

Auditing and inspection checklist for sprouting facilities

Purpose:

The purpose of this audit is to confirm that the Sprout Company has achieved a multi-hurdle approach to minimize the risk of microbial contamination of sprouts. The three hurdle areas targeted in this audit are: 1) Seed Sanitation, 2) Spent irrigation water hold and release testing program and 3) Effective training of management and other workers in critical areas of Good Manufacturing Practices (creating a culture of food safety & continuous improvement). The questions are designed based on HACCP principles and include elements of Good Manufacturing Practices and recommendations provided by international food safety guidelines for sprouts as listed below.

U.S. Food and Drug Administration. 1999. Guidance for industry: Reducing microbial food safety hazards for sprouted seeds. *Fed. Regist.* 64:57893-57896. Available at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm120244.htm>

U.S. Food and Drug Administration. 1999. Guidance for industry: Sampling and microbial testing of spent irrigation water during sprout production. *Fed. Regist.* 64:57896-57902. Available at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm120246.htm>

Codex Alimentarius Committee. 2003. Code of hygienic practice for fresh fruit and vegetables. Annex II: Annex for sprout production. Available at: www.codexalimentarius.net/download/standards/10200/CXP_053e.pdf

Canadian Food Inspection Agency. 2007. Code of practice for the hygienic production of sprouted seeds. Available at: <http://www.inspection.gc.ca/english/fssa/frefra/safsal/sprointe.shtml>

Canadian Food Inspection Agency. 2008. Food safety practices guidance for sprout manufacturers. Available at: http://www.sproutnet.com/Reports/CFIA_FSPG_EN.pdf

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Sprout Specific Safety Audit



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	Points	Score	Comment
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Firm's Information:

Firm Name: _____

Address: _____

Phone: _____

Date of audit: _____

Most Responsible Individual: _____

Auditor Information:

Name: _____

Agency: _____

Phone: _____

A. Documentation and Records

	Points	Score	Comment
1 Overview of Documents			
a. Is there one person responsible for keeping and verifying safety documentation records who has been GMP and HACCP trained? Is there evidence that this person is confirming that the policies are in fact being followed and documentation kept?	10		
b. Is there an updated organizational chart which shows the line of command in the firm?	10		
c. Is there a written Management Policy and job descriptions for senior management as their job(s) relate to Food Safety, keeping abreast of current regulations, a commitment to continual improvement of food safety practices and maintaining a culture of Food Safety among all employees?	10		

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	Points	Score	Comment
d. Is there a written policy that the firm's senior management will review the verification of the food safety management system and HACCP Plan, at least once a year, to ensure its continuing suitability, adequacy and effectiveness?	10		
e. Is there a chart that displays the schedule for each task from sanitation of different parts of the plant to verification of HACCP	10		
f. Are there job descriptions and training documentation for all employees in the firm which include an awareness of food safety and its importance, and specific training for key workers?	10		
9. Is there a flow chart of the buildings and processes? Check it before proceeding.	10		
h. Do records include written procedures, controls, limits, monitoring results, corrective actions and follow-up documents, maintained for a minimum of two years, for each of the following?			
Seed sources and lot numbers	15		
Purchases of chlorine and other sanitizers	15		
Source water analysis results	10		
Monitoring of production rooms, seed storage areas and food contact surfaces for sanitation program effectiveness.	15		
Seed sanitization procedures	15		
Pest control monitoring	10		
Sprout lot codes	15		
Spent irrigation water analysis results	20		
Production volumes	15		
Storage temperature monitoring	10		
Product distribution and consumer complaints	10		
i. When defects occur or limits of acceptability are exceeded, does the firm have written procedures to identify and isolate affected products?	15		
j. Request the firm's documented corrective actions following any deviation and record the number of occurrences (corrective actions taken) in the last year. Do the records include:			
Investigation to determine the cause of the deviation?	15		
Re-evaluation of preventive measures?	15		
Verification of the effectiveness of the corrective action taken?	15		

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	Points	Score	Comment
k. Does the firm have records documenting self-audits at least annually?	10		
290		0	
2 Sprout Production Buildings & Equipment			
a. Where the source of water used is from a municipal water supply, is it tested once a year for potability? Where any other source of water is used, it is tested a minimum of twice a year for potability, as well as immediately after flood or runoff? Is private source checked for physical security and structural soundness at least once a year? Check documentation.	15		
b. Is there a written program in place to control physical hazards such as nuts, bolts, glass and brittle plastic from contaminating products?	5		
20		0	
3 Cleaning & Sanitation			
a. Does the firm have a written cleaning and sanitation program for use inside the production and storage areas?	15		
b. Does the firm have written SOPs for cleaning trucks and coolers used for storage and transportation of products?	10		
c. Does the firm have written SOPs for inspecting incoming trucks, truck loads and third party trucks that are used for delivery of the firm's product.	10		
d. Does the written cleaning and sanitation program for production rooms, equipment and utensils include the following?			
Name of the activity and the position of the responsible person	10		
The frequency of the activity	10		
The procedures for cleaning, rinsing, and sanitizing	10		
Procedures for monitoring chemicals and concentrations used during the cleaning process, and temperatures in the case where heating is required	10		
The type and frequency of inspection to verify the effectiveness of the program, including documentation	10		
Disassembly/re-assembly instructions	10		
e. Are the chemicals and concentrations described in the written instructions used in accordance with the manufacturers instructions?	10		

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	Points	Score	Comment
f. Is there a written procedure for at least monthly environmental sampling, by zones, of equipment, floors, drains, cooler pans, etc. for <i>Listeria spp</i> ?	10		
g. If the firm is swabbing food contact surfaces for pathogens, is there a program for retaining control over the product until the results of the tests are back from the lab. Are records maintained of test results?	15		NA option
h. Does the firm have written SOPs for cleaning and sanitizing production rooms and equipment after contamination was found?	15		
i. Does the firm have written SOPs for verification of sanitization before resuming production after contamination is found?	15		
160		0	
4 Pest Control			
a. Does the firm have a written pest control program?	10		
b. Does the pest control service and/or the person applying chemicals or servicing the facility have a current license/permit on file? Check that the name of the responsible person, copies of applicators licenses for each application, name of pest control company and contact person and a copy of certificate of insurance for responsible entity, as applicable, are on file.	5		
c. Does the firm have a complete list of pesticides approved for use, the methods of use and concentrations used, and the designated areas where they are approved for application?	10		
d. Is there a provision in the program for at least weekly inspection and servicing of traps to remove dead pests and to identify and immediately eliminate the source of infestation?	5		
30		0	
5 Waste Management			
Does the firm have written SOPs for the storage and removal of waste from production and outside areas, including the frequency of removal?	5		
5		0	

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	Points	Score	Comment
6 Personal Hygiene			
a. Does the firm have a written worker health policy that:			
i. Restricts employees and visitors with symptoms of potentially infectious illness such as diarrhea, fever, or vomiting from working with or being in the vicinity of seeds/sprouts or food-contact surfaces, and requires employees to report such symptoms to their supervisor before beginning work?	15		
ii. Instructs employees to report any active case of illness such as diarrhea, fever, or vomiting to their supervisor before beginning work?	15		
iii. Requires employees with open sores, cuts, burns, boils, and similar conditions report the conditions, and to not handle food or food contact surfaces unless the injury is completely protected by a secure waterproof covering (e.g., rubber gloves)?	15		
iv. Has corrective action for instances of failure to follow the firm's policy?	10		
b. Does the firm have written requirements, including corrective action, for cleanliness and personal behaviors that include:			
i. Protective clothing, hair covering, footwear and gloves should be worn and maintained in a sanitary manner.	15		
ii. Workers must wash and sanitize their hands before starting work each day, after visit to toilet facilities or blowing their nose, after other absence from the work station, and after handling contaminated materials (e.g., picking objects off the floor).	15		
iii. Waterproof gloves should be discarded upon leaving the production rooms or whenever they get soiled, hands washed and clean gloves put on and washed and sanitized similarly to hand washing upon returning to the production rooms.	15		
iv. Reusable gowns, aprons, boots and gloves should be properly maintained and cleaned.	10		
v. Eating, using tobacco, chewing gum, or unhygienic practices such as spitting is prohibited in food handling areas.	10		
vi. Exposed jewelry is prohibited with the exception of plain wedding bands that are covered by gloves.	5		

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	Points	Score	Comment
c. Does the firm have a written policy, with a corrective action statement, to ensure good hygienic practices are followed by visitors, contractors and contract service providers?	10		
	135	0	
7 Control of General Operations			
a. Does the firm have a written description and procedures for control of entire production processes?	20		
b. Does the firm have a program of requesting certificate of analysis or conformity for all raw materials and ingredients that could impact on finished product safety, documented and kept current with the materials in use.	15		
c. Does the firm have effective systems to prevent the use of contaminated, damaged or defective containers (e.g., receiving and storage controls, visual examination prior to use)?	15		
d. Does the firm have controls in place to prevent the presence of undeclared allergens, including prevention of cross-contact, such as from soy or wheat sprouts, etc.?	15		
e. Does the firm document supplementary methods of evaluation to verify the conformance and effectiveness of controls affecting product safety. Methods of verification should include:			
i. Review of all specifications for incoming ingredients and materials as well as letters of agreement at a specified frequency.	10		
ii. On-site assessment of the monitoring procedures.	10		
iii. Review of records for completeness.	10		
iv. Review of deviation records to ensure that appropriate corrective actions have been taken.	10		
v. Independent external or internal audits.	10		
vi. Analysis of consumer complaint trends.	20		
	135	0	
8 Control of Seed Supplier Sources			
a. Does the firm have a letter from each of its seed suppliers stating that they are requesting conformance with Good Agricultural Practices for the growing and harvesting of seed for sprouting and are expecting their seed growers to attain these standards.	10		

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	Points	Score	Comment
b.	10		
c.	10		
d.	10		
		40	0
9 Control of Sprouting Operations			
a. Seed Receiving and Storage			
i	15		
ii	10		
iii	15		
iv	15		NA option
		55	0
b. Seed Sanitization and Treatment			
i.			Automatic Failure

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	Points	Score	Comment
ii. Does the firm have documents with the following information on antimicrobial treatment(s) used by the firm for each seed type:			
Type of seed	10		
Biocide (include brand)	10		
Concentration	10		
Treatment method (including agitation method)	10		
Duration of treatment	10		
iii. Does the firm maintain daily logs for each of the treatment applications used, including quantity of seed, water, sanitizer used, levels attained, duration of soak?	15		
iv. Does the firm document the method and procedures that are used to verify the concentration (e.g., test strips, dilutions, etc.)? Including brand, model and test range.	10		
	75	0	
c. Sprout Production			
i. Does the firm have a written SOP for sprout production?	15		
ii. Does the firm have written sprout production logs working in conjunction with the seed log, to show what seed lots were used on what production days?	25		
iii. What types of seeds are sprouted at the firm? List all:			
iv. Is the water chlorinated or otherwise sanitized by the firm? If yes, what level of chlorine is used? - (note: chlorination of irrigation water may affect microbial testing of spent irrigation water)			
v. Does the firm capture and reuse spent irrigation water? If so, does it have a documented, validated effective and monitored treatment process to prevent cross-contamination?			Automatic Failure N/A Option
	40	0	
d. Post Harvest Washing, Dehulling, and Dewatering			
i. Does the firm have a written SOP for the dehulling, washing, and dewatering processes?	10		N/A Option
ii. If the wash water is recycled, is there a written procedure and documentation that the sanitizer level is tested prior to use, and that the sanitizer level maintained?	10		N/A Option
	20	0	

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	Points	Score	Comment
e. Packing & Labeling			
i	10		Does the firm have a written SOP for packing finished product, including a method of trace-back?
ii	15		Does the firm have controls in place to ensure that labels are complete and accurate?
		25	0
f. Spent Irrigation Water Testing for Pathogens			
i			Does the firm have a written SOP for microbial sampling and testing of spent irrigation water, including collecting a water sample representative of the production lot being tested and defining a batch that is appropriate for the growing system used.
ii	15		Are there separate and appropriate spent irrigation water sampling procedures for drum grown, tray grown, bin grown, etc. sprouts?
iii			Are mung or soy bean bins sampled in such a way that a small amount of water has passed over the whole bin and been collected for testing?
iv	15		If sprouts are grown in a rotary drum, is water sampled equally from each of the quads for a given sample?
v	15		If sprouts are grown on trays, is water sampled equally from each of the trays in the tower for a given sample?
vi			Does the firm's written SOP have procedures for holding finished product until lab results (either preliminary or confirmed results) are returned before release to market? If yes, review copies of procedures.
vii			Does the firm have sampling records that confirm that product is being sampled according to the written protocols?
viii			Is spent irrigation water tested for: E. coli O157:H7 Salmonella spp. Others? Specify.
ix			Is the initial microbial testing of spent irrigation water performed by a contract laboratory or the firm's in-house lab?
			Automatic Failure
			Automatic Failure

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	Points	Score	Comment
x	15		
Is there documentation that the lab is certified for each of the tests used, by A2LA and/or ISO 17025 or other nationally recognized certification system?			
xi	15		N/A Option
Does lab participate in the American Proficiency Institute "check sample program" or a similarly recognized program?			
xii	15		N/A Option
Does the laboratory run Check Samples on the testing method used?			
xiii	15		N/A Option
Is the in-house technician certified to perform the tests?			
xiv			
Is the contract or in-house laboratory that is testing the irrigation water using a testing method that has been validated specifically for sprout irrigation water for each pathogen being tested for, and following the validated protocol for microbial testing of spent irrigation water, including the size of samples used for testing and the enrichment protocol used? See Appendix B.			
xv			
If rapid test kits are used, list brand name for each test			
			Salmonella spp.
			E. coli O157:H7
			Other (specify)
xvi	NA		
Did the firm have any presumptive positive results within the last year?			
xvii	NA		
Is a confirmation test done when a preliminary positive test result is received? If yes, check lab report results to verify.			
xviii			
If confirmation testing was done and product was released, was the original enrichment media used for confirmation testing? A new sample of spent irrigation water should not be used.			
	20		NA option
g. Soil Grown Sprouts			
Firms growing sprouts in soil must have written documentation for safe production procedures that include:			
i.	20		NA option
prohibiting bringing soil into a room where water grown sprouts are grown or processed			
ii.	20		NA option
a testing program for the soil for Salmonella and Ecoli O157:H7			

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	Points	Score	Comment
iii. prevention of contamination of the sprouts through contact with birds, rodents, other pests or their feces, and insanitary conditions in the production rooms	20		NA option
iv. prevention of cross-contamination with other growing or production rooms by workers moving between rooms.	20		NA option
220		0	
10 Storage and Distribution			
a. Is the cooler temperature recorded at least twice a day?	10		
b. Is the truck refrigeration temperature recorded for every run on the truck log, monitoring device or invoices, etc.?	10		
20		0	
11 Traceback and Recalls			
a. Does the firm have written procedures for the recall of product?	15		
b. Has the firm tested its traceback, hold and release and recall system twice a year at a minimum? Confirm with documentation.	15		
c. Was all of the product accounted for in the recall test? If not, was a corrective action put into place for each incident?	15		
d. Was the traceback successful to the seed supplier? If not was a corrective action put into place?	10		
e. Does the firm have a complaint log documenting each complaint received, the response to the complaint and the corrective action taken relative to the complaint? Were complaints handled immediately, evaluated for potential risk to consumers, and information shared with all potentially affected parties?	10		
f. Does the firm have a procedure for receiving complaints such that whoever receives customer's complaints has a list of questions to ask to determine seriousness of complaint and allow traceback?	10		
g. Does the firm have a policy of notifying FDA, CFIA or other regulatory authority, if the firm determines that sprouts that have been transferred to another person present a reasonable probability of serious adverse health consequences.	Automatic Failure		
h. Is the firm registered with the Reportable Food Registry? Is the Reportable Food Registry referenced, and the appropriate phone number listed in the policy?	10		
85		0	

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Points	Score	Comment
12 Food/Facility Defence (Security) Program		
a. Is the firm registration under the FDA Bioterrorism Act on file on the production premises?	10	
b. Has the firm conducted a Vulnerability Assessment to identify food defense risks?	10	
c. Does the firm have a documented Food/Facility defense (security) plan that includes:	10	
i.		
A Coordinator familiar with the Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188)? See link: http://www.fda.gov/Food/FoodDefense/Bioterrorism/ucm2006917.htm	10	
ii. Food Defense Team members and contact information?	5	
iii.		
Key regulatory agency representatives and contact information?	10	
iv. First responders and contact information?	10	
v. Annual documented Food Defense training and education?	5	
vi. Annual Food Defense Program review?	5	
d. Does the firm conduct routine physical security inspections of their premises to verify control measures are in place?	10	
e. Does the firm pre-screen employees prior to hiring, such as an application form and reference check?	10	
f. Does the firm have a restricted access policy?	10	
g. Does the firm have a written protocol for corrective action following a security breach?	25	
h. Does the firm reserve the right to inspect visitor incoming vehicles, packages and briefcases?	10	
i. Does the firm perform random inspection of any off-site storage facilities and trailers?	5	
145		0
13 Training		
a. Does the firm have a written food safety policy describing its GMP training program for management and all other employees with documented training sessions for each person employed?	15	
b. Is management trained or experienced in food safety?	10	

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	Points	Score	Comment
c. Does the firm have training materials for: Seed sanitizing?	10		
Every batch spent Irrigation water sampling and preparation for Hold and Release programs?	15		
d. Does the firm have signed records of training sessions, which are reviewed by the supervisor after observation of the workers and signed off that the training was effective?	10		
e. Does the firm have training records for recent hires, signed of by a supervisor that they were effective?	10		
f. Does the firm have training records for at least annual refresher training for all employees?	10		
g. Are all training programs reviewed and updated at least annually?	10		
	105	0	

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	Points	Score	Comment
B. Site Inspection			
1 Overview of Documents			
a. With the responsible person, assess the firm's record keeping system. Is it well organized and easy for multiple users to get forms, fill them out and save them for future review and inspection as necessary? Are they stored securely, protected against damage by fire, flood, theft, or access by unauthorized personnel?		5	
b. Are records legible, accurate and signed and dated by individuals responsible?		15	
	20	0	
2 Sprout Production Buildings & Equipment			
a. Walk around the perimeter of the building:			
i. Are buildings and surrounding areas designed, constructed and maintained in a manner which prevents conditions that may result in the contamination of food? (e.g., exterior has no unprotected openings that would allow entry of contaminants and pests, the roof, walls and foundation are maintained to prevent leakage, the surrounding land is maintained to control sources of contamination such as pest harborage areas, the building is not impacted by any environmental contaminants of concern, etc).		10	
ii. Are all production buildings (Sheds, greenhouses, screen houses, etc.) fully enclosed (including a solid roof on the screen house) and protected from outside contaminants?		10	
iii. Does the firm have controls in place to prevent contaminants from entering the sprouting production areas (e.g., boot washing stations in entrances with frequent monitoring of sanitizer level, and/or dedicated boots for inside operation).		10	
b. Walk around the interior of the building:			
i. Assess building and production area cleanliness (e.g., food residues on floor, insufficient draining of excess water on floor, dripping from ceiling or light fixture, moldy wall, rusted equipment, water from floor contacting product)		15	

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	Points	Score	Comment
ii	10		Are floors smooth, non porous, impervious to water and sufficiently sloped to permit proper drainage?
iii	10		Is the operation free of puddles, drips, condensation onto food contact areas and in areas that could contaminate food?
iv	10		Are walls, doors and ceilings smooth, non porous, non-chipping and impervious to water?
v	10		Are light bulbs and fixtures protected to prevent contamination of sprouts in case of breakage?
vi			Does the facility layout permit good hygienic practices, including protection against cross-contamination between operations and during cleaning and sanitation of utensils and equipment?
vii	10		Are storage, seed sanitization, germination and packaging areas separated from each other or has the potential for cross contamination between them been otherwise adequately addressed?
viii	5		Do the production rooms have adequate ventilation to minimize condensation?
ix	10		Is the ventilation system constructed to avoid air flow from contaminated to clean areas?
x	10		Is the ventilation system designed to be adequately maintained and cleaned?
xi	10		Are ventilation openings equipped with close-fitting screens or filters to reduce risk of contaminated air intakes?
xii			Describe the water source/sources used for sprout production and processing and include any microbiological or chemical test results within the last 12 months.
xiii			Check the most recent water analysis. Is the water potable?
xiv	10		Are sewage, effluent and waste storage and disposal systems designed, constructed and maintained to prevent
xv	10		Are draining and sewage systems equipped with appropriate traps and vents?
xvi			Are there back flow preventers on all areas where water from sewage, wash tanks, hoses, etc. might flow back into the main source of water?
		185	0

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	Points	Score	Comment
3 Cleaning and Sanitation			
a. Are equipment and utensils used during sprout production clean and well maintained and stored in such a manner as not to become contaminated?	10		
b. Are there separate, color coded utensils for each of the areas of cleaning and sanitation, such as food preparation vs. cleanup, for use with allergenic vs. non allergenic foods, floors vs. food contact areas, etc.	10		
c. Is the sprouting area and food contact surfaces clean and well maintained?.	15		
d. Review production records for each of the following: Are the records consistent with the firm's written sanitary procedures?			
Seed storage area/room and equipment	10		
Seed sanitization area/room and equipment	10		
Sprouting area/room and equipment	10		
Packaging area/room and equipment	10		
Sprout coolers, drip pans and other cooler equipment	10		
Trucks	10		
e. Are there records for <i>Listeria spp</i> testing frequency matching the written program?	10		
f. Ask to speak to an employee who does cleanup work. Ask how he/she checks after cleaning and sanitizing the room to make sure the room has been adequately cleaned and sanitized. Does the employee know the appropriate protocols?	15		
g. Is there a supervisor or other responsible person to insure that employees are following written procedures in cleaning and sanitizing?	15		
		135	0
4 Pest Control			
a. If pest control chemicals are stored on site, are they secured in a locked cabinet or room?	10		N/A Option
b. Are dilution and application information for chemicals on file?	5		
c. Are Material Safety Data Sheets (MSDS) for chemical use on file?	5		
d. Review the service report. Are chemicals applied according to written procedures?	5		
e. Are usage levels as written?	5		

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	Points	Score	Comment
f. Does the firm have a current plot diagram schematic that documents the locations, description and identifies markers of all stations (live traps, bait stations, glue boards, ketchalls, tin-cats, & insectocutors)?	5		
g. Do records indicate that the firm is doing its own inspection at least weekly?	5		
h. Do the Pest Control Service reports show the conditions found and the corrective actions needed to prevent future pest problems?	5		
i. Are there inside rodent traps (ketchalls, tin-cats or glue boards etc.) against the wall on both sides of all outside pedestrian, cooler and dock doors and every 30-40' (9-12m) against the inside of all exterior walls in the dry storage areas, boiler rooms, etc.?	5		
j. If insect light traps are installed are they cleaned and operating properly, and do they have shields to prevent glass cross-contamination?	5		N/A Option
k. Are the locations of traps away from exposed food, food packaging materials and food processing equipment?	10		
l. Is there a perimeter maintained around the inside of exterior walls of the seed storage areas so as to facilitate the ability to do pest control?	5		
m. Are interior walls, floors and ceilings well maintained and free of major cracks and crevices that could be entry points?	5		
n. Check outside traps or bait stations. Are stations clean, filled with fresh bait, undamaged, secured to the ground, free from dead rodents and properly serviced, with bait secured inside the station?	5		
o. Are the bait stations positioned every 50-70' (15-21m) against the outside walls of the buildings all the way around?	5		
p. Are there gaskets around dock levelers to reduce all gaps to less than 0.25" (6mm) to prevent rodent entry?	5		
q. Are there screens on doors, windows and louvered ventilation fans?	5		
r. Is the outside perimeter of the building free of standing water that might attract or breed pests?	5		

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	Points	Score	Comment
s. Have trees, overhanging beams, ledges, etc. been treated to discourage birds from roosting near the sprouting operation?	5		
t. To prevent pest harborage is there an 24" open area maintained around the perimeter of the building with no items stored up against the building?	5		
u. Is the outside of the buildings free of rodent burrows?	5		
v. Are dumpsters in good repair, lids closed, and stored away from the	5		
	120	0	
5 Waste Management			
a. Are waste storage areas separated from the plant? Away from seed and sprout handling and storage areas?	10		
b. Are all waste containers clearly labeled, leak-proof and where appropriate, covered?	5		
	15	0	
6 Personal Hygiene			
a. Assess the overall operation. Does management promote a culture of food safety which will include the importance of sanitation and cleanliness among their employees?	25		
b. Do the buildings have adequate and conveniently located changing facilities and toilets?	15		
c. Are toilet facilities designed to allow hygienic removal of waste and be segregated from production and storage areas?	10		
d. Are toilet facilities maintained under sanitary conditions and good repair?	10		
e. Does the firm provide adequate means of washing and drying hands, including wash basins, soap, disposable towels and a supply of hot and cold water adjacent to toilets?	10		
f. Are hand washing and hand sanitizing stations located where needed?	10		
g. Are boot sanitizing troughs or mats placed at all entrances to post seed sanitization areas?	10		
h. Are sanitizer chemical levels checked and documented at a frequency sufficient to maintain the specified levels?	10		
i. Are the employees dressed in clean garments according to the firm's specifications?	10		
j. Are employees free of any visible jewelry? Plain wedding bands may be worn under gloves.	10		

Sprout Specific Safety Audit

	Points	Score	Comment
k. Are employees wearing hair nets, beard covers, head bands, caps or other effective hair restraint?	10		
l. Are clothing pockets (above the waste) free of objects that might fall into product?	10		
m. Ask the employee what she/he does with raw or packaged product that has fallen on the floor. Does employee know the firm's protocols?	15		
155		0	
7 Control of General Operations			
a. Are packing materials new (or cleaned and sanitized if reusable), clean, suitable for use with food, and transported and stored in sanitary conditions?	15		
b. Is each lot of packaging material examined for physical damage, signs of contamination (e.g., stains, bird droppings, insect) and foreign material at receiving? Check receiving logs.	15		
c. Are production lines and equipment dedicated to one seed type where allergens (such as soy, wheat, peanut, etc. sprouts) are present? If not, are they properly cleaned with a detergent between products in order to remove the allergen materials? Ask an employee to explain what they do when switching from an allergy product to another product.	15		
45		0	
8 Control of Sprouting Operations			
a. Seed Receiving and Storage			
i. Ask to speak to an employee who is responsible for receiving seeds. Ask that employee to describe the procedure for receiving, inspecting and storing seeds. Is he/she aware of the firm's protocols and appear to be following them?	15		
ii. Does the firm have documentation of seed supplier testing results for <i>Salmonella and Ecoli</i> O157:H7 (including documented procedures for sampling and testing) as part of a certificate of analysis (COA) or certificate of conformance from the seed supplier for every seed lot received?	10		

Sprout Specific Safety Audit

	Points	Score	Comment
iii	How are seeds stored?		
	Is there a dedicated seed storage area?	10	
	Is storage area dry and clean?	10	
	Stored off the floor and away from walls?	10	
	Are opened bags of seed stored in containers?	10	
	Are containers emptied and sanitized between lots?	10	
	Are seed lot numbers clearly marked on storage containers?	10	
	Are seed storage containers covered/closed?	10	
		95	0
b. Seed Sanitization/Treatment			
i	Ask an employee responsible for seed sanitization to re-create an actual seed sanitization process from mixing of chemicals to actual sanitization of seeds while you observe and record data.		
	Describe process and observations		
	What volume of seed to what volume of solution is used?		
	Is the seed/solution agitated according to the written sanitizing procedures during treatment?	10	
	Method of agitation?		
	How long is the treatment?		
	Are seeds pre-rinsed, prior to any antimicrobial treatment?	10	
	Rinsed after treatment?	10	
	Method of disposal of sanitation material?		
ii	Is the employee able to demonstrate that the concentration of the solution was within the established target range? Is it documented?	10	
iii	Does the firm have copies of invoices for sanitization chemicals purchased that approximate their written sanitization procedures?		Automatic Failure
iv	How are the sanitized seeds transferred/transported to sprout production?		
		40	0

Sprout Specific Safety Audit

	Points	Score	Comment
c. Sprout Production			
i Ask to speak with an employee in production. Ask him/her how he/she fills out the logs to document the plantings and harvestings each day. Is the employee using the logs according to the documentation?	25		
ii Did you observe any potential cross-contamination situations in the growing and harvesting process, such as harvesting containers placed on floors, employees handling seed after harvesting sprouts without washing hands and changing gloves, etc.?	25		
	50	0	
d. Post Harvest Washing, Dehulling, and Dewatering			
i Observe the dehulling, washing, and dewatering processes. Is the worker following the written procedures?	15		
ii Is there a potential cross-contamination of clean sprouts with the environment or older sprouts in this process, such as grime or mold on equipment or a buildup of particulate in recirculating water.	15		
	30	0	
e. Packing & Labeling			
i Is the packing area clean and protected from potential cross contamination?	10		
ii Does the firm adhere to all packaging and labeling regulations?	10		
ii Are sprouts labeled with the statement "Keep refrigerated"?	10		
iii Are pre-packaged sprouts identified with sell-by, use by, best before, or other code on the label or container to allow the identification of product in the event of a recall?			Automatic Failure
iv Is it clear from the name on the main identification panel what is in the product, and is the list of ingredients complete? (ie. labels are not misleading).	15		
	45	0	

Sprout Specific Safety Audit

	Points	Score	Comment
f. Spent Irrigation Water Testing for Pathogens			
i Does the firm collect spent irrigation water for microbiological testing?			Automatic Failure
Is spent irrigation water collected for microbiological testing for every production batch, for each variety of sprouts?			Automatic Failure
Does the firm sample/test every homogenous production batch, collecting a water sample representative of the production lot being tested and defining a batch that is appropriate for the growing system used. (Pooling seed lots in less than production size batches up to 50 lbs of raw seed is considered acceptable.)			Automatic Failure
Are spent irrigation water samples collected after approximately 48 hours of sprouting?	15		N/A Option
If collected less than 40 hours, note the firm's justification for other time frame?			
Is the firm collecting at least 1 liter of spent irrigation water per sample?	15		
Is neutralizing chemical (e.g., sodium thiosulphate supplied in sampling containers) added in the sampling container (this may be needed if chlorinated water is used for irrigating sprouts. Water can be checked with a chlorine meter)?	15		N/A Option
If samples are held more than 24 hours before testing, are samples stored and shipped under refrigeration prior to testing? (It has been shown that some pathogens will die if not stored at cold temperature)	15		
Are samples clearly marked for tracking?	15		
ii If positive or unconfirmed presumptive positive, are there records to confirm proper disposition of all product in that batch?			Automatic Failure
iii Does the firm keep two years of hold and release records that demonstrate that no contaminated product has gotten into the marketplace? Pick a random week and ask to see the firm's lab reports, shipping slips and invoices to confirm.			Automatic Failure
iv Does the firm notify seed suppliers of positive results?	15		

Sprout Specific Safety Audit

	Points	Score	Comment
v	25		Have the firm re-create an actual spent irrigation water sample collection and preparation for lab.
	25		Are sampling containers clean, sterile and free of anti-microbials?
	25		Are samples collected in such a way as to insure as much as possible that water has run over the entire batch of sprouts being sampled?
	25		Does the volume of water sampled match the volume specified in the written program?
			If water is collected from multiple quads or trays for a single sample, are the individual samples combined in a way so as to create a complete sample of all the sprouts?
	10		Was the sample collected aseptically?
vi	15		Do samples arrive at the lab within 24 hours of sampling?
vii			Does the lab confirm they did the testing?
g.			If the firm is growing sprouts in soil, check for documentation of testing the soil for Salmonella and E. coli O157:H7; notice if the growing units are protected from contact with birds, rodents, other pests or their feces; and look for insanitary conditions in the production rooms, and possible cross-contamination with other sprouts in the same growing or packing rooms.
215		0	Automatic Failure NA option
9 Storage and Distribution			
a.	5		Is the temperature in the cooler being maintained between 34°F and 40°F (1-4°C)?
b.	15		Are sprouts being cooled under sanitary conditions?
c.	15		Does the firm distribute sprouts under refrigeration?
35		0	Automatic Failure
10 Traceback and Recalls			
a.			Looking at the firm's lab reports, select one product that has been sampled and gone to the lab for which the results have not come back yet. Can the company account for all of that product still in their control on hold? Reconcile the amount produced against amount on hold.
Automatic Failure			

Sprout Specific Safety Audit

	Points	Score	Comment
b. Looking at a current mock recall document, choose one product to test for current traceability. Record the percentage accounted for in the comment column.	25		
	25	0	
11 Food/Facility Defense (Security) Program			
a. Does the firm use some form of identification for employees, such as name tags, or everyone knows each other?	5		
b. Does the firm restrict entry to the establishment?	10		
c. Is the firm protecting the perimeter access with fencing or other deterrent such as locked doors?	5		
d. Does the firm secure their doors to the outside?	25		
e. Does the firm minimize the number of entrances to restricted areas?	5		
	50	0	
12 Training			
a. Are personnel and supervisors responsible for the sanitation program trained to understand the principles and methods required for effective cleaning and sanitation?	15		
b. Check the records of training for the last year, who was trained and what material was covered. Do the records show the firm is meeting its written standards?	15		
c. Are there proficiency criteria to show that the training was actually understood and retained by employees?	10		
d. Ask a random employee when the last time he/she received training, what he/she learned, if he/she signed a document showing attendance, or if it was on the spot training. Does this response verify the documented training program?	25		
	65	0	

Sprout Specific Safety Audit

	Points	Score	Comment
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Scoring

	Points	Score
1 Overview of Documents	310	0
2 Sprout Production Buildings & Equipment	205	0
3 Cleaning & Sanitation	295	0
4 Pest Control	150	0
5 Waste Management	20	0
6 Personal Hygiene	290	0
7 Control of General Operations	180	0
8 Control of Seed Supplier Sources	40	0
9 Control of Sprouting Operations		
a. Seed Receiving and Storage	150	0
b. Seed Sanitization and Treatment	115	0
c. Sprout Production	90	0
d. Post Harvest Washing, Dehulling, and Dewatering	50	0
e. Packing & Labeling	70	0
f. Spent Irrigation Water Testing for Pathogens	435	0
10 Storage and Distribution	55	0
11 Traceback and Recalls	110	0
12 Food/Facility Defence (Security) Program	195	0
13 Training	170	0
	<u>2,930</u>	<u>-</u>

Any failed question that has an "Automatic Failure" status, shall cause the company to fail this audit and make immediate corrections prior to a followup inspection. Auditor may complete the audit at the customer's request.

Any failed question that has 25 points (major non-conformance) is considered critical and shall be subject to immediate corrective action (30 days first time or 14 days once you are credited)

Any failed question that has 15 points or less (minor non-conformance) shall be subject to corrective action in 30 days.

"NA option": delete the score in both columns, so the final score will be x points out of y possible, and grower will not be penalized for NA option responses.

Sprout Specific Safety Audit

	Points	Score	Comment
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To the Sprout Grower

1. Use This Check List to Prepare for this audit; Please read and go through this audit ahead of time to understand what the auditor will be looking for.

2. Before the inspector arrives have the following ready :

A flow chart of your operation showing the entrances for people and materials, the storage, work rooms, employee facilities, offices, workshops and coolers and the exits for materials. This flow chart can be very simple as long as it makes your operation clear to the inspector. Have a different chart for each floor of the building.

A list of your seed suppliers and their documented GAPs requirements and their protocols for minimizing the risk of supplying contaminated seeds to the sprout growers, including seed testing and possible sanitation steps

List all the different sprouts and sprout mixes you grow

- Classify them into methods of seed sanitation used
- Classify them into spent irrigation water sampling methods
- For each product indicate which days you harvest per week (See attached sample grid)
- For each product indicate the approximate # of pounds of seed planted per harvest
- For each product indicate the approximate yield in lbs of sprouts per one lb of seeds

Have written instructions available for:

- Seed Sanitation Step
 - Each seed sanitation method you use
 - Which seeds or mixes are treated with each sanitation method
 - Which sanitizer and what concentration used for each method
 - How much sanitizer used per quantity of seed and water
 - Length of time and amount of stirring or agitation
- Every Batch Hold and Release Program:
 - Each method of sampling spent irrigation water including the size of sample, the time (after the start of sprouting) when sample should be collected, and whether neutralizing chemical is added
 - Which seed types from which spent irrigation water are sampled by each method
 - The upper limit of # of pounds of seed from which one spent irrigation water sample is collected
 - If/when more than one seed type is sampled for a single sample, which and how many lbs of seeds are pooled together

Sprout Specific Safety Audit

	Points	Score	Comment
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To the Auditor/Inspector

Section one of this audit is set up to evaluate the documentation, either before arriving on site, or first thing upon arriving.

The sprout company should have access to the audit as far in advance of the audit as possible. They can then prepare appropriately for the audit and collect all of the required documentation to send to you for evaluation.

This audit can be used in printed form, and/or electronically. It will total the score automatically if used electronically:

Print information page and the table of contents (pages one through three) of this "Cover Page" tab to attach to the audit if you are planning to print the audit; or fill out the information on the top of page one if filing electronically.

Emphasize the importance of complete and quickly accessible documentation.

Meet the person responsible for record keeping, find out where records are kept, and find a good place nearby where you can study the records. Check the flow charts to get an overview of the buildings and the operation.

Check the above list of sprouts grown and the instructions for sanitizing, sampling and lab preparation. Are written instructions adequate and complete?

Request report from previous inspection. Ask for Corrective Actions. Check deficiencies.

Randomly select one week in the period since the last inspection. For each seed batch produced that week, examine:

Sales records for quantities of each seed lot sold

Seed sanitation records – do they match written instructions?

Lab records – is there a negative result for each batch sold that week?

Call the lab and confirm that these tests were actually performed that week by that lab.

Hold and release records – are they adequate to insure no contaminated product will get into the marketplace?

Based on the average yield for each sprout batch, check quantities sold against quantities sampled

Make sure the lot codes on invoices match codes on sanitation, sampling and test result records and confirm that the trace back is complete to the seed supplier.

Ask for most recent lab report of presumptive positive. Check the following:

Did the test go on to confirmation or was the product destroyed and and facility cleaned as if it were positive?

Was confirmation positive or negative?

If positive or unconfirmed presumptive positive, check records for proper disposition of all product in that batch of seeds, and that no product was sold before results were confirmed.

Sprout Specific Safety Audit

	Points	Score	Comment
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Examine purchasing records of sanitizers. Request two consecutive purchases to check quantities of sanitizers purchased to match the approximate volume of sprouts sold between the purchases. Use sprout sales records for random week to estimate amount used between purchases.

Examine Employee Training Program:

- Check training materials for sanitizing and Every Batch Testing, Hold and Release program
- Check signed records of training sessions
- Check training records for recent hires
- Check training records for regular refresher training for all employees.

Ask to observe a sanitation demonstration, a spent irrigation water sampling procedure, and sample preparation for lab. Note the following:

- Measurements of sanitation
- Confirmation of concentration
- Method of agitation
- Length of time of contact
- Method of disposal of sanitation material
- Cleanliness of sampling container
- How is production batch defined, one drum/rack of trays of multiple drums/racks of trays
- Methods of collection of spent irrigation water
- Is sample collected at 48 h after the start of sprouting?
- Is neutralizing chemical added if needed?
- Method of pooling sampling water
- Volume of sample appropriate to the validated testing method used
- Accuracy of lab documentation (tracking sheet)
- How samples are stored before shipping to testing lab?
- Is the lab using a rapid test method that has been validated specifically for sprout irrigation water?
- The size of sample that is tested by the lab (375 ml for Salmonella and 100 ml for E. coli O157:H7).
- Is the lab doing duplicate tests?

There are some questions in this audit that specify if the firm is sprouting seeds in soil or for microgreens (loosely defined here as greens that are cut off from their seed, whether grown in soil or hydroponically). It is the intent of this audit to accommodate those products into the sprout protocol within a sprout company. A company that is growing just microgreens, might choose to be audited with the leafy-greens audit, but since there is not at this time an audit specific to microgreens or sprouts grown in soil, this gives the grower the opportunity to have those products included in an audit. If those products are grown in this facility, please include comments at the appropriate places in the audit.

Disclaimer for this Letter, and all attachments Provided with the Sprout Safety Audit Checklist

The compiled material is offered as a sample for your reference and consideration only and is not intended to represent necessarily the best or only approach to the safe production of sprouts. It presents merely a model of operations and an example of best practice systems. Further, the procedures set forth in this document have not been approved or sanctioned by any governmental body. This material is not, and is not intended to be, all inclusive and does not contain information relative to the specific and comprehensive operations of any particular grower, processor, manufacturer or handler of sprouts. The user of this material acknowledges and agrees that its authors are not assuming, and shall not be deemed to have assumed, any responsibility or liability for the consequences of the user's decisions resulting from the information contained herein. The user of this material is expected to evaluate and determine the applicability of the content of this material to its specific operations and should consult with an expert or specialist as appropriate. To the fullest extent allowed by law, neither IIT, IFSH, NCFST nor any of the individuals or entities participating in the Sprout Safety Task Force make any representation, warranty or guarantee, express or implied, including, but not limited to, merchantability or fitness for any particular purpose, with regard to the accuracy, completeness or suitability of the material, and neither IIT, IFSH, NCFST nor any of the individuals or entities participating in the Sprout Safety Task Force assume any responsibility or liability, under any theory, for any actual or indirect, special, consequential, punitive or exemplary damages, in connection with the use or misuse of any such material.

