Key Takeaways:

Biological Soil Amendments of Animal Origin (BSAAO) & Produce Safety

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Panelists:

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1. Regulatory Baseline: What FSMA's Produce Safety Rule Requires

- The Produce Safety Rule establishes a baseline standard for managing BSAAO, regardless of whether a grower is fully covered under FSMA.
- Subpart F focuses on handling, storage, conveyance, treatment, and application of soil amendments to prevent contamination of produce, food contact surfaces, and water sources.
- The rule is intentionally risk-based rather than prescriptive, recognizing that farming operations differ widely in scale, geography, and practices.
- Growers must ensure soil amendments are not stored or handled in a way that creates contamination risks, including preventing cross-contamination between treated and untreated materials.
- If there is any doubt that a treated amendment has been re-contaminated, it must be treated and managed as an untreated BSAAO.

2. Treatment Categories and Application Considerations

- FSMA recognizes two categories for treated BSAAO:
    - Treatment A: Highly processed amendments (e.g., heat-treated pellets, fish hydrolysates) expected to have no detectable pathogens and may be applied without application restrictions.
    - Treatment B: Treated but non-sterile materials (e.g., compost), which require application methods that minimize contact with produce.
- Compost is not expected to be sterile, nor should it be; its microbial community supports soil health.
- Compost can be applied pre-plant, at the base of crops, or even close to harvest, provided contact with produce is minimized and drift or dust risks are managed.
- Raw manure may be used, but must never be applied in a way that contacts produce, and growers should maximize the time between application and harvest as a precaution.

3. Alignment Between FSMA and the National Organic Program (NOP)

- Both FSMA and the NOP take a risk-based approach to managing untreated BSAAO, particularly raw manure.
- Both programs acknowledge that untreated amendments pose inherent food safety risks and must be managed through treatment controls or time-to-harvest considerations.
- Differences in structure and enforcement between the programs can create confusion, but the shared goal is protecting produce safety.
- Understanding how both frameworks apply simultaneously is critical for organic growers supplying regulated markets.

4. Where Growers Commonly Get Confused

- Growers often assume that purchasing compost from a supplier automatically transfers food safety responsibility to the vendor; in reality, the burden remains with the grower.
- Confusion frequently arises around:
    - Treatment categories (Treatment A vs. Treatment B)
    - Differences between organic intervals and FSMA expectations
    - Whether testing is required versus when process controls are sufficient
- Many gaps occur during implementation, not intent — particularly when risk assessments are incomplete or undocumented.

5. Risk Assessment as the Foundation

- BSAAO should be treated as an ingredient in the growing process, not an afterthought.
- Effective risk assessments consider:
    - Source and treatment of the amendment
    - Storage and segregation practices
    - Application method, timing, and crop characteristics
    - Environmental factors such as wind, weather, and water flow
- Risk assessments should be specific to the operation, not only following generic templates, and the grower must clearly justify mitigation strategies.

6. Verification, Validation, and Testing: What Matters Most

- Validation confirms that a treatment process can eliminate or reduce pathogens when properly executed.
- Verification confirms that a specific batch or process was carried out as intended.
- Testing alone cannot “prove” compost safety due to the heterogeneous nature of compost piles.

- FDA does not require pathogen testing for on-farm compost made according to prescribed time and temperature controls; instead, process control documentation is key.
- When testing is used (e.g., for purchased amendments), it must be:
    - Conducted by laboratories experienced with BSAAO
    - Conducted on representative samples of the amendment
    - Performed using methods validated for the specific amendment type

7. Audit and Buyer Expectations

- Auditors look for objective evidence, including:
    - Supplier approval programs
    - Certificates of analysis or treatment documentation
    - Application records and pre-harvest considerations
    - Worker training and equipment practices
- Records should be complete but streamlined — overly complex systems increase the risk of errors and non-compliance.
- Buyers may require third-party audits to verify practices beyond regulatory minimums.

8. Practical Improvements That Drive System-Wide Gains

- Training of personnel handling BSAAO is one of the most impactful improvements growers can make.
- Simplifying procedures and records makes compliance more sustainable and effective.
- Small, well-implemented fixes often create momentum for broader food safety system improvements.
- Growers are encouraged to ask questions early, seek clarification, and use available technical resources rather than proceeding with uncertainty.