-to-harvest interval</b>

**Application**



**Harvest**



# §112.56 – Application Requirements

<b>Treated BSAAO</b>	<b>Contact <u>During application</u></b>	<b>Contact <u>After Application</u></b>	<b>Minimum Application Interval</b>
<p><b>Treatment A</b> 112.54 (a)/112.55(a)</p>	<p>In any manner (i.e. no restrictions)</p>	<p>In any manner (i.e. no restrictions)</p>	<p><i>Zero days-to-harvest interval</i></p>



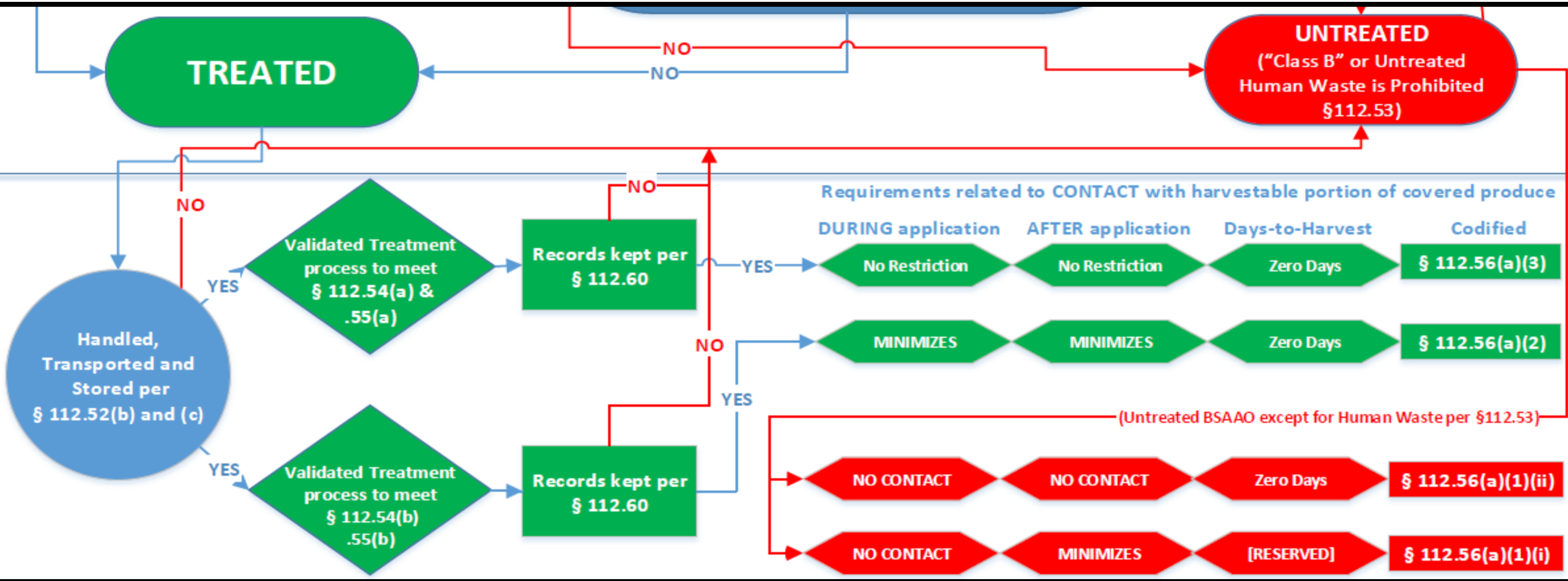
# §112.56 – Application Requirements



<b>Treated BSAAO</b>	<b>Contact <u>During Application</u></b>	<b>Contact <u>After Application</u></b>	<b>Minimum Application Interval</b>
<b>Treatment B</b> 112.54 (b)/112.55(b)	minimizes potential for contact with covered produce <i>during application</i>	<i>And</i> minimizes potential for contact with covered produce <i>after application</i>	<i>Zero days-to-harvest interval</i>



# Combining §112.54/55/56



# FDA BSAAO Research and Risk Assessment

- FDA is conducting risk assessment to evaluate and, if feasible, quantify the risk of human illness associated with the consumption of produce grown in fields or other growing areas amended with untreated BSAAO
- This process involves assessing the impact of certain interventions, such as use of a time interval or intervals between application and harvest, on the predicted risk
- Prevalence, Population, Persistence, Potential for Pathogenicity





# FDA BSAAO Research and Assessment

Risk Assessment Team - OAC

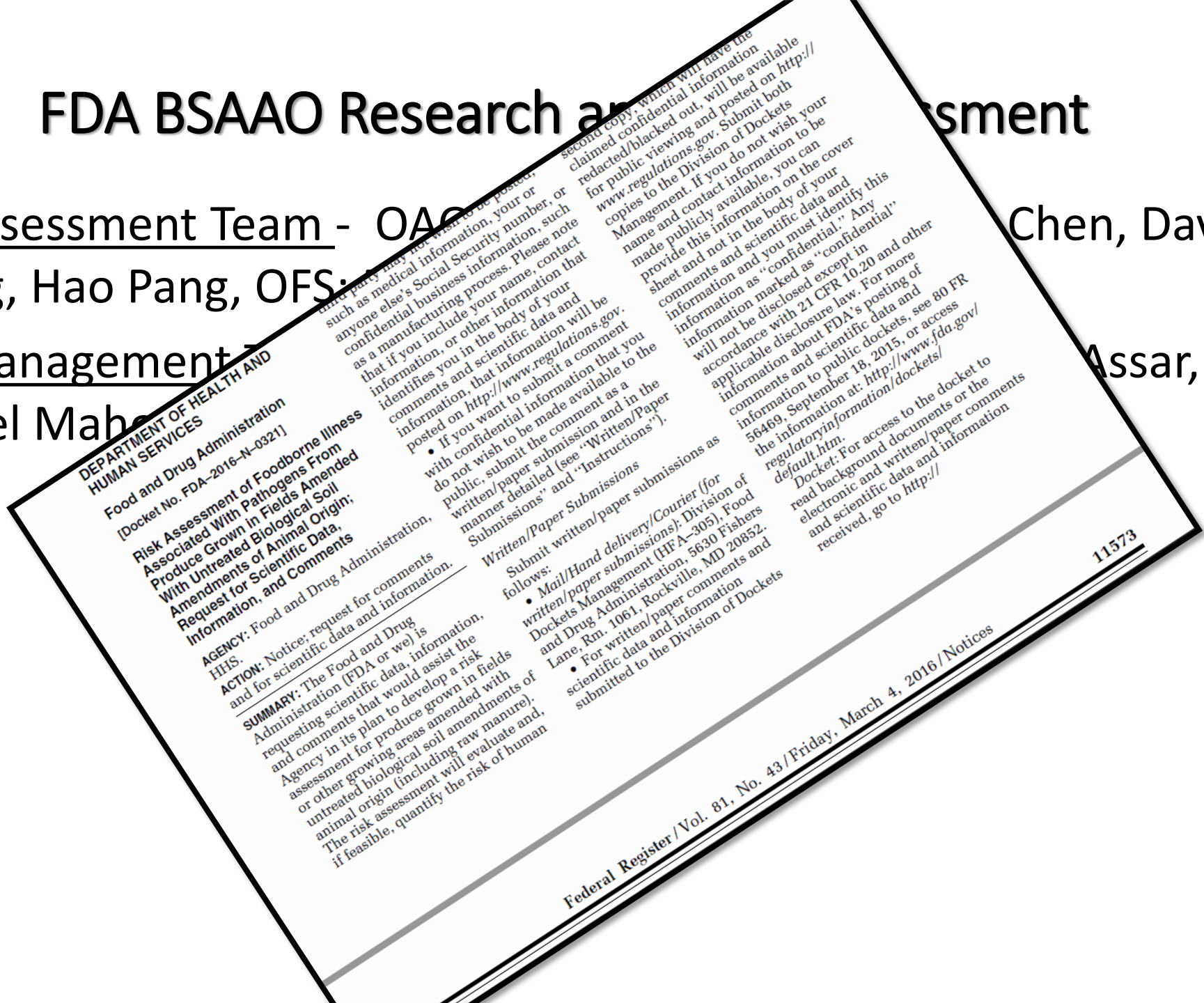
Oryang, Hao Pang, OFS:

Risk Management

Michael Mahoney

Chen, David

Assar,



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
[Docket No. FDA-2016-N-0321]

**Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin: Request for Scientific Data, Information, and Comments**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice; request for comments and for scientific data and information.

**SUMMARY:** The Food and Drug Administration (FDA or we) is requesting scientific data, information, and comments that would assist the Agency in its plan to develop a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin (including raw manure). The risk assessment will evaluate and, if feasible, quantify the risk of human

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments and scientific data and information, that information will be posted on <http://www.regulations.gov>.  
• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

**Written/Paper Submissions**  
Submit written/paper submissions as follows:  
• **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.  
• **For written/paper comments and scientific data and information submitted to the Division of Dockets**

**second copy, which will have the redacted/confidential information for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and scientific data and information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments and scientific data and information to public docket, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.  
**Docket:** For access to the docket to read background documents or the electronic and written/paper comments and scientific data and information received, go to <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.**

Federal Register / Vol. 81, No. 43 / Friday, March 4, 2016 / Notices

11573

# Pathogen pathway

## Biological Soil Amendments of Animal Origin (BSAAO) to Produce

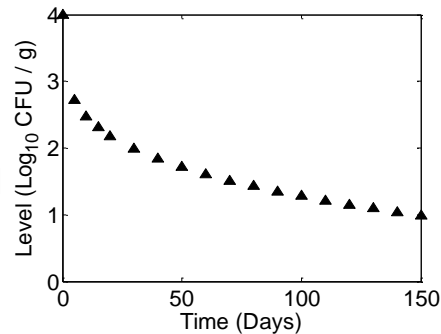
1

Pathogens may be present in BSAAO prior to application



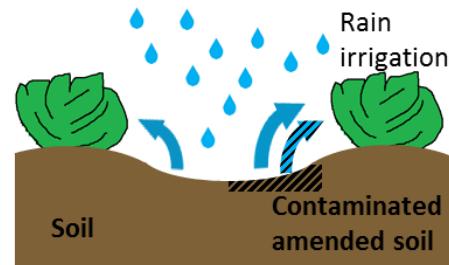
2

Pathogens may persist in amended soil for a long time period considering environmental factors (e.g., soil moisture, temperature)



3

Pathogens may be transferred from amended soil to produce through different pathways (e.g., water splash, wind, animal encroachment)



4

Pathogen levels on crops may be impacted by harvesting practices, processing practices, storage conditions, etc.





## 5. Determine the Requirements for Handling, Transporting and Storing your BSAAO

- Recommendations
  - Evaluate your practices for BSAAOs (both treated and untreated) for the potential to contaminate your:
    - Growing areas;
    - Water sources;
    - Water distribution systems;
    - Other soil amendments (including treated BSAAOs); and
    - Areas used for covered activities, covered produce, and food contact surfaces.
  - Evaluate storage practices and locations
  - Evaluate use of equipment and tools
  - Ensure personnel, supervisors and responsible parties:
    - Understand the potential routes of contamination associated with BSAAOs; and
    - Understand how to take appropriate corrective measures

## 6. Requirements for Records (§ 112.60)

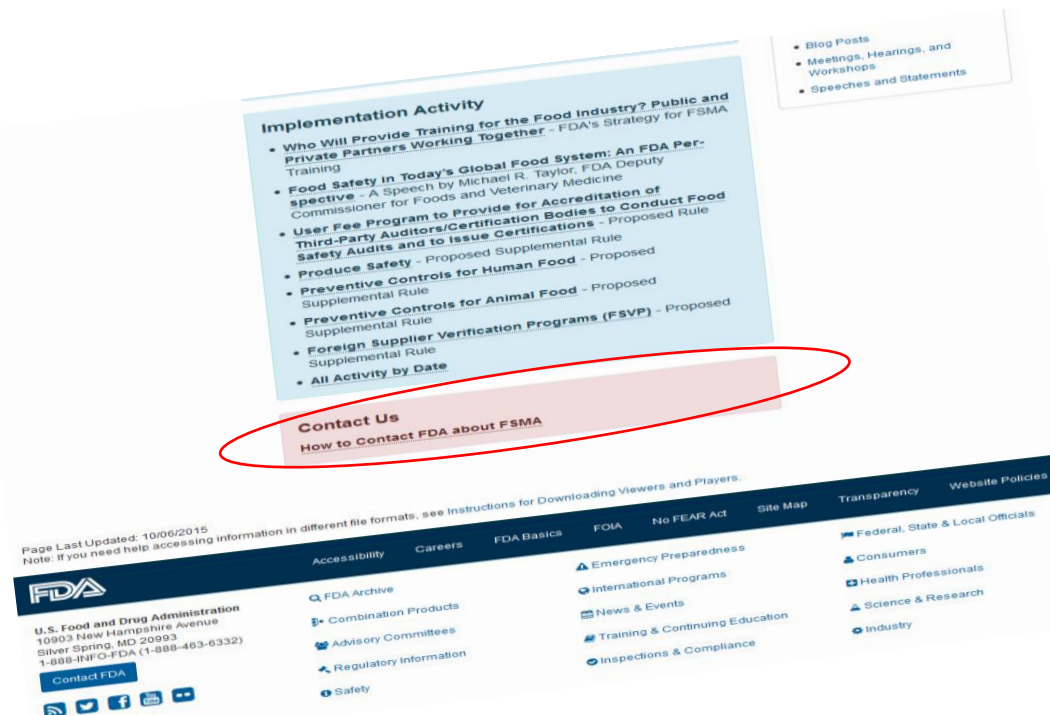
- Documentation only necessary for treated BSAAO:
- **3<sup>rd</sup> party purchased BSAAO**
  - §112.60(b)(1) – Documentation required (annual)
    - (i) – Process used to treat BSAAO is scientifically validated with appropriate process monitoring
    - (ii) – BSAAO has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in-process BSAAO
- **On-farm prepared BSAAO**
  - §112.60(b)(2) – Documentation that process controls were achieved

## 6. Requirements for Records (§ 112.60)

For example, a farm that receives a treated BSAAO from a third party could keep a record that includes a statement such as: “A scientifically valid thermal treatment was applied and carried out with appropriate process monitoring to satisfy the microbial standard in 21 CFR 11.55(a). The BSAAO has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination.” In addition, other information related to producing or managing the BSAAO, such as the BSAAO materials used, process parameters monitored and their results, and any applicable test results could be included.

# For More Information

- Web site: [www.fda.gov/fsma](http://www.fda.gov/fsma)
- Subscription feature available
- To submit a question about FSMA, visit [www.fda.gov/fsma](http://www.fda.gov/fsma) and go to [Contact Us](#)



# Produce Safety Network Contact Information

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2) **Dr. Oscar Galagarza** ●  
Produce Safety Expert  
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[Oscar.GalagarzaAngulo@fda.hhs.gov](mailto:Oscar.GalagarzaAngulo@fda.hhs.gov)





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# Thank you for your time!

**David T. Ingram**

*Consumer Safety Officer*

**Division of Produce Safety | Fresh Produce Branch**

**Center for Food Safety and Applied Nutrition  
Office of Food Safety**

**U.S. Food and Drug Administration**

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[David.Ingram@fda.hhs.gov](mailto:David.Ingram@fda.hhs.gov)

**For assistance in Spanish:**

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