



Regulatory Needs: Produce Safety and CEA

Where do CEA systems fall within
regulations and current policy?

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The Produce Safety Rule

- PSR establishes minimum requirements to enhance the safety of growing, harvesting, packing and holding covered produce while recognizing the diversity of farms across commodities, practices and growing conditions.
- Diversity in CEA:
 - Types of CEA operations (AP HP Aeroponic and more)
 - Wide range of sizes and variety of systems used
 - Not all AP HP operations are indoors
- Farms should follow the highest standards appropriate to their operations and implement protocols to ensure relevant requirements are correctly and consistently implemented

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>



Technical Assistance Network (TAN)

TAN Case 67235 (paraphrased)

- We did not establish additional standards specifically applicable to AP or HP production of crops other than sprouts
- Unlike sprouts*, we believe that the production methods and safety considerations associated with AP generally, HP production of crops other than sprouts, are sufficiently addressed through the provisions of the rule that are generally applicable to covered produce
- We will consider issuing guidance on these topics in the future, as appropriate.

Application of PSR Requirements

- If the farm/produce is covered by the PSR, it must comply with ALL applicable requirements of the PSR. For example:
 - If a farm (any farm) doesn't use BSAAOs, then BSAAO requirements don't apply
 - Every operation that has people, tools and equipment, etc., needs to comply with all requirements relevant to the operation
 - A CEA operation may be less vulnerable to some types of contamination more often associated with open field production, such as wild animal intrusion, but may need to pay more attention to other requirements

Questions Raised

Q: Is “fish water” in an AP system ag water or a BSAAO?

A: Preamble “*growth media includes solid or semi-solid matrices in which plants are grown, not liquid only matrices*”

- Concluded water with fish waste is not a BSAAO, it’s water

Water with fish waste, or other nutrient solution, is ag water if it is *intended to or likely to* touch the harvestable portion of the crop

Questions (cont.)

Q: Water isn't intended to touch the harvestable portion of the crop. Is it ag water under the PSR?

A: Definition of ag water “water that is *intended to or likely to* contact the harvestable portion of the crop

Q: If I grow leafy greens then cut and wash them, is that processing?

A: Not necessarily. PSR covered activities include: growing, harvesting, packing & holding. Cutting as part of harvest, washing as part of packing, or cooling as part of holding are all activities under the PSR

- Further cutting (e.g., slicing or chopping) would be processing
- Operations that do both are considered mixed farm-type facilities, covered by both PSR and PCHF as applicable to activity

Misconceptions: Food Contact Surfaces (FCS)

- PSR 112.3 defines “Food contact surfaces” as surfaces that contact food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations
 - The definition further states that “Food contact surfaces” includes food contact surfaces of equipment and tools used during harvest, packing and holding
- Scope: PSR 112.123(d)(1) requires that you inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary

In the Pipeline....

- Subpart E: Reviewing comments to the Ag Water proposal
 - Rule requirements often supplemented with guidance
- Final Compliance & Implementation Guidance
 - Draft C&I guidance <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-standards-growing-harvesting-packing-and-holding-produce-human-consumption>
- Update 1998 GAPs Guidance

Expanding Demand & Investments in CEA

- Response to increasing needs & demands, including:
 - labor shortages, concerns over climate change, retailer interest, consumer demand, shorter supply chains, underserved markets
- 2021 Outbreak involving packaged leafy greens & *Salmonella* Typhimurium
 - Inform future prevention efforts in CEA, and
 - Emphasize that while CEA is considered safer by some, CEA is not without food safety risks that need to be considered in their design, maintenance and operation



Outbreak Reports

“Factors Potentially Contributing to the Contamination of Packaged Leafy Greens Implicated in the Outbreak of Salmonella Typhimurium During the Summer of 2021”

<https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-packaged-leafy-greens-implicated-outbreak-salmonella>

Specific Observations

Objective: Insight into potential source and route(s) of contamination; future prevention

Observations:

- **Protection of raw materials:** unprotected, outdoor storage of nutrient-rich growth media
- **Pond water quality management:** Pond water (+) for *Salmonella* (not outbreak strain)
 - Observed lettuce leaves directly contacting pond water
 - No procedure or systematic approach to ensure adequate pond water treatment
- **Design & maintenance of operation,** dripping condensate over product, growing ponds & harvested product conveyance belts
- **Cleaning & sanitizing buildings, tools and equipment:** not adequately documented
- **Cooling and cold holding of finished product:** not adequately verified/documentated
- **Adjacent and nearby land:** Stormwater retention basin within 25 feet of CEA bldg. (+) for *Salmonella* Typhimurium (matched outbreak strain)

Recommendations

- Develop an understanding of possible sources of contamination throughout the operation as well as the raw materials and inputs used
- Implement effective cleaning & sanitation procedures while also paying close attention to hygienic operations and equipment design and use
- If sampling and testing, seek to identify and inform sampling plans
- Ensure growing pond water is safe and of adequate sanitary quality for its intended use, including implementing measures (such as water treatment) necessary to reduce the potential for contamination by known or reasonably foreseeable hazards
- Implement effective procedures for rapidly cooling and cold holding harvested leafy greens; monitor and verify the effectiveness of cooling and cold holding procedures
- If something does go wrong (e.g., human pathogen identification): Perform a root cause analysis to determine how the contamination likely occurred and implement appropriate prevention and verification measures

What we do can only be as good as the information that we have

- **Observations:** friendly farm visits, inspections, outbreak investigations
- **Interactions:** meetings, conferences, feedback, questions
- **Risk and Science Based:** Research, SME consultations, expert elicitations
- **Current Industry Best Practices:** As set out in industry-led guidance, audit programs, and other standards & programs

Thanks!!!

FSMA: Ultimate responsibility for food safety rests with the firm producing food



- Observe your operation to identify opportunities to prevent or minimize sources and routes of contamination
- FDA ready to help support these efforts
- As growth of the CEA industry accelerates, so do efforts to identify available food safety information, identify knowledge gaps and fill them

Working Independently & Together

FDA Produce Safety Guidance page <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/produce-plant-products-guidance-documents-regulatory-information>

- FDA guidance and guidance developed by others, often w FDA technical assistance and support as appropriate to FDA resources and needs & desires of the group

These experiences led to outreach to the larger food industry....

- **How to Work with FDA on Food Guidance Documents**
<https://www.fda.gov/food/cfsan-constituent-updates/how-work-fda-food-guidance-documents>
- **Working with FDA on Human and Animal Food Guidance Documents**
<https://www.fda.gov/food/food-safety-modernization-act-fsma/working-fda-human-and-animal-food-guidance-documents>
- **Case Study: Food Safety Guidelines for Cantaloupes**
<https://www.fda.gov/food/food-safety-modernization-act-fsma/case-study-food-safety-guidelines-cantaloupes>