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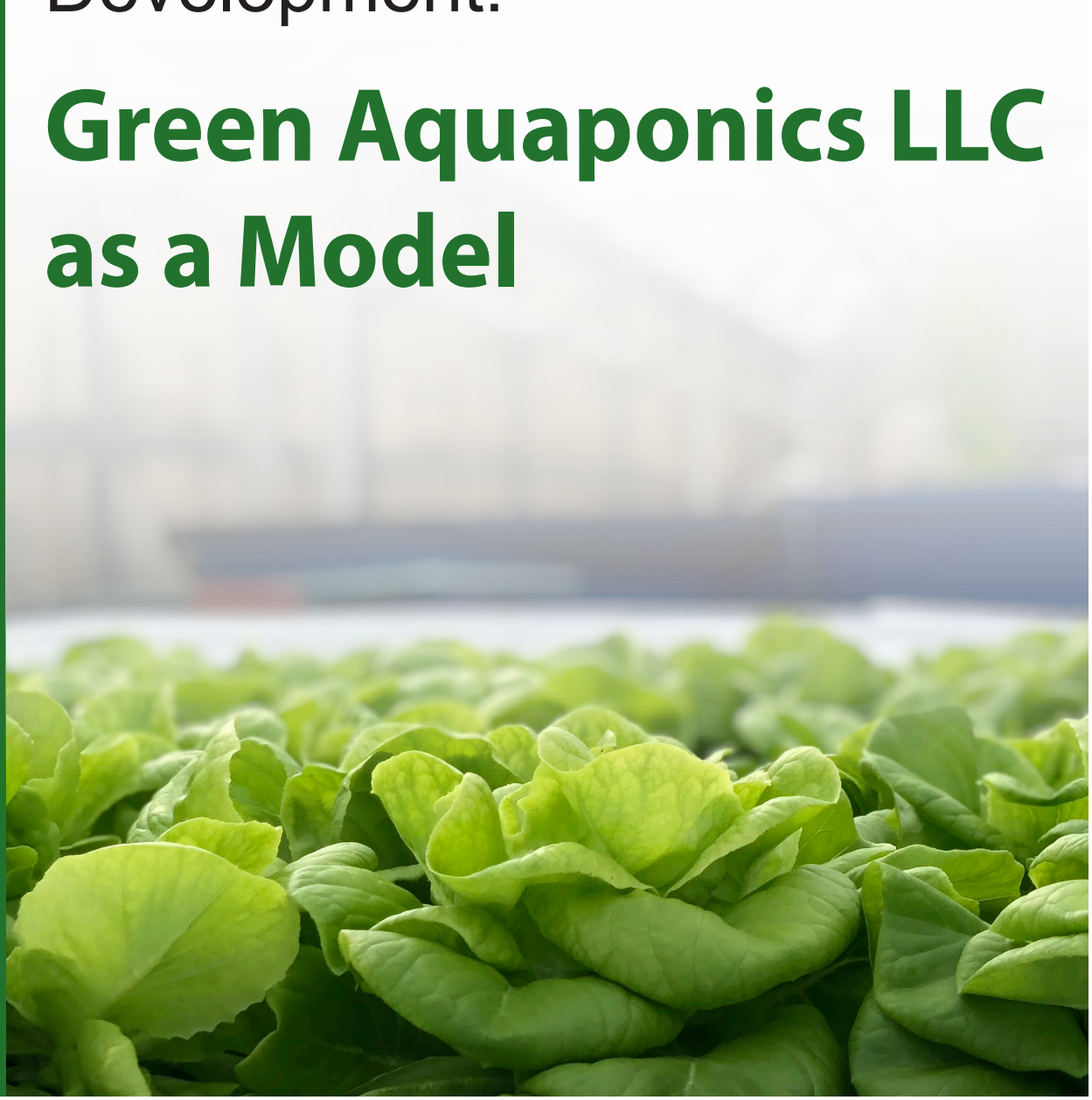
A Guide to the Aquaponics Food Safety Plan Development:

Green Aquaponics LLC as a Model



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School of Food Science
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For Training, Education, Extension, Outreach and Technical Assistance to Enhance Produce Safety

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Mahmoudreza Ovissipour, Assistant Professor and Extension Specialist, Seafood Agriculture Research and Extension Center, Department of Food Science and Technology, Virginia Tech

Barbara Rasco, Professor and Director, School of Food Science, Washington State University

Gleyn Bledsoe, Adjunct Professor, Washington State University

Setareh Shiroodi, Postdoctoral Associate in Food Safety, Seafood Agricultural Research and Extension Center, Virginia Tech

DISCLAIMER: The plan provides an example of best practices. It is for training purposes only and does not represent any specific operation. Development of a food safety plan is site-specific, and plans for each location should be developed separately.

This model includes both required and optional information to illustrate how a food safety plan might be designed under regulations in 21 Code of Federal Regulations (CFR) Parts 112, 117, and 123, associated with the Food Safety Modernization Act (Public Law (PL) 111-353). Conditions and specifications used (e.g., validation information) are for illustrative purposes only and may not represent actual process conditions.

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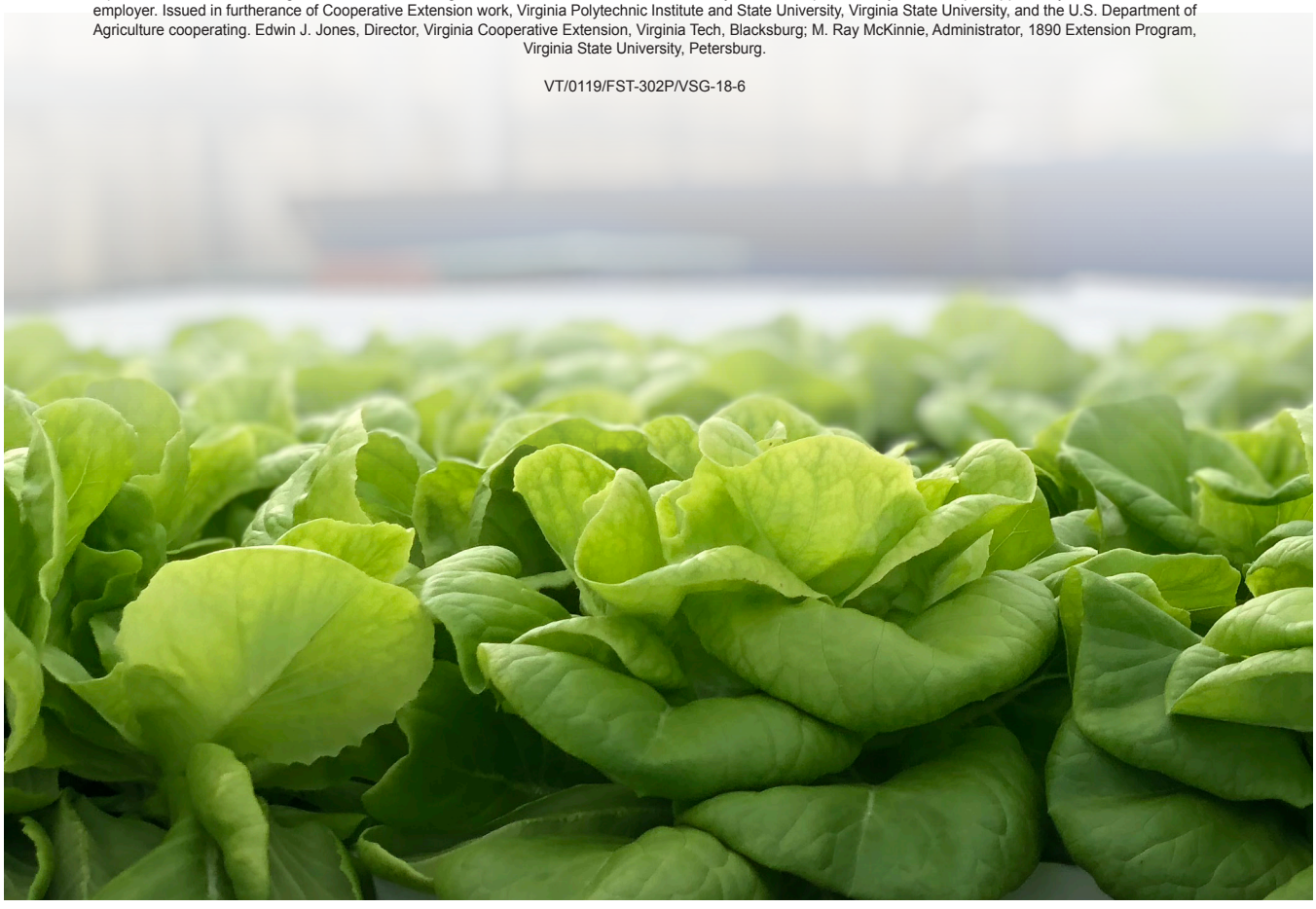

A Guide to the Aquaponics Food Safety Plan Development:

Green Aquaponics LLC as a Model

Company Overview

Green Aquaponics LLC. was established in 2000 as an aquaculture farm in Idaho, first developed for producing fish, specifically male blue tilapia (*Tilapia aurea*) and in 2010, Green Aquaponics coupled its indoor aquaculture system with an indoor fresh produce production unit into an aquaponics system and expanded operations to their Washington facility in Aquatown. This company produces lettuces on rafts in a recirculation system. The aquaculture capacity is 10,000 lb of tilapia per year. The hydroponic area is 12,000 square feet in an indoor production system with an indoor raft system producing approximately 90,000 lb per year presuming a harvestable crop of lettuce every 4 weeks after transplant. The first harvestable fish follow in 9 months and are then harvested monthly based upon market demand. The water source is tested potable well water that feeds the aquaculture section, and after passing through the aquaculture section proceeds through a biofilter converting ammonia to nitrate providing water for irrigating the fresh produce. Water quality entering the produce unit is tested at least monthly to ensure that it meets requirements under the Produce Safety Rule. The light source is partially from natural light plus LED based artificial lighting.

The company sells live fish to local restaurants and whole fish (bled and eviscerated), shipped on fresh water ice, to local distributers and retailers. Lettuce is packed in plastic clamshells or plastic-coated cardboard boxes with ice as needed and then shipped to local distributers.

Product Descriptions

Table 1. Product description for fresh/whole on-ice fish. (See page 2)

Table 2. Product description for live fish. (See page 3)

Table 3. Product description for lettuce. (See page 4)

Product Descriptions Flow Diagrams

Coupled Aquaponic Process Flow Diagram

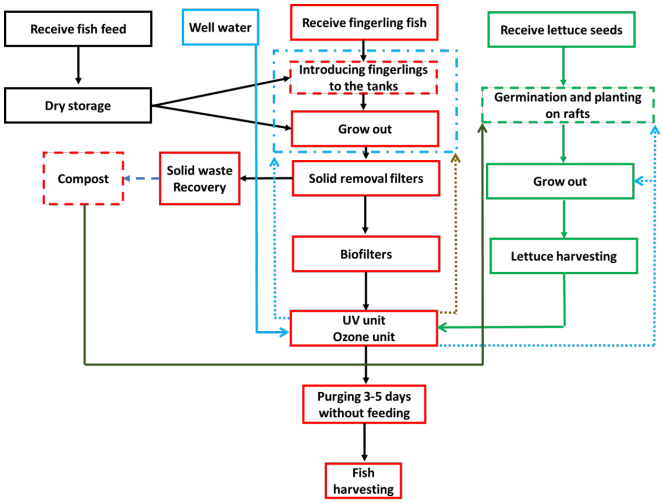

Figure 1. Coupled aquaponic process flow diagram.

Decoupled Aquaponic Process Flow Diagram

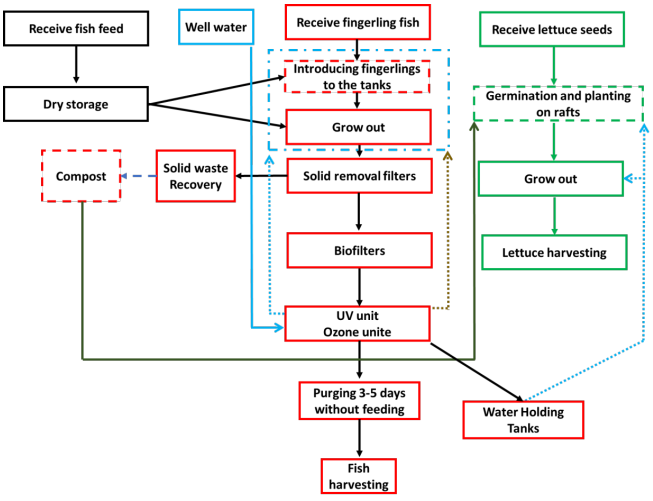

Figure 2. Decoupled aquaponic process flow diagram.

Table 1. Product description for fresh/whole on-ice fish.

Food Safety Plan – Product Description, Distribution, Consumers, and Intended Use	Blue tilapia (*Tilapia aurea*) – Whole on ice
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017
Product Name	Blue tilapia – Fresh, whole on ice
Product Description, Including Important Food Safety Characteristics	
Ingredients	Fish: blue tilapia (*Tilapia aurea*)
Packing Used	Polystyrene boxes (25-lb. net weight fish) with potable water ice. Boxes are sealed with tape having company logo as a tamper-evident feature and have printed lot code, species, weight, date of harvest, and company address information.
Intended Use	Fresh tilapia sold to retailers, restaurants, processors
Intended Consumers	General public, to be cooked prior to consumption
Shelf Life	5-7 days at 37-45 F/3-7 C
Allergens	Fish: tilapia
Labeling Instructions	Keep refrigerated (37-45 F/3-7 C). Contains fish (tilapia) to be cooked prior to consumption.
Other Labeling (as applicable)	Lot number, best use-by date, intact container sealing tape as tamper-evident feature. Species listed (allergen warning).
Storage and Distribution	Keep refrigerated (37-45 F/3-7 C)
Approved: P. Green Signature: *P. Green* Peter Green, Processing Manager	Date: 09.09.2018

Table 2. Product description for live fish.

Food Safety Plan – Product Description, Distribution, Consumers, and Intended Use	Blue tilapia (*Tilapia aurea*) – Live
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017
Product Name	Blue tilapia – Live
Product Description, Including Important Food Safety Characteristics	
Ingredients	Fish: tilapia
Packing Used	Stainless steel fish tanks containing potable well water, with air bubblers or oxygen injectors used during transport as needed. For short-term transport, tanks are filled one-third full. Headspace provides sufficient oxygen for the fish during short hauls. Tanks are sealed with a numbered seal. Accompanying documentation includes lot code, harvest date, number and fish weight, company contact information.
Intended Use	Live tilapia sold to restaurants for consumption by the general public
Intended Consumers	General public, to be cooked prior to consumption
Shelf Life	14 days at 69-77 F (20-25 C) in restaurant aquarium
Allergens	Fish: tilapia
Labeling Instructions	Keep live in freshwater tank; to be cooked prior to consumption
Other Labeling (as applicable)	Lot number, best use-by date, intact container seal as tamper-evident feature
Storage and Distribution	Keep live and use within 2 weeks
Approved: P. Green Signature: *P. Green* Peter Green, Processing Manager	Date: 09.09.2018

Table 3. Product description for lettuce.

Food Safety Plan – Product Description, Distribution, Consumers, and Intended Use	Lettuce, buttercrunch
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017
Product Name	Lettuce, buttercrunch
Product Description, Including Important Food Safety Characteristics	
Ingredients	Lettuce, buttercrunch
Packing Used	Individually packaged in plastic clamshells with a lot code and tamper-evident tape seal or plastic-coated boxes for retail sale. Potable water ice added as needed to maintain quality.
Intended Use	Fresh lettuce sold via retailer as whole heads
Intended Consumers	General public
Shelf Life	7-10 days after packing under refrigeration
Allergens	Water source is also used for fish. Allergen risk unlikely, but lettuce retailers should consider labeling the products as being produced in a system in which tilapia are also grown. Lettuce and tilapia are processed in the same facility with operations physically segregated by walls and separate entries to reduce the risk of allergen cross-contact.
Labeling Instructions	Keep refrigerated (40-50 F/4-10 C). Allergen warning: Processed in an aquaponics facility that raises fish (tilapia).
Other Labeling (as applicable)	Lot number, best use-by date, intact tape on clamshell as tamper-evident feature, company contact information
Storage and Distribution	Refrigerated (40-50 F/4-10 C)
Approved: P. Green Signature: *P. Green* Peter Green, Processing Manager	Date: 09.09.2018

Fish and Plants Processing Flow Diagram

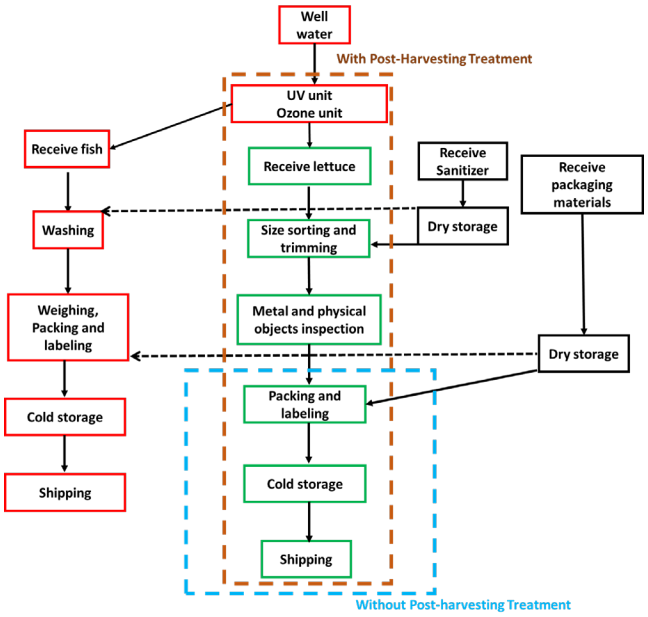

Figure 3. Fish and plants processing flow diagram.

Process Descriptions

Fish Production

Receive tilapia (fingerlings from fish fingerling producers): Healthy blue tilapia (Tilapia aurea) fingerlings are transported in trailers equipped with oxygenation tanks from a licensed fish breeder. Fingerlings are inspected for quality, lack of disease, and presence of parasites before a lot number is assigned. Health certificates are received for each lot of fingerlings. Health certificates are required from the suppliers as a condition of purchase.

Receive fish feed: Fish feed is received in 50-pound bags from fish feed producers, and the bags are checked for any physical defects. Date of feed production, date of expiration, lot number, feed ingredients, and the chemical composition of the feeds are also checked for nutritional quality and for any unanticipated allergens. We inspect our feed producer annually as part of our approved supplier program. Feed comes with a certificate of analysis. Feed is sent out quarterly for analysis for pathogens (e.g., *Salmonella* spp.) and allergens (e.g., soy, wheat) and for nutrient profile. We do not use medicated feed or animal drugs in the cultivation of the tilapia in this facility.

Fish feed storage: All fish feed bags are stored at a temperature below 90 degrees Fahrenheit (F)/32 degrees Celsius (C) in a storage room, where they are covered and kept on pallets off the floor, isolated from the lettuce production unit and lettuce processing area. To avoid cross-contamination, feeds with allergenic components are stored together and labeled as such. Fish feeds containing plant- and animal-based proteins that might be allergenic are segregated and stored in a separate storage area. A trained employee conducts daily pest control inspections of the feed storage room, and pest control is contracted to an outside firm that visits the facility on a monthly basis.

Well water: Well water is treated with UV or ozone prior to entering the fish tanks. Median well water temperature is 50 F/10 C. The water samples are tested every week for total coliforms (<4 CFU/ml) and presence or absence of *Escherichia coli*, *Listeria monocytogenes*, *Salmonella* spp., and *Vibrio* spp. The intensity of UV light is checked weekly to monitor remaining bulb life following the manufacturer's recommendations. If ozone is used, the concentration is tested daily using a calibrated, dissolved ozone monitor. Surface fouling of the UV system is monitored daily, and fouling is removed as needed.

Fish culturing: Fish fingerlings are introduced into previously cleaned tanks containing clean potable water from the well. Well water is tested on a continuous real-time basis for temperature, pH, and oxygen. Daily tests are conducted for oxygen reduction potential; weekly tests are conducted for *E. coli*, *Salmonella* spp., and *Listeria monocytogenes*; monthly tests are conducted for ammonia, nitrite, and sulfide; and yearly tests are conducted for arsenic. Tanks are monitored every day for dead fish, and if there are any, they are removed from the tanks, the loss is recorded, and a visual exam for signs of disease is conducted. Fish feeding is conducted using an automatic fish feeder to eliminate the human error of overfeeding, missed feedings or cross contamination (from human to feed and from human hands to lettuce after touching the feed). Feeding is controlled because overfeeding results in more solid waste and higher ammonia concentrations. Workers pose a risk of introducing fungal disease to the fish from their hands. During handling of the fish, workers are required to wash and sanitize their hands. Workers are also required to wear the personal protection equipment necessary for the job.

Farm animals, specifically dogs, are kept away from fish tanks and out of the production areas. Cultivation areas are covered with netting to reduce the risk of contamination from birds and bird predation.

Solids removal filters: After fish tanks, there are solid removal filters to remove fish fecal matter and uneaten feed from the aquaculture system. These solid materials are collected and then further processed into compost.

Solids waste recovery: Solid waste materials (e.g., dead fish) are recovered and are acid-hydrolyzed to a liquid form and used to provide nutrients to plants. Hydrolysate could be added to irrigation water and passed through a UV treatment system to inactivate any pathogens that may be present prior to its use. Fish hydrolysate can also be used as a fertilizer for plants grown in soil off-site as it meets the criteria for organic fertilizer. In addition, the waste can be digested through anaerobic digestion.

Biofilters: Biofilters convert ammonia to nitrite, and nitrite to nitrate. Nitrate is 400 times less toxic to fish than ammonia and can be utilized by plants as a nitrogen source. *Nitrosomonas* spp. convert ammonia to nitrite, and *Nitrobacter* spp. convert nitrite to nitrate. It takes 4.5 grams of oxygen to convert 1 gram of ammonia to nitrate. The survival of the two types of bacteria in biofilters depends on maintaining a proper dissolved oxygen level (at least 2 mg/L), pH (above 7), alkalinity (50-100 mg/L $CaCO_3$), and temperature (around 68 F/20 C). Hence, oxygen is provided by a U-tube or a blower into the biofilter system. Water recovered off the biofilters is passed through a UV unit or treated with ozone and then used for irrigating the lettuce. Water quality is tested to ensure that it meets chemical and microbial quality (i.e., turbidity, aroma, appearance) before being used for irrigation. Testing is conducted so water is shown to meet water quality standards for irrigation water under 21 CFR Part 112.

Fish depuration: Tilapia are transferred to separate tanks and held in fresh water for three to five days to empty gut contents and to remove any benthic off-flavors from the flesh that may have resulted from cultivation in a recirculating system. Microbial quality of the water is tested. Fresh water in the tanks is exchanged every two days or more frequently if fish stocking density is high.

Fish harvesting: Fish are harvested directly from the tanks with a net by workers wearing clean uniforms, clean gloves, and personal protective equipment. Fish are transferred to either the live shipments tanks or to totes for transport to the whole fish processing room. The processing room is air conditioned to a temperature of less than 50 F/10 C and held under positive pressure relative to the outside to reduce the risk of environmental airborne microbial contamination. Sanitary potable ice is on hand to keep the fish cold if ambient temperatures are high.

Live fish processing and shipping: Fish are taken from the tanks with nets that have a load cell to measure weight, and they are transferred directly to the live hold tanks for shipment. Live hold tanks are cleaned and sanitized following each shipment and inspected prior to filling for odor or indications that the tanks have not been adequately cleaned. Tanks are affixed with a numbered seal that is recorded and sent in advance to the customer for verification upon arrival; this is part of our traceability and food defense programs. If air or oxygen is needed for any shipment, food-grade gas that has been sourced from an approved supplier is used. Any fixtures or devices used for aeration are cleaned and sanitized prior to each shipment. Temperature during shipment is controlled to maintain fish quality.

Whole fish processing and shipping: Fish are received from the production unit and are handled by workers who wear gloves, clean uniforms, hair coverings, and personal protection equipment. Fish are stunned (if required by customer), their throats are cut, and they are allowed to bleed out in slush ice made from potable water. Otherwise, tilapia are killed by placing them into slush ice and then bled out. Fish are immediately processed if possible — within 24 hours as long as fish temperature can remain at 39.2 F/4 C or below. Fish are eviscerated by hand by workers who have been trained in good manufacturing practices, and sanitation and hygiene practices, as per the requirements of 21 CFR Part 117 with their training documented.

Washing: Eviscerated fish are washed in potable water containing a sanitizer (chlorinated well water [2-4 ppm] or other appropriate treatment) to reduce the number of environmental bacteria on the surface of the fish. Fish are weighed (25 pounds +/- 5% allowance) and then layered with clean potable iced water into clean polystyrene boxes that have clean plastic liners. Neither the boxes nor the liners can have signs of damage or contamination. Both the boxes and the liners are from approved suppliers.

Ice: Ice is made from potable well water in a commercial ice maker and is stored in sanitary containers and handled with sanitary utensils. Any ice that is not in immediate use is held in a covered tote with a drain so that water can run out to a floor drain. Any ice transferred to a tote is used within 24 hours.

Packaging materials: Packaging materials (plastic liners, polystyrene containers) are inspected for signs of odor, damage, or contamination. Label tape is inspected for logo. Print stock for labeling containers is inspected to see that it meets technical specifications and shows no visible signs of contamination. These materials are part of our supply chain program, and the distributor is visited on an annual basis. Materials come with a letter of guarantee that they are appropriate for food contact and they meet our technical specifications per contract. Packaging materials are stored covered in an area segregated from the food processing or production areas and away from where any allergenic materials or chemicals are stored. Temperatures should not exceed 110 F /44 C.

Weighing, labeling, and shipping – whole fish: Boxes are labeled with lot code, species, production location, address, contact information, and harvest date, and then shipped on ice to the market. Temperature is monitored during shipment with a thermometer, a data logger, or the presence of adequate ice at receiving.

Lettuce Production

Receive lettuce seeds: Lettuce seeds are received from an approved supplier and germinated in sanitized single-use rockwool starter cubes in potable well water.

Germination and planting on rafts: After germination, the lettuce plants are placed into holes in rafts to receive water and nutrients from the aquaculture section of the operations. Rafts are made from polystyrene and are cleaned and sanitized after every use.

Plant nutrients: Supplemental liquid nutrient mix is purchased from an approved supplier who provides a certificate of analysis annually. These nutrients are added in cases where nutrients in the water from the aquaculture tanks are not sufficient, and signs of nutrient deficiency are present. Plant nutrients are transferred to the growing tanks using a metering pump with clean and sanitized tubing. Plant nutrients are stored in a secured area away from cultivation and processing operations.

All handling of plants in the produce production area are conducted by workers who maintain the best personal hygiene practices. Workers wear clean uniforms and head covers and use disposable gloves to reduce the risk of cross-contamination. They are trained as required under 21 CFR Parts 112 and 117, with their training documented. Worker refresher training is provided at least annually; training for seasonal workers is provided at the beginning of the season or anytime when a deficiency is noted. Biosecurity measures are maintained in the growing area by use of hand and foot dips containing sanitizer. Farm animals, specifically dogs, are kept out of the produce production areas.

UV or ozone unit – plant production: Water is passed through a UV unit or ozonated after use in the fish rearing tanks and prior to irrigating lettuce. Either UV or ozone sanitizes the water and reduces risk of accumulation of pathogenic microorganisms. The water samples are tested every week for total coliforms (<4 CFU/ml) and for presence or absence of *Escherichia coli, Listeria monocytogenes, Salmonella* spp., and *Vibrio* spp. The intensity of UV light is checked weekly to determine remaining bulb life following the manufacturer's instructions. Surface fouling of the UV system is monitored daily, and fouling is removed as needed. Ozone level is checked using a calibrated, dissolved ozone monitor.

Lettuce harvesting: Sanitation during harvesting is critical. All workers wear disposable gloves, hair coverings, sanitizable footwear, and clean uniforms during the harvesting process, and they enter the processing area with sanitized footwear. Workers change into sanitized footwear in the processing room; this footwear is allowed only in the processing room. Any worker in this area has received relevant training under 21 CFR Parts 112 and 117 with training documented. Harvesting is conducted by removing the raft from the water tanks. When removing the rafts, workers must ensure that the water from the bottom of the rafts and the plant roots does not splash in a manner that it could contaminate the edible portion of plants on other racks.

The rafts are transported to the processing area on a clean and sanitized handcart. The roots of the lettuce plants are cut off from the underside of the raft using clean and sanitized knives. Lettuce is then transferred to previously sanitized bins. These bins are transferred to the packing area where the lettuce is rinsed in potable water and drained. This area contains a stainless steel sink with hot and cold potable water, a stainless steel drainage table, and a packing table. A separate hand-wash sink with hand sanitizer is available in this processing area. The water source is well water that has been sanitized (chlorinated [2-4 ppm]) before being used to wash the lettuce. Foot dips containing sanitizer are at the entrance, and hand dips are located in the harvest area.

Dewatering and draining: Lettuce is placed on a clean and sanitary stainless steel table for draining.

Size sorting and trimming: The washed lettuce is sorted based on size, and rejected produce that does not meet quality standards is discarded, or it is collected, segregated in a separate bin, and sent to a local farm for use as animal feed.

Ice: Ice is made from potable well water in a commercial ice maker and is stored in sanitary containers and handled with sanitary utensils. Any ice that is not in immediate use is held in a covered tote with a drain so that water can run out of the container to a floor drain. Any ice transferred to a tote or smaller container is to be used within 24 hours, after which it is discarded.

Packaging materials: Packaging materials (plastic clam shells, fiberboard boxes, polyethylene liners, adhesive seals, logo sealing tape) are inspected for signs of damage or physical contamination. These materials are part of our supply chain program, and the distributor is visited on an annual basis. Materials come with a letter of guarantee that they are appropriate for food contact and they meet our technical specifications as per the contract. Packaging materials are stored covered in an area segregated from the food processing or production areas and away from any allergenic materials, dust, moisture, or chemicals. Temperatures should not to exceed 110 F/44 C.

Metal and physical objects inspection: After sorting, lettuce is visually inspected by workers for the presence of foreign matter, including raft or rockwool residue.

Packing: Lettuce is packed in plastic clamshells and labeled with the common name of the produce, production date and location, lot code, best-by date, storage and use instructions, and allergen warning (produced in an aquaponics facility that also produces tilapia). Clamshells are sealed with a tamper-evident adhesive seal. For wholesale distribution, fiberboard boxes are lined with a gas-permeable polyethylene case liner and filled with 24 count per carton. The lot code is applied, and the carton is sealed with company logo tape.

Cold storage: The products are stored in a cold room (34-36 F/1.5-3.0 C) until transferred to the market that is to occur within two days.

Shipping: Lettuce is shipped refrigerated to the market by common carrier. First in, first out (FIFO) rules will apply to distribution. The vehicle used for shipment is evaluated so that it meets the requirements for sanitary transport (21 CFR Parts 1 and 11).

Note: The fish and plant production are physically separated so the fish are not in contact with the plants for biosecurity and allergen control. In addition, the fish processing and packing room is a separate room from the lettuce processing and packing room to reduce the risk of cross-contamination. Individuals are not to move between the two areas unless they follow the sanitation, phytosanitary, and biosecurity procedures in place to reduce cross-contamination.

Note: The facility has restrooms located on the farm and in each processing room. They are equipped with hand-washing sinks, sanitizers, and disposable paper towels, which meets the requirements of 21 CFR Parts 117 and 123.

Hazard Analysis

Fish Culturing

Fish Culturing in Coupled System

Table 4. Food safety plan for fish culturing in a coupled aquaponic system. (See page 10)

Fish Culturing in Decoupled System

Table 5. Food safety plan for fish culturing in a decoupled aquaponic system. (See page 15)

Fish Processing

Live Fish

Table 6. Food safety plan for live fish processing. (See page 20)

Whole Fish

Table 7. Food safety plan for whole fish processing. (See page 25)

Plant Processing

Lettuce Cultivation

Table 8. Food safety plan for lettuce cultivation. (See page 31)

Table 4. Food safety plan for fish culturing in a coupled aquaponic system.

Food Safety Plan – Hazard Analysis Coupled Aquaponics System	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce in a coupled system
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Receiving fish fingerlings	B	Biological hazard: microbial contamination such as *L. monocytogenes, Aeromonas hydrophila*	X		History of outbreak	Supply chain control, approved supplier third-party audit Microbial testing of fish as part of health certificate sent with each lot of fish	X	
	C	Chemical hazard: antibiotics		X	Unapproved antibiotics unlikely for fish			X
	P	Physical hazard: foreign materials		X	Unlikely for fish fingerlings			X
	A	Allergen contamination		X	No allergens introduced besides fish itself			X
	E	Economic fraud: wrong species		X	Fresh water fish are not histamine-forming species; biotoxin risk is low			X
	I	Intentional contamination		X	Risk low because likely toxicants would affect fish health or behavior	Supply chain control program		X

Table 4. Food safety plan for fish culturing in a coupled aquaponic system. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Introducing fingerlings to tank	B	Biological hazard: microbial contamination		X	Fish from biosecure area and not released unless cleared for stocking by animal health professional	Biosecurity program		X
	C	Chemical hazard: animal drugs or unapproved chemicals		X	Fish from biosecure area and not released unless cleared for stocking by animal health professional	Biosecurity program		X
	P	Physical hazard: foreign materials		X	Easily removed if present			X
	A	Allergen contamination		X	No allergens introduced			X
	E	Economic fraud		X	Species substitution	Species identification verified when fingerlings received		X
	I	Intentional contamination		X	Fish transferred under monitored conditions, making risk low			X
Fish culturing or grow out	B	Biological hazard: microbial contamination and growth: *A. hydrophila,* *L. monocytogenes,* *Vibrio* spp., *Salmonella* spp., Pathogenic *E. coli*	X		History of outbreak	Sampling and providing tests results from third-party lab Sampling from water, fish, and feed Water meets specifications required under Part 112 Pest control program Personnel hygiene training program Restrict access of warm-blooded animals to the farm	X	

Table 4. Food safety plan for fish culturing in a coupled aquaponic system. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
	C	Chemical hazard: antibiotics	X		Possibility of harmful residues in fish flesh	Antibiotics are used under proper supervision and only in fish removed from production Fish are not to be fed therapeutic feeds in production tanks	X	
	P	Physical hazard: debris		X	Debris would settle in tank			X
	A	Allergen contamination		X	No allergens introduced			X
	E	Economic fraud		X				X
	I	Intentional contamination	X		Contamination of feed or water	Feed is stored in locked storage area with controlled access Water source is monitored and access controlled; 24-hr video surveillance	X	
Solids removal filters	B	Biological hazard: bacterial contamination and growth		X	Wet, solid materials are a source of nutrients for environmental bacteria, including pathogens	Correct management of filter operation and Good Manufacturing Practices (GMPs); collecting and removing solids from the system critical for fish quality		X
	C	Chemical hazard		X	No chemical addition at this step			X
	P	Physical hazard		X	Physical hazards removed at this step			X
	A	Allergens contamination		X	No allergens introduced from filter operation			X
	E	Economic fraud		X	Low risk of a hazard that would affect food			X
	I	Intentional adulteration		X	At a discharge point; low risk			X

Table 4. Food safety plan for fish culturing in a coupled aquaponic system. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Biofilters	B	Biological hazard: microbial contamination		X	Contamination in biofilters possible	GMPs control spurious microbial growth		X
	C	Chemical hazard: contamination	X		Ammonia levels high If biofilters do not work appropriately, the ammonia level increases and could be harmful to fish	Collect samples from biofilters to measure ammonia, nitrite, and nitrate as part of GMPs A fish health factor but not a food safety risk		X
	P	Physical hazard: foreign materials		X	Biofilter should not be clogged	Regular checking of the biofilter to remove any solid materials		X
	A	Allergen contamination		X	No allergens introduced			X
	E	Economic fraud		X	Low risk for a food safety hazard			X
	I	Intentional adulteration		X	Enclosed and difficult to contaminate			X
UV or ozonated discharge to hydroponic unit	B	Biological hazard: microbial contamination and growth	X		UV system verified by manufacturer and operated according to their instructions; system has been validated on-site for microbial control If ozone used, concentrations are monitored and controlled to standards for irrigation water under Part 112	Daily check on operation of UV system for fouling, and weekly monitoring of light intensity Monitoring of ozone concentration	X	

Table 4. Food safety plan for fish culturing in a coupled aquaponic system. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
UV or ozonated discharge to hydroponic unit (cont.)	C	Chemical hazard: contamination		X	No chemicals used at this step	GMPs		X
	P	Physical hazard: foreign materials		X	Unlikely	Settled out or removed by filters		X
	A	Allergen contamination		X	No allergens introduced	GMPs control water distribution system No cross-connections		X
	E	Economic fraud		X	Low-quality system functionality easily detected; does not pose direct food safety threat			X
	I	Intentional contamination		X				X
Purging fish – transfer fish to purge tanks	B	Biological hazard: microbial contamination and growth		X	Potable water used	Routine water testing program in place		X
	C	Chemical hazard: contamination		X	Potable water used	Routine water testing program in place		X
	P	Physical hazard: foreign material		X		Visual detection and removal		X
	A	Allergen contamination		X	No allergens introduced	Fish are not fed during purging or transfer		X
	E	Economic fraud		X				X
	I	Intentional contamination: access to fish		X	Fish are held in secured area	Control access to approved individuals only		X

Table 5. Food safety plan for fish culturing in a decoupled aquaponic system.

Food Safety Plan – Hazard Analysis Decoupled Aquaponics System	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce in decoupled system
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Receiving fish fingerlings	B	Biological hazard: microbial contamination such as *L. monocytogenes, A. hydrophila*	X		History of outbreak	Supply chain control, approved supplier, third-party audit	X	
	C	Chemical hazard: antibiotics		X	Unapproved antibiotics unlikely for fish			X
	P	Physical hazard: foreign materials		X	Unlikely for fish fingerling			X
	A	Allergen contamination		X	No allergens introduced			X
	E	Economic fraud		X	Wrong species Fresh water fish are not histamine-forming species; biotoxin risk is low	Supply chain control, approved supplier, third-party audit		X
	I	Intentional contamination		X	Low risk because likely toxicants would affect fish health or behavior	Supply chain control program		X

Table 5. Food safety plan for fish culturing in a decoupled aquaponic system. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Introducing fingerlings to tank	B	Biological hazard: microbial contamination		X	Fish are from biosecure area and not released unless cleared for stocking by animal health professional	Biosecurity program		X
	C	Chemical hazard: animal drugs or unapproved chemicals		X	Fish are from biosecure area and not released unless cleared for stocking by animal health professional	Biosecurity program		X
	P	Physical hazard: foreign materials		X	Easily removed if present			X
	A	Allergen contamination		X	No unique allergens introduced			X
	E	Economic fraud		X	Species identification verified			X
	I	Intentional contamination		X	Fish transferred under monitored conditions, making risk low			X
	I	Intentional contamination	X		Contamination of feed or water	Feed is stored in locked storage area with controlled access Water source is monitored and access controlled 24-hr video surveillance		X
Solids removal filters	B	Biological hazard: bacterial contamination and growth		X	Wet, solid materials are a source of nutrients for environmental bacteria, including pathogens	Correct management of filtration system and GMPs; collecting and removing solids from the system is critical for fish health and product quality		X

Table 5. Food safety plan for fish culturing in a decoupled aquaponic system. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Solids removal filters (cont.)	C	Chemical hazard		X	No chemicals added			X
	P	Physical hazard		X	Debris would be removed at this step			X
	A	Allergen contamination		X	No allergens introduced			X
	E	Economic fraud		X				X
	I	Intentional adulteration		X				X
Biofilters	B	Biological hazard: microbial contamination and growth		X	Microbial contamination with pathogens possible	GMPs control growth of spurious microorganisms; if filter is contaminated, it is taken off-line		X
	C	Chemical hazard: ammonia		X	If biofilters do not work appropriately, the ammonia level increases and could be harmful to fish; could lead to the proliferation of harmful microbes	Collecting samples from biofilters to measure ammonia, nitrite, and nitrate as part of GMPs. This is primarily a fish health and product quality issue		X
	P	Physical hazard: solid materials		X	Biofilter should not be clogged. Filter would remove some foreign material	Regular checking of the biofilter to remove any solid materials		X
	A	Allergen contamination		X	No allergens introduced			X
	E	Economic fraud		X	Would not pose a food safety risk			X
	I	Intentional adulteration		X	Unlikely in a closed system	Operation of biofilters would likely be impacted quickly if toxins were introduced		X

Table 5. Food safety plan for fish culturing in a decoupled aquaponic system. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
UV or ozonated discharge to hydroponic unit	B	Biological hazard: microbial contamination and growth	X		UV or ozone systems installed to reduce microbes to target levels, (i.e., to agricultural water standards)	Daily check on operation of UV system for fouling, and weekly monitoring of light intensity Monitor concentration of ozone in water	X	
	C	Chemical hazard		X	No chemicals introduced			X
	P	Physical hazard		X	No debris introduced			X
	A	Allergen contamination		X	No allergens introduced			X
	E	Economic fraud		X	Low-quality system functionality easily detected; does not pose direct food safety threat	Daily and weekly checks for light intensity and ozone levels		X
	I	Intentional adulteration		X	UV and ozone generators are closed systems			X
Purging fish – transfer fish to purge tanks	B	Biological hazard: microbial contamination and growth	X		Treated or potable water used	Routine water testing program in place		X
	C	Chemical hazard		X	No chemicals introduced			X
	P	Physical hazard		X	Debris, if any, removed at later steps			X
	A	Allergen contamination		X	No allergens introduced			X
	E	Economic fraud		X	Step is to eliminate gut contents and improve flesh quality			X

Table 5. Food safety plan for fish culturing in a decoupled aquaponic system. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Purging fish – transfer fish to purge tanks (cont.)	I	Intentional contamination: access to fish		X	Fish are held in secured area Controlled access for approved individuals only			X

Table 6. Food safety plan for live fish processing.

Food Safety Plan – Hazard Analysis Decoupled Aquaponics Systems	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Gas (oxygen or air)	B	Biological hazard		X	Contamination of pressurized gas unlikely			X
	C	Chemical hazard	X		Gas is food-grade Contamination of pressurized gas unlikely	Supply chain controls, certificate of analysis		X
	P	Physical hazard		X	Gas is filtered			X
	A	Allergen contamination		X	No unique allergens introduced			X
	E	Economic fraud		X	Gas substitution unlikely			X
	I	Intentional adulteration		X	Pressurized cylinders are closed and secured			X
Tanks	B	Biological hazard: microbial contamination and growth		X	Live hauls are short; temperature kept cool	GMPs		X
	C	Chemical hazard: chemical contamination		X	Fish are transferred in clean water; no chemicals are added except infused gas			X

Table 6. Food safety plan for live fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Tanks (cont.)	P	Physical hazard		X	Physical hazards would settle out in tank			X
	A	Allergen contamination		X	No unique allergens introduced			X
	E	Economic fraud		X	Transportation step for fish of known species			X
	I	Intentional adulteration		X	Tanks are sealed with a numbered seal. Access during transit unlikely			
Receive fish for processing from purge tanks	B	Biological hazard: microbial contamination and growth such as *L. monocytogenes*, *E. coli*, *Salmonella*	X		History of outbreak	Sampling and third-party microbial analysis from fish meat and water Proper fish handling and minimized cross-contamination	X	
	C	Chemical hazard: antibiotics, pesticide		X	Unapproved chemical use	For pest control, no chemicals should be used inside facility; biological pest control should be applied No animal drugs used in fish production		X
	P	Physical hazard: foreign materials		X	Unlikely	Unlikely to have foreign objects in fish, but would be visually apparent and then removed		
	A	Tilapia fish allergen	X					X

Table 6. Food safety plan for live fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Receive fish for processing from purge tanks (cont.)	E	Species substitution		X		Fish species controlled within facility at receiving step; only fish cultured at the facility are processed at this facility		X
	I	Intentional adulteration	X		Tanks are secured	Internal inventory control and monitoring, including video surveillance Reduce risk for contamination of water used by securing source and controlling access		X
Weigh using load cell in net; transfer fish to live tank for shipment	B	Biological hazard: microbial contamination		X	Process is short and conducted under refrigerated conditions	Refrigeration and sanitation SOPs maintained		X
	C	Chemical hazard: unapproved chemicals		X	Only approved chemicals used for cleaning and sanitizing	Sanitation SOPs maintained		X
	P	Physical hazard: foreign material		X	Easily removed			X
	A	Allergen contamination		X	No unique allergens introduced			X
	E	Economic fraud: fish are inaccurately weighed		X	Unlikely, and would not pose a food safety threat	Load cell is calibrated and operators properly trained to take and record weights		X
	I	Intentional contamination		X	Transfer step with minimal handling			X
Label	B	Biological hazard: microbial contamination	X		Fish are handled at this step and could become contaminated	Sanitation and GMP programs to reduce risk of contamination, and short shipment		X

Table 6. Food safety plan for live fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Label (cont.)	C	Chemical hazard: allergens	X		Fish contain allergens	Labeled as containing fish allergens and with species name	X	
	P	Physical hazard			Any foreign material that might be harmful would be visible and easily removed	Visual inspection		X
	A	Tilapia fish allergen	X		Fish allergen labeling is required	Allergen labeling statement needed	X	
	E	Species and net weight		X	Proper species ID and net weight on package	GMPs and technical specifications followed	X	
	I	Intentional adulteration	X			Tamper-evident feature on live tanks (unique seal) and lot code for traceability in case of a recall	X	
Ship	B	Biological hazard: microbial growth		X	Temperature control needed by monitoring ice level	Short shipment; fish on adequate amount of ice maintained, and ice level and fish temperature at customer receipt documented		X
	C	Chemical hazard: contamination		X	Live tank sealed; any oxygen or air used is food-grade	Tank integrity ensured Food-grade gas use monitored by GMPs		X
	P	Physical hazard: foreign material		X	Live tank sealed, so contamination unlikely	Visual inspection		X
	A	Allergen contamination: tilapia fish allergen		X	Container sealed	Allergen labeling statement, fish species, and common name on shipping container		X

Table 6. Food safety plan for live fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Ship (cont.)	E	Economic fraud: species ID and net weight		X	Container sealed	Proper species ID and net weight on packages		X
	I	Intentional adulteration		X		Tamper-evident feature on tank (unique seal) and lot code for traceability in case of a recall Package integrity maintained during shipment; shipment rejected if seal missing, number incorrect, or package damaged		X

Table 7. Food safety plan for whole fish processing.

Food Safety Plan – Hazard Analysis Decoupled Aquaponics Systems	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Packaging	B	Biological hazard		X	Packaging has a heat step during manufacture; no recycled paper is used	Physical inspection on receipt		X
	C	Chemical hazard: chemical contamination	X		Packaging must be food-grade	Supply chain control program; letter of guarantee	X	
	P	Physical hazard		X	Debris, foreign matter	GMP; physical inspection on receipt		X
	A	Allergen contamination		X	No allergenic materials used	Supply chain control program		X
	E	Economic fraud		X	Safety issue not likely to result from inferior materials	Supply chain control program		X
	I	Intentional adulteration		X	Materials are in sealed containers	Sealed packaging stored in secure location		X
Ice	B	Biological hazard: microbial contamination	X		Microbially contaminated water	GMP; use only tested potable water that meets drinking water standards	X	
	C	Chemical hazard: chemical contamination	X		Chemically contaminated water	GMP; use only tested potable water that meets drinking water standards	X	

Table 7. Food safety plan for whole fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Ice (cont.)	P	Physical hazard: foreign material		X	Physical debris	GMP; debris would be detected visually and removed; if small metallic debris, would be rinsed off during process or removed by filtration		X
	A	Allergen contamination		X	Not likely to be present in well water			X
	E	Economic fraud		X	Water from secured private well			X
	I	Intentional contamination		X	Water from secured private well			X
Receive fish from purge tank for processing	B	Contamination with *L. monocytogenes*, *E. coli*, *Salmonella* spp. Microbial growth	X		History of outbreak Processing temperature (50 F or less) will reduce risk of microbial growth	Sampling and third-party microbial analysis from fish meat and water Proper fish handling and minimized cross-contamination. Verify proper processing environment temperature	X	
	C	Antibiotics, Pesticides		X	No unapproved chemical use	No antibiotics or animal drugs used For pest control, no chemicals should be used inside facility; biological pest control should be applied		X
	P	Foreign materials		X	Unlikely	Visual inspection and removal		X
	A	Tilapia fish allergen	X		No unique allergen introduced at this step	No unique allergen introduced at this step		X
	E	Species substitution		X	Unlikely because only one species processed at facility	Fish species controlled within facility at receiving step; only fish cultured here are processed at this facility		X

Table 7. Food safety plan for whole fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Receive fish from purge tank for processing (cont.)	I	Intentional adulteration		X	Unlikely; step monitored and access controlled	Internal inventory control and monitoring, including video surveillance		X
Bleed and eviscerate	B	Microbial contamination and growth		X	Processed under sanitary conditions and with potable water	Sanitary conditions are maintained; fish at cold temperature; viscera promptly separated from fish and disposed of		X
	C	Chemical contamination		X	Unlikely; only potable water used at this step	No unapproved chemicals are used in facility Water is potable		X
	P	Foreign material		X	Unlikely; fish have already been washed to remove any debris in next processing step	Would be visible and easily removed		X
	A	Allergen		X	No unique allergens introduced at this step			X
	E	Economic fraud		X	Unlikely to pose food safety hazard; trained individuals perform this step	Technical specifications on grading and cuts are met		X
	I	Intentional adulteration		X	Unlikely; process is monitored	Operation monitored; later steps would remove contamination		X
Washing	B	Microbial contamination: *E. coli*, *L. monocytogenes*	X		History of outbreak	Sanitizing the water with chlorine or other approved sanitizer; daily water sampling and testing for chlorine or other sanitizer as part of sanitation program	X	
	C	Chemical contamination		X	No unapproved chemicals used	Water is filtered and potable		X

Table 7. Food safety plan for whole fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Washing (cont.)	P	Foreign material		X	Filtered, potable water used	Water is filtered and potable		X
	A	Tilapia fish allergen	X		No unique allergens introduced at this step	No unique allergens present in processing facility		X
	E	N/A		X				X
	I	Intentional adulteration	X			Reduce risk for contamination of water used		X
Weighing, pack, ice, label	B	Biological hazard: microbial contamination and growth	X		Fish are handled by people at this step Ice could be contaminated Bins or packaging could be contaminated	Sanitation and GMP programs to reduce risk of contamination		X
	C	Chemical hazard: contamination	X		No chemicals used at this step	Appropriate GMPs		X
	P	Physical hazard: foreign material		X		Any foreign material that might be harmful would be visible and easily removed		X
	A	Allergen contamination: tilapia fish allergen	X		Fish is a recognized allergen	Fish are allergens and should be labeled as allergens Species and common names on package Allergen labeling statement	X	
	E	Economic fraud: species and net weight		X	Proper species ID and net weight must be on package Cultivated fresh water fish pose little safety risk from species substitution	GMPs and technical specifications followed Only one species grown in facility		X

Table 7. Food safety plan for whole fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Weighing, pack, ice, label (cont.)	I	Intentional adulteration	X			Tamper-evident feature on package (unique sealing tape) and lot code for traceability in case of a recall	X	
Store on ice	B	Biological hazard -microbial growth	X		Ice could be contaminated	Potable water and clean totes used; sanitation Standard Sanitation Operating Procedures (SSOPs) FIFO stock rotation and temperature monitoring		X
	C	Chemical hazard: contamination		X	Ice could be contaminated	Potable water and clean totes used		X
	P	Physical hazard: foreign material		X	Debris could be present in ice	Ice made from potable water and held under sanitary conditions Any debris would be visible and could be removed		X
	A	Allergen contamination		X	Allergen introduction unlikely	Container is sealed		X
	E	Economic fraud		X	Species mislabeled	Only one type of fish grown in facility		X
	I	Intentional adulteration		X	Contaminated ice	Ice kept in secure area with controlled access		X
Ship	B	Biological hazard: microbial growth		X	Temperature control needed by monitoring ice level	Short shipment; fish on adequate amount of ice		X
	C	Chemical hazard: contamination		X	Container sealed	Package integrity ensured		X
	P	Physical hazard: foreign material		X	Container sealed	Visual inspection		X
	A	Allergen contamination: tilapia fish allergen		X	Container sealed	Readable and prominent allergen labeling statement; fish species and common names on shipping container		X

Table 7. Food safety plan for whole fish processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Ship (cont.)	E	Economic fraud		X	Container sealed	Proper species ID and net weight on package		X
	I	Intentional adulteration	X			Tamper-evident feature on package (unique seal) and lot code for traceability in case of a recall Package integrity ensured during shipment		X

Table 8. Food safety plan for lettuce cultivation.

Food Safety Plan – Hazard Analysis Decoupled Aquaponics Systems	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Packaging	B	Biological hazard: microbial contamination		X	Packaging has low risk of contamination during manufacture and is inspected on receipt for damage; no recycled content in boxes	Physical inspection on receipt for damage and odor; all packaging must be sealed		X
	C	Chemical hazard: chemical contamination	X		Packaging must be food-grade	Supply chain control, letter of guarantee	X	
	P	Physical hazard: foreign material		X	Debris, foreign matter	GMP, physical inspection on receipt; if present, shipment rejected		X
	A	Allergen contamination		X	No allergenic materials used in manufacture	Supply chain control program		X
	E	Economic fraud		X	Safety issue not likely to result from inferior materials	Supply chain control program		X
	I	Intentional adulteration		X	Materials in sealed containers	Materials stored in secure location with limited access		X

Table 8. Food safety plan for lettuce cultivation. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Nutrient mixes	B	Biological hazard: microbial contamination		X	Nutrient mixes are treated to reduce microbial load during manufacture by filtration or heating	Supply chain program, certificate of analysis, inspection at receipt		X
	C	Chemical hazard: chemical contamination	X		Nutrient mix must be food-grade	Supply chain program, certificate of analysis	X	
	P	Physical hazard: physical		X	Liquid material	Supply chain program Containers with foreign materials rejected		X
	A	Allergen contamination		X	Formulations not likely to contain allergens	Supply chain program, letter of guarantee		X
	E	Economic fraud		X	Fraud not likely to cause food safety concern but could affect plant growth	Supply chain program, letter of guarantee		X
	I	Intentional adulteration	X		Addition of nutrients into large volume of water poses a risk; disgruntled employees	Nutrients stored in secure area with limited access Tight inventory control Use only by trained and trusted employee Food defense program	X	
Ice	B	Biological hazard: microbial contamination	X		Microbially contaminated water	GMP, use tested potable water that meets drinking water standards	X	
	C	Chemical hazard: chemical contamination	X		Chemically contaminated water	GMP, use tested potable water that meets drinking water standards	X	

Table 8. Food safety plan for lettuce cultivation. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Ice (cont.)	P	Physical hazard: foreign material		X	Physical debris	GMP, debris would be visually detected and removed; small metallic debris would be rinsed off during processing or removed by filtration		
	A	Allergen contamination-		X	Not likely in well water			X
	E	Economic fraud		X	Water from secured private well			X
	I	Intentional adulteration		X	Water from secured private well	Limited access to well		X
Receive lettuce seed	B	Biological hazard: microbial contamination such as *L. monocytogenes*, *Salmonella* spp. *E. coli*	X		History of outbreak	Supply chain control, approved supplier third-party audit	X	
	C	Chemical hazard: pesticide residues		X	Unapproved pesticides not used. Seed from approved suppliers Periodic analysis for verification Letter of guarantee		X	
	P	Physical hazard: foreign materials		X	Unlikely	Foreign materials do not cause any food safety concern when seeds are used for germination and not eaten as is		X
	A	Allergen contamination		X	Fish and lettuce production physically segregated	GMPs		X

Table 8. Food safety plan for lettuce cultivation. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Receive lettuce seed (cont.)	E	Economic fraud		X	Lettuce seed purchased from approved supplier	Supply chain control program		X
	I	Intentional adulteration	X		Seeds from approved supplier who is inspected and audited annually	Supply chain control program	X	
Germination of seeds on rafts	B	Biological hazard: microbial contamination and growth	X		Pathogens and spoilage microbes could grow on rafts, plants, or in water	Monitor water quality in GMPs Observe for presence of microbial growth or plant disease		X
	C	Chemical hazard: chemical contamination	X		Unapproved chemical use	Maintain proper GMPs (water chemistry) and sanitation SOPs		X
	P	Physical hazard: foreign material		X	Debris from rafts or tanks	Any debris would sink or be easily removed		X
	A	Allergen contamination: allergen introduction		X	No unique allergens added at this step Germination media, seeds, and nutrients are allergen-free	Fish and lettuce cultivation operations are physically segregated		X
	E	Economic fraud		X	Not likely that substitution of seeds nutrients would pose a food safety risk	Letters of guarantee, supply chain program		X

Table 8. Food safety plan for lettuce cultivation. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Germination of seeds on rafts (cont.)	I	Intentional contamination	X		Germination system contaminated	System closely monitored; biosecurity maintained		X
Lettuce grow out on rafts	B	Biological hazard: microbial contamination and growth	X		Water, nutrients, and plant tissue can support microbial growth	Water is sanitized prior to use with UV light or ozone Facility is kept clean and sanitary Operators look for signs of disease	X	
	C	Chemical hazard: unapproved chemicals		X	Cultivation conditions are carefully controlled Water chemistry monitored	GMPs		X
	P	Physical hazard: foreign materials		X	Any debris would be removed at a later step	GMPs		X
	A	Allergen contamination		X	Fish and lettuce production physically segregated; no containers or utensils are transferred between fish and lettuce production areas	GMPs		X
	E	Economic fraud		X	Not likely to occur; not likely to pose food safety hazard			X

Table 8. Food safety plan for lettuce cultivation. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Lettuce grow out on rafts (cont.)	I	Intentional adulteration: contaminants introduced into water system	X		Cultivation conditions are carefully controlled and monitored	24-hr video surveillance	X	
Lettuce harvesting	B	Biological hazard: microbial contamination such as *L. monocytogenes, E. coli, Salmonella* spp., *Vibrio* spp.	X		History of outbreak	Use previously sanitized harvesting tools and gloves, and proper hand-washing practices to prevent any cross-contamination Trained workers employ best hygiene practices	X	
	C	Chemical hazard: pesticide residues	X		GMPs make pesticide use unlikely	Pesticides should not be used in aquaponic systems and are banned from this facility		X
	P	Physical hazard: raft residue, metal fragments	X		Possible metal and raft residue into the lettuce	Metal detection by visually checking lettuce and removing any metal and residue during harvesting; later rinse step to remove debris	X	
	A	Allergen contamination: allergen transfer		X	Harvest conditions are carefully controlled	GMPs Fish and plant operations physically segregated Workers from aquaponics section not permitted to handle lettuce unless they follow sanitation and allergen control procedures		X
	E	Economic fraud		X	Not likely; no food safety hazard anticipated			X

Table 8. Food safety plan for lettuce cultivation. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Lettuce harvesting (cont.)	I	Intentional adulteration	X		Harvest conditions are carefully controlled and monitored	No individuals work alone in harvesting and production areas 24-hr video surveillance. No personal items or chemicals are permitted in harvest area		X
Cut lettuce from raft and place into bin	B	Biological hazard: microbial contamination	X		Drip from plants could contain microbes; bins could be contaminated	GMPs have lettuce plants not draining onto each other Bins and utensils are cleaned, sanitized, and stored off the ground	X	
	C	Chemical hazard: chemical contamination		X	No chemicals used in process	GMPs in place to control hazard		X
	P	Physical hazard: foreign material		X	Any introduced debris would be large enough to visually remove	GMPs in place to control hazard		X
	A	Allergen contamination: allergen transfer		X	Harvest conditions are carefully controlled	GMPs Fish and plant operations physically segregated Workers trained in sanitation and allergen control procedures		X
	E	Economic fraud		X	Nothing at this step likely to create a food safety hazard			X
	I	Intentional adulteration		X	Harvest conditions are carefully controlled and monitored	No individuals work alone in harvesting and production areas 24-hr video surveillance No personal items or chemicals permitted in harvest area		X

Table 9. Food safety plan for lettuce processing.

Food Safety Plan – Hazard Analysis Decoupled Aquaponics Systems	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

(1) Ingredient/ processing step	**(2) Identify potential food safety hazards introduced, controlled, or enhanced**		**(3) Do any potential food safety hazards require a preventive control?**		**(4) Justify your decision for column 3**	**(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls**	**(6) Is preventive control applied at this step?**	
			Yes	**No**			**Yes**	**No**
Receive lettuce into processing area	B	Biological hazard: microbial contamination: *L. monocytogenes,* *E. coli,* *Salmonella* spp.	X		History of outbreak	Maintain good hygiene in facility. Workers trained in hygiene practices and activities monitored Microbial analysis from lettuce and water Appropriate separation between fish and lettuce production units to reduce risk of microbial contamination and ensure biosecurity	X	
	C	Chemical hazard: unapproved chemicals		X	Only approved chemicals used in facility; these are properly handled by trained employees Chemicals are not stored in processing area	GMPs and sanitation control program		X

Table 9. Food safety plan for lettuce processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Receive lettuce into processing area (cont.)	P	Physical hazard: foreign materials	X			During planting and growing lettuce, there is a possibility of transferring metal and raft materials to the lettuce Visual exams and rinsing provide controls		X
	A	Allergen contamination		X	No allergen introduction likely at this step Processing conditions are carefully controlled and monitored	GMPs. Fish and plant operations physically segregated		X
	E	Economic fraud		X	Nothing at this step likely to pose a food safety hazard			X
	I	Intentional adulteration	X		Processing conditions are carefully controlled and monitored	No individuals work alone in production area 24-hr video surveillance		X
Sort and grade	B	Biological hazard: microbial contamination		X	Processing conditions and worker hygiene are carefully controlled and monitored	Sanitation and GMPs		X
	C	Chemical hazard: chemical contamination		X	Chemicals not used at this step	Sanitation and GMPs		X

Table 9. Food safety plan for lettuce processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Sort and grade (cont.)	P	Physical hazard: foreign materials		X	Unlikely	Visual inspection for any foreign materials		X
	A	Allergen contamination		X	No unique allergens at this step	GMPs		X
	E	Economic fraud		X	Nothing at this step likely to pose a food safety hazard			X
	I	Intentional adulteration		X	Processing conditions carefully controlled and monitored	GMPs		X
Washing and draining	B	Biological hazard: microbial contamination: *L monocytogenes, E. coli*, *Salmonella* spp.	X		History of outbreak	Use sanitizer in wash water. Proper sanitizing of washing and draining area Swab for environmental bacteria as part of verification program	X	
	C	Chemical hazard: improper sanitizer use	X		Correct sanitizers are used at proper concentration	SSOPs, records, and employee training in proper use of sanitizers	X	
	P	Physical hazard: debris		X	Particles are visible and can be removed	GMPs		X
	A	Allergen contamination		X	Processing conditions are carefully controlled and monitored, so introduction unlikely	GMPs		X

Table 9. Food safety plan for lettuce processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Washing and draining (cont.)	E	Economic fraud		X	Nothing likely at this step to pose a food safety hazard			X
	I	Intentional adulteration: contaminated water		X	Processing conditions are carefully controlled and monitored	GMPs		X
Metal and foreign materials inspection	B	Biological hazard: microbial contamination		X	Short process under sanitary conditions	SSOPs		X
	C	Chemical hazard: chemical contamination		X	Sanitizer chemicals used at this step are controlled	SSOPs		X
	P	Physical hazard: metals and debris	X			Visually check the lettuce	X	
	A	Allergen contamination		X	No additives at this step	GMPs		X
	E	Economic fraud		X	Nothing likely at this step to pose a food safety hazard			X
	I	Intentional adulteration		X	Processing conditions are carefully controlled and monitored			X
Packaging and labeling	B	Biological hazard: microbial contamination		X	Sanitation controls	SSOPs		X
	C	Chemical hazard: chemical contamination		X	Low risk of contamination	SSOPs and GMPs		X

Table 9. Food safety plan for lettuce processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Packaging and labeling (cont.)	P	Physical hazard: introduction of foreign material		X	Low risk of introduction; could be seen and removed	GMPs		X
	A	Allergen contamination: warning label	X		Allergen warning label recommended Label lettuce as produced in a facility that also processes fish (tilapia)	GMPs for labeling	X	
	E	Economic fraud		X	Product is properly labeled			X
	I	Intentional adulteration				Label indicating what the tamper-evident feature of package is Tamper-evident feature present Lot code for traceability in case of recall	X	
Cold storage	B	Biological hazard: environmental pathogen contamination and growth		X	Package sealed; low risk of microbial contamination Packages kept refrigerated	GMPs Short shelf life Refrigeration will reduce rate of microbial growth		X
	C	Chemical hazard: chemical contamination		X	No chemicals used	GMPs		X
	P	Physical hazard: foreign materials			Package sealed	GMPs		X

Table 9. Food safety plan for lettuce processing. (cont.)

(1) Ingredient/ processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Processes include CCPs, allergens, sanitation, supply chain, other preventive controls	(6) Is preventive control applied at this step?	
			Yes	No			Yes	No
Cold storage (cont.)	A	Allergen contamination			Package sealed Product has proper allergen label applied	GMPs		X
	E	Economic fraud		X	Package sealed			X
	I	Intentional contamination			Package sealed			
Shipping	B	Biological hazard: microbial growth		X	Refrigerated shipping as needed	Product refrigerated or on ice Temperature controlled		X
	C	Chemical hazard: chemical contamination		X	Package sealed			X
	P	Physical hazard: Foreign materials		X	Package sealed			X
	A	Allergen contamination		X	Package sealed			X
	E	Economic fraud		X	Package sealed			X
	I	Intentional contamination		X	Package sealed			X

Table 10. Food safety plan: Process preventive controls for fish culturing in coupled aquaponics system.

Food Safety Plan – Process Preventive Controls	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce – Coupled systems
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH CULTURING: COUPLED SYSTEM									
Receive fish fingerlings	Pathogenic bacteria	Fish appear to be healthy and disease-free Each lot of fingerlings has a health certificate	Fish appearance and behavior Presence of certificate indicating pathogen-free fingerlings	Visual inspection of fish	Each lot received	QA manager	Reject lot if critical limit is not met, AND discontinue use until supplier agrees to provide certificate for each lot Review supplier program and update audit program as needed Conduct root cause analysis and take action to prevent reoccurrence	Visit all new suppliers within the year and all existing suppliers at least once a per year to review the grower's cultivation facilities and procedures and fish health program Review certificate and audit reports and receiving record	Producer's certificates Audit reports Receiving record showing visual inspection of fish

Table 10. Food safety plan: Process preventive controls for fish culturing in coupled aquaponics system. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH CULTURING: COUPLED SYSTEM									
Fish culturing or grow out	Pathogenic bacteria	Feed is pathogen-free	Supplier provides certificate or results from third-party lab showing feed is pathogen-free	Visual inspection of feed and feed records	Each lot	QA manager	Reject lot of feed if microbial load out of spec Review supply chain program Provide appropriate storage for feed Evaluate pest control system to reduce risk of contamination from pests Conduct root cause analysis and take action to prevent reoccurrence Treat water to regain microbial control	Records review Review of feed label Periodic testing of feed for pathogens (monthly) Periodic testing of fish and water (monthly)	Lab results for water Lab results for feed Lab results for fish
	Pathogenic bacteria	Water is safe for intended use	Water is not contaminated Water treatment system functioning properly	Operation of water treatment system; visual, aroma, and pH of water	Daily	QA manager	Discontinue use of contaminated feed and review supply chain program Consider new suppliers Conduct root cause analysis and take action to prevent reoccurrence	Weekly water testing for microbes Records review for water quality, calibration, and micro lab results	Water treatment system operation record Water quality pH, temperature records Instrument calibration records Testing records for monthly well test results

Table 10. Food safety plan: Process preventive controls for fish culturing in coupled aquaponics system. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH CULTURING: COUPLED SYSTEM									
Fish culturing or grow out (cont.)	Antibiotics or unapproved chemicals	Feed is free from unapproved chemicals	Certificate showing drug-free feed	Certificate for each lot	Each lot	QA manager	Discontinue use of suspect feed; hold product (fish) and examine for safety Identify potentially impacted product and remove from value chain Conduct root cause analysis and take action to prevent reoccurrence	Periodic testing for unapproved chemicals Review records for feed composition and certificates of analysis, drug-testing records	Feed composition records Drug testing records
	Intentional adulteration	Microbial, chemical, or physical contamination	Monitoring workers and facility security	Ongoing	Daily	QA and production manager		Product testing records Review food defense records Revised worker training program and records	Food defense records Worker training records
	UV or ozone – water discharge to hydroponic unit	Pathogenic bacteria	Water quality must meet coliform standards for irrigation water and be pathogen-free	Water quality testing in facility shows water meets standards	Operation of UV system (daily) Check and record intensity of UV light and operational parameters for (cont.)				

Table 10. Food safety plan: Process preventive controls for fish culturing in coupled aquaponics system. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH CULTURING: COUPLED SYSTEM									
Fish culturing or grow out (cont.)				(cont.) ozone unit, including ozone levels in discharge water (daily) Cleaning schedule to remove fouling from UV lamp unit (weekly or as needed) Monitor operation of ozone units and ozone level in water, and record operational parameters and ozone levels (at least daily)	Daily/weekly	QA manager	Check operation of the UV or ozone sanitation system and repair as needed; switch to alternative system for water purification Conduct root cause analysis and take action to prevent reoccurrence	Total counts and targeted pathogen samples analyzed (weekly) Review records for operation of UV and ozone systems and calibration of monitoring equipment (weekly) Review water flow and water quality records Review lab test results	Daily water quality and volume, measurement records UV system records Ozone system records Review of sanitation records (for fouling of UV unit) UV light calibration records (lux) Ozone monitor calibration records Water flow and water quality records Analytical lab results

Table 11. Food safety plan: Process preventive controls for fish culturing in decoupled aquaponics system.

Food Safety Plan – Process Preventive Controls	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce – Decoupled system
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH CULTURING: DECOUPLED SYSTEM									
Receiving fish fingerling	Pathogenic bacteria	Fish appear to be healthy and disease-free Each lot of fingerlings has a health certificate	Fish appearance and behavior Presence of certificate indicating pathogen-free fingerlings	Visual inspection of fish	Each lot received	QA manager	Reject lot if critical limit is not met, AND discontinue use until supplier agrees to provide certificate for each lot Review supplier program and update audit program as needed Conduct root cause analysis and take action to prevent reoccurrence	Visit all new suppliers within the year and all existing suppliers at least once a year to review the grower's cultivation facilities, procedures, and fish health program	Producer's certificates Audit reports Receiving record showing visual inspection of and records from all lots

Table 11. Food safety plan: Process preventive controls for fish culturing in decoupled aquaponics system. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH CULTURING: DECOUPLED SYSTEM									
Fish culturing or grow out	Pathogenic bacteria	Feed is pathogen-free	Supplier provides certificate or results from third-party lab showing microbial load of feed	Visual inspection of feed and feed records	Each lot	QA manager	Reject lot of feed if microload is out of spec Review supply chain program Provide appropriate storage for feed Improve pest control system Conduct root cause analysis and take action to prevent reoccurrence	Records review for certificates, audit reports, receiving documentation Review of feed label Periodic testing of feed for pathogens (monthly) Periodic testing of fish and water (monthly)	Lab results for water Lab results for feed Lab results for fish
	Pathogenic bacteria	Water is safe	Water is not contaminated; UV or ozone system functioning according to manufacturer standards	Operation of UV or ozone system, appearance, aroma, and pH of water	Daily	QA manager	Treat water to regain microbial control Conduct root cause analysis and take action to prevent reoccurrence	Weekly water testing for microbes	Review of UV or ozone operation, light intensity, pH, temperature records Calibration records for UV and ozone monitoring equipment and their review Microbial test records Testing records and certificates Testing records and certificates for monthly well test results

Table 11. Food safety plan: Process preventive controls for fish culturing in decoupled aquaponics system. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH CULTURING: DECOUPLED SYSTEM									
Fish culturing or grow out (cont.)	Antibiotics or other chemicals	Feed is free from unapproved chemicals	Certificate showing drug-free feed	Each lot	Each lot	QA manager	Discontinue use of contaminated feed and review supply chain program Conduct root cause analysis and take action to prevent reoccurrence	Periodic testing for unapproved chemicals (quarterly) Records review	Feed records Drug testing records
	Intentional adulteration	Microbes or chemicals not added	Monitoring workers and facility security	Ongoing	Daily	QA and production manager	Hold product and examine for safety Conduct root cause analysis and take action to prevent reoccurrence	Product testing records review Food defense records and worker training Records review	Food defense records Worker training records
UV or ozone discharge to hydroponic unit	Pathogenic bacteria	Water quality must meet coliform standards	Water quality testing in facility shows water meets standards	Operation of UV or ozone system	Daily	QA manager	Check operation of the UV or ozone system and repair as needed; switch to alternative system for water purification Conduct root cause analysis and take action to prevent reoccurrence	UV light records Cleaning schedule and records Review sanitation records Verify ozone system operation and review records Water flow and water quality review records	Daily water quality and volume measurements records UV or ozone system operation records Sanitation records (for fouling of UV unit) UV light calibration records (lux) Ozone monitoring equipment Calibration records Microbiological test results

Table 12. Food safety plan: Process preventive controls for live fish processing.

Food Safety Plan – Process Preventive Controls	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce. Fish processing – live fish
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH PROCESSING: LIVE FISH									
Receive fish for processing	Pathogenic microbial contamination and growth	Sensory properties of fish	Provide monitoring data from food safety plan, including sanitation; inspect fish for visual defects Temperature control and monitoring of processing room	Visual	Each lot	QA manager	Reject lot if it does not meet sensory or target temperature Conduct root cause analysis and take action to prevent reoccurrence	Samples from fish and meat tested periodically for microbes Provides third-party certificate and lab results for lots sampled quarterly Review sanitation records, temperature records, and calibration records	Sanitation records Lab results from periodic microbiological testing Thermometer calibration records Temperature records

Table 12. Food safety plan: Process preventive controls for live fish processing. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH PROCESSING: LIVE FISH									
Labeling	Allergens	Proper label Labels on finished product must have common name of fish, source, and lot number Allergen warning label is present	Proper label Attach one label to record labeling sheet each time new labels are used	Visual inspection of label for accuracy	Every time labels are applied	Packaging supervisor	Segregate and re-label any improperly labeled product Modify labeling procedure as appropriate	Label and labeling records review	Label Labeling records
	Traceability	Labels on finished product must have clear lot code	Lot code present and readable	Visual	Each package	Packaging supervisor	Segregate and re-label any improperly labeled product Modify labeling procedure as appropriate	Label and labeling records review	Label Labeling records
	Tamper evidence	Tamper-evident feature present and functional	Tamper-evident feature is described on label; feature present and functional	Visual	Each package	Packaging supervisor	Segregate affected packages and reapply tamper-evident feature Modify labeling procedure as appropriate	Pack records review	Pack records
	Economic fraud	Proper label	Weight and species is accurate	Visual	Each package	Packaging supervisor	Segregate affected package and re-label Modify labeling procedure as appropriate	Labeling and pack records review Calibration records review	Labeling records Packing records Scale calibration records

Table 13. Food safety plan: Process preventive controls for whole fish processing.

Food Safety Plan – Process Preventive Controls	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce Fish processing – Whole fish, bled and eviscerated
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH PROCESSING: LIVE FISH, BLED, AND EVISCERATED									
Receive fish for processing	Pathogenic bacteria	Sensory quality of fish, temperature of fish	Provide monitoring data from food safety plan, including review of sanitation records to show control in earlier operations Inspect fish for visual defects indicative of microbial growth	Visual	Each lot	QA manager	Reject lot if it does not meet sensory or target temperature Conduct root cause analysis and take action to prevent reoccurrence	Samples from fish and meat tested periodically for APC, *Salmonella* spp., *L monocytogenes* Provides third-party certificate and lab results for lots sampled quarterly Review sanitation and lab records	Sanitation records Lab results from periodic testing

Table 13. Food safety plan: Process preventive controls for whole fish processing. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH PROCESSING: LIVE FISH, BLED, AND EVISCERATED									
Receive fish for processing (cont.)	Microbial growth	Process room and product temperature	Temperature control and monitoring of temperature in processing room	Thermometer	Twice daily	Production manager	Reduce T for HVAC system and retest Add sanitary ice if needed to keep fish cool Conduct root cause analysis and take action to prevent reoccurrence	Review temperature and temperature calibration records	Temperature records Thermometer calibration records
Washing	Pathogenic bacteria	Chlorine between 2 and 4 ppm in wash water	Chlorine test results	Chlorine test kit	Every hour	QA manager	Adjust chlorine levels as needed Check calibration and ensure that chlorine measurements are being properly made Conduct root cause analysis and take action to prevent reoccurrence	Calibration results for chlorine test kit Review chlorine test and municipal water records	Chlorine test records Municipal water test reports
Weigh, pack, label	Microbial contamination and growth	Stored fish must be maintained at internal temperature of less than 45 F	Look for presence of ice and record internal temperature of 2 fish/100 lbs.	Visual	Every hour	QA manager	Add ice when needed OR add ice if internal T > 45 F and recheck temperatures to make sure fish temperature is below 45 F	Hand-held digital thermometer used to take internal temperature calibrated weekly; if outside +/- 2 F, replace with new one Review temperature records	Records of internal temperature of fish at receipt and during processing Daily processing room temperatures

Table 13. Food safety plan: Process preventive controls for whole fish processing.

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
FISH PROCESSING: LIVE FISH, BLED, AND EVISCERATED									
Weigh, pack, label (cont.)								Review process room and thermometer calibration records Review sanitation records – ice is sanitary Review water quality sanitation records	Weekly calibration of hand-held digital thermometer Ice production and sanitation records
	Allergens	Label accuracy	Labels on finished product must have common name of fish, source, and lot number	Visual Attach one label to record labeling sheet each time new labels are made	Every time labels are applied	Packaging supervisor	Segregate and re-label any improperly labeled product Modify labeling procedure	Review of label and labeling records	Label Labeling record
	Traceability	Lot code present and readable	Allergen warning label present Labels on finished product must include lot number	Visual	Each package	Packaging supervisor	Segregate and re-label any improperly labeled product Modify labeling procedure as appropriate	Review labels and label records	Label Labeling records
	Tamper evidence	Label and feature	Tamper-evident feature described on label is present and functional	Visual	Each package	Packaging supervisor	Segregate affected packages and reapply tamper-evident feature	Review labels and label records	Label Labeling records

Table 14. Food safety plan: Process preventive controls for lettuce cultivation.

Food Safety Plan – Process Preventive Controls	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce – Lettuce cultivation
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
LETTUCE CULTIVATION									
Receive lettuce seed	Pathogenic bacteria	Supply chain control, use only approved suppliers, third-party audit	Presence of certificate indicating patho-gen-free seeds	Visual	Each lot received	QA man-ager	Reject lot if criti-cal limit is not met AND discontinue use until supplier agrees to provide compliant product certificate for each lot	Visit all new sup-pliers within the year and all ex-isting suppliers at least once a year to review seed op-erations or obtain audit results from third-party auditor (annually) Test seed ship-ments quarterly for pathogens Review receiving records, certifi-cates, test records, and audit reports	Producer's certif-icates Audit reports Receiving record for all lots Analytical records

Table 14. Food safety plan: Process preventive controls for lettuce cultivation. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
LETTUCE CULTIVATION									
Receive lettuce seed (cont.)	Chemical residue	Supply chain control, approved supplier third-party audit	Presence of certificate indicating pesticide-free seeds	Visual	Each lot received	QA manager	Reject lot if critical limit is not met AND discontinue use until supplier agrees to provide compliant product and certificate for each lot	Visit all new suppliers within the year and all existing suppliers twice per year on a rotating basis to review seed operations or obtain audit results from third-party auditor (annually) Test seed shipments quarterly for pesticides Review test records, receiving records, and audit reports	Receiving record for all lots
	Intentional adulteration	Supply chain control, approved supplier, third-party audit	Visual and sensory inspection at receipt	Visual	Each lot received	QA manager	Reject suspicious shipments, including rejection of seedlings that fail to thrive for no apparent reason Conduct root cause analysis and take action to prevent reoccurrence	Review receiving logs and germination records	Receiving records Germination records
	Pathogenic bacteria	Water quality meets specification for irrigation water quality	Daily water sampling for turbidity (indicative of microbial growth)	Visual and instrumental tests	Daily water samples for pH	QA manager	Repair or replace the UV unit if it does not provide enough microbial reduction	Verify that new or repaired UV or ozone unit functions properly Review records	Water quality records

Table 14. Food safety plan: Process preventive controls for lettuce cultivation. (cont.)

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
LETTUCE CULTIVATION									
Lettuce grow out on rafts (cont.)			Check UV operating at proper light intensity and unit has no fouling. For ozone, concentration in cultivation water is adequate for microbial control		Daily check of UV unit or daily check on ozone concentration in water		Increase ozone addition if microbial control inadequate Use backup chemical sanitizer, and if this is not possible, discontinue operations until sanitary conditions can be verified Conduct root cause analysis and take action to prevent reoccurrence	Review lab, ozone, UV operational and calibration records	Lab results for UV or ozone operation log, light intensity and bulb life, records for ozone concentration Calibration records for ozone or UV monitoring instrumentation
Lettuce harvesting	Pathogens	Lettuce – general appearance, sensory quality, and signs of microbial load	Visual inspection	Visual	Each lot	QA manager	Retrain if proper hand-washing and tool sanitation practices are not followed during harvesting Verify glove use during harvesting and handling Segregate suspected product and do not ship Conduct root cause analysis for source of microbial contamination	Verify sanitation procedures and sanitizer concentration Test lettuce for bacteria weekly Review of product harvest and quality records, lab records, and sanitation records	Product harvest and quality records Lab records Sanitation records

Table 15. Food safety plan: Process preventive controls for lettuce processing.

Food Safety Plan – Process Preventive Controls	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*) and hydroponic lettuce – Lettuce processing
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

Process control step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective action	Verification	Records
			What	How	Frequency	Who			
LETTUCE PROCESSING									
Receive lettuce	Pathogens	Visual exam and sampling for testing	Appearance	Visual	Each lot	QA manager	Reject if micro tests out of spec	Periodic lab testing and review records	Receiving lab results
Wash and drain	Pathogens	Chlorine 2-4 ppm, pH 6.5	Chlorine test kits pH	Visual pH meter	Hourly	QA manager	Discontinue processing until chlorine level is sufficient for sanitization Check the chlorine source; if it is deactivated, add more fresh chlorine	Verify operation of chlorine addition unit Records review	Records of chlorine concentration and pH
Metal and physical objects inspection	Metals	Metals inclusion	Visual exam for metal	Visual	Each lot	QA manager	If metal found, hold product and recheck the rest of the lot prior to release. Conduct root cause analysis and take action to prevent reoccurrence.	Periodically verify that processors can detect these materials (training). Review inspection records.	Inspection records

Table 16. Food safety plan: Allergen preventive controls for fish products.

Food Safety Plan – Allergen Preventive Controls	Aquaponic tilapia – Blue tilapia (*Tilapia aurea*)
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Peter Green, Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

(1) Allergen control	(2) Hazard	(3) Criterion	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Fish	Undeclared allergen	Product must contain allergen declaration: "INGREDIENTS: Fish: tilapia"	Presence or absence or allergen declaration	Trained employee (packaging lead) checks product labeling at the beginning and end of each shift and on lot changes Trained employee records observations on packaging records	Beginning and end of each shift and on lot changes	Packaging lead	In the event that the allergen declaration is not on the label, packaging lead will notify supervisor and place affected product on hold until the last good check Product is then properly labeled Root cause analysis conducted to determine why failure occurred, and issue is corrected	Label review Labeling records are reviewed and verified by QC	Packaging records

Table 17. Fish products labeling.

Products		Allergen Statement							
Tilapia		**INGREDIENTS: Tilapia**							
Product name	**Production line**	**Intentional Allergens**							
		Egg	**Milk**	**Soy**	**Wheat**	**Tree nut**	**Peanut**	**Fish**	**Shellfish**
Tilapia	All facility equipment	N/A	N/A	N/A	N/A	N/A	N/A	Declared	N/A

Table 18. Food safety plan: Allergen preventive controls for lettuce.

Food Safety Plan – Allergen Preventive Controls	Aquaponics lettuce
Green Aquaponics LLC, 456 River Way, Aquatown, WA 98765	
Approved by: P. Green Signature: *P. Green* Processing Manager	Version 2: Sept. 9, 2018
	Supercedes: Version 1: Aug. 1, 2017

(1) Allergen control	(2) Hazard	(3) Criterion	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Fish	Undeclared allergen	Product must contain allergen declaration: "INGREDIENTS: Lettuce, produced in a facility that also processes fish (tilapia)"	Presence or absence or allergen declaration: "Produced in a facility that also processes fish (tilapia)"	Trained employee (packaging lead) checks product labeling at the beginning and end of each shift and on lot changes Employee records observations on packaging records	Beginning and end of each shift and on lot changes	Packaging lead	In the event that the allergen declaration is not on the label, packaging lead will notify supervisor and place affected product on hold until the last good check Product is relabeled Root cause analysis conducted to determine why deviation occurred, and steps taken to fix deficiency	Label review Records are reviewed and verified by QC	Packaging records

Table 19. Lettuce products labeling.

Products		Allergen Statement							
Lettuce		INGREDIENTS: Lettuce, produced in a facility that also processes fish (tilapia)							
Product name	**Production line**	**Intentional Allergens**							
		Egg	**Milk**	**Soy**	**Wheat**	**Tree nut**	**Peanut**	**Fish**	**Shellfish**
Lettuce	All facility equipment	N/A	N/A	N/A	N/A	N/A	N/A	Declared	N/A

Table 20. Sanitation preventive control: Facility sanitation monitoring master list.

Equipment	Process monitor	SOP/form	Monitoring frequency	Action limit	Correction	Records/ location	Person responsible	Monitoring record review	Person responsible
Product contact surfaces	Visual inspection	Daily pre-op inspection log	Daily	Visible soil	Reclean and resanitize until visible soil is removed	QC office	Department manager	Daily pre-op inspection log	QC manager
Nonproduct contact surfaces	Visual inspection	Master sanitation schedule	As determined on schedule	As determined on schedule	Reclean and resanitize until visually clean	QC office	Production employees	Master sanitation schedule	QC or department manager

Table 21. Sanitation preventive controls: Facility sanitation verification activities.

Equipment/ record	Verification activity	SOP/form	Frequency	Action limit	Person responsible	Corrective action	Implement	Person responsible	Records/ location
Product contact surfaces	Adenosine triphosphate (ATP) swabbing	SSOP ATP swabs	Daily	0-10RLU: Pass 11-30 RLU: Caution 31 RLU <: Fail Check the kit manufacturer manuals for instruction and action limits	Production employee	Reclean and resanitize until ATP results meet action limit	N/A	QC manager	QC office

Table 22. Sanitation preventive controls: Facility sanitation implementation/effectiveness.

Test	Equipment/ reagent	Calibration	Calibration frequency	SOP #	Person responsible	Records/location	Monitoring record review	Person responsible
Environmental swabbing (*Listeria* spp.)	Sponge stick swab	Controls are run by outside laboratory for the methods used to test the sponge	Daily	Provided by laboratory	QA manager	QC office and outside laboratory	QC manager	QC manager
ATP swabbing and testing	Nova LUM II or equivalent	Positive and negative controls	• Negative control = monthly • Positive con trol = monthly	ATP swabbing and testing	Quality department associate or designee	Quality department	ATP controls: performance checks	Quality department associate or designee

Food Safety Plan: General Assessment Information

Assessment – Food Protection

Our employees are trained to meet the technical and documented training requirements of 21 CFR Parts 11, 112, 117, 121, and 123, as per the requirements of their jobs. At least one person on each shift has received training to serve as a qualified individual, as appropriate, for produce production under the Produce Safety Rule, or is trained to serve as a preventive controls qualified individual for food processing. Individuals who have had seafood HACCP training should become familiar with the new requirements of Food Safety Modernization Act, either on their own or through additional training so they have the background information needed to serve as a Preventive Controls Qualified Individual (PCQI). These individual(s) will be required to prepare the food safety plan, develop the hazard analysis, validate the preventive controls, review food safety and food protection records, and conduct a re-analysis of the food safety plan. The individual(s) will be deemed to be capable through successful work performance of these tasks, although attendance at a course in one or more of the regulations listed here is anticipated. A qualified individual in our facility will also be one who understands the importance of sanitation and biosecurity and can implement an effective plan to reduce the risk for human, animal, and plant disease in our operation. There will be at least one qualified individual on-site at all times who has training and understanding of the intentional adulteration rule and how it is to be implemented at our facility.

Any worker or contractor who has a role in ensuring some aspect of food safety will have training that is documented with records retained in personnel or contractor files. Training for all employees is updated as hazard analyses change or at least twice per year. Table 23 provides an assessment rubric showing when a food protection plan is satisfactory and when it is not.

Table 23. Food protection plan.

Food protection – General factors	Unsatisfactory	Satisfactory
• Trained designated employee(s) in charge of food safety plan for fish production, plant production, GMPs, SOPs, supply chain controls, sanitary transport, and food defense. • Trained designated employee(s) trained on vulnerability assessment, actionable process steps, and mitigation strategies to significantly minimize risk of intentional contamination. • Trained individual in plant phytosanitary best practices and fish health.	• No trained employees.	• Trained employee(s). • Designated employees attend food safety training courses or receives sufficient training on-site to ensure they are capable of successfully performing these tasks.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Written and documented hazard analysis and food protection plan, including food defense, GMPs, and SOPs. • Written plant and animal protection programs.	• No food safety plan, GMPs, or SOPs are available. • No updated HACCP/HARPC hazard analysis. • No updated GMPs and SOPs. • FSMA compliance lacking. • Phytosanitary and biosecurity provisions lacking.	• Well-written and available food protection plan, GMPs, and SOPs. • Plan adequately addresses food defense. • Well-drafted biosecurity protocols. • Indication that food safety plan and SOPs are re-evaluated and updated when there is a change in product, process, or distribution that could affect food safety, and at least annually (21 CFR Part 123 Seafood HACCP). • Staff is familiar with FSMA requirements. • Staff is familiar with plant and animal health requirements and biosecurity measures.
• Visitor protocol program in place.	• Visitors come and visit with no supervision, posing a biosecurity, food safety, and food defense risk. • Visitors bring animals on-site. • Visitors do not comply with dress or personal protective equipment requirements on-site. • No indication that visitors have received any training about the facility and facility's food safety requirements.	• Visitor policies developed and implemented. • Visitor hygiene protocol developed and implemented. • Visitor plant health and animal biosecurity protocols developed and implemented. • Visitor supervision protocol developed and implemented.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Written pest control program. • Written domestic animal policies.	• Pests (insects, rodents, birds) have access to production, processing, and material storage areas. • Animal waste near production or processing areas; improper waste management could attract pests. • Improper feed storage; feed not isolated and protected, giving pests access to food and transmission of pathogens (viruses, *Salmonella* spp., *E. coli*, etc.).	• Third-party pest control with regular checking. • Proper feed storage. • Feed kept in designated storage room, isolated from other dry goods and packaging. • Warm-blooded animals kept out of facility. • Any domestic animals are away from production and processing areas, preferably at the edge of property (for guard animals). • Employees trained about possible sources of cross-contamination when moving between fish production site and lettuce production unit. • Required use of boot sanitation stations outside the fish production and processing sites and the lettuce production and processing units. • Proper maintenance of boot sanitations stations and footwear, including footwear storage; dedicated footwear for use at the facility. • Hand-sanitizer units outside fish and lettuce production areas and outside processing areas. • Properly constructed and maintained restrooms. • Regular grass and brush removal on-site to decrease the number of pests in the environment, including birds, and rodents. • Removal of standing water (insects). • Garbage removed from site at least weekly. Garbage receptacles are covered and the area around them kept clean. • Fish processing waste is covered and refrigerated until disposed of.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Water used for plant and fish production meets appropriate water quality standards.	• Water is contaminated. • No assurance that water meets required standards for its intended purpose.	• Compliance with agricultural water provisions in Produce Safety Rule, including testing provisions. • Water used to raise fish is safe and not a source of contamination for either the fish or plants.
• The water used for hand-washing, produce-washing, fish-washing, contact surfaces, etc., should be potable and for processing activities, sanitized, and at proper temperature.	• No potable water is available. • No hot water available for hand-washing in restrooms.. • No regular water testing conducted. • Water not properly sanitized. • Ice not made from potable water. • Water testing not conducted at appropriate frequency. • Water testing conducted using an inappropriate method. • Water sampling done improperly or at less than necessary frequency.	• Potable water is available. • Hot water is available • Regular tests performed for E. coli, coliform, *Listeria monocytogenes*, pH, alkalinity, ammonia, nitrite, nitrate, and arsenic (important in areas where background levels are high).
• Regular worker training for personal hygiene, food handling, food processing, fish feeding, plant growth requirements, water recirculation systems, food defense, and biosecurity.	• No regular training is available. • Training is not effective. • Training not documented.	• Workers trained for skills needed in their job description. • Training is effective. • Training is documented. • Training refresher provided at least once a year.
• Rest area for workers with appropriate lockers for storing personal items; lunchroom/ breakroom provided. • Convenient place to hang work clothes provided so work clothes are not taken out of processing area. • Discourage prescription or OTC drugs, tobacco, and allergenic foods from being brought on-site.	• No designated lunchroom, rest area, lockers. • Workers wear work clothes (coats, hats, aprons, boots, gloves) into toilet area, breakroom, or outside; no place to hang or store their clothing or personal protection equipment prior to using toilet. • Personal items stored in processing or production areas. • Prohibited substances on-site. • Prohibited substances in production area.	• Well-designed rest area, lunchroom, and lockers that are convenient and easy to use. • Sufficient storage for personal items. • Sufficient storage for work clothing and personal protection equipment. • Consumption of allergen-containing foods on-site is discouraged; if these foods are consumed, workers take decontamination precautions prior to returning to work (proper hand-washing should be sufficient). • No prohibited substances on-site.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Restroom for men and women provided outside of the production and processing area but easily accessible with potable hot and cold water, sanitizers, and required materials for maintaining a sanitary toilet area. • Area to hang work clothes outside toilet area provided. • Restrooms and rest areas are kept clean.	• Restroom inside the production or processing areas serving as a possible source of contamination. • Restroom not properly constructed, serving as a potential source of contamination. • No place to hang uniforms, boots prior to use of toilet. • No clean uniforms or boots provided for workers to change into. • No clean water, sanitizer, towels, etc. • Restrooms not clean or well-maintained.	• Restroom located outside the production building. • Hot and cold water, sanitizers, and clean stuffs are available. • Routine cleaning schedule followed. • SOPs are available for workers. • Restrooms are well-maintained and stocked with clean paper towels. • Uniforms and footwear are properly stocked and cleaned. • Work clothes are properly stored.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Aquaculture facility: tanks, plumbing, lighting.	• Workers not trained to operate pumps and plumbing system. • Water quality is not adequate. • Water testing not conducted or test results not available. • Effective SOPs for cleaning tanks and plumbing system, and use of sanitizer, as needed, are not implemented. • Design does not provide a means to isolate individual production tanks. • Maintenance inadequate. • Calibration or operation of testing equipment for water quality inadequate. • UV or ozone systems used for water sanitization are not functioning, do not control microbial growth, or are not being operated or maintained properly.	• Workers are trained on operation of aquaculture system, and training is documented. • Water quality testing (pH, T, dissolved oxygen, alkalinity, ammonia, nitrite, nitrate) is conducted. • Test equipment is operational and properly calibrated. • Effective SOPs are developed and implemented for cleaning aquaculture facility. • System has been redesigned and reconstructed so tanks can be isolated from the system for disease control or for sanitizing individual tanks. • Appropriate maintenance schedule developed and implemented. • Appropriate cleaning schedule developed and implemented. • Adequate ventilation to reduce risk of environmental microbe growth. • Proper lighting with bulbs that are protected against breakage. • UV or ozone systems are functioning and providing adequate sanitation. • Effectiveness of UV and ozone systems checked at least weekly. • Ozone concentration tested daily with a calibrated liquid ozone meter. • UV lamp output checked weekly; assembly checked for fouling and cleaned as needed.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Aquaculture feeding system.	• No certificate of analysis on feed or inadequate ingredient statement. • Improper on-site formulation of diets. • Improper diet purchased. • No medicated feed permissible in facility, but medicated feed found on-site. • Improper feed storage in an open area, or in a building with improper ventilation and temperature control. • Improper feed use, feed particle size, or feeding rate. • Improper allergen segregation or unique allergens on-site for which there is no control program. • Workers do not maintain proper hygiene during feed handling or feeding operations. • Improper use of automatic feeders, clogged or empty feeders. • Failure to clean and/or maintain feeding system. • Workers lack knowledge of fish feed requirements and fish behavior. • Improper pest control. • Feed storage not segregated from rest of operation (allergens) or is not secured (food defense). • Inventory of feed use inadequate. • Medicated feeds on site. • No control program.	• Feed shipment lacking proper documentation is rejected. • Nonconforming feed is segregated and evaluated for safety. Rework if possible. Workers retrained on proper feed production techniques. • No medicated feed at facility. • Workers trained to use proper hygiene; and training is documented and annual updates are provided. • Workers trained on allergen and security risks associated with feeds. • Feed stored in a way to reduce risk of pest contamination and at proper temperature with adequate ventilation. • Allergen control program in place so that feeds with unique allergens are segregated, properly stored, and inventoried. • Recalculate the mass balance of fish. Workers observe fish behavior to see if they are consuming feed. Feeding rate is adjusted based on the amount of uneaten feed in the system. • Proper particle size for the size of fish is used, based on feed manufacturer's recommendations. • Automatic feeders are cleaned, properly filled, and maintained. • Smaller fish are fed by hand using best hygiene practices. • Workers trained on what behavioral features to observe in fish to determine satiety and signs of stress. • Effective SOPs for pest control are followed.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Aquaculture unit biofilter.	• Dead fish in water. • No microbial lab test for water. • No water quality test (T, pH, ammonia, nitrite, nitrate, dissolved oxygen) is available. • Biofilters are clogged and not working efficiently. • Water level too high and overflowing biofilter.	• Dead fish are removed from water as soon as possible. • Portable device is available for water quality measurements. • Regular water sampling and microbial testing is conducted. • Biofilters are checked regularly for clogs, and any solid materials are removed. • Filter is checked for damage or signs that removal of solid materials is not as effective as necessary. • Pump for biofilter system properly maintained.
• Solid removal: Solids from fish tanks include fish fecal matter and leftover feed, which can be sources of cross-contamination (allergens) or microbial contamination.	• Clogged or torn filter cannot remove the solids effectively. • No SOPs for removing the solids from the plant. • No regular inspection of filters. • No effective maintenance program. • Lack of proper storage of recovered solids and use or disposal.	• Solid removal filters inspected daily. • Solid waste is consistently removed from the fish production unit. • Effective, operational SOPs, and maintenance program are in place. • Recovery and the removal of solids removed.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Plant germination and grow-out units, and water for this system.	• No microbial and chemical water testing results are available; improper level of testing. • Water is in contact with the edible part of the plant and is not of appropriate microbial quality. • No SOPs for germination, grow out, and harvesting. • No training for employees. • No effective program for cleaning and maintaining culture units. • Insufficient phytosanitary program in place to reduce risk of plant disease. • UV or ozone systems are not functional or not operated properly. • UV output or ozone concentration not measured or measurements are not reliable.	• Regular water tests conducted for pathogens and indicator organisms. • Regular water tests conducted for ammonia, nitrite, nitrate, pH, phosphorous. • Water does not touch the edible part of the plant. • SOPs available for germination, growing, and harvesting plants. • Employee trained for handling rafts and harvesting plants. • Hydroponic system design is appropriate for easy access, removal of rafts, and low risk of contamination during harvesting operations. • Rafts inspected for damage. • Rafts cleaned and sanitized. • Germination and grow-out tanks cleaned at appropriate intervals to reduce biofilm formation. • Proper ventilation reduces risk of microbial growth. • Proper lighting with bulbs protected from breakage. • SOPs for cleaning the facility. • GMPs for maintaining operation, water flow, quality, and conditions for plant growth. • UV and ozone systems are functioning as needed, with appropriate level of sanitization. • UV and ozone systems are properly calibrated at appropriate intervals and calibrations recorded.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Cross-contamination: microbes or allergens.	• No training available: microbes, allergens. • No gloves, sanitizers, hand-washing/sanitizing stations or foot dips are available. • Poor physical isolation between aquaculture unit and plant grow-out site. • Facility lacks access controls to reduce risk of intentional contamination.	• Well-documented and routine training is provided for employees. • Appropriate isolation exists between aquaculture and plant germination and grow-out units. These operations are in separate buildings. Access is controlled into the separate buildings. • Boot and hand sanitizer stations are available. • Gloves are available, along with hand-washing stations. • Workers trained on use of hand and foot washing/sanitizing facilities. • Facility access is restricted to authorized individuals only. • No personal items are brought into production area. • No chemicals stored in processing area, and chemical inventory is tightly monitored and controlled.
• Equipment and utensils.	• Production equipment is rusty, broken, cracked, greasy, leaking, etc. • Production equipment is unsanitary. • Utensils are unsanitary. • Utensils are not stored to protect them from contamination.	• Good maintenance program instituted as part of GMPs. • Effective sanitation SOPs in place. • Broken, rusty, and leaking parts are replaced; food-grade oils and lubricants are used; the use of metals is controlled, including screw and staples.
• Harvesting methods to reduce risk of cross-contamination.	• No training for workers. • No sanitation equipment for harvesting tools. • No protective gloves or clothing for harvesting. • Cross-contamination from water, hands, ice (if used), utensils, or other food contact surfaces.	• Workers trained in produce safety; training is documented. • Sanitation equipment provided for tools; workers trained to maintain equipment in a sanitary state. • Workers wear protective gloves and have clean uniforms. • Good GMPs ensure no cross-contamination from water to food crop.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Fish harvesting.	• No clean totes or containers available. • No SOPs for harvesting and handling fish. • No cooling system or sanitary ice for harvested fish. • Food-grade gas not available for live hauling. • Hauling or brailing systems not sanitary. • Fish are not secure from contamination during brailing or transport.	• Clean boxes or totes for harvesting fish are available and properly stored. • SOPs are in place for harvesting and handling fish, including worker training. • Ice available for cooling fish; mechanical refrigeration is functioning and adequate. • Food-grade oxygen or air is available for live hauls; tanks are clean; tanks are secured. • Brailing systems are kept sanitary; there is controlled access to brailing systems.
• Lettuce harvesting.	• Workers handling plants with no hand protection. • Workers lack clean clothing, head coverings, and footwear. • Workers handling rafts and plants during harvesting without proper sanitary procedures. • Knives and other utensils are not clean. • Storage for knives and utensils inadequate. • Harvest containers made of improper material or not clean.	• Workers wear clean gloves and clothing all the time. • Workers have clean clothing, head coverings, and footwear. • Workers only handle plants during the harvesting operation and not at other times; handling follows GMPs. • Individuals trained in horticulture and plant health evaluate plants daily. Plants that need to be removed for further examination are handled in a sanitary manner. • Utensils and food contact surfaces are made of suitable food-grade material and are in good repair, clean, and sanitary. • Storage for knives and utensils is sanitary and protects workers from inadvertent injury.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Lettuce washing, packaging, and storage.	• No lab test available for water. • No on-site test available for chlorine. • No SOPs for sanitizing the contact surfaces. • No environmental sampling or tests. • No cold storage available. • No label. • No allergen warning. • No lot code or traceability. • No tamper-evident feature with packaging. • Transport vehicle unsuitable or dirty.	• Routine water sampling and tests conducted. • Calibrated test kit for chlorine is on-site. • SOPs in place for sanitizing the contact surfaces. • Environmental sampling and tests conducted. • Cold storage exists that is different from fish cold storage. • Proper labeling for identification of product, storage conditions, allergen warning, traceability, and evidence of tampering. • Storage area refrigerated, clean, and sanitary. • Ice (if used) is clean and sanitary. • Water is tested, potable, and contains chlorine at level to control microbial growth during wash step. • Food contact surfaces are of durable, food-grade, cleanable material and are kept clean and sanitary. • Environmental sampling conducted for ready-to-eat food; test results recorded, and product call-back program is in place if an issue is found with pathogenic microbes.
• Product traceability.	• No records and lot number for shipment.	• Proper tracking system for tracking the products through the value chain.

Table 23. Food protection plan. (cont.)

Food protection – General factors	Unsatisfactory	Satisfactory
• Chemicals.	• No SOPs available. • No MSDS available. • Improper storage of chemicals. • Improper containers and containment for chemicals in use. • Chemicals (bulk) stored in production or processing area. • No spill plan. • Use of antibiotics; animal drugs prohibited. • No training program for workers who make, use, or are exposed to chemicals. No documentation of worker training.	• SOPs are available. • MSDS is available. • Proper storage (toxic chemicals in locker). • Inventory of chemicals is available. •Third-party sanitizer provider (plastic containers with lock, on the wall). • SOPs for spills and spill plan are available. • Workers trained to handle, test, use, and store chemicals properly. • Only enough chemicals needed for immediate use is in production or processing areas. • No unapproved chemicals are on-site.
• Recall program.	• No recall program and no mock recalls conducted. • Recall team members and roles not noted or out of date. • Contact information for regulatory agencies missing or inaccurate. • Recall plan not integrated into overall crisis management program. • No crisis management program.	• Well-written recall program in place, and mock recall held at least once a year. • Recall members identified and trained, and their contact information kept up to date. • List of key contacts is in place, including contacts for regulatory authorities. One person is tasked with keeping this list up to date and reviewing quarterly. • Crisis management plan in place. (This is in addition to food defense plan.) Plan is exercised at least annually.

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