First Edition

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Commodity Specific Food Safety Guidelines for Controlled Environment Agriculture

focused on leafy greens and herbs

produced by

Controlled Environment Agriculture (CEA) Alliance

in cooperation with the

International Fresh Produce Association

All applicable U.S. and/or other regulations must be followed. This document assumes basic food safety practices are in place and provides additional guidance specific to produce grown under Controlled Environment Agriculture conditions.

ACKNOWLEDGEMENTS

This document was developed by the Controlled Environment Agriculture (CEA) Alliance, in collaboration with the International Fresh Produce Association.

The CEA Alliance is a membership association representing and serving indoor vertical farms and high-tech greenhouse producers growing fruits and vegetables in a highly controlled indoor production environment. The International Fresh Produce Association is the largest and most diverse international association serving the entire fresh produce and floral supply chain.

Controlled environment growers employ a variety of agricultural production methods and technology to create optimal growing conditions with rigorous environmental controls. Growing indoors allows greater ability to control multiple variables, thus enhancing overall efficiency, quality, sustainability and other attributes. Despite these multiple controls, the CEA Alliance recognizes that food safety must always be the first priority for indoor growers. That is why the Alliance has developed this best practices document, designed to share food safety knowledge across all CEA growers and stakeholders.

Special thanks to the companies, agencies, trade associations, and individuals who helped in developing these guidelines. The document was also shared with government agencies and food law attorneys, and their input is appreciated. The acknowledgements below do not indicate endorsement of or agreement with all recommendations in this document. The editors made a good faith effort to reach consensus and present a balanced portrayal of options based on the input from the diversity of stakeholders.

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USERS' NOTE

These guidelines provide recommended food safety practices that are intended to minimize the microbiological public health hazards associated with fresh leafy greens and herbs grown under controlled environments. This guide addresses areas identified by an industry working group with diverse stakeholder input from academics, buyers, state and federal governments, and the U.S. Food and Drug Administration (FDA), to provide guidance to reduce risks that could lead to product contamination. It does not address every known hazard, singular, or cumulative risk factors. It is expected that growers are following the minimum food safety standards as they pertain to production practices in CEA as laid out by the FDA's 21 CFR 112 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (i.e., the FSMA Produce Safety Rule), as applicable 21 CFR 117 Hazard Analysis and Risk Based Preventive Controls for Human Food (i.e., the FSMA Preventive Controls Rule), as well as those required local, state, or federal regulations.

The information provided herein is offered in good faith and believed to be reliable, but is made without warranty, expressed or implied, as to merchantability, fitness for a particular purpose, or any other matter. These recommended guidelines were not designed to apply to any specific operation. It is the responsibility of the user of this document to verify that these guidelines are appropriate for their operation. The publishing trade associations, their members and contributors do not assume any responsibility for compliance with applicable laws and regulations. It is recommended that users consult with their own legal and technical advisers to be sure that their own procedures meet applicable requirements.

Throughout this document, the word "must" is used to designate practices, policies, and procedures that are required by regulation. The word "should" is used to designate recommendations that operations should consider using and are accepted by the US-based CEA industry as best practice.

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HOW TO USE THIS DOCUMENT

The best practices described in this document represent a current understanding of food safety risks and mitigations available to the fresh produce industry for controlled environment agriculture (CEA) production, with a focus on leafy green and herb production. While an attempt has been made to represent the wide variety of CEA production practices across the United States, it is not possible to characterize every operation's activity due to the diversity of practices that occur within the industry. In some cases, a company may need to consider the guidelines outlined in more than one section of this document and adapt the recommended best practices to fit their operation's needs. Food safety and postharvest practices may differ among different commodities grown under CEA production. Judgment must be made on the applicability and appropriateness of practices for individual operations.

This document is intended to aid the CEA production community as food safety staff and other management roles consider how to manage food safety risks associated with CEA production, given the rapid growth in this sector. Because CEA includes novel production practices, the document is also intended to help educate regulators, auditors, and members of the buying community who are involved in understanding or verifying food safety practices. It also serves as an opportunity to identify practices and conditions which CEA producers and handlers may not have previously considered as potential food safety risks. The best practices outlined in this document are not prescriptive to accommodate the wide variety of CEA operations. Regulatory requirements are noted for context and awareness to readers, and this document in no way ensures regulatory or third-party audit compliance. Ultimately, the responsibility for food safety is shared within the fresh produce supply chain and therefore, these best practices have relevancy to many individuals from farm to fork.

DO'S AND DON'T'S

DO follow Good Agricultural Practices, the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR), and other applicable regulations and guidance as they pertain to production activities in CEA.

DO conduct a risk assessment of your operation and actively and continuously evaluate potential food safety hazards.

DO train workers and visitors on applicable food safety practices to understand the specifics of Controlled Environment Agricultural (CEA) production and food safety considerations.

DO maintain appropriate documentation to meet regulatory and market food safety requirements.

DO assess the risk associated with inputs (seeds, substrate, etc.) in the context of the overall production system.

DO map out water sources and distribution systems to help identify specific points where hazards (biological and chemical) might be introduced.

DO manage production water (e.g., nutrient solution, irrigation, circulating water) so that it does not become a source of contamination to the produce.

DO take measures to prevent accidental or unintended contact between the plant and water or nutrient solution.

DO consider risks associated with the building, the inside environment, and adjacent uses outside the building.

DO protect produce and food contact surfaces from potential contamination due to condensation.

DO implement a robust animal/pest prevention program.

DO consider hygienic design, the cleanability of equipment, and building infrastructure to identify possible improvements according to your risk assessment as new CEA operations are being updated or built.

DO assess product and process flow, as well as traffic patterns, to limit cross contamination.

DO include a rigorous sanitation program as part of the food safety plan, including validation and verification that sanitation activities are effective.

DO build in time for sanitation as part of the production plan, especially if operators are responsible for sanitation at the end of their shift.

DO develop and implement an environmental monitoring program that informs and provides feedback to the sanitation program.

DO evaluate the efficacy of Clean-In-Place (CIP) systems, if used.

DO develop a plan to dispose of used substrate and other materials so that they do not serve as an attractant for pests or otherwise increase food safety risks.

DO communicate to customers through the supply chain about the need to properly store and handle produce grown, harvested, and packed using CEA production practices.

DO actively keep records that accurately capture food safety information (e.g., training records, water treatments, test data, traceability).

DO review recalls and outbreaks related to fresh produce and/or CEA production and consider how these events can be avoided in your operation.

DON'T assume that an indoor production environment is risk-free.

DON'T rely on product testing to "guarantee" a pathogen-free product.

DON'T make food safety statements or other claims (e.g., "pesticide free") on labels and marketing materials that are not scientifically supported.

DON'T assume that just because your operation meets the FDA definition of "farm", the Produce Safety Rule requirements are adequate to address the unique aspects of CEA operations.

DON'T become complacent in continuing to evolve your operation's food safety program.

BACKGROUND

This document seeks to promote a common understanding of CEA production practices for leafy greens and herbs and associated food safety risks, with an emphasis on microbiological risks. Considering recent outbreaks and recalls associated with CEA produce, the industry has developed these food safety guidelines to highlight key practices in order to reduce risk, and which reflect recent and emerging science (FDA, 2022a, McClure et al., 2023). Though the production practices described in this document are primarily reflective of CEA operations in the United States, many of the recommendations in this guidance might also be appropriate for operations outside of the United States. In 2019, a group of CEA leafy green producers formed the CEA Food Safety Coalition, aimed at defining food safety requirements unique to the sector through the development of a specific audit. As the industry acquired new knowledge, and because the variety of substrates, growing systems, and post-harvest handling activities limit audit specificity, the industry, through the Controlled Environment Agriculture Alliance (the successor to the CEA Coalition), sought to develop an explanatory guidance document.

Overview of the CEA Industry in the U.S.

Food crop production in controlled environments has become an increasingly important sector of both United States and global agriculture. Though CEA production may seem like a relatively new concept, principles of indoor agriculture can be dated back to Roman times between 14-37 A.D. (Paris and Janick, 2022). Modern indoor production did not fully evolve until the early 1900's when electric lamps began to become more commonplace to mimic sunshine that plants would receive from the outdoor growing environment (Mitchell, 2022). Today, it is estimated that "food crops grown under protection" account for $700 million in sales in the United States. Tomatoes, lettuce, cucumbers, peppers, berries, and herbs account for 54% of this total production (cwt). Globally, a recent report projected the current CEA market to grow from $75 billion in 2020 to over $172 billion in 2025 (USDA NASS, 2021).

There are a number of benefits that CEA production provides to food systems. With a growing demand for fresh produce, CEA production enables the growth and availability of food crops year-round, even in areas where the climate is not conducive to continuous outdoor growing. This also fosters more local food systems, including the opportunity for growth closer to population centers, as most of the fresh produce consumed in the United States originates from a few areas of the country (e.g., CA, AZ, FL, TX) or is imported.

The technology-based approach toward food production is a major component of the evolution of modern-day CEA production systems. CEA operations must balance water, energy, space, capital, and labor to ensure a productive and profitable business venture. Regardless of the historical focus on the optimization of these aspects, food safety must be a priority and early consideration for all CEA ventures.

Regulatory Requirements

The regulatory requirements and market expectations highlighted below are provided for informational purposes, but compliance alone is unlikely to help CEA producers adapt to changing risks and new information.

CEA producers must be able to navigate the regulatory landscape since several of the FDA's Food Safety Modernization Act (FSMA) rules are likely to apply to growing and processing facilities. Through the FSMA Produce Safety Rule (PSR), a primary production farm is defined as "an operation under one management in one general…physical location devoted to the growing of crops, the harvesting of crops…" and includes packing or holding raw agricultural commodities (RACs), as well as "packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing" (FDA, 2015a). From a regulatory standpoint, farms are subject to the PSR. There is little question that produce grown under CEA is subject to the PSR, unless exemptions apply.

FDA's Preventive Controls Rule for Human Food (PC Rule) applies to facilities that are required to register with FDA because they manufacture, process, pack or hold food (FDA 2015b). In some instances, CEA operations may be viewed as conducting further processing, which would qualify the processing part of an operation as a "registered facility" subject to the PC Rule. An example of this would be harvesting greens, chopping the leaves, and then adding additional ingredients for a salad mix (e.g., matchstick carrots, croutons). In general, as soon as a raw agricultural commodity is transformed into a different type of product (e.g., whole apples sliced for snack bags), these activities are likely considered "processing" that will trigger the PC Rule.

Table 1 below provides a few examples of activities that may be defined as subject to the PSR and/or PC Rule. It is important to note that some companies may be subject to both. In this case, FDA's draft guidance defines a "farm mixed-type facility" as an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered (FDA, 2016). While these definitions are still in draft guidance, it is prudent to consider whether a CEA operation conducts activities that may move it beyond the farm definition. For "farm mixed-type facilities", the "farm" operations must abide by the requirements of the PSR while the "processing" operations are subject to the PC Rule. Additionally, CEA operations may consider submitting a question to FDA's Technical Assistance Network (TAN) to receive more definitive insight on whether their activities and operation must be in compliance with the PSR and/or PC Rule.

Table 1

Examples* of activity classification for the FSMA Produce Safety Rule versus the Preventive Controls Rule for Human Food.

Product Safety Rule		
Harvesting	**Packing/Packaging**	**Holding**
Cutting (or otherwise separating) the edible portion of the RAC from the plant; removing or trimming part of the RAC; cooling; trimming of outer leaves; washing* (see corresponding asterisk in the PC example for differences in how washing is treated)	Sorting, culling, grading, weighing, conveying; blending different lots of the same food together; putting produce into a plastic bag that directly contacts the food and that the consumer receives; mixing intact RACs in a packing container (e.g., placing three different bell peppers into a box for further distribution); washing for safe/effective packing (e.g., washing RACs to remove dirt, including using pesticides in wash water)	Storing food; coating RACs with wax/oil resin for safe storage and transport; heat treatment for purposes of pest control; cooling
Product Safety Rule		
Harvesting	**Packing/Packaging**	
Slicing/chopping; drying/dehydrating a RAC so that it creates a distinct commodity (e.g., drying herbs)	Mixing intact RACs in a container that directly contacts the food and that the consumer receives without creating a processed food (e.g., placing three different varieties of greens into a clamshell that the consumer receives) is packaging; washing* at a facility during the production of a fresh-cut salad mix, including using pesticides (e.g., antimicrobials) in wash water	

**Based on FDA draft guidance (FDA, 2016), adapted for CEA-relevant examples.*

Example Scenario of Regulation Applicability

Excerpts from FDA draft guidance

Business A's growing and harvesting operations (growing the lettuce/greens, cutting the stems, field coring the lettuce, trimming outer leaves of the lettuce/greens, and washing the intact lettuce/greens) are within the "farm" definition. Business A's packing of RACs (packing intact lettuce for distribution) and storing of RACs (storing intact lettuce/greens under refrigeration) are also within the "farm" definition and therefore subject to the Produce Safety Rule.

When Business A chops lettuces/salad greens to create fresh-cut lettuce/greens, this changes the intact RACs into distinct commodities, which means they become processed foods and are no longer RACs. This is a manufacturing/processing. This manufacturing/processing activity is not specifically included in the farm definition unless done for consumption on farm. In this example, the chopped lettuce/greens are for distribution into commerce and not for on-farm consumption, so this activity is outside the farm definition. Assuming that no exemptions from the registration requirement apply (see 21 CFR 1.225 and 1.226), Business A is required to register as a food facility. Because Business A is a farm (see paragraph above), but also conducts some activities outside the farm definition that require it to be registered, Business A is a "farm mixed-type facility." Assuming Business A's operation is not exempt based on business size, chopping of lettuce/greens would be subject to the requirements of the Preventive Controls Rule for Human Food.

CEA Supply Chain and Market Requirements

The distribution chain for produce grown under CEA spans all types of go-to-market strategies. On-site, institutional, foodservice, and retail sales are all common outlets for CEA produce. Because of this supply chain variability, market requirements will depend on the customer's requirements, which are often verified by third-party audits. While these audits generally exceed the minimum food safety requirements established by the FSMA PSR or PC Rule (FDA 2015a, FDA 2015b), they may not fully capture the nuances or variety within CEA production. Some 3rd party audits have developed standards for indoor growing operations in recognition of the fact that many CEA operations blend elements of farming with elements of processing facilities (SQF, 2020; CEA Food Safety Coalition, 2021).

CEA producers who add components other than lettuce (e.g., salad kits containing dressing, croutons, etc.) are likely considered 'processors' from a regulatory standpoint. In many cases, buyers will consider these operations as processors, and expect them to adhere to HACCP principles and meet specific audit standards, particularly if the CEA operation is supplying the buyer with a private label product.

Scope of Guidance

This document is intended to provide guidance to producers of leafy greens and culinary herbs that are grown in CEA settings. The term "Controlled Environment Agriculture" has gained the attention of the produce community and investors over the last decade. For the purposes of this food safety guidance document, the term refers to the method of growing specialty crops in a fully enclosed, structurally sound, climate-controlled environment, where the plant (consisting of at least one true leaf grown under light) is supported in a medium other than the earth and grown in nutrient solution. The list below, which is not exhaustive, provides examples of

In Scope	Out of Scope
Microgreens	Sprouts
Vertical farms/fully-enclosed, structurally sound, climate-controlled greenhouses	Hoophouses and high tunnels
Hydroponics and Aeroponics	Aquaponics
CEA grown intact leafy greens and herbs	Other CEA grown commodities
CEA grown fresh-cut processing	Addition of non-CEA grown ingredients (e.g., additions to salad blends)

the types of operations intended to find value in this document, as well as those that are considered out of scope (though portions of this document may be relevant). CEA producers of crops other than leafy greens and culinary herbs may also find value in this document but should be mindful of differences that apply to their commodity.

This document focuses primarily on microbiological hazards associated with the leafy greens and herbs grown using CEA production practices. The following topics are outside the scope of this document, but resources and references are provided to help readers access relevant information:

Allergen management (e.g., from the inclusion of nuts, croutons, salad dressings, etc.)

Learn more at: (Food Allergen Labeling Guidance; FDA, 2022d, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule and Draft Guidance; FDA, 2015b, 2018b)

Organic Production

Learn more at: National Organic Program (USDA, 2023a), National Organic Standards Board (USDA, 2023b)

Fresh-cut/processing

Learn more at: (Fresh-Cut Produce Draft Guidance; FDA, 2018a)

Supply chain management programs (e.g., sourcing produce or other ingredients from outside vendors to use in blends/ kits)

Learn more at: (Supply Chain Program, p 221, Chapter 15 in Hazard Analysis and Risk-Based Preventive Controls for Human Food Draft Guidance; FDA, 2018b)

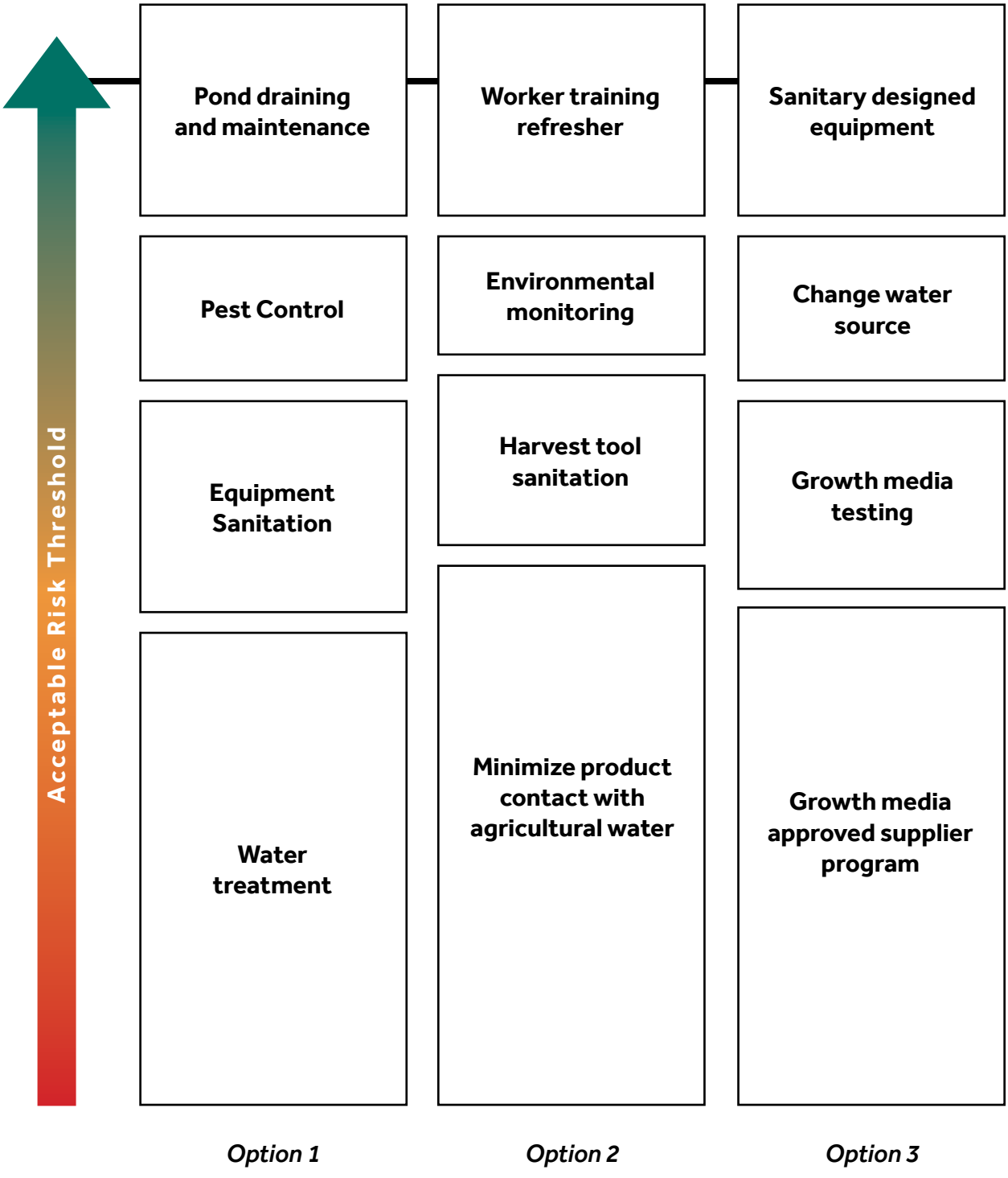
Systems Approach to Risk Management

Because there is no kill step for fresh produce, food safety must be managed throughout the production process and the supply chain. Given the variables associated with CEA production: degree of automation and mechanization, water sources, water treatments, growing systems, substrate used, harvesting approaches, etc., a food safety professional working in the CEA growing environment should carefully assess risks associated with each step. It is only after this analysis has been conducted that the operation can identify the most logical risk mitigation measures. While this document presents many recommendations, they will not all be equally applicable to all CEA farms. For example, water should be managed very differently in a farm where there is no chance of contact with the crop versus a farm where deliberate or inadvertent water contact occurs.

Fundamental to this assessment is a clear understanding of the difference between hazards and risks. Hazards are agents that have the potential to cause harm (e.g., bacterial pathogens, pesticides, heavy metals, glass). Risk is the likelihood that hazards will cause harm, combined with the severity of injury or illness if exposure occurs. CEA operations should use recall and outbreak history, scientific research, and expert consultation to identify potential hazards. They should then evaluate the likelihood of each hazard to occur in their specific production system. The prioritization of risks should guide the selection and implementation of mitigation steps. As new information becomes available, either publicly, or because of internal findings (e.g., monitoring and verification activities), risk and mitigations should be re-assessed.

Figure 1

A systems-based approach to food safety risk management may involve 'stacking' multiple interventions appropriate to the hazards identified and likelihood and severity that they will occur. The figure below highlights a few examples of different combinations of mitigations that can be combined to achieve a comparable level of acceptable risk, represented by the horizontal black line. No CEA production system or environment will present the same 'stack' of priorities to meet the end goal of food safety.



Key Food Safety Considerations for CEA Producers

Producing safe fruits and vegetables, including using CEA production practices, requires management of several potential hazards. There is no single hazard that dominates, nor is there one single control for CEA that can overcome poor agricultural or handling practices. K areas that CEA growers and packers should be mindful include the following:

1. Agricultural inputs, especially growth substrates, nutrient solutions, and seeds

2. Water quality, including use in nutrient solutions (e.g. germination, transplanting, production, and postharve uses, especially when water is recycled for use across multiple production lots)

3. Hygienic design of facilities and equipment

4. Sanitation of propagation, growing, processing, packing and storage equipment and environments, including environmental monitoring programs

5. Packing and storage conditions, especially for Work in Process (WIP)

While CEA is partially protected from weather elements, food safety risks should not be underestimated. For example, wildlife intrusion presents a risk to food safety. Wild birds, rodents, and other pests can be trespassers in CEA operations. In addition, the CEA environment includes some unique food safety hazards that pose different risks, such as those associated with recirculated water and equipmer design. The CEA industry should not become complace because of falsely perceiving their produce as "safer" than produce grown outdoors. Commercial buyers will likely impose the same food safety requirements on CEA producers as conventional producers (e.g., passing a GFSI- recognized audit, compliance with regulations, etc.). Food safety must be at the forefront in the planni stages of any new and expanding CEA operation, not as an afterthought. Facility location, equipment design traffic and waste flow, and quality water access are a few factors that cannot be easily changed after capital investments have been made.

There are also general stages of production commor to most CEA operations. This document is organized to describe practices, potential food safety risks, and possible mitigations based on production stage, recognizing that there is no "one-size-fits-all" guidance that can represent the diversity of all CEA operations.

WORKER HEALTH AND HYGIENE

There are varying degrees of mechanization and automation associated with CEA production. In many cases, production may require handling by workers during the production, harvest, or postharvest handling stages. Worker health and hygiene is important since workers can contaminate water sources and food contact surfaces which can lead to cross-contamination if they do not understand or follow proper health and hygiene practices. Worker training is the front line of defense in any food safety program – from the resources necessary to accomplish safe food practices (e.g., toilets, handwashing stations) to the practices which workers can implement in the growing, harvesting and packing areas. CEA companies should consider the inclusion of other practices relevant to each worker's job responsibilities beyond the basic hygienic practices listed below. All workers, including management, should be aware of the practices and standard operating procedures outlined in the food safety plan which can help foster a culture of food safety.

What are additional training topics specific to CEA workers?

Individuals involved in seeding, planting, and growing should be trained to recognize if inputs or materials have been improperly stored, or handled, presenting a potential food safety risk.

Depending on the design of the operation, workers that move or transplant plants from the germination area to the growing area to the harvest area must understand the risks associated with water and worker health and hygiene and receive proper training and resources to limit cross-contamination. This includes minimizing contact of water with the harvestable portions of the agricultural commodity and understanding proper bathroom and handwashing protocols. Workers may make assumptions that food safety is not as critical during the growing stage, but all workers must be trained to follow food safety practices throughout all activities conducted within the CEA operation.

Workers should be aware of physical hazards and report incidents of broken glass, cracked trays, or other issues that may impact food safety.

Worker Health, Hygiene, and Training

The bullets below highlight the requirements of the FDA Produce Safety Rule (FDA, 2015a), with minor adaptations and edits appropriate for CEA producers.

Qualifications and Training

All workers, whether temporary (including contractors) or permanent employees, who handle produce or food contact surfaces must receive training adequate to their job responsibilities upon hiring, and at least annually. Workers should also receive training when policies change or if a food safety incident occurs, which may require retraining workers on a particular topic.

Training must be provided in a language and manner the workers understand and include 1) principles of food hygiene and food safety and 2) the importance of health and hygiene for all workers and visitors, including recognizing symptoms of a health condition (e.g., vomiting, diarrhea, jaundice, fever, open or bandaged cuts or lesions on exposed skin) that could lead to the contamination of produce or food contact surfaces with human pathogens.

Workers involved in harvest should be trained to inspect harvest containers (if produce is to be stored prior to packaging) and equipment to ensure they are functioning properly, are cleaned, sanitized if appropriate, and maintained, and correct problems with harvest containers or equipment (e.g., fixing/replacing bins in poor condition or visibly dirty), when necessary.

At least one supervisor or responsible party for the farm must have successfully completed food safety training at least equivalent to that received under the standardized curriculum recognized by the FDA (i.e., Produce Safety Alliance training) if they are subject to the FSMA Produce Safety Rule. If some activities (e.g., fresh-cut processing) are covered by the Preventive Controls Rule, then the Preventive Controls Qualified Individual Training developed by the Food Safety Preventive Controls Alliance should be taken.

At least one individual must be assigned to supervise or otherwise be responsible for food safety practices.

A record must be kept documenting the date of training, topics covered, and person(s) trained.

Visitors, including technicians and contract services, must be made aware of the farm food safety policies.

Health and Hygiene Practices

Take measures to prevent contamination of produce and food contact surfaces with human pathogens from any person with an applicable health condition. This includes communicable diseases that present a public health risk in the context of normal work duties including infection, open lesions, vomiting, or diarrhea.

- There should be clear and enforceable health policies in place that prevent sick workers from harvesting and/or packing or otherwise handling fresh produce.

Maintain adequate personal cleanliness to protect against contamination of produce and food contact surfaces, including arriving with clean clothing, and changing personal protective equipment (aprons, sleeves, etc.) when necessary.

Avoid contact with animals and take steps (such as adequate handwashing) to minimize the potential for cross-contamination.

Wash hands thoroughly (e.g., for at least 20 seconds) by scrubbing with soap and clean water and dry hands thoroughly with single service towels, electric hand driers, use of a sanitary towel service, or other hand drying device. Handwashing must occur before starting work, before putting on gloves, after using the toilet, upon return to work after breaks, after re-entering the building (in the event there are multiple buildings or units), after touching potentially contaminated material (including seeds and substrate) and any other time hands may be dirty.

Hand sanitizer cannot be used as a replacement for washing hands with soap and water but can be used in addition to proper handwashing.

Glove use is common in CEA operations. Maintain gloves in a sanitary condition, if used. This can be achieved by either using single use, disposable gloves or by washing and storing reusable gloves so that they are clean prior to contacting produce or food contact surfaces. The use of gloves is not a substitute for handwashing.

Remove or cover hand jewelry that cannot be adequately cleaned or sanitized during activities in which produce is being contacted by hand.

Do not eat, chew gum, or use tobacco products in growing, harvesting, processing, packing, or storage areas.

- Sensory/organoleptic testing of the products should take place only in designated areas away from produce growing and handling areas.

Personal items, such as phones and jackets, should be handled and stored so they are not a source of contamination (e.g., in a designated area, away from produce packing and handling areas).

Consider boot wash, foam, or dry sanitizer crystals with or without a captive footwear program to minimize the likelihood people will spread contamination from lower to higher care (e.g., harvesting) areas of the operation.

- If not managed properly, including maintaining appropriate levels of sanitizer, and cleaning and maintaining the boot wash system, these types of interventions can serve as a source rather than mitigator of contamination (Lupo, 2015; Meritech, 2019).

Sanitary Facilities and Resources

Though CEA production does present unique differences as compared to outdoor agricultural production, from a regulatory standpoint, the same access to and practices around toilet and hand-washing facilities are required. Additional evaluation of plumbing may be warranted in CEA production since water delivery systems including nutrient delivery systems can be complex and interconnected. Proper plumbing and backflow prevention (Callahan, 2019) should be evaluated to ensure no potential cross-contamination risks exist.

An adequate number of toilet facilities must be provided and readily accessible to the growing, processing and packing areas whenever people are present.

Toilet facilities must be designed, located, and maintained to prevent contamination of produce, be accessible for servicing, and provide for sanitary disposal of human waste, toilet paper, and used paper towels for handwashing. Ideally, facilities would be designed without doors to toilet facilities or with hands-free devices (e.g., pedals or handle-free swinging doors) to reduce the need to open doors and recontamination of hands.

Restrooms without doors should not open directly into the production environment. Air curtains, air locks, vestibules, foot baths, secondary handwashing stations, etc. can be used to limit the risk of pathogen entry.

Handwashing facilities must be provided and readily accessible to the growing and packing areas and include soap, clean hot/cold water, adequate means for drying hands, and a way to properly dispose of waste and wastewater.

Proper handwashing signage is expected and should be provided in language(s) or graphics that all workers can understand.

Plumbing for handwashing and toilet facilities should be carefully evaluated to ensure wastewater cannot contaminate other water sources or the production/ processing facilities. Backflow prevention valves should be professionally installed and inspected annually.

FACILITY AND EQUIPMENT DESIGN

Although there is tremendous variation in the ways CEA production environments are set up, there are fundamentals of facility and equipment design that apply universally, that are consistent with regulatory requirements and industry practices.

Understand previous uses of the building/facility to determine if there are any food safety risks that may be inherited. For example, was the space previously used to house animals or for the production of animal products that may carry pathogens? Was it used as a retail space, and is it now suitable for food production? Can it be cleaned and sanitized before use?

- Consider pathways for construction equipment, contractors, trash, etc., when adding additional greenhouses to the site. Have a plan for ensuring the safety of food products during ongoing construction in and around the growing operations.
- Be prepared to manage pests that may emerge as a result of the ground being disturbed during construction or expansion.
- Proper initial sanitation and the food safety related aspects of qualifying and commissioning new CEA farms is discussed later in this document (e.g., using environmental monitoring to assess the hygienic status).

It is recommended that lights, including grow lights and lights in processing areas, be shatterproof to minimize the introduction of physical food safety hazards.

Ensure building materials, particularly materials used for walls and floors in packing, storage, and high traffic areas, are cleanable. This includes understanding the nature of the building materials so that chemical compatibility (e.g., cleaners and sanitizers) can be assessed.

Because farms are not dry operations, determine the appropriate number, size, location, flow direction, and style of drains needed to manage water associated with sanitation, as well as water that may need to be drained from tanks, ponds, cold storage areas, etc. and consider slope and flow (Callahan and Chamberlin, 2020).

Ensure floors in packing, storage, and high traffic areas are constructed, appropriately graded, and maintained to limit the harborage of environmental pathogens.

- This includes taking into consideration the CEA growing operation and activities being conducted in particular areas. Floor material selection should be considered for areas of higher care (e.g., packing, handling areas, footpaths) where cross-contamination and harborage of human pathogens may present a greater concern.

Install equipment in ways that facilitate easy access for sanitation and limit the opportunity for niches where pathogens can hide.

Where space is limited, equipment should be dismantled or otherwise moved to enable proper cleaning and sanitation. Ensure equipment that is low to the ground is not re-contaminated due to splashing from floors.

Consider layout and mitigation strategies (such as foot baths) that eliminate or minimize the risks from movement of people from low care (e.g., growing) areas to higher care (e.g., harvesting and packaging) areas.

Install a heating, ventilation, and air conditioning (HVAC) system that minimizes the likelihood of condensation, especially in areas where moisture may condense and drip on produce.

When accessing the crop from above the canopy or overhead areas, mitigation measures must be in place to avoid potential contamination of the crop from footwear or overhead equipment.

When performing maintenance (e.g., replacement of glass panels), preventive measures should be implemented to avoid potential contamination of the crop.

Sanitary Design of Equipment and Facilities

Equipment used in CEA production environments is often unique and constructed specifically for the operation. Some surfaces are not cleanable or are not compatible with chemical sanitizers. With the rapid growth in the CEA industry, there is currently tension between the need to procure equipment quickly and the time and cost associated with sourcing equipment that is hygienically designed. In many cases, easier-to-clean equipment also saves time and money.

There are several resources to guide how equipment and facilities can be designed in a way to minimize food safety risk:

Food Plant Engineering, Sanitary Design

Food Plant Engineering, Food Facility Sanitary Design Principles

Food Safety Magazine, Six Steps to Effective Sanitary Design for the Food Plant

University of Florida, IFAS Extension, Sanitary Design and Construction of Food Equipment

3-A Sanitary Standards Incorporated, Overview of Principles of Hygienic Design

Commercial Food Sanitation Facility Design Checklist Produce and Fruit

Hygienic and Sanitary Design for Produce Farms

Produce is at heightened vulnerability during cutting/harvesting and therefore the food safety team should be involved when companies are considering the purchase of growing and harvest equipment. Other items to consider include:

Cleanability would ideally be considered when designing and installing equipment such as tubing and piping that transport water and nutrient solutions, channels, and gutters used for growing; at a minimum, each piece of equipment should be assessed by food safety and sanitation professionals to determine the appropriate frequency and method of sanitation.

- Equipment should be monitored for the end of its shelf life, as the ability to clean surfaces is likely to diminish (e.g., irrigation lines in an NFT system).
- Evaluate and address problematic areas of equipment and nutrient solution delivery systems that may be impacted by the growth of algae or biofilms (e.g., dead end legs of irrigation channels).

Construction and materials: Food contact materials should be corrosion resistant, smooth (or impervious) to enable cleaning and sanitation and constructed without crevices or smoothly seamed. Assess areas with threads, bolts, corners, and low flow (dead zone) areas where biofilm may accumulate. When designing equipment with drainage, consider the slope so that water does not accumulate.

Design, Layout, and Traffic Flow

The layout and design of CEA environments are quite varied. Some farms may have distinct, separate areas for seeding, germination, transplanting, growing, harvesting, and packing. In some instances, they may occur in separate rooms or even closely located but separate buildings. In other cases, these operations may occur within the same shared space. Some may have high degrees of automation and limited human activity; others may have a high degree of human activity. Regardless, CEA operators should evaluate the flow of produce and the flow of people in order to identify areas of greatest risk. To the extent practicable, employee movement should be limited to the area where they are actively working. This could include, for example, the use of captive footwear, color coded smocks or bump caps that relate to the work area, etc. Forklift traffic should be monitored, and forklifts would ideally be dedicated to either indoor or outdoor use. If forklifts need to transport materials between the indoor and outdoor environments, controls should be in place to limit opportunities to track contaminants from the outdoors into areas where produce or the production environment could become contaminated. This could include, for example the use of sanitizers at entryways, regular sanitation of the forklifts, or identified traffic flow patterns within the operation.

Coverings on equipment should be made of materials resistant to breaking and deterioration, and be included in sanitation (e.g., guards or covers on metals blades used for slicing, plastic covering over conveyors or elevators).

Cracked equipment and components can allow pathogen harborages. Assess the entire system, including connection equipment, seals (O-rings) or gaskets, and other non-produce contact areas of equipment.

Gears and other mechanisms for moving conveyors should be assessed for their ability to transfer pathogens. Additionally, assess the potential for chemical contamination from lubrication.

Some highly automated systems may have lifts or other machinery to pick up and move trays or produce from one area to another. This equipment and areas that touch or hold produce should be assessed for their food contact suitability.

Growing trays should be assessed for their suitability as a food contact material, kept in good condition, and maintained clean and sanitary.

5 Key Points of Hygienic Design

Callahan et. al. 2020

Visible and Reachable Surfaces

Smooth and Cleanable Surfaces

No Collection Points

Compatible Materials

Preventing Contamination

PEST CONTROL

Four basic principles can help guide CEA producers in minimizing the food safety risks associated with pest activity: reduce attraction, minimize "cover" (places where pests nest or hide), reduce access, and reduce population (Callahan and Chamberlin, 2017; Lewis Ivey and Ilic, 2019). Though CEA operations should conduct a pre-harvest crop assessment to evaluate for food safety risks, such as for indicators of rodent activity (e.g., fecal contamination, damage to crop, nesting materials), the focus should be on preventing pest activity from occurring in the first place. Pests such as mice, rats, and birds can still be present, even in a fully enclosed building. An evaluation of the CEA site should be conducted, as external building factors may contribute to an increased risk for pest activity. For example, CEA operations located in urban areas or those which neighbor properties with high human activity may be more susceptible to pest pressure. For the purposes of compliance with the FSMA Produce Safety Rule, § 112.128 requires at minimum that a pest control program in buildings must take measures to protect covered produce, food contact surfaces, and food packing materials from contamination by pests, including routine monitoring for pests as necessary and appropriate. In addition, for fully enclosed buildings, there must be measures in place to exclude pests.

The following are additional considerations when building a robust pest management program:

Address and minimize any entry opportunities for pests such as small gaps between doors, walls, or windows. Keep in mind that mice can fit in a pencil-sized hole and rats through a hole the size of a quarter.

- Passive exclusion measures can be incorporated through limited entry ways, curbing, buried barriers, netting, or screens (NECAFS, 2023a). This includes roof top ventilation and other areas that may provide easy entry to pests but may be overlooked. Ceiling windows, open external pipes, hoods, roof gutters, and other openings may otherwise provide access points for pests.

Train workers to identify and report any signs of pest activity such as pest droppings, damage to the crop, or indicators of nesting activities.

Never harvest produce that has been visibly contaminated with animal feces or shows signs of pest damage.

Use unbaited traps to monitor and capture any existing pests within the facility. Consider consulting or contracting with a pest management service experienced with food production establishments to determine the proper location, number, type, and management of pest traps. Traps should be identified on a map and monitored to help identify any trends or areas needing higher attention.

- For insects, do not place light traps above or near produce growing, handling, or packing areas.

Store trash and organic waste including substrate in a manner that does not attract pests and dispose of materials at regular intervals. Keep the growing and packing areas clean and free from plant debris which may serve as a harborage site or food source for pests.

Storage of packaging materials should be well protected from pests. This may mean keeping materials wrapped and covered until ready to use.

Any materials used for growing plants such as seed, substrate, fertilizer, and other agricultural inputs should be stored securely and away from produce production, packing, and storage areas.

The exterior of CEA operations should also be kept clean and uncluttered. This includes mowing or removing vegetation around the building that can serve as a harborage site for pests.

INPUTS AND RAW MATERIALS

A supplier approval program should set the foundation of food safety practices for agricultural inputs, even prior to receipt of the materials. This includes food safety risks associated with all inputs and raw materials including fertilizer, seeds, substrate (also referred to as growing/growth media), and packaging materials.

Fertilizers

In general, conventional (chemical) fertilizers present low food safety risks from a microbiological standpoint. Chemical food safety risks associated with conventional fertilizers can be minimized by following product labels and use of personal protective equipment (PPE) for worker safety. Although CEA producers often prefer a higher grade of fertilizer inputs compared to those used in field production, this is driven primarily to prevent the accumulation of impurities in recirculated water and is unrelated to food safety. Some organic fertilizers are animal derived (e.g., fish emulsions) and should be evaluated for potential human pathogen risk. Questions that can be asked of suppliers to help inform the farms assessment of risk include:

Are organic components of fertilizers, nutrients, and buffers treated to minimize or eliminate the risk of human pathogens?

- If so, is the supplier able to produce testing or treatment parameters as validation?
- If not, how is the supplier managing risk?

Is a letter of guarantee (LoG) or letter of assurance (LOA) available stating that the supplier complies with applicable laws?

Based on the risk associated with the type of fertilizer (e.g., based on its composition, how it is going to be used, and information provided by the supplier), the purchaser may perform an in-house test for hazards of concern at a specified frequency (e.g., each lot, quarterly, annually, etc.), before using, or upon preparation of nutrient solution. If a vendor's product does not meet established standards (whether internal standards, or regulatory standards), the input should not be used and alternative suppliers should be identified and utilized.

Seeds Including Coated/Pelleted Seeds

The public health consequence of using seeds that are contaminated with human pathogens in CEA production of leafy greens is unknown (Topalcengiz et al., 2023, Xiao et al., 2014; Xiao et al., 2015). The systems approach to food safety management should include consideration of the likelihood of dust, debris, or other components of seed stock contacting mature plants (either by air, tools/equipment/surfaces, via worker cross-contamination, or by other means). If a seed is contaminated, the likelihood that the edible portion of the crop will be contaminated is dependent on many factors, including the type of crop, maturity of the plant at harvest, type of growing system, mobility of the pathogen, and location of the pathogen in association with the seed. At this time, it is unknown whether the plant would internalize pathogens from the seed or seed coating, whether pathogens would move up the plant, and whether the substrate, water, or surfaces would or could become contaminated if the seed or its coating (if applicable) are contaminated. Given the variety of growing systems, each producer should assess the risk associated with their seed and seed suppliers.

CEA operations can consider asking their seed suppliers the following questions when sourcing seeds:

Is there a letter of guarantee or certification stating seeds come from farms which have established food safety programs available? Can the supplier describe those practices, for example:

Are seeds treated for food safety (e.g., similar to treatment of seeds for sprouting, FDA, 2022b; FAO, 2023)?

Are surfaces which seeds contact easily cleaned and sanitizable?

How are seed lots separated?

Is the seed supplier currently doing any seed testing or environmental monitoring? If so, what specific organism(s) are they testing for?

Is seed stored in closed or covered containers and stored in a clean dry area?

Is the seed packaging adequate to minimize the potential for contamination during transportation?

Are there seasonal supply changes that the company should be aware of? Will the supplier notify the company if seed supply (e.g., origin, processing steps) changes?

If coated, does the seed coating present any food safety issues (e.g., is it able to support the growth of human pathogens, is it appropriate for use on human food crops)?

Does the supplier implement practices to minimize cross-contamination during the seed coating process including pre- and post-treatment storage, pest control measures, and lot code management?

The following can help limit risk:

Seeds should be purchased or sourced from reputable commercial providers. Most of the CEA industry uses commercial seed sources.

Seed suppliers should provide the lot numbers associated with seed lots and CEA producers should record this information and associate it with the finished product lot number.

Although a Certificate of Analysis is typically provided, today, it generally lacks information on foodborne pathogens.

- If the CEA company chooses to test seeds for pathogens based on their evaluation of risk, they should alert the supplier, and should delay using seeds from that seed lot until test results are received (known as a "test and hold" or "positive release" policy).
- Before testing, the CEA operation should determine what to test for (pathogens or indicators), statistically relevant sampling plan, acceptable limits, and corrective and preventive actions in the event limits are exceeded.
- The limitations of product testing apply equally to testing seed and should be considered. Testing is better used to verify food safety than as a lot acceptance measure. See call out box on page 50 for more information.
- Limits and corrective actions should consider the entirety of the production system, including factors that may amplify risk as well as controls that might mitigate risk.

If applicable, seed suppliers should provide assurance that materials used to coat or pellet seeds are appropriate for food use.

Upon receipt, seeds should be inspected to ensure the integrity of the packaging and absence of insects, pests, or visual defects.

Seeds should be stored in their original packaging in a cool, dry area where contamination is unlikely to occur. Seeds should not be stored on the floor or in the production area.

Substrate

Different types of growing media are used to support the growth of crops in CEA systems. Seeds may be planted in a wide variety of substrate (also called growing/growth media or soil-less substrate). The information below covers the main types of substrate in use by larger CEA producers. The information is expected to change as the CEA industry and suppliers of substrate engage in continued discussion around best food safety management practices, and as the body of knowledge about risks and mitigation measures related to substrate increases.

There are a few common types of substrates: peat, coir, vermiculite, pine shavings, and stone wool (a.k.a., rock wool or mineral wool) (Leaffin, 2020).

Peat is formed in bogs, is biologically active and generally contains beneficial microbes which may compete with pathogens. Peat is not generally heated unless it is pelletized, though CEA producers should ask these questions of their supplier since not all pelletized products have been heat treated. CEA producers should ask suppliers how the product is protected from contamination during production and at other points in the supply chain in order to minimize food safety risks.

Peat is often mixed with coir and other fibrous components that change their moisture retention capabilities. If that is the case, the producer should consider asking for a COA demonstrating the absence of pathogens, and if applicable, RHP certified or equivalent.

Perlite (used as a component of other mixtures), **vermiculite**, and **stone wool** are heat treated to temperatures that will kill vegetative pathogens (e.g., temperatures greater than 400C) and therefore, the microbial food safety risks during production are very low. Still, the integrity of the packaging needs to be maintained throughout the supply chain so that pathogens are not reintroduced. Depending on the nature of the substrate, toxic heavy metals could be present.

Coir (coconut husks) is generally dried, and occasionally heat treated. CEA companies should ask suppliers for details of the production practice, including the quality of water used for washing the coconut husks, the target treatment temperature, and the minimum time the product achieves that temperature. Post-treatment handling should be managed to avoid the introduction of pathogens during the packaging and distribution processes.

Growing mats (e.g., hemp, wood, sodium polyacrylate) are lightweight matting used for microgreens. Hemp or wood (generally bamboo) is biodegradable, introducing

a sustainable option, but not without potential microbiological hazards. These products may introduce new potential pathogens, depending on the source. Sodium polyacrylate is a powder that absorbs water and turns into gel, holding moisture and is less likely than natural sources of matting (e.g., hemp, wood) to introduce contamination. Supplier controls and GMP should be considered. Reuse of products should be addressed in risk assessment for likelihood of cross-contamination from one batch to another.

Compost is rarely, if ever, used by major CEA producers as a component of the substrate. The U.S. Composting Council, USDA Agriculture Marketing Service, and others have resources on appropriate use of compost. CEA producers should take note that if substrate contains ingredients of animal origin (e.g., bone meal, blood meal, manure), ensuring adequate treatment will be critical to minimizing risks of introducing human pathogens into the growing environment. Subpart F of the FSMA PSR includes microbial standards for soil amendments of animal origin (FDA, 2015a; FDA's Biological Soil Amendments of Animal Origin Factsheet).

Similar to seeds and seed coating, the public health relevance of using substrate contaminated with human pathogens likely depends on the overall production system, including whether the substrate is:

- **intentionally included in the finished product ("roots on") (highest risk)**
- **incidentally included as the plant is harvested, or**
- **unlikely to contact the finished product (lowest risk)**

Further, the potential for product contamination including internalization of pathogens resulting from the use of contaminated substrate is not well understood. Research is evolving in this area.

Regardless of the nature of the substrate, it should be sourced from reputable suppliers and the CEA operation should have an understanding of how food safety is managed including details of the production practices of the substrate/material. Substrate should be inspected upon receipt for the absence of pests, quality deterioration, or other signs of contamination that may indicate that the substrate was not produced, stored, or handled properly. Upon receipt, the integrity of the packaging should be evaluated. Although quality specifications should not be mistaken for food safety specifications, demonstrated adherence to standards (e.g., RHP certification, ISO certification) may be indicative of suppliers that have better systems and controls. The limitations of testing that apply to finished product also apply to raw materials, such as substrate.

Questions that could be asked of substrate providers include:

What is the type of substrate (e.g., peat, coir, a mixture)?

Are there microbiological or chemical risks associated with the substrate (based on its composition, the commodity, and the growing system)?

How is the supplier managing risks that could impact food safety?

- Is the supplier able to produce testing or treatment/ process parameters?
- If not, are other measures taken that would minimize food safety risks?

How are product lots delineated? Is there a traceability system in place?

Is the substrate stored in a manner to protect it from potential contamination?

Is the substrate packaged adequately and transported appropriately to prevent cross-contamination during transportation?

Although this document focuses mainly on microbiological risks, prudent suppliers may consider asking about the potential for toxic heavy metals (e.g., cadmium, lead, arsenic) in substrate. For example, an annual certificate of analysis representative of the origin of the material could be useful. If the CEA operation has an approved supplier program, a certificate of analysis may be requested more frequently depending on the type of material and potential variation in its composition, source, or handling practices. This is why it is important to get to know agricultural input suppliers to better understand the incoming raw material quality and safety.

Onsite Storage and Handling of Inputs

Inputs should be stored indoors and sealed in their original containers/packaging. Storage of agricultural inputs should also include effective pest management programs including training workers to identify when pests may have contaminated inputs (such as through observations of droppings, nesting in materials, etc.). Agricultural inputs should be stored off the floor and away from walls in a location that will not present cross-contamination risks to other parts of the growing, harvest, or handling environment.

For CEA producers who purchase substrate or other agricultural inputs in bulk, care should be taken during preparation and handling to prevent cross-contamination of food contact surfaces or produce. For example, substrate plugs, or large bales of media should be partitioned in an area where dust from these activities will not impact other areas of the operation.

WATER

Water is critical for CEA production as it serves as the primary delivery mechanism of nutrients to the plants. In fact, many CEA operations do not refer to the water used as 'agricultural water' or 'irrigation water', but instead, 'nutrient solution' since it is a dynamic system that includes more than just water. Regardless of the terminology used, care must be taken for the proper management of water and nutrient solution since it can be a route of contamination and potential carrier of many different microorganisms of public health concern including bacteria such as *Salmonella*, pathogenic *E. coli*, *Listeria monocytogenes* and *Shigella*; protozoa including *Giardia lamblia* and *Cryptosporidium parvum*, and human viruses such as hepatitis A, not to mention plant pathogens and chemical contaminants. In addition, several prior produce-related outbreaks have cited water as a suspected vehicle for contamination including in CEA operations (FDA, 2022a).

Agricultural water is defined in the FSMA PSR as 'water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing, harvesting, packing, and holding activities' (FDA, 2015a, FDA, 2021a). Agricultural water must be of safe and adequate sanitary quality for the intended use. Generic *E. coli* has historically been used by industry, including as a component of audit standards as an indicator of fecal contamination. More information about agricultural water quality testing is included in this section.

FDA defines "agricultural water" as water that is intended to, or likely to, contact the produce or food contact surfaces. Although most water contact in CEA systems occur through the roots and as such, would not constitute 'agricultural water' per FDA's definition because it is not intended to directly contact the harvestable portion of the crop. However, irrigation water may inadvertently contact the harvestable plant tissue, for example, as mature plants are moved from the growing environment to the harvesting area. Opportunities for water to drip onto plants should be minimized, especially if farms do not consider their preharvest water use as 'agricultural water'.

Water used to mist crops or apply crop protection chemicals would meet the definition of agricultural water, as would water that is used post-harvest. If plants are packed with roots, then water used for irrigation would reasonably be considered agricultural water and subject to the standards of the Produce Safety Rule since the water directly contacted the roots. When water is used for further processing, such as for final rinse or the production of fresh-cut produce, the

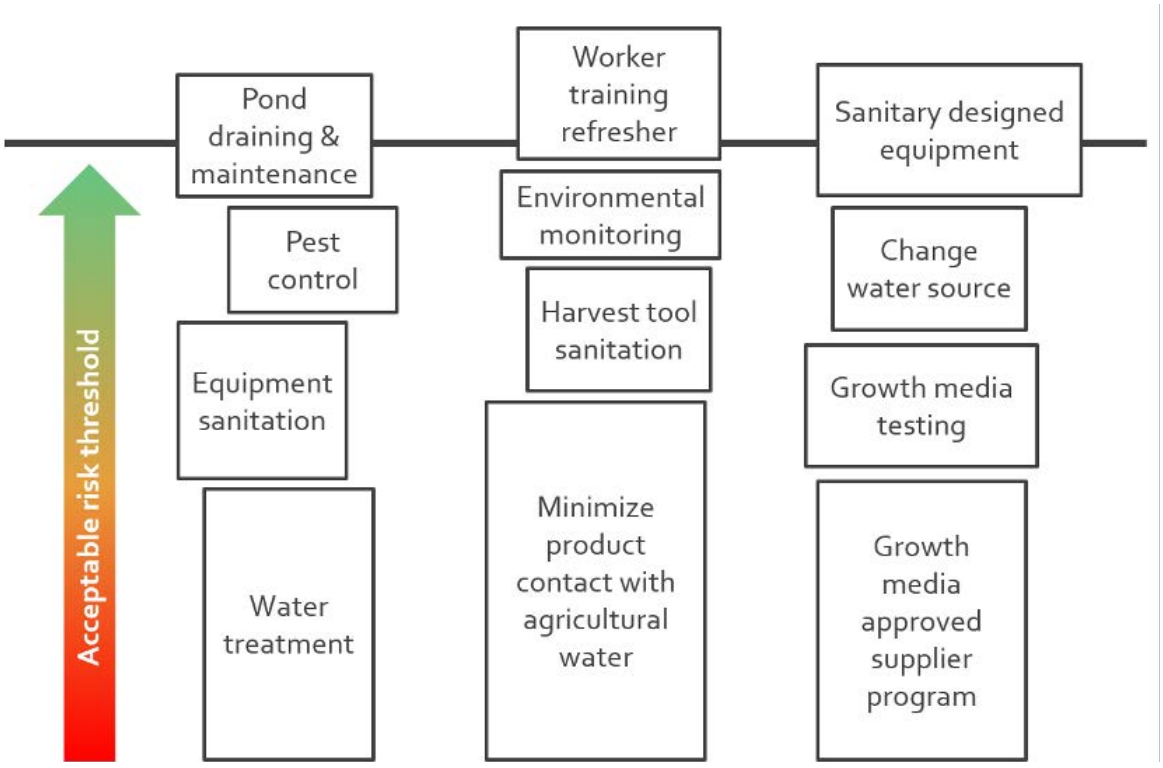
CEA operation will need to determine if which activities are still part of the "farm" definition and subject to the PSR, and which are part of "processing", in which case the PC Rule (FDA, 2015b) would apply. Regardless, post-harvest wash water can be a vehicle for cross-contamination and risks should be evaluated.

Even if water used for irrigation is unlikely to touch the harvestable portion of the crop and thus would not be subject to the agricultural water requirements under the PSR, most CEA producers monitor water quality to ensure plant health, appropriate levels of nutrients in the solution, as well as metrics which can impact food safety such as electrical conductivity and pH. Recommendations on appropriate water testing plans for both incoming as well as recirculated water are included later in this section. Several factors will play into the management of CEA water systems including the source type, delivery and growing system, and treatment options.

Water System Inspection and Assessment

In many ways, CEA production is likely to present a more complex agricultural water system than many outdoor growing systems due to the nature of the growing environment and requirements for plant production and nutrient delivery indoors. For this reason, it is strongly suggested that all CEA producers map out their water sources and distribution systems to help identify specific points where hazards might be introduced. This includes noting all types of conveyances of water such as gutters, tanks, holding ponds, irrigation system components, filtration

Figure 2 Example water system diagram with inputs and water treatments. Note that there is no single "correct" way to set up a water distribution and treatment system. There are many variables that will need to be accounted for during the risk assessment which will help determine what interventions or controls might be necessary.



systems, and any backflow prevention devices and plumbing connections. Also consider any uses of water prior to the plant establishment, such as water used for seeding and pre-wetting substrate. Taking a holistic approach to evaluation of the water system will enable CEA producers to identify potential hazards and prioritize actions that may need to be taken (whether pre-scheduled or triggered by other monitoring) to reduce risks. Mapping and describing the entire agricultural water system also helps create a common language for communicating to workers what types of sanitation, water treatment, or other system maintenance tasks need to be completed and at what frequency. The agricultural water system diagram should serve as the foundation to all standard operating procedures (SOPs) associated with managing agricultural water safety and quality.

Figure 2 shows an example water system diagram with a municipal water source. Some antimicrobial treatments, such as the use of UV and filtration in this diagram, may be aimed at addressing plant, not human, pathogens. The diagram should distinguish which processes and treatments are aimed at public health protection, versus those that are intended to protect plant health, reduce algal growth, etc.

While mapping the water system is a current expectation of CEA producers, there are also proposed regulatory requirements related to water system inspections and assessments outlined in the FSMA PSR Subpart E. Unless CEA growers qualify for an exemption to the PSR, growers will have to inspect their water system at least once annually, to the extent which it is under the grower's control, to identify any conditions that may introduce hazards onto the crop. In the CEA production environment, production may be continuous, and therefore, CEA producers should evaluate how often to inspect their water system, since the FSMA PSR only requires at the "beginning of the season or at least once annually". Water system inspections might occur in conjunction with other maintenance activities common to CEA production, such as cleaning and sanitation of growing ponds, channels, or equipment.

A water system inspection includes consideration of: the nature of each water source (e.g., ground, surface, municipal); the extent of control over the water source (e.g., is distribution entirely under your control or is water being sourced from a location where contamination could be introduced along its path); the degree of protection of each water source; uses of nearby and adjacent land; the likelihood that another upstream user of the water introduces a hazard to the water source.

Additionally, Subpart E requires that an agricultural water assessment be conducted annually and include information about the water system, agricultural water practices, crop characteristics, environmental conditions, and additional relevant factors such as water testing results. At the release date of this document, a final version of Subpart E has yet to be published (FDA, 2021a). This means growers, educators, regulators, and industry members must seek out the most up-to-date information regarding the status of Subpart E until the final provisions are released and able to be incorporated into this document. There are several templates and guides available to help CEA producers document their agricultural water assessments and inspections (IFPA, 2023; Woods et al., 2020; FDA, 2021b; FDA, 2021c; Stoeckel et al., 2023a; Stoeckel et al., 2023b).

Water Source Type

Depending on the source type, water may be subject to often-transient conditions that can introduce human pathogens. For example, if surface water sources are used for growing CEA produce, wildlife activity upstream, run-off from storms, dredging of canal systems, or many other environmental impacts may cause pathogen populations to spike temporarily. There may also be more permanent sources of contamination that might be identified through the agricultural water mapping activity described above, such as a failing septic system that is leaching low levels of contamination into an agricultural water source. Therefore, both common and transient conditions that may increase the likelihood of human pathogen presence in agricultural water sources and distribution systems must be assessed. The type of water source (e.g., surface, ground, recirculated, or municipal) can influence potential food safety risks during CEA production as shown in **Table 2 on page 29**.

The majority of CEA producers utilize municipal or ground water sources, however use of surface water is not uncommon.

SURFACE WATER The source of the surface water varies greatly depending on the operation and region. Environmental factors have a greater influence on surface water sources. Environmental conditions can change rapidly in the event of heavy rain or other severe weather events, migratory wildlife and domestic animal activity, or human activity such as recreational use, canal maintenance, or sewage discharge. Knowledge

Managing Recirculated Production Water

Water is often recirculated in CEA systems for efficiency and sustainable use of resources, whether the original source is surface, ground, or municipal. It is important to develop and validate appropriate treatment systems to prevent the presence and growth of human pathogens and the risk of cross-contamination is reduced.

In a recirculating system, water and/or nutrient solution is delivered to the plant roots and then drained back into the system. This allows for the reuse of water and nutrients until they are depleted. The challenge, from a food safety standpoint, is managing the potential for the growth or dissemination of human pathogens as the water cycles through the system and potential contaminants are introduced into the water system without a full cleaning and sanitation break.

There are different approaches to managing recirculated water. Depending on the type of system, a combination of actions may need to be taken (also called a hurdle or multi-barrier approach) to maintain water quality through its intended use. The key point is that if water is reused, there needs to be a plan in place for how it will be managed. At a minimum, CEA producers should determine how water and nutrient solution is replenished, as appropriate to their system based on trends and aberrations in turbidity and organic load, stability of the overall solution (pH, nutrient content), and production cycle timing to avoid disruptions and minimize food safety risks. The overall sanitation of the production system must also be factored in – for example, when tanks are drained, the bottom is dredged, cleaned, and sanitized before refilling for the next cycle. Additional information on sanitation appears later in this document. Some of these same production parameters may need to be managed for the purposes of maintaining adequate plant nutrients, which is outside of the scope of this document.

of nearby and adjacent land use and potential impacts upstream through monitoring can help identify hazards which may cause water quality to change.

- Rainwater that is collected for irrigation purposes would also be categorized as surface water since it can be impacted by the greater environment, especially from run-off from roofs (e.g., dust, debris, vehicle exhaust, bird excrement). A mechanism to divert first-flush rainwater so that the system only collects the water after the roof has been "rinsed" can help to reduce the contamination load.

GROUND WATER If properly constructed and maintained, ground water sources are typically less variable in quality over time. Ground water from wells can be compromised in situations where wells are not properly sited (e.g., located near septic systems or livestock production areas), improperly constructed (e.g., well casing defects or subject to run-off), or not maintained or inspected (e.g., well head not intact).

MUNICIPAL WATER Public water systems provide the lowest likelihood of being contaminated with human pathogens. In the United States, public water systems are required to meet EPA drinking water regulations which provide microbiological standards that the treatment facility must achieve. Not all growers have access to public water systems for production purposes and furthermore, the use of municipal water may be cost prohibitive, especially for larger scale operations.

OTHER WATER SOURCES Careful evaluation of water collected from heating and cooling (HVAC) or other collection systems should be conducted to determine whether cross-contamination might have occurred prior to use of water in CEA production systems. In addition, some CEA operations may use more than one type of water source, in which case, each water source must be evaluated for potential risks.

Water Delivery System

Innovation within the CEA community is one of the hallmarks of CEA production. This guidance serves to provide descriptions of a few of the most common water delivery systems used within the industry but is not all-inclusive. Technology and methods for CEA production are continually evolving and broader categories of production systems are discussed on the opposite page in context to potential food safety risks.

Table 2

Water source type risk profile for CEA production.

Surface (rivers, canals, ponds, captured rain water)
More susceptible to contamination due to open nature of water source

Ground (wells, springs)
If properly protected and maintained, ground water sources may limit introduction of contamination to the water source

Municipal (public water system)
Treated to eliminate pathogen presence; however, water distribution system may still introduce contamination

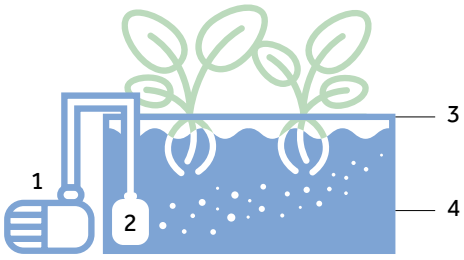
Table 3

Water delivery system risk profile for CEA production.

Water System Delivery Type
OVERHEAD Water is distributed to the plant from an overhead sprinkler or mister. This type of water will contact the harvestable portion of the crop, and therefore presents the highest risk.
DEEP WATER CULTURE (DWC) Plants are placed into holes of floating rafts which sit on top of the surface of an irrigation pond or tank. The roots are submerged in water. Depending on production and harvesting methods, water used in these types of systems may inadvertently contact the harvestable portion of the crop and therefore presents higher risk.
FLOOD AND DRAIN (ebb and flow) Plant roots are flooded with nutrient solution and drained intermittently. Trays of plants can be removed from the system at any time. The water contacts the root system but can contact the harvestable portion during movement of trays, presenting a medium risk. Cross-contamination risks between plants could be high if the nutrient solution is contaminated.
NUTRIENT FILM TECHNOLOGY (NFT) A nutrient solution is delivered in a thin film via gutters or channels to plant roots. Plants stay in place until the production cycle is over. Cleaning and sanitation of channels/gutters is conducted at the end of the production cycle. The risk is lower since water is unlikely to contact the harvestable portion.
DRIP/TRICKLE (substrate culture with drip irrigation) Drip and trickle type systems often deliver small amounts of water directly to the plant roots at a low rate, and therefore present lower risk of contacting the harvestable portion of the crop. Plants are often elevated on gutters or tables with emitters placed under the surface of the growing medium, further reducing risk.
OTHER APPLICATIONS Any water that contacts the plant will be considered agricultural water under the FSMA PSR. Occasionally, water may be utilized in ways that could impact the microbial safety of the crop, especially if water is applied close to harvest. Well or municipal water is the recommended water source for chemical applications such as pesticides because the water will directly contact the crop. Additionally, there are fewer particulates, so these water sources are less likely to cause clogs or other issues with the application equipment and/or distribution system.

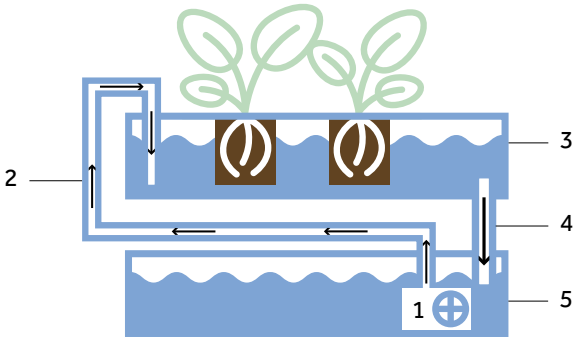
Figure 3 Schematic illustration of CEA water/nutrient delivery systems: a) deep water culture; b) nutrient film techniques; c) aeroponics; d) ebb and flow. Image adapted from Dr. Boce Zhang, Assistant Professor, University of Florida and Dr. Yaguang Luo, USDA.

A



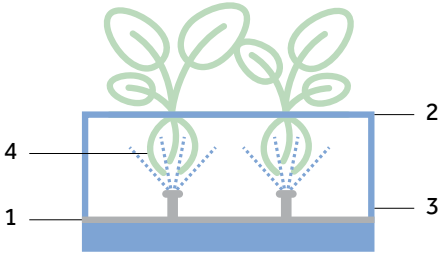
1 Aerator
2 Diffuser
3 Support Media
4 Nutrient Solution

B



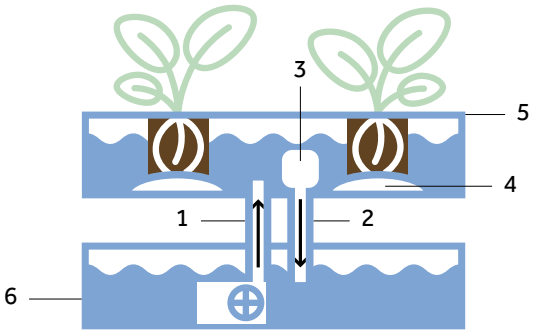
1 Pump
2 Pipeline
3 Media
4 Return
5 Nutrient Solution

C



1 Sprinklers
2 Support Media
3 Nutrient Solution
4 Roots

D



1 Pump
2 Return
3 Bell Siphon
4 Flood and Drain Tray
5 Media
6 Reservoir

Water Treatment

Maintaining water and nutrient solution quality within a CEA system is foundational to producing a safe, quality product. Water treatment methods will vary, and generally are conducted both before and during production of the crop. Treating incoming water, prior to the system set up, removes impurities, mitigates water quality concerns, and could be an important factor in minimizing human pathogen risks, depending on the risk associated with the water source. In addition to removing build up associated with nutrient delivery, treatment during the production cycle can help manage potential pathogen contamination while allowing for an effective use of resources. A few examples of treatment options are included below. As noted elsewhere in this document, it may be beneficial to consider multiple hurdles to treating water and/or nutrient solution, depending on the complexity of the system, likelihood of contact with the plant, incoming quality of water, and frequency of recirculation.

Physical treatment filtration is a common method to physically remove potential organic material and potential plant and human pathogens depending on the filtration pore size. Some CEA growers utilize reverse osmosis treatment for incoming water sources with low levels of organic matter present. Larger pore sized filtration is often utilized to remove gross debris and organic matter during water and nutrient solution recirculation but does not necessarily reduce microorganisms of concern. This could be accomplished by using filters with small pore sizes after passage through large pore size filters.

- **Reverse osmosis (RO)** is a process through which pressurized water is passed across a semi-permeable membrane, removing unwanted salts, minerals, and potential contaminants. RO systems typically utilize a series of filtration steps, including sand and larger pore size filters to remove large particles before moving to filters sized on the molecular level. Most RO systems will have backflushing filters to remove build-up, which increases flow of water across and membrane and extends the filter's life. It is important to establish maintenance schedules for RO systems as membranes can become worn out and efficiency and efficacy can drop.

Ultraviolet (UV) treatment (van Os, 2009; Zhang and Tu, 2000) uses UV irradiation, part of the electromagnetic spectrum between 200-400 nm that is typically divided into three ranges: UV-C (200-280 nm), UV-B (280-320), and UV-A (320-400 nm). UV-C has been identified as the best wavelength to damage cells, leading to greater pathogen reduction. The efficacy of UV treatment of water depends on the intensity and exposure time. While UV provides the benefit of no or limited use of chemical water treatment, the downside is that turbidity of the water can have a greater impact on the treatment's efficacy. Utilizing a filtration method may be necessary to keep water quality within an appropriate range for UV treatment. Validation of UV systems is suggested under a variety of operating parameters (e.g., during different points of production when organic matter levels may be higher) to ensure consistent and effective water treatment.

Chemical treatment is often not viable for CEA producers given that the water is also being used to deliver nutrients and support growth and may disrupt the overall development of the plant. Occasionally, chemical treatments such as peracetic acid and chlorine are utilized to treat water but are not necessarily labeled for the reduction of human pathogens in irrigation water (e.g., labeled use is to prevent biofouling or algae build-up). CEA producers must use chemicals according to their labeled use, as the label is the law. Chemical treatments may also be utilized to treat incoming water, prior to entry into the growing system where the water is then stored in tanks before being utilized (see example in Figure 2). Chemical water treatments should be closely monitored to ensure target levels of active chemistry are available to effectively reduce microorganisms of concern.

Ozone (O_3) treatment has been used as an effective disinfecting treatment for drinking water and has been applied to produce irrigation and wash water systems to reduce microbial populations (Seridou and Kalogerakis, 2021). O_3 decomposes spontaneously during the treatment process, forming hydroxyl free radicals (-OH) which are oxidizing agents that can inactivate human pathogens. One disadvantage attributed to the use of O3 in water treatment is the instability of the reaction in the presence of organic matter. For this reason, many CEA growers are using ozone to treat incoming water sources (e.g., municipal or ground) that have lower levels of organic matter.

Effective treatment of irrigation water relies upon understanding, monitoring, and managing a variety

of water quality characteristics. A few water quality parameters are described below and may be relevant to a variety of CEA productions systems. Not all water quality parameters managed in CEA systems have direct food safety relevance, though some may impact the efficacy of water treatments such as sanitizers. In addition, setting a water change schedule may be necessary, especially for CEA producers using deep water culture and recycled water systems. An SOP should be developed that outlines water quality parameters, such as the ones included in the list below, and other operating characteristics (such as total volume of produce grown, time since tank last drained) to establish the best schedule for refreshing water systems and conducting cleaning and sanitation efforts before starting another production cycle.

The following parameters also have food safety relevance, as well as potential impact on plant health and the quality of the product:

Chemical oxygen demand (COD) is a measurement of organic load in a system. COD in the CEA water system is significantly affected by the presence of plant tissues exudates. Its value also often influences the pathogen inactivation efficacy through UV, ozone, etc.

Biological oxygen demand (BOD) represents the amount of oxygen consumed by bacteria and other microorganisms while they decompose organic matter under aerobic (oxygen is present) conditions at a specified temperature.

Turbidity is a measure of the clarity of water, i.e., the amount of light that is scattered by particles in the water. The term 'turbidity' has been used loosely in the produce industry to refer to the organic load; however, the correlation between turbidity and organic load can be impacted by many factors. In CEA irrigation water, turbidity can be significantly impacted by the presence of silt, clay, and other particles.

Validation and Verification

Validation and verification are two concepts that CEA producers should become familiar with when managing the overall effectiveness of water quality management and other food safety activities (e.g., sanitation, role of testing, etc.). Validation means developing scientifically proven methods to control a food safety hazard and answers the question 'How do you know the process or treatment works?' This includes establishing and documenting the scientific evidence that hazards are being effectively controlled. Verification means confirming that the process or treatment was performed correctly and answers the question 'How do you know the process or treatment was done properly?' These two complimentary concepts should be considered an on-going component of the overall food safety system but must be completed as separate tasks. Consider which team members would be the most valuable in completing each task; management or the food safety manager might lead the validation development process and the operations team is likely to participate in verification activities. Verification activities should be conducted by someone other than the individual responsible for performing monitoring and corrective actions (Brackett et al., 2014; Gombas et al., 2017). This ensures an unbiased and objective assessment is conducted and may need to be performed by an external party (e.g., consultant or expert third party) if resources are not available in-house. Increasingly, automated systems (e.g., sensors) can be used to perform verification activities. However, mechanisms should be in place to ensure the systems are active and functioning properly. Data capture and management should also be considered. Finally, the accuracy of these systems should be verified, and contingency plans should be made if the systems go down.

Preparing for the Unexpected

As with any type of production agriculture, unexpected challenges may arise. From the food safety context, there are some events that may occur that you can reasonably predict to occur based on an evaluation of prior history, meteorological occurrences, or other crises faced by the company or similar operations. Consider a few of the following situations and think about how a CEA operation might prepare to minimize the impacts to the overall operation and safety of the produce. A crisis management/emergency response plan should be developed to address any potential issues that are likely to arise.

Power loss can impact the entire production system including water circulation and treatment. How do you know that the water was effectively treated and will not serve as a source of contamination to the produce? Do you know the date(s) and time(s) the power outage occurred so that you can identify potentially affected produce lots?

Extreme weather events can cause many types of disruptions to a CEA operation. Think about the quality of incoming water sources and treatment, leaks in the facility, or unexpected flooding. Is there a seasonality (e.g., hurricane season) where you can be more likely to expect these events to occur? How have prior weather events impacted the operation?

Flood events—though flooding may be a result of extreme weather, it can also be the result of improperly functioning CEA production systems or a tank leak. How will produce be evaluated to determine whether it is safe to consume?

Construction/repair activities (any type of disruption within the operation such as repairs to equipment or infrastructure) can introduce potential microbiological and chemical hazards. Production tanks or lines may need to be taken out of commission to ensure no cross-contamination will occur from construction activities. Has the production and sanitation team been briefed and trained on the planned activities? A protocol should also be in place to manage visitors into the facility and ensure that repair team members are aware of food safety protocols and know where they can/cannot go within the operation.

Other crises/issues like an unknown health hazard or workplace injury, food safety recall, family event, among many other crises could occur. Does your operation have a crisis management plan? If so, are the individuals designated within the plan aware of their responsibilities and roles? Crisis management requires advanced preparation and practice—so do not wait until an actual crisis occurs to test the system.

Water Testing

Microbiological testing can be a valuable tool during the development of the food safety program and for verification activities, but it is not a guarantee of product safety. (UFPA, 2010). Microbiological testing is also not a substitute for a reliable and validated process for managing water quality. Ongoing, validated process control, if achievable, will be more effective and reliable than microbiological testing in assuring microbiological safety. For example, real time monitoring and verification of water treatment efficacy provides actionable information for immediate process control, as opposed to microbiological testing which provides information after the fact and too late to take effective action.

Testing might be conducted for several reasons – to help establish an understanding of microbial populations in an environment, verify food safety activities, or satisfy buyer or regulatory requirements. Regardless of the type of testing (whether water, as discussed here, or seeds, substrate, the environment or product (all discussed elsewhere in this document), the operation must always have a plan in place for how to interpret and act upon results, especially if testing for human pathogens is conducted. Testing is both an investment in time and money and can result in unintended consequences if not properly executed. The best use of the operation's resources is to have a thorough sampling plan with methodology properly designed and performed. Even prior to implementation, the operation (including upper management) should understand why testing is being performed, basic assumptions underlying the test, relative potential of detecting an issue, potential results, and plans of action based on results (UFPA, 2010). Drawing on historical perspectives from past facility/growing environment challenges or issues (e.g., repeated positive tests in specific locations, outliers in data during monitoring activities) can help begin to inform where resources should be allocated.

In the CEA production environment, production water is a critical resource that must be managed carefully to both deliver the required nutrients for plant growth as well as maintain quality, so it does not serve as a potential source of contamination to the produce. From a regulatory standpoint, FDA distinguishes between pre-harvest water (for which FDA has proposed to revise the requirements) and harvest and post-harvest water, which, amongst other requirements, require this water to meet a standard of no detectable colony-forming units (CFU) generic *E. coli* per 100mL water. It's important to note that this is the minimum standard for all growers, all systems, and all commodities. Research has shown that

the recovery of *Salmonella* and *Listeria monocytogenes* from surface waters was greater as the sample volume increased from 100mL, to 1L, to 10L. This effect is likely to be observed in CEA as well, even though the water quality and routes of contamination differ (Sharma et al., 2020). Additionally, the levels of pathogens in water, if present, do not always correlate with pathogen levels in parts of the plant (Ilic et al., 2022).

While there is not one prescriptive standard for testing of water sources used for growing, there are several places where testing is prudent to help inform and evaluate potential food safety risks within the agricultural water system.

INCOMING WATER While most municipalities will provide annual water test results upon request, it may be important to test incoming water sources to ensure there is no contamination being introduced within the water distribution system at your location. If any treatment is applied to incoming sources (e.g., reverse osmosis, UV, or chemical), testing should be conducted both before and after treatment to validate that the treatment is effective (e.g., that appropriate reductions are achieved). Once validated, scheduled, periodic testing can be used on an ongoing basis as verification that the system is functioning properly. If concerns exist about the quality of the source water (e.g., a boil water advisory was issued or impact to water distribution system prior to entry at facility), water testing before to the treatment stage can also provide insight as to whether concerns from the source still exist (e.g., evaluate the sufficiency of the treatment, in light of an unanticipated incoming load).

RECIRCULATED WATER Recirculating water systems pose a unique set of challenges to CEA producers in both managing nutrient availability and maintaining water safety. As displayed in Figure 2, water systems that involve recirculation require additional management and potentially multiple treatment steps, depending on the system, organic load, and volume of water being recirculated. It's important for CEA producers to validate that the treatments are effective at reducing pathogens to an appropriate level for that operation (e.g., based on the likelihood that hazards would be introduced to recirculated water, and that contaminated water might result in contamination of the product). Testing can help verify the efficacy of the treatments when water is recirculated.

POND/TANK WATER Bulk water used in the production process is valuable to test, especially if there is any likelihood that the water will contact the harvestable portion of the crop. One challenge with large volumes of water is managing the build-up of materials in the bottom of tanks or ponds. The likelihood that the build-up could serve as a reservoir for harmful pathogens in CEA environments is unknown, but evidence suggests that further exploration of sediment as a potential risk may be warranted. Pond/tank draining should be followed by sanitation steps before the next production cycle is initiated.

OTHER WATER APPLICATIONS It may also be valuable to test water being used for watering in seed or misting/fogging applications, depending on the water source.

Frequency of Water Testing

Establishing a baseline of water quality is important to understanding trends with water quality and can aid in identifying early signs of a problem. CEA producers who are just beginning production should be testing more frequently initially to gather this baseline data from which future decisions and outlying trends can be identified to help manage the water quality long term. If water treatment(s) are used, reduced frequency of testing may be conducted after validation and verification of the processes occur.

Frequency of testing will depend on several factors including:

- **the type of system, water source and initial water quality entering the CEA system**
- **how often water is recirculated and/or changed production schedules (e.g., after ponds have been in production for a specific amount of time, or build-up of sediment suggests additional testing)**
- **the trend of water quality changes in each operation**
- **likelihood of the water to contact the product**
- **market demands such as third-party food safety audits**

What to Test For and Microbiological Limits

There is no silver-bullet solution for testing water that will definitively provide whether a human pathogen is present or not. Currently, the most effective way to gather data on water quality is to test for indicator organisms such as generic *E. coli* or fecal coliforms, despite the limitations associated with these indicators. These indicator organisms can provide CEA operations insight as to whether the water has been exposed to

fecal contamination (whether from humans or animals). Microbiological limits for indicator organisms cited in audit standards and other commonly referenced limits should be evaluated for their relevance to the CEA operations. For example, if a farm is using municipal water, and there are multiple treatments that further reduce microbial levels, the "standard" limits may be inappropriately high for this operation. On the other hand, if the water is prevented from contacting the crop, a higher microbial limit may be acceptable. In any case, each CEA operation should establish microbiological limits based on their circumstances (and consultation with experts, if helpful) and, importantly, establish clear preventive and corrective actions if those limits are exceeded.

Indicator organisms do not necessarily correlate to human pathogen presence, however, testing directly for human pathogens is not recommended as using this approach would be like trying to find a needle in a haystack and has a much higher associated cost for testing. Ideally, the production system would be assessed (especially considering the extent and timing of water contact with the plant), and controls implemented to minimize the likelihood of pathogen presence, with testing serving to verify that the system is performing as designed.

Documentation

For the purposes of the FSMA PSR, documentation must be kept of water test results, water treatment methods and monitoring, annual water system inspections, and supporting literature for determining appropriate testing frequency and analyte. CEA growers likely are already keeping much of this documentation as they manage nutrient levels and quality parameters within the production system. There are a number of templates available for recordkeeping purposes (Woods et al., 2020; FDA, 2021c; UFPA, 2021 [water assessment tool]).

More important than just keeping a record is utilizing the data collected in a meaningful way. Results of testing, water quality parameters such as pH or turbidity, and other observations from water and production system inspections are extremely valuable in understanding trends and preventing problems before they arise. The food safety plan should be a living document, with continual review of process parameters to ensure hazards are being appropriately controlled. Though not always possible or practical in the production environment, electronic records are useful for collaboration and the ability to address food safety issues that arise in a timely manner. At the very least, documentation (both electronic and paper) should be reviewed frequently and stored in a protected location. Also keep in mind that recordkeeping should be made easy for employees to complete—use of clip boards and pens at the location of the activity or smart phone applications accessible at worker's fingertips—use what works best and most consistently with employees. Other recordkeeping systems may be fully electronic and include components of automation. Care should be taken in electronic systems to ensure data is being inputted properly, security measures are in place to prevent falsification of records, and the overall system is validated at a specified frequency.

GERMINATION/SEEDING AND TRANSPLANTING

Because fresh produce, including those grown under CEA conditions, lacks a 'kill step', food safety must be managed at all points of the process, including germination and transplanting. Seeds are planted in a variety of ways, including using shakers, seed guns, or via automated, mechanized systems. Germination may be done in separate rooms, in enclosed chambers, with misters, etc. Food safety risks should be evaluated and managed.

Germination

The lot number of the seed should be associated with the lot number of the finished product; germination lots should be tracked to finished product.

All trays, racks, tools, and equipment used during germination must be cleaned to reduce food safety risk, and when appropriate and informed by the operation's risk assessment, including environmental monitoring data, sanitized.

Seeds and substrate should be handled in a way that minimizes the generation of dust.

Workers should be attentive to and alert management if pests including birds or rodents are present.

All workers must follow proper health and hygiene policies including hand washing, toilet use, avoiding contact with produce and food contact surfaces if they are ill, and using separate break areas for eating/ smoking regardless of whether activities are conducted mechanically or by hand.

Transplanting

Traceability should be maintained, even for transplants.

All trays, racks, tools, and equipment used during transplanting activities must be cleaned, and when appropriate, sanitized.

All workers must follow proper health and hygiene policies including hand washing, toilet use, avoiding contact with produce and food contact surfaces if they are ill, and using separate break areas for eating/ smoking regardless of whether activities are conducted mechanically or by hand.

GROWING

Growing styles vary widely in CEA production environments. Key factors that should be considered from a food safety standpoint include:

WATER AND NUTRIENT SOLUTION As discussed in prevoius sections, water and nutrient solution quality needs to be managed, including inadvertent contact with the plant tissue.

FOOD CONTACT SURFACES CEA operators should carefully observe the growing environment and identify areas where plant tissue may contact structures, edges, lights, tubes for fertigation, monitoring devices, etc. that are not intended to come into direct contact with the plant. The frequency of cleaning and sanitizing these surfaces should be assessed as definitions of "lots" and assertions of "clean breaks" are established (Krug et al., 2020).

CONDENSATION/DRIPPING CEA producers should also be attentive to conditions under which droplets may drip onto the product, for example, in high humidity environments. Condensation can be a natural phenomenon that occurs under high relative humidity. Produce should be physically protected from condensate drip and/or the interior of a facility or surfaces where droplets originate (e.g., overhead pipes, HVAC units, etc.). Facilities should be evaluated to determine the potential level of risk (e.g., are the walls or surface where drip originates part of the regular sanitation program?) and managed to reduce the likelihood of serving as a source of contamination.

HARVESTING

If harvesting requires the manual removal of structures holding the mature plants, workers should take care to avoid touching parts of the structure (e.g., the bottom of a rack), and then parts of the plant. It may also be valuable to designate different crews for these activities—for example, the individuals moving equipment to prepare for harvest are different than the crews handling the product directly to minimize the potential for cross-contamination.

Product that appears to be contaminated (e.g., evidence of bird or bat droppings) should not be harvested. Surfaces that may have come in contact with animal droppings should be segregated and carefully cleaned and sanitized.

As the plants mature and are ready for harvest, they should remain segregated and traceable. Lots are generally identified by the combination of variety, location (pond/rack), and date of harvest. The potential impacts of a recall can be minimized with delineation of smaller lot sizes and accurate recordkeeping.

All workers must follow proper health and hygiene policies including hand washing, toilet use, avoiding contact with the crop and food contact surfaces if they are ill, and using separate break areas for eating/ smoking regardless of whether activities are conducted mechanically or by hand.

Visually inspect food contact surfaces including transportation equipment to ensure they are visibly clean, free from debris, and in good repair.

Harvesting equipment should be inspected regularly to ensure blades are not chipped, which may indicate that foreign material has entered the finished product.

- When products are mechanically harvested, a system to detect foreign objects (e.g., a metal detector calibrated with 2.5 mm ferrous, 3.5 mm nonferrous and 3.5 mm 316 stainless steel at least twice per shift) should be implemented.

Cut height should be determined and verified to ensure substrate and/or roots are not accidentally harvested.

For products that include roots (living plants), the harvesting and packaging should be done in a way to reduce risk, including limiting to the extent practicable, the likelihood that water/ nutrient solution will contact the edible leaf.

Depending on the type of leafy green, the environment in the harvesting area may be cooler than in the growing environment. This supports product quality by slowing respiration and decreasing the growth potential of spoilage organisms. Some organisms, such as *Listeria* can actively grow in colder environments and may have a competitive advantage, if present.

Harvested product may be immediately packaged, may be further processed on site, or may be temporarily stored in bulk as work-in-process (WIP).

Work-In-Progress (WIP) Considerations

The use of work-in-progress is predominantly driven by product quality and shelf-life considerations. However, managing sanitation of containers and capturing accurate lot information will help to minimize food safety risks. The following are recommendations for those using WIP and should be adapted based on the operation's risk assessment.

Storage containers should be clean and not serve as a source of contamination.

- WIP containers should be cleaned and sanitized once emptied, before new WIP is added. This helps to establish a 'clean break' and limit the possibility of spreading contamination between lots.

WIP should be clearly identified, including traceability information.

- To the extent practicable, limit combining WIP with product from different lots, since if an issue occurs, this will expand the scope of a recall.
- Rework, if used, must also be tracked and will also expand the scope of a recall if mixed with different lots.

CEA operators should be mindful of time and temperature of WIP. Although this is primarily a quality consideration, if contamination has occurred, food safety risks can increase with increased time and/or temperature.

- Particular attention should be paid to the depth of the WIP product, ensuring that product in the middle of the container can be cooled quickly.

The use of WIP should be minimized to the extent practicable. Depending on the product, its shelf life, and the company's business decisions, best practice would be to use WIP product within 24 hours.

PROCESSING

Some but not all CEA operations further process harvested produce. If further processing occurs, these activities would require compliance with the Preventive Controls Rule (FDA, 2015b), including adherence to Good Manufacturing Practices (21 CFR 117 Subpart B), the development and implementation of a Food Safety Plan including a hazard analysis and the identification of risk-based preventive controls (21 CFR 117 Subpart C), and, if ingredients are being sourced from other companies (e.g., shredded carrots, salad dressings, etc.), compliance with the Supply Chain Program requirements (21 CFR 117 Subpart G).

Wash water control

If CEA facilities are chopping,slicing, or cutting produce and are using water to wash or convey the product, the water must not serve as a source of cross-contamination. Operations should carefully review FDA guidance when considering how to validate the efficacy of antimicrobials in their wash water systems. Although the use of antimicrobials in wash water does not serve as a "kill step", their importance in reducing the risk of cross contamination frequently results in its designation as a Preventive Control/Critical Control Point in food safety plans. (See p. 35 and beyond in FDA, 2018a.)

Supply Chain Program

If "kits" are prepared using ingredients from other suppliers, the CEA operation has an obligation to ensure the safety of those ingredients. This is generally outside the scope of this guidance document and may involve other regulatory agencies (e.g., USDA FSIS). Readers are referred to FDA guidance for additional information. (See p. 32 in FDA, 2018a.)

PACKAGING

Packaging material must be safe and suitable for direct contact with fresh produce. CEA companies should check with local and state regulations specific to packaging materials (e.g., PFAS).

The packaging must be stored in a manner to minimize the potential for cross-contamination, away from pests, dust, dirt, water, or other sources of contamination.

Verification systems should be in place to ensure the correct packaging is used for the correct product, including labeling for allergens, if applicable.

The nature of the packaging material is generally selected with quality in mind (e.g., the appropriate oxygen transfer rates based on the respiration of the product). However, CEA producers should be mindful of food safety considerations.

Companies should be aware of the levels of oxygen present as the product reaches the end of shelf life, especially under moderate conditions of temperature abuse, to be confident that anaerobic conditions that favor the growth of Clostridium botulinum are not present (Toivonen et al., 2009). If product is packaged under low oxygen conditions and/or is flushed with nitrogen, CEA producers can consider conducting a research project on retains that evaluates the packaging conditions over the product shelf life.

FINISHED PRODUCT STORAGE

Finished product, and especially work-in-progress (WIP) storage areas must be kept clean, dry, and properly maintained.

Temperature control is primarily implemented for quality reasons but can also serve to slow the growth of human pathogens, if present.

Domesticated animals and pests must be excluded from fully enclosed buildings including storage areas.

Finished product storage areas, including coolers and warehouses must be suitable in size, construction, and design to facilitate proper cleaning and maintenance activities.

The flow of traffic, including foot and equipment, should be evaluated to minimize introduction of contamination into storage areas, especially if produce is not in enclosed packaging.

Storage areas must have adequate drainage and minimize potential for contamination from drip or condensate from equipment such as air exchanges, heaters, or humidity management.

Finished product storage should have well marked, dedicated areas for product being held pending test results, or otherwise ineligible for shipment. Software systems should be set up to prevent shipping these products, as applicable, and personnel should be trained on positive release controls (e.g., when inventory is or is not eligible to be shipped).

SANITATION

Regardless of regulatory requirements, sanitation of tools, equipment, and the facility is a critical component of a food safety program for any kind of food producer, including those in the CEA industry. Although this document focuses primarily on microbiological hazards, if allergens are present, sanitation is also instrumental in limiting allergen cross contact. CEA operations may benefit from having newer equipment compared to other types of produce operations, however the uniqueness and complexity of the system, combined with the rapid growth of the industry, could result in the installation of equipment and systems that are challenging to clean, such as tubes and piping.

Regulatory Requirements

The Produce Safety Rule requires that farms "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 to protect against contamination of covered produce" ((112.123(d)(1)).

The Good Manufacturing Practices that apply to facilities required to register with FDA (e.g., CEA operations engaged in further processing) have more specific sanitation requirements (117.35).

Further, if a registered facility determines that a sanitation preventive control is needed to manage an identified hazard (e.g., post process contamination from *L. monocytogenes*), the requirements—and documentation—have more rigor ((117.135(c)(3)).

Neither rule requires validation of sanitation. However, verification is required by the PC rule when a sanitation preventive control is necessary. Still, CEA producers should have assurance sanitation is effective (e.g., through appropriate use of detergents, equipment, sanitizers, etc.). Verification of sanitation and the implementation of a strong environmental monitoring program is recommended within CEA operations and is discussed in detail later in this section.

Cleaning and Sanitizing: Best Practices for CEA Producers

There are two components to sanitation: cleaning and sanitizing. **Cleaning** is the physical removal of dirt and debris, and this often supports the physical removal of microorganisms as well. **Sanitizers** serve to reduce the numbers of microorganisms that remain on a cleaned surface. It is important to note that sanitizing is not effective on surfaces that are not clean.

Because of availability of labor and the nature of the operation, sanitation is often performed by operators or contracted individuals in CEA environments. In this instance, it is critical to ensure that sanitation is part of the overall production plan. In some companies, there may be separate sanitation crews for certain parts of the system, such as the irrigation or harvest equipment and/or packing line. Other companies may have nightly sanitation crews. Regardless of who is responsible for sanitation, the following practices should be employed:

Follow the industry standard 7 steps of sanitation (Burnett, 2017).

Work with your chemical provider to determine which detergents and sanitizers are compatible with the materials to be cleaned, appropriate concentrations and contact times, and for sanitizers, if a rinse is required.

Use cleaning chemicals in accordance with their label instructions.

Develop standard operating procedures of sanitation to follow proper application of detergents and sanitizers for cleaning and sanitization.

Color-coding of sanitation tools can help identify the areas each tool can be used. For example, brushes used to clean drains should never be used on a food contact surface and should be colored-coded differently from tools approved for use on food contact surfaces.

Document sanitation efforts, as needed.

- Both the PSR and PC rule require records demonstrate compliance with sanitation requirements.

Growing Area Sanitation

Water storage and conveyance systems including tanks, gutters, towers, ponds, and columns should be cleaned and sanitized each time water is emptied from the system. Water changes are typically driven by maintenance or nutrition/fertigation needs. Depending on the system, this could happen as frequently as every two weeks to on an "as needed" basis. Each operation should evaluate if the equipment can be cleaned in place (CIP), or if components are better cleaned out of place (COP).

Growing trays/boards/gutters should be cleaned and sanitized after each use. If automated wash systems are used, their efficacy should be evaluated through visual observation, as well as verification using ATP or microbial

indicators, as discussed later. They should be replaced at the point that they are no longer cleanable, which can be assessed visually (e.g., gauges, cracks, scratches) as well as with ATP and/or APC results as discussed in the verification section.

Structures/equipment should be cleaned depending on the operation. CEA producers will want to determine and document the appropriate cleaning frequency for various pieces of equipment, such as racking systems and walls. This could be based on manufacturers' recommendations, which would be enhanced by using environmental monitoring data to identify areas in need of more frequent attention.

Harvesting and Processing Sanitation

If tools such as shears are used for manual harvest, these should be cleaned at a frequency adequate to reduce the likelihood of cross-contamination. For example, they could be dipped in sanitizers solution on a regular basis, such as once per hour, or upon change in product or finished product lot number.

- The concentration of the sanitizer solution would need to be monitored to determine when a new solution would be appropriate.

Totes, bins, and other materials used for harvest and/or processing should be cleaned and sanitized when product types or lots change, and whenever they appear dirty or may otherwise be contaminated.

Harvesting and processing equipment, including conveyors and other surfaces that touch product, should be cleaned and sanitized at least daily, and more often based on product build-up.

- If different products, SKUs, or lot numbers are harvested during a day or shift, companies should consider the value of sanitation between products to establish a clean break (Krug et al., 2020).

If automated equipment is used for harvesting, the operation should carefully evaluate how sanitation is conducted to limit the opportunities of microbial growth within the equipment that could compromise food safety. This includes verifying the effectiveness of sanitation through an environmental monitoring program (UFPA, 2018).

Some CEA companies may conduct further processing (e.g., cutting greens), and sanitation considerations are like those of harvesting.

If spin dryers are used, extra attention should be given to sanitation and sanitation verification given that, depending on the manufacturer and age of equipment, these can be difficult to properly clean and sanitize.

Periodic Equipment Cleaning (PEC)

Sanitation of product contact surfaces is critical to food safety and helps establish a clean break. However, product contact surfaces are not the only areas that need attention. The frequency of sanitation in other parts of the operation should be conducted on a risk-based schedule, the Master Sanitation Schedule, which can be developed and refined based on verification activities including environmental monitoring (discussed later). There may be instances where food contact surfaces are cleaned and sanitized daily, but also deserve extra attention on a less frequent, but still periodic, basis. This typically involves disassembly of more complex equipment and systems. Guidance is available that identifies some pieces of equipment (e.g., conveyors) that may be found in CEA operations (CFS, 2018).

Within the CEA production environment, other pieces of equipment and areas that should be considered, and for which the operation should determine the frequency of enhanced cleaning, include:

- **Racks and carts**
- **Forklifts**
- **Tables used to transport produce**
- **Machinery used to move growing trays**
- **Seeding and sowing equipment**
- **Germination rooms**
- **Gutter and tray cleaning areas where green waste accumulates**
- **Transition and gas exchange piping from the growing areas to other areas at colder temperatures where condensation often accumulates**
- **Transition walls and wet areas that separate the growing area from the processing/packing rooms**

When a CEA farm has more than one piece of similar or identical equipment that is part of a PEC program, it should be readily identifiable so that the Master Sanitation Program can determine when a specific piece of equipment was last cleaned in the rotation.

What's a Zone 1/food contact surface, and where should the EMP begin?

As the name implies, a food contact surface is any surface that touches the food. However, the uniqueness of CEA systems warrants elaboration on surfaces that could be considered Zone 1/ FCS. This has implications for environmental monitoring, since most environmental monitoring plans indicate the number of swabs per zone. Although many surfaces, beginning with the seeding process, could be considered Zone 1, this does not mean that they provide equally valuable locations for environmental monitoring. Environmental monitoring should be focused in areas that present the greatest risk for *Listeria* harborage and subsequent product contamination, based on the hygienic design of the equipment or surface, temperature, water/humidity conditions, and sanitation. Many CEA operations will focus their EMP from the harvest area onward. This is because the growing area is typically warmer where *Listeria* may not be very competitive with other microflora. The cooler environments of harvest and storage are amenable to *Listeria* persistence and growth compared to other existing microbes. Harvest equipment that is difficult to clean may allow *Listeria* to establish a niche that could result in product contamination. The nature of the EMP, if any, earlier in the production process should be defensible. Some areas that might be considered Zone 1, and should be evaluated as potential environmental monitoring sites include:

- **Growing containers, racks, gutters, if the produce touches the surface**
- **Overhead areas where condensate may collect and drip on exposed plants/product**
- **Conveyors and belts for harvested or processed product**
- **Bins or storage containers for WIP**
- **Devices that measure or weigh product for packaging**

SANITATION VERIFICATION AND ENVIRONMENTAL MONITORING PROGRAMS

The most important aspect of verification is using the results to drive your program moving forward. Verification tools should be used to identify areas that warrant additional attention. Typically, an operation identifies areas and surfaces based on four zones. Zone 1 is the product contact surface. Obviously, it is critical that this area is clean and sanitized. Zone 4 represents outer areas (e.g., lockers, office areas) that are unlikely to serve as direct sources of contamination but may reveal routes by which pathogens can enter the more sensitive parts of the area. Zone 2 represents areas adjacent to Zone 1 (e.g., legs of equipment that are close to conveyors) and Zone 3 indicates other parts of the production area that are further from Zone 1 (e.g., floors, drains).

If your operation handles allergens, the food safety plan may also include testing for allergens as a verification step. Additional resources on allergen controls are listed under the 'Scope of Guidance' section within this document.

The chart on the opposite page summarizes the different analytes/techniques and provides general information on when and how they can provide value to an operation.

The hygienic state of the CEA operation can be verified in a number of ways. The feedback should help inform the evaluation of risk in different parts of the farm. Each operation should consider the nature of risk at each part of the system and the opportunities for mitigations and select and implement the following appropriate verification approaches.

1. Commissioning or qualifying a new farm, facility, or piece of equipment.

Before production begins in a new operation, the food safety team should evaluate that the operation and equipment is clean and will not serve as a source of product contamination.

If equipment is newly purchased, it should not have any microbiological buildup. Cleanliness can be verified by testing for indicator organisms such as aerobic or total plate count, or another broad category of organisms.

Table 4 Different analytes/techniques for sanitation verification and environmental monitoring and their various uses and benefits

Analyte	What it tells you	When to use	Where to use	Cautions/Notes
ATP	Cleaning verification; presence of organic material	Post cleaning, to get an instant read on effectiveness of cleaning	Hard-to-reach areas, corners, etc.	Is not correlated with and therefore not a replacement for microbiological testing
Aerobic/Total plate count	Sanitation verification; general hygienic state	Initial stages of routine post-harvest environmental monitoring (can be done before and after sanitation to understand the reduction); equipment facility qualification	Equipment, to help inform the cleaning frequency for a master sanitation schedule	Not a substitute for *Listeria* spp. testing; results take days (versus ATP which is instant)
Salmonella	Pathogen presence	Based on risk assessment; possibly after construction	Dry areas, areas of high risk (e.g. input storage, seeding, germination)	All *Salmonella* are pathogens; hold product if testing product or FCS
Listeria monocytogenes	Pathogen presence	Routine testing is discouraged; consult experts before speciating	In rare circumstances, with expert input, as an advanced investigative step, or in finished product	Pathogen; hold product if testing product or FCS
Enterobacteriaceae (EB)	General hygienic state; subset of APC	Similar to *Salmonella* testing; more appropriate for Z1/FCS testing	Similar to *Salmonella* testing	Sometimes used as an indicator for *Salmonella* but is not an indicator for *Listeria*

If equipment was in prior use (by the company, or was purchased from another entity), it should be carefully evaluated, especially if it had been modified resulting in rough edges or areas where liquid or product could accumulate. Equipment should be disassembled and should be visually clean. If it is not, the food safety and sanitation teams should consider how the equipment should be cleaned prior to use and how it should be cleaned on an ongoing basis to prevent accumulation of materials/ debris and potential contamination issues.

- The operation should apply the principles of Sanitation Verification below to any used equipment prior to bringing it online and should consider the value of testing for *Listeria* spp. for harvest equipment or other parts of the production system.
- Depending on the nature of the prior use, it may be appropriate to ensure the equipment is free of allergen residues as well.

A new CEA production area should be verified to be clean prior to start up. The prior history of the space (new construction vs repurposed space) should be considered when determining the appropriate areas to test, number of tests/swabs, and the target analytes. This includes microbiological testing such as APC/TPC, *Listeria*, and *Salmonella*.

- *Salmonella* contamination has been associated with construction events and can be "released" into the production environment (FDA Good Manufacturing Practices Study, 2004), and increased levels of *Listeria* have been associated with recent renovations (Dunn et al., 2021).

2. Assessing potential risks associated with substrate, seed, and inputs.

Depending on the risk evaluation and risk reduction strategies associated with inputs (substrate, seed, and other inputs), conducting environmental monitoring for hazards of concern or indicators in storage, seeding, and/or germination areas may be useful.

- If the operation has identified risks associated with inputs and the suppliers are not able to provide adequate assurance of risk management, the CEA operation may choose to swab the input storage area for *Salmonella, Enterobacteriaceae,* or another appropriate organism. Swabbing for *Listeria*, especially in moist areas, could also be considered. Similarly, conducting microbiological monitoring during the early parts of the process (seeding, germination) may give an indication of issues associated with the product or process.
- Testing should be done in areas where there may be dust, spillage, or other events that would allow the operation to identify risks.

3. Routine verification of sanitation.

Whether the CEA operation is covered by the PSR or PC Rule, the nature of the most operations warrant the implementation of an environmental monitoring plan that can assess the adequacy of sanitation and provide assurance that the equipment and tools in the farm do not serve as a source of contamination.

Verification of Cleaning using ATP

Food contact surfaces should be visually assessed to ensure no visible soil, food residue, or other material remains after cleaning. If residue remains, food contact surfaces should be re-cleaned. While the sanitation team should be responsible for identifying areas that need additional cleaning, a food safety team member should provide regular oversight and verification, including occasionally observing the sanitation process (3M, 2019; NECAFS, 2023b).

ATP swabs indicate the presence of organic material (plant tissue, debris, etc.) and should be used as a verification tool after cleaning and before the application of sanitizer.

Each manufacturer provides recommendations on acceptable levels (generally expressed in relative light units/ RLUs), and the operation will want to conduct baseline studies to determine the levels that are achievable in their operation, which might be surface or material specific.

Swabs should focus on Zone 1 product contact surfaces, and target the areas that are most difficult to clean, including:

- **Hard to reach areas**
- **Corners**
- **Areas with bolts and screws**
- **Other areas, including Zone 2 and possible Zone 3, if there are problematic areas that could compromise the product.**

Note that ATP, total plate counts, and specific tests such as *Listeria* spp. cannot be correlated because they measure different things. They each provide unique information and cannot be used in place of one another.

Role of Microbiological Testing in Sanitation Verification

Because ATP results do not correlate with microbiological levels, microbiological testing is also generally used as part of an overall sanitation verification program. Compared to ATP results, which are instantly provided so that re-cleaning can occur immediately, microbiological test results take many hours and up to several days before receipt. This means that product would likely have been produced, and the operation might have had one or more rounds of sanitation between the time a surface was sampled and the test result received. For this reason, companies generally avoid routinely testing product contact surfaces (Zone 1) for pathogens and consult with experts if this seems to be an appropriate step as part of an investigation.

There are several types of microorganisms that can be tested for. Regardless of which tests a company chooses to perform, it is critical that they establish limits and corrective actions prior to starting testing.

Total Plate Count/ Aerobic Plate Count (TPC/ APC)

TPC/APC can provide an overall assessment of the hygienic status of the operation. It generally takes several days to get results, such that an immediate correction is not possible (unlike ATP results, which are instantaneous).

If a CEA operation chooses to include TPC/APC as part of their sanitation verification plan, they should first establish a baseline identifying typical results. These may vary based on the commodity being produced, time of year, and part of the operation. The baseline should inform operational and critical limits, with clear identification of steps to be taken if the limits are exceeded.

Listeria spp.

FDA's Preventive Controls Rule requires registered facilities to evaluate the risk for post process contamination of ready to eat (RTE) foods with environmental pathogens such as *Listeria monocytogenes*.

- Crops that can be consumed without additional processing, including leafy greens and herbs, should be considered RTE.
- Even if the CEA producer is a farm (and does not conduct further processing that would require it to register as a facility with FDA subjecting it to the PC Rule) and is not subject to a regulatory requirement to evaluate and manage *Listeria* risk, the farm should still consider verifying sanitation through a *Listeria* environmental monitoring program.
- *Listeria* are considered ubiquitous in the environment, meaning CEA operations should expect that *Listeria* will occasionally enter the farm by way of people, materials, forklifts, etc. Testing for the group of *Listeria* species in general (as opposed to *monocytogenes* specifically), gives an indication of areas that might serve as harborage points. It also reduces regulatory risk, since these indicators do not necessarily mean that a pathogen is present.
- The sanitation program is critical to ensuring *Listeria* remain transient and are readily removed, and do not establish themselves in the operation.

Unlike most other microorganisms, *Listeria* can grow in cool, damp environments, such as the conditions that might be found during harvesting, storage, further processing, or cold storage areas.

Produce-related outbreaks and recalls associated with the pathogenic strain of the organism, *Listeria monocytogenes*, are generally traced to harborage sites in equipment or in the facility.

- The goal of a *Listeria* environmental monitoring program (EMP) is not only to eliminate the organism, but to identify potential harborage sites, whether due to issues of hygienic design or sanitation, and eliminate them so that the organism cannot find residence there in the future.

In one recall, the pathogen was found on the finished product by a customer and was also found by the farm during routine testing of their rainwater holding tanks. (FDA, 2023a).

- If a company chooses to speciate to determine if a positive on a Zone 1 food contact surface is *L. monocytogenes*, product should be held and not released for distribution. Otherwise, a recall will be necessary.

FDA guidance on managing *Listeria* (FDA, 2017) as well as the United Fresh Produce Associations *Listeria*

management for the fresh produce industry (UFPA, 2018) are both applicable to CEA operations and identify locations where *Listeria* has often been found.

Specific areas that should be part of a CEA operations EMP, based on proximity to growing and harvest areas, traffic flow, and other variables that influence product risk include:

- **Hollow legs**
- **Bolt holes in feet (that are not filled in/ sealed)**
- **Tray cleaning systems**
- **Augers for organic matter**
- **Waste areas, including delivery and return pathways**
- **Electrical boxes**

Salmonella

All *Salmonella* species are considered pathogens. Environmental monitoring for *Salmonella* is most appropriate in dry environments producing low moisture foods (such as chocolate, peanut butter, or dried milk).

- It is rare that a CEA operation would derive substantial value from routinely including *Salmonella* in an EMP.
- Environmental testing for *Salmonella* could be most useful in areas where *Salmonella* risk is highest, e.g., in seed or substrate storage areas, or where those materials may generate dust or particles.

Should a CEA operation choose to include *Salmonella* in their EMP, they should be mindful of holding product while awaiting test results for Zone 1 surfaces, since a positive would otherwise necessitate a product recall.

As noted above, testing for *Salmonella* could be appropriate if there is construction in the operation, or to help assess risk associated with inputs (e.g., seeds, substrate, etc.)

WASTE MANAGEMENT

As discussed in the pest management section earlier in this document, managing waste within the operation is crucial for minimizing potential pest or pathogen related issues. CEA operations should consider both long and short-term storage of waste. Trash cans used within the operation during daily production should be emptied frequently and secured with properly fitting lids to prevent pest access. For larger volumes of waste, such as waste collected over the course of the week, a long-term/high volume storage solution or management strategy should be established. This might include contracting with a waste or composting company (depending on the nature of the waste; organic vs. inorganic) to empty waste storage containers located outside of the facility on a regular basis. Small CEA operations may be able to identify other waste streams, such as farms, that are interested in taking organic waste. Movement of waste throughout the operation should also be mapped. Moving waste containers through higher care or finished product areas should be avoided. Depending on the operation's SOPs, specific protocols should be outlined for cleaning and disposing of waste from areas like trench drains, production towers, and growing ponds.

TRACEABILITY

Consumer-level units should be marked with a traceability-related identifier, such as a use-by, sell-by, or other marking. This should also include a way to determine the farm location.

In the event of an outbreak, consumers generally do not have original packaging. Therefore, CEA operations must retain records relating the traceability lot code with the immediate commercial customer.

Compliance with FDA's traceability recordkeeping requirements will begin in January 2026 (FDA, 2022c). Although the rule applies to a subset of foods (those on the Food Traceability List), many produce RACs, as well as all fresh-cut produce, is subject to the rule. Covered RACs include cucumbers, herbs, leafy greens, melons, peppers, sprouts, tomatoes, and tropical tree fruits (FDA, 2023b).

There is a partial exemption when farms producing FTL foods package the food on the farm such that the packaging of the food remains in place until it reaches the consumer, and the packaging maintains the integrity of the product and prevents subsequent contamination. In this case the labeling must include the complete farm address and business phone number of the farm. Produce packaged in vented containers would likely not qualify for the partial exemption.

Finished Product Testing

Testing CEA produce (or any other commodity) for levels of indicator organisms or the presence of human pathogens can provide a false sense of security (UFPA, 2010). Testing is a tool but is not a control.

The points in the process selected for testing (e.g., germination, growing, harvesting, finished product) should be based on the results of the operations risk assessment and should correlate with the relative risk of the different areas and different processes. Ideally, risks would be managed to prevent contamination, which would obviate the need for testing. Finished product testing can be used as a means of verifying the adequacy of the food safety system, but the statistical relevance of the sampling plan should be well understood. A well designed and well implemented preventive food safety system should yield product with a very low likelihood of contamination. The lower the chance that produce is contaminated, the less likely it is that testing will detect contamination. Statistics do not favor product testing when other controls are in place.

If finished product is tested for pathogens, it is recommended to hold (not ship) the product until acceptable test results are obtained. If produce is tested for indicators, the company should have a rationale for established limits, with clear corrective actions if the limits are exceeded. Whenever an unfavorable test result is obtained, whether for pathogens or indicators, investigation into the root cause should be conducted to reduce the chance the situation will occur in the future. Although some buyers require testing of finished product, growers and their customers should discuss the following questions before beginning a testing program:

1. What is the purpose of testing? Is testing being used to ascertain trends, or for lot acceptance?

2. What is the desired balance between resources aimed at proactive prevention measures compared to resources dedicated to reactive measures such as testing, while also recognizing that better preventive measures result in lower contamination rates, which are less likely to be detected?

3. Has a statistician calculated the percent contamination likely to be detected in the proposed sampling plan?

4. How will testing data be evaluated on an ongoing basis to reveal trends (geographic, seasonal, etc.) to inform risk assessments?

5. Additional resources are available at freshproduce.com/resources/food-safety/sampling-and-testing/ (UFPA, 2021).

SHIPPING AND TRANSPORTATION

CEA operations may or may not be subject to the Sanitary Transportation Rule. Although farms are exempt, if transportation is conducted by a third party (not the farm), the rule applies.

The rule is aligned with industry best practices and requires communication of transportation requirements (sanitation, temperature controls for safety, etc.) by the shipper to the transporter (FDA, 2016b).

Regardless of storage length prior to shipping, sanitary conditions must be maintained throughout storage, transportation, and distribution (Pabst et al., 2019; IFPA, 2022).

Inspect transportation vehicles for cleanliness, odors, and visible dirt, and debris before loading. If needed, the vehicle should be cleaned, or cleaned and sanitized, prior to loading.

If vehicles are used for multiple purposes besides transportation of the CEA producers' products, they should be checked for cleanliness between uses. Should there be any potential food safety risks, such as garbage, debris, off-odors, or other indicators of contamination, then the vehicle must be cleaned and a corrective action documented prior to transporting produce.

Temperature Control

Climate control is an important component of the CEA production model not only for the growth of plants, but also for maintaining post-harvest quality of fresh produce. Some CEA operations may have sophisticated climate control systems which provide the ability to have multi-zone temperature controls for various parts of the facility. The technology of climate control is outside of the scope of this document; however, many resources exist to help CEA operations establish and maintain climate-controlled systems. Cornell University's CEA page has several helpful resources.

For post-harvest handling, the temperature of the commodity is the number one factor in maintaining the shelf-life of the product. Proper temperature of commodities is required through the entire supply chain. Not all commodities require cooling, and in fact, some can be chilling sensitive (UC Davis's Postharvest Center has resources by commodity and topic like chilling injury). Though the FSMA Produce Safety Rule

does not require cooling of produce commodities, some buyers or third-party audits may stipulate that product be kept at specific temperatures.

CEA operations should determine with the relevance of other FSMA regulations such as the Sanitary Transportation Rule or Preventive Controls Rule (FDA 2015b; FDA 2016b). The Preventive Controls rule requires companies to evaluate hazards and identify and implement preventive controls. The rule itself does not specify temperature limits for specific products but expects producers to determine if temperature control is critical in reducing risk of a specific pathogen. As noted previously, this rule applies to CEA operations that are conducting processing operations outside the farm definition.

Strictly speaking, the Sanitary Transportation rule, which applies to many entities in the supply chain (except farms transporting their own goods), also lacks a prescriptive requirement for temperature control. However, the rule references, but does not define, a category of foods for which temperature control is required for safety (called TCS foods). The rule leaves it up to the shipper to determine the appropriate times and temperatures needed to ensure safety.

Another regulatory reference is FDA's model food code, which is adopted and used by most states to govern their food safety authority at retail and foodservice operations. This has the most prescriptive and explicit requirements for temperature control, but it should be noted that the time at each temperature is equally as important. Some foods that are required to adhere to these time-temperature combinations in the retail and foodservice settings include cut melon, cut leafy greens, cut tomatoes) (FDA, 2023c). Many industry members use the Food Code list as the basis for their determinations for TCS foods for the purpose of the Sanitary Transportation rule.

It is important for food safety and quality assurance professionals to understand how each of these regulations apply to the specific activities and commodities produced in each operation, and to be prepared to have conversations with buyers as to why/why not specific temperature management is required (McEntire, 2019).

Managing temperature is less of a food safety issue than it is a quality or plant growth requirement. The following are recommendations for managing temperature and potential food safety impacts:

- CEA operations that are also conducting processing activities (e.g., fresh-cut or manufacturing) should be more aware of the impacts of temperature, especially if the processing areas are cooled. Human pathogens such as *Listeria monocytogenes* can grow, even at refrigeration temperatures, and therefore more vigilance through a robust environmental monitoring program may be warranted.

- If coolers or HVAC systems are utilized, care should be taken to ensure that no condensation is occurring inside the facility which could drip onto food contact surfaces or produce. Pooling water can result from improperly functioning HVAC units, leading to potential risks for cross-contamination if the water were to splash.

- The temperature of post-harvest water (e.g., for rinsing, cooling, crisping, or commodity movement) can also be important to monitor and manage. If the water is more than 10 degrees (F) cooler than the produce, a phenomenon called infiltration can occur in certain commodities. Though not as relevant to leafy greens and herbs which are the focus of this document, CEA producers may also be growing and packing other produce commodities on-site. Cantaloupe, tomatoes, and produce that have an air vacuole inside are more susceptible to infiltration. Infiltration occurs when the temperature differential results in a vacuum which can draw water to the inside of the commodity. Infiltration can be avoided by pre-cooling produce before placing into a water bath, limiting time spent in flumes or wash tanks, and ensuring that the water temperature is not more than 10 degrees cooler than the product.

Research and Outreach Initiatives in CEA

Controlled environment agriculture is a fast-paced and growing sector of the produce industry. Research specifically focused on CEA production practices is underway to fill food safety knowledge gaps that may be unique to this style of agriculture. These projects are just a subset of organizations that have current initiatives in this space that may provide supporting information for the implementation of CEA food safety best practices.

Center for Produce Safety (visit the funded research portion of the website for more info)

USDA Agricultural Research Service

- AmplifiedAg
- Environmental Microbial and Food Safety Laboratory

Northeast Center to Advance Food Safety (NECAFS) Food Safety Resource Clearinghouse (CEA resources)

- Produce Safety in Hydroponic and Aquaponic Operations (topic-based factsheets)

Ohio State Controlled Environment Agriculture Center

FURTHER RESEARCH

Through the initial scoping of this best practices document, and as discussions with industry members progressed, several key research questions were identified. While several projects are currently underway or in the proposal stage, specific research focused on CEA production is currently limited.

1. If seeds are contaminated with human pathogens (e.g., *Salmonella*) at a low level, what is the likelihood that the pathogen is detectable in the finished product?

2. If substrate is contaminated with human pathogens (e.g., *Salmonella*) at a low level, what is the likelihood that the pathogen is detectable in the finished product? How does the pathogen level change over time (e.g., level at emergence of the first leaf, level on the edible portion of the plant pre-harvest, level during the shelf life of the packaged product)?

3. Research to understand major food safety risk profiles (pathogen uptake, survival, growth, and spread) associated with different hydroponic systems (NFT, Deep water culture, ebb and flow, aeroponics, etc.) and identify preventive controls.

4. Novel and practical solutions to prevent pathogen survival, growth, and spread during irrigation water/ nutrient solution reuse and recirculation.

5. During outdoor field operations, *E. coli* O157:H7 has been traditionally associated with leafy greens while *Salmonella* with tomatoes. However, *Salmonella* has been responsible for the majority of the outbreaks and recalls linked to CEA leafy greens to date. Is this simply a coincidence or are there any underlining factors that contribute to this? Research is needed to understand the comparative survival and growth profile of major food-borne human pathogens during CEA leafy green production and storage conditions.

6. Water is often recirculated in CEA systems for efficiency and sustainable use of resources. It is important to develop and validate appropriate treatment systems to prevent the presence and growth of human pathogens and therefore reduce the chances for cross-contamination. Research is needed to understand physiochemical (e.g., turbidity, chemical oxygen demand) and microbiological parameters that can be used by the industry to determine the frequency of or when to change or treat water during production cycle.

7. Many CEA farms maintain warm temperature, high humidity, and use artificial LED lights for plant growth. Research is needed to understand these growth conditions on pathogen survival and growth on leafy greens, and if any of these conditions can be modulated (e.g., special lighting) to inhibit pathogen growth and promote fast pathogen die-offs in the environment and on harvestable plant tissues.

8. Water treatment

- **If UV is limited by particles in water, can coagulation and/or flocculation treatments be designed to improve the efficacy of UV treatment?**
- **What are the appropriate scientific parameters to consider when determining water change schedules, given that turbidity may be due to the accumulation of nutrients without affecting food safety risks?**

9. The relationship between Enterobacteriaceae (EB) and other organisms, namely generic *E. coli* (as relevant to monitoring water quality) and *Salmonella* (as relevant to environmental monitoring) should be evaluated in CEA environments.

RESOURCES

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