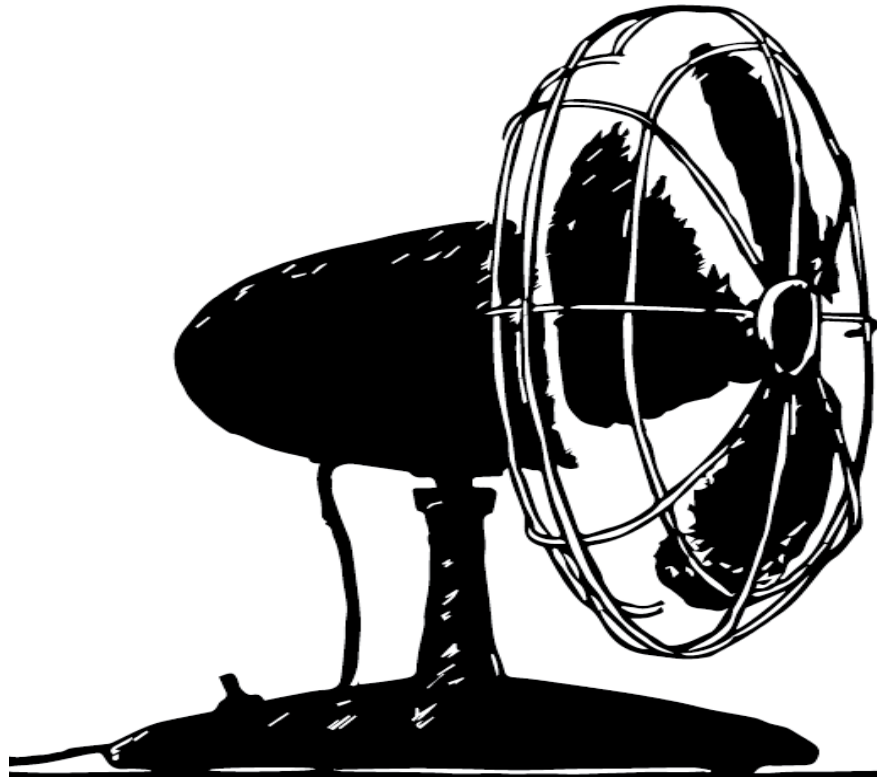


FDA's Current Thinking and an Update on :



**FDA FOOD SAFETY
MODERNIZATION ACT**

David T. Ingram, Ph.D.

THE FUTURE IS NOW

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

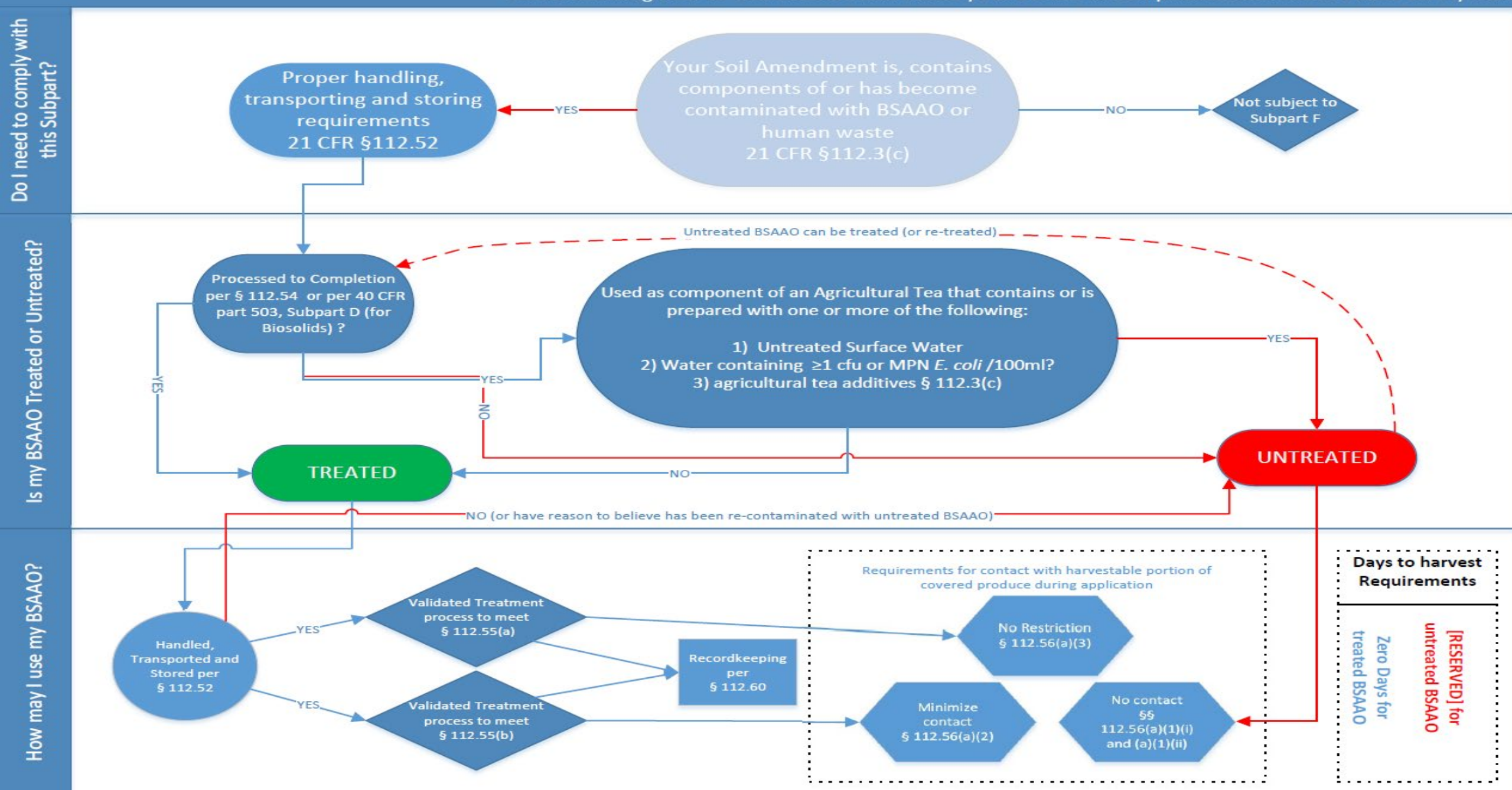
Chapter 4: Biological Soil Amendments of Animal Origin and Human Waste Overview



1. Determine Whether your Soil Amendment is a BSAAO
2. Determine Whether your BSAAO is “Treated” or “Untreated”
3. Determine the Microbial Standard Associated *with 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



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(c)

NO

Not subject to Subpart F

YES

Is my BSAAO Treated or Untreated?

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

YES

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

YES

YES

TREATED

NO

NO

UNTREATED

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

Untreated BSAAO can be treated (or re-treated)

How may I use my BSAAO?

NO

YES

Validated Treatment process to meet § 112.55(a)

Records kept per § 112.60

YES

Requirements related to CONTACT with harvestable portion of covered produce

DURING application

AFTER application

Days-to-Harvest

Codified

No Restriction

No Restriction

Zero Days

§ 112.56(a)(3)

MINIMIZES

MINIMIZES

Zero Days

§ 112.56(a)(2)

NO

YES

Validated Treatment process to meet § 112.55(b)

Records kept per § 112.60

(Untreated BSAAO except for Human Waste per §112.53)

NO CONTACT

NO CONTACT

Zero Days

§ 112.56(a)(1)(ii)

NO CONTACT

MINIMIZES

[RESERVED]

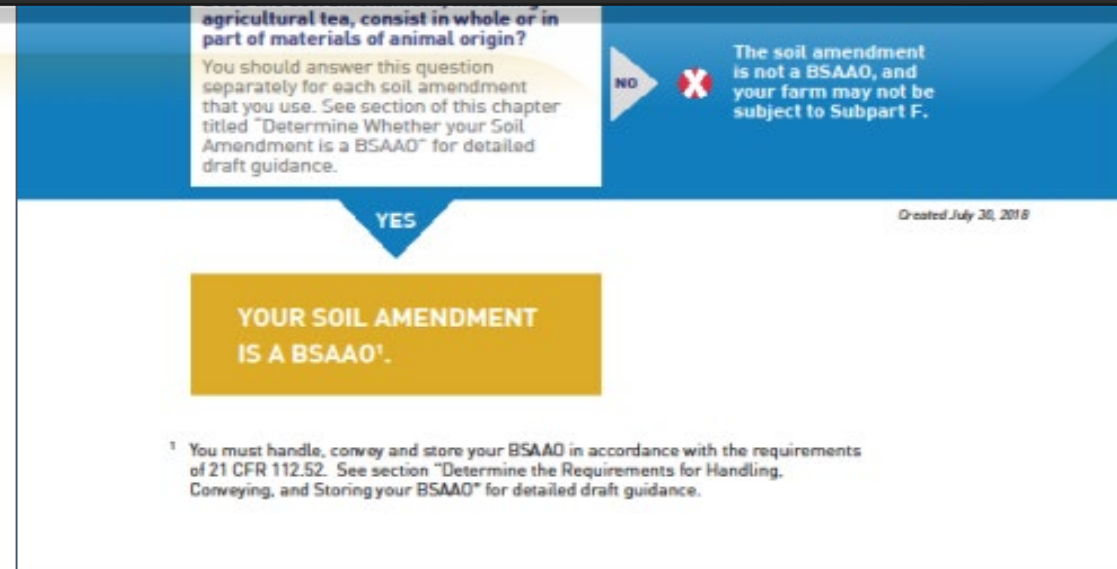
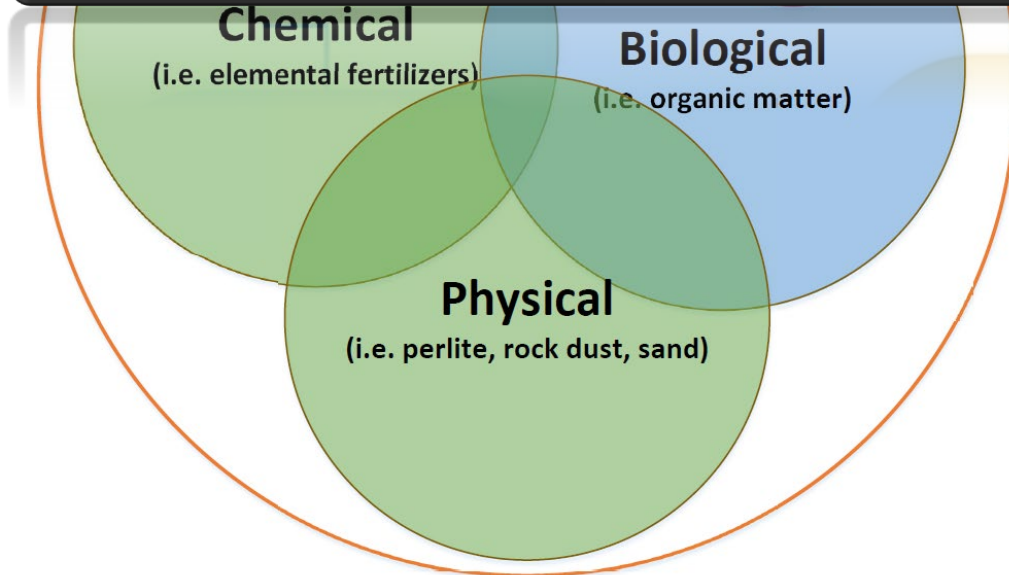
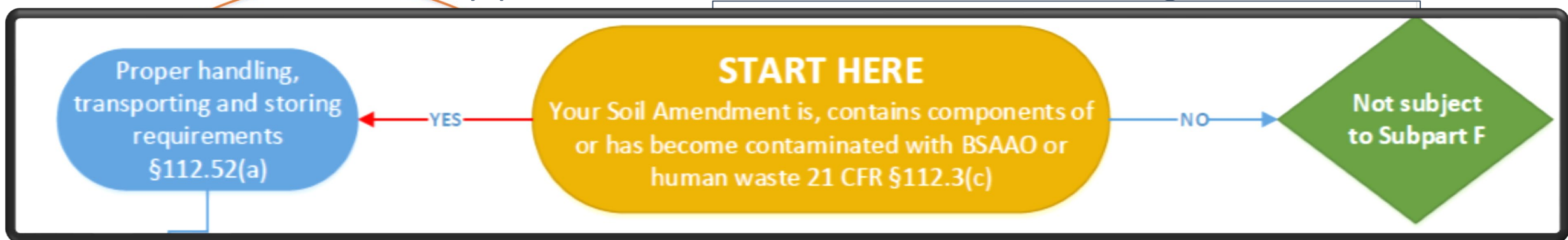
§ 112.56(a)(1)(i)

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

1. Determine Whether Your Soil Amendment is a BSAAO



- Defined terms, including:
 - Soil Amendment, Biological Soil Amendment, Agricultural Tea, Curing, Non-fecal animal by-products, Table waste, and Yard trimmings



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



- **Treated** BSAAO

- BSAAOs
- Agricultural Teas that are BSAAOs
- The rule does not require you or your supplier to conduct lot-by-lot microbial testing of treated BSAAOs

- **Untreated** BSAAO

- Examples
- Options for management



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

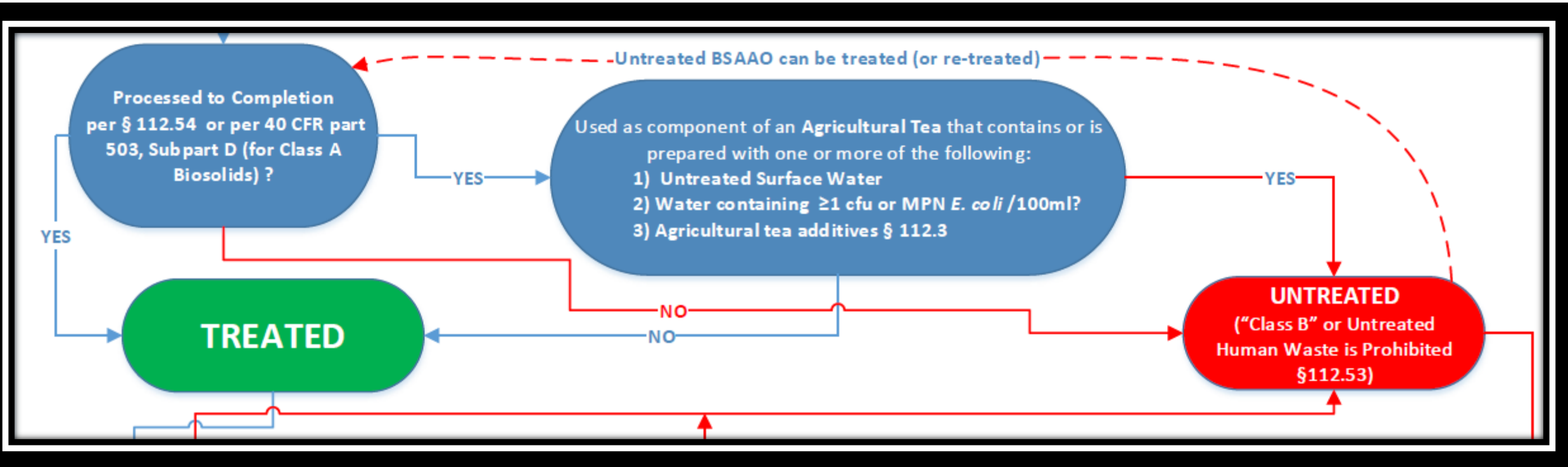


- **Agricultural Tea** may be considered “**treated**” if:
 - “treated” BSAAO feedstock is used
 - No untreated surface water is used
 - Water has NO detectable *E. coli* per 100ml
 - No agricultural tea additives are used

§ 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 Microbial Standard Associated with the Treatment Process



- 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

USDA NOP - Vermicompost

1. It is made from allowed feedstock materials (either nonsynthetic substances not prohibited at §205.602, or synthetics approved for use as plant or soil amendments);
2. Aerobic conditions are maintained by regular additions of layers of organic matter, turning, or employing forced air pipes such that moisture is maintained at 70-90%; and
3. The duration of vermicomposting is sufficient to produce a finished product that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.



§112.56 – Application Requirements



- **Untreated BSAAO** – MUST Apply in a manner that does **not contact** covered produce **during application**
 - (a)(1)(i) – *and* minimizes potential for contact with covered produce **after application** – [Reserved] harvest interval
 - (a)(1)(ii) – *and* No contact **after application** – **Zero days-to-harvest interval**
- **Treated BSAAO** - Zero days-to-harvest interval provided:
 - (a)(2) – §112.54(b)/ §112.55(b) – **minimizes potential** for contact with covered produce during and after application
 - (a)(3) – §112.54(a)/ §112.55(a) – applied in any manner (no restrictions)

Requirements for Records (§ 112.60)

- Documentation only necessary for treated BSAOs

- **3rd party purchased BSAO**

§112.60(b)(1) –

(i)

For example, a farm that receives a treated BSAO 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 BSAO 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 BSAO, such as the BSAO materials used, process parameters monitored and their results, and any applicable test results could be included.

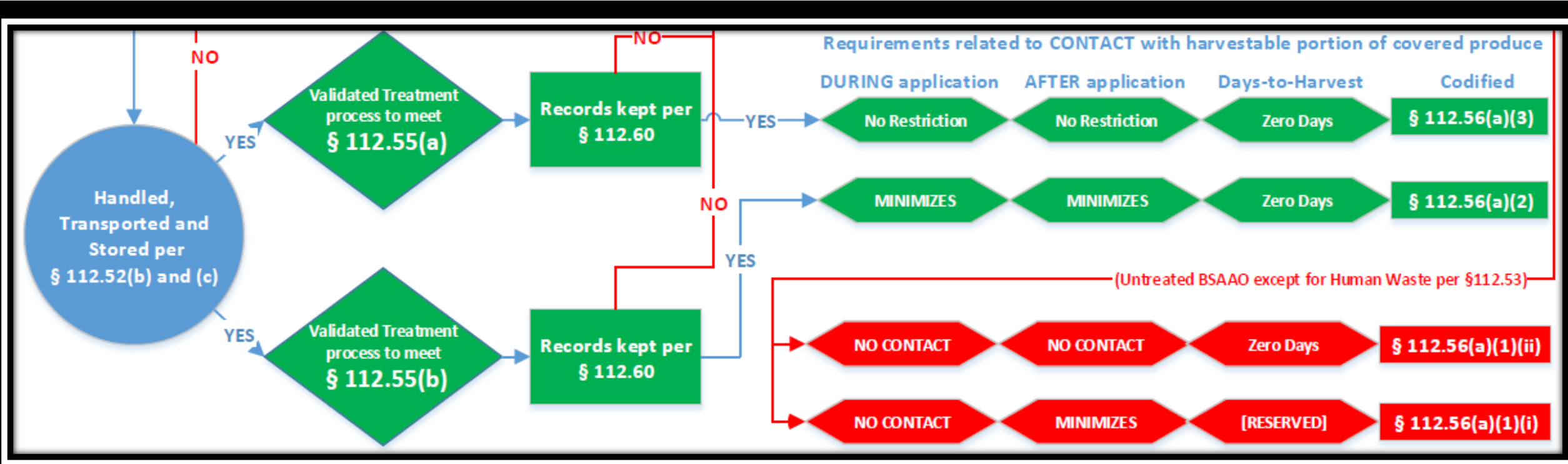
- **On-farm prepared BSAO**

§112.60(b)(2) – Documentation that process controls were achieved

4. Determine How to Apply Your BSAAO

- Factors to Consider
 - Treatment Status, Level of Treatment 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
- Recommendations, Examples and Figures for Application of Untreated and Treated BSAAOs

Combining §112.54/55/56



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

For More Information



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



Any Questions ?

