

Auditing and inspection checklist for sprouting facilities

Firm's Information:

Firm Name: _____

Address: _____

Phone: _____

Date of audit: _____

Most Responsible Individual: _____

Auditor Information:

Name: _____

Agency: _____

Phone: _____

Purpose:

This program is intended to assess a sprouting facility's efforts to minimize the risk of microbial contamination of sprouts. 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.

1. 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>
2. 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>
3. 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
4. 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>
5. Canadian Food Inspection Agency. 2008. Food safety practices guidance for sprout manufacturers. Available at: http://www.sproutnet.com/Reports/CFIA_FSPG_EN.pdf

Two alternative formats are being considered. The first has an initial document review followed by a site inspection (see table of contents below)

The second has each section divided into document review and site inspection (see table of contents on next page). This is open for comments and suggestions.

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 - c. Sprout Production
 - d. Post Harvest Washing, Dehulling and Dewatering
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 - f. Spent Irrigation Water Testing for Pathogens
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How to Use This Check List

To the Sprout Grower, Preparing for this audit:

Please read and go through this audit ahead of time to understand what the auditor will be looking for. This is not a complete list, but it is a suggested list. An auditor may have additional questions.

Have the following ready before the inspector arrives

1. 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
2. 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
3. Have written instructions available for:
 - Each seed sanitation method you use
 - i. Which seeds or mixes are treated with each sanitation method
 - ii. Which sanitizer and what concentration used for each method
 - iii. How much sanitizer used per quantity of seed and water
 - iv. Length of time and amount of stirring or agitation
 - Every Batch Hold and Release Program:
 - i. Each method of sampling spent irrigation water and
 1. Which seeds are sampled by each method
 2. The upper limit of # of pounds of seed in each lab sample
 3. If/when more than one seed is sampled for a single sample, which seeds are pooled together
 - ii. Sample preparation for lab, including
 1. lot code marking and tracking through from supplier to consumer
 2. name, address & phone # of lab
 3. rapid test method used
 4. confirmation method used in case of a presumptive positive
 5. Remediation required in case of a non-confirmed presumptive positive
 6. Remediation required in case of a confirmed positive
 7. System for holding finished product until lab results are returned before release to market.

To the Auditor/Inspector, prepare for this audit by checking the following records, followed by a walk through the whole operation.

- 1 Check the above list of sprouts grown and the instructions for sanitizing, sampling and lab preparation. Are written instructions adequate and complete?
- 2 Request report from previous inspection. Check deficiencies.
- 3 Randomly select one week in the period since the last inspection. For each seed batch produced that week, examine:
 - a. Sales records for quantities of each seed lot sold
 - b. Seed sanitation records – do they match written instructions?
 - c. Lab records – is there a negative result for each batch sold that week?
 - d. Call the lab and confirm that these tests were actually performed that week by that lab.
 - e. Hold and release records – are they adequate to insure no contaminated product will get into the marketplace?
- 4 Based on the average yield for each sprout batch, check quantities sold against quantities sampled
- 5 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.
- 6 Ask for most recent lab report of presumptive positive. Check the following: (Answer in I6q)
 - a. Did the test go on to confirmation or was the product destroyed and and facility cleaned as if it were positive?
 - b. Was confirmation positive or negative?
 - c. 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.
- 7 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.
- 8 Examine Employee Training Program:
 - a. Check training materials for sanitizing and Every Batch Testing, Hold and Release program
 - b. Check signed records of training sessions
 - c. Check training records for recent hires
 - d. Check training records for regular refresher training for all employees.
- 9 Ask to observe a sanitation demonstration, a spent irrigation water sampling procedure, and sample preparation for lab. Note the following:
 - a. Measurements of sanitation
 - b. Confirmation of concentration
 - c. Method of agitation
 - d. Length of time of contact
 - e. Method of disposal of sanitation material
 - f. Cleanliness of sampling container
 - g. Method of pooling sampling water
 - h. Volume of sample appropriate to the validated testing method used
 - i. Accuracy of lab documentation (tracking sheet)

Here are some of the questions the sub-committee has not fully answered:

Is this audit treating the small grower with consideration?

Start with an assessment of the company's documentation:

Flow chart of facility

Explanation of scoring system (what does Doc stand for? It stands for Documentation. Place a check in Doc if you have seen the documentation (numer system for how comprehensive can be developed later). – More area for comments

Comment from Jay Louie: the auditor checks off yes or no. It is not often black and white, but shades of gray. In reviewing your list, I apply it to my own facility as a self evaluation. There are instances where there is compliance, and some partial compliance. Suggest a point system, 1,2,3,4 to 5. By adding up the points, you get a score to create a grading scale. This assumes that each item is of relatively equal importance. If an item is very important, perhaps, expand that item into 2-3 items for greater scoring weight.

Comment from Bob Rust: no way to tell whether a microbiological Hold and Release Program is more important than knowing the core temp of the sprouts. It appears that environmental testing was left out as was product and building security

Bob Sanderson - Thoughts on Audit checklist draft 2/9/10

1. -Under "purpose" was it intentional to omit mention of the ISGA Guidelines, which have probably been the basis for several other "Guideline" products.
2. General comment: the audit contains some elements (but not all) that are a standard part of a food processing GMP audit, and some that are sprout-specific. If it's intended use is as an add-on to a GMP audit, does it need to include GMP details that are more generic? If the sprout-specific interventions are clearly defined, could the check list be simpler if it instructed the auditor to inspect documentation regarding these interventions?
3. In this case, the challenge is to describe proper procedures to the point where someone with little previous knowledge of sprouts can do an effective evaluation.
4. Including more general GMP parts, with sprout specific parts, may introduce confusions over grading. If the audit is "stand-alone" the present draft would duplicate quite a lot of what the GMP audit includes. If it's intended as an add-on it would have to integrate with existing GMP audits. These audits presently have a detailed grading system, so it needs to be determined whether the checklist would be factored into the existing grading system, or graded separately. In which case, one might get an "excellent" on the GMP audit, but fail the checklist audit, and vice-versa.
5. Within what might be considered "sprout-specific fundamentals" are seed sampling, seed disinfection, sample taking, handling, storage and transportation, verification of appropriate lab procedures, and protocols for responses to presumptive and confirmed positives.
6. Which, if any of these, is "pass-fail"?

From David Sasuga, Fresh Origins, 760 822-6171 – microgreen grower - If the sprout people insist that their product is the same as microgreens, it would be fair to have a microgreen grower represented in any draft regulations being proposed. - Could you briefly describe what you think would be required if microgreens were included in the sprout guidance "rules"? It would really help me to understand what may potentially be proposed for growing microgreens. I might then be in a better position to speak to the issues. Maybe I would even support the ideas. For example:

-What about seed testing? I have about 80 plus different varieties (no alfalfa) and no part of the seed is consumed.

-What about tail water? We really don't have any; growing in soil, it does not run through.

-What nature of testing would we do?

-What else might there be?

By the way, my company is a member in good standing of the LGMA (California Leafy Greens).

The way we grow our product is closer to the methods used for leafy greens than to producing and selling spouted seeds

[---STEVE MEYEROWITZ] I would make two distinctions. #1 - Soil vs. non-soil. So shoots would be under the umbrella of “Sprouts” and so would “micro-greens” as long as they are grown without soil. #2 - Length of time to maturity. I would draw a line at 2 weeks. If it is under 2 weeks it is sprouting. If it is over 2 weeks, and uses soil, it is NOT sprouting. In my model, the terms may overlap, but the method determines whether it is sprouting or gardening.

A. Documentation and Records

#	Questions	Yes	No	Doc	Comment
A1	Is there one person responsible for keeping and validating safety documentation records?				
A1	With the responsible person, assess the company's record keeping system. Is it well organized and easy for multiple users to get forms, fill them out and save them for future inspection when necessary?				
A2	Are records legible, accurate and signed and dated by individuals responsible?				
A3	Do records include written procedures, controls, limits, monitoring results, corrective actions and follow-up documents, maintained for a minimum of one year, for each of the following?				
	seed sources and lot numbers				
	Source water analysis results				
	Sanitation checks				
	Pest control monitoring				
	Sprout lot codes				
	spent irrigation water analysis results				
	production volumes				
	storage temperature monitoring				
	product distribution and consumer complaints				
A5	Are records retained for at least one year for each lot of sprouts?				

B. Establishment for Sprout Production

#	Questions	Yes	No	Doc	Comment
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B1	Assess facility 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)				Inspection
B2	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 to prevent 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 located in close proximity to any environmental contaminants, etc).				Inspection
B3	Does the facility layout permit good hygienic practices, including protection against cross-contamination between operations and during cleaning and sanitation of utensils and equipment?				Inspection
B4	Is the facility (Building, greenhouse, screen house) fully enclosed (including a solid roof on the screen house) and protected from outside contaminants?				Inspection
B5	Are storage, seed disinfection, germination and packaging areas separated from each other or has the potential for cross contamination between them been otherwise adequately addressed.?				Inspection
B6	Are floors smooth, non porous, impervious to water and sufficiently sloped to permit proper drainage?				Inspection
B7	Are walls, doors and ceilings smooth, non porous, non-chipping and impervious to water?				Inspection
B8	Is there a glass and brittle plastic program in place?				Document
B9	Are light bulbs and fixtures protected to prevent contamination of sprouts in case of breakage?				Inspection
B10	Is there a metal contamination prevention program in place (i.e. to prevent nuts & bolts from equipment from entering finished product)?				Document
B11	Are equipment and containers coming in contact with sprouts made of materials which have no leaching toxic effects?				Inspection
B12	Are equipment and utensils used during sprout production clean and well maintained and stored in such a manner as not to become contaminated?				Inspection
B13	Are equipment and utensils inspected to determine adequacy of cleaning and records of the sanitizing treatments and inspections kept?				Document
B14	Are food-contact surfaces clean and free from potential contamination from dripping ceilings, floors, etc.				Inspection
B15	Does the facility have written programs to ensure water				Document

	quality?				
B16	Is water used for irrigation and finished produce washing from a potable source?				inspection
B17	Describe the water source/sources used for sprout production and processing and include any microbiological or chemical test results within the last 12 months.	Document			
B18	If the water source is wells or cisterns, are they tested at least twice a year? Check documentation.				Document
B19	If the facility is on a municipal water supply, is there a current document (within 12 months) on file from the supplier that verifies that the water is of adequate quality?				Document
B20	Does the facility have adequate ventilation to prevent condensation, dust, and minimize entry of contaminated air?				inspection
B21	Is the ventilation system constructed to avoid air flow from contaminated to clean areas?				inspection
B22	Is the ventilation system designed to be adequately maintained and cleaned?				inspection
B23	Are ventilation openings equipped with close-fitting screens or filters to reduce risk of contaminated air intakes?				inspection
B24	Are sewage, effluent and waste storage and disposal systems designed, constructed and maintained to prevent contamination?				inspection
B25	Are draining and sewage systems equipped with appropriate traps and vents?				inspection
B26	Is there evidence of cross-connection between the sewage system or other waste effluent systems and the sources of potable water?				inspection

C. Cleaning and Sanitation

#	Questions	Yes	No	Doc	Comment
C1	Does the firm have written cleaning and sanitation program for the premises (production and storage areas)?				Document
C2	Does the firm have written cleaning and sanitation program for all equipment?				Document
C3	Does the written cleaning and sanitation program for facility, equipment and utensils include the following? Document				
	- name of the responsible person				
	- the frequency of the activity				
	- the procedures for cleaning, sanitizing and rinsing				
	- chemicals and concentrations used				

	<ul style="list-style-type: none"> - temperature requirements - the type and frequency of inspection to verify the effectiveness of the program equipment and utensils used during sprout production -disassembly/re-assembly instructions 				
C4	How often does the firm clean and sanitize each of the following, review records: Are the records consistent the written documentation? Document				
	<ul style="list-style-type: none"> - seed storage area/room and equipment - seed disinfection area/room and equipment - sprouting area/room and equipment - packaging area/room and equipment - sprout Coolers, drip pans and other cooler equipment 	Yes	Comments how often		
C5	What chemicals and concentrations are used to sanitize the following areas/rooms? Does documentation verify that chemicals are used in accordance with manufacturer's instructions?				
	<ul style="list-style-type: none"> - seed storage area/room and equipment - seed disinfection area/room and equipment - sprouting area/room and equipment - packaging area/room and equipment - - sprout Coolers, drip pans and other cooler equipment equipment and utensils used during sprout production 	yes	Chemical/concentration		
			Document		
C6	Is the sprouting area and food contact surfaces clean and well maintained?.				Inspection
C7	Does the firm have written procedures for routine verification of its cleaning and sanitation procedures?				Document
C8	Is a method in place to verify the effectiveness of cleaning and sanitation?				Document
C9	Is there a written procedure for at least weekly sampling of equipment, floors, drains, cooler pans, etc. for <i>Listeria sp</i> ?				Document
C10	Are there records for regular <i>Listeria sp</i> testing?				Document
C11	Does the firm have written SOPs for cleaning and disinfecting facility and equipment after contamination was found?				Document

C12	Does the firm have written procedures to verify the effectiveness of their cleaning and sanitation procedures?				Document
C13	Does the firm have written SOPs for corrective actions before resuming production after contamination is found?				Document

D. Pest Control

#	Questions	Yes	No	Doc	Comment
D1	Does the facility have a written pest control program?				Document
D2	Does the firm use properly trained and licensed pest control technicians, whether internally employed or externally hired on at least a monthly basis?				Document
D3	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.				Document
D4	Does the facility have a complete list of pesticides approved for use and the designated areas where they are approved for application?				Document
D5	Are dilution and application information for chemicals on file?				Document
D6	Are Material Safety Data Sheets (MSDS) for chemical use on file?				Document
D7	Review the service report. Are chemicals applied appropriately? Are usage levels as recommended?				Document
D8	If pest control chemicals are stored on site, are they secured in a locked cabinet or room?				Inspect
D9	Does the facility have a current plot diagram schematic that documents the locations, description and identifies markers of <i>all</i> stations (live traps, bait stations, glue boards ketchalls, tin-cats, & insectocutors)?				Document
D10	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 <i>exterior walls</i> in the <i>dry storage areas, boiler rooms, etc.?</i>				Inspect
D11	Is the inspection of these traps documented weekly?				Document
D12	Do records indicate that the firm's management is doing their				Document

	own inspection at least monthly?				
D13	Do the Pest Control Service reports show the conditions found and the corrective actions needed to prevent future pest problems?				Document
D14	If insect light traps are installed are they cleaned and operating properly, and do they have shields to prevent glass cross-contamination?				<u>Inspect</u>
D15	Are the locations of traps away from exposed food, food packaging materials and food processing equipment?				<u>Inspect</u>
D16	Is there a provision in the program for determining the effectiveness and servicing of traps weekly to remove dead pests and to try to identify the source of infestation?				Document
D17	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?				<u>Inspect</u>
D18	Are interior walls, floors and ceilings well maintained and free of major cracks and crevices that could be entry points?				Inspect
D19	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?				<u>Inspect</u>
D20	Are the bait stations positioned every 50-70' (15-21m) against the outside walls of the facility all the way around?				<u>Inspect</u>
D21	Are there gaskets around dock levelers to reduce all gaps to less than 0.25" (6mm) to prevent rodent entry?				<u>Inspect</u>
D22	Are there screens on doors, windows and louvered ventilation fans?				<u>Inspect</u>
D23	Is there a lack of standing water on the outside perimeter of the building to prevent pest harborage?				<u>Inspect</u>
D24	Have trees, overhanging beams, ledges, etc. been treated to discourage birds from roosting near the facility?				<u>Inspect</u>
D25	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?				<u>Inspect</u>
D26	Is the outside of the facility free of rodent burrows?				<u>Inspect</u>
D27	Are dumpsters in good repair and stored away from building?				<u>Inspect</u>

Management

E1	Does the firm have written SOPs for the storage and removal of waste from production and outside areas, including the frequency of removal?				<u>document</u>
E2	Are waste storage areas separated from the plant? Away from seed and sprout handling and storage areas?				<u>inspect</u>

E3	Are all waste containers clearly labeled, leak-proof and where appropriate, covered?				inspect
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F. Personal Hygiene

#	Questions	Yes	No	Doc	Comment
F1	Does the facility have adequate and conveniently located changing facilities and toilets?				Inspect
F2	Are toilet facilities designed to allow hygienic removal of waste and be segregated from production and storage areas?				Inspect
F3	Are toilet facilities maintained under sanitary conditions and good repair?				Inspect
F4	Does the facility 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?				Inspect
F5	Are hand washing and hand sanitizing stations located at all entrances and throughout sprouting and packaging rooms and properly maintained?				Inspect
F6	Are boot sanitizing troughs or mats placed at all entrances to post seed disinfection areas?				Inspect
F7	Are sanitizer chemical levels checked and documented at a frequency sufficient to maintain the specified levels?				Inspect
F8	. Does the firm have a written worker health policy that:	Document			
	- 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?				
	- Instructs employees to report any active case of illness to their supervisor before beginning work?				
	- 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)?				
	- Has corrective action for instances of contamination?				
F9	Does the firm have written requirements for cleanliness and personal behaviors that include:				

	<ul style="list-style-type: none"> - Protective clothing, hair covering, footwear and gloves should be worn and maintained in a sanitary manner - 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). - Waterproof gloves should be washed and sanitized similarly to hand washing. - Proper maintenance and cleaning of reusable gowns, aprons, boots and gloves? - Eating, using tobacco, chewing gum, or unhygienic practices such as spitting in food handling areas is prohibited - Jewelry shall not be worn 				Document
F11	Does the firm have a written policy to ensure good hygienic practices are followed by visitors?				Document

G. Control of general operations

#	Questions	Yes	No	Doc	Comment
G1	Does the firm have a written description and procedures for control of entire production processes including				Document
	<ul style="list-style-type: none"> - Process flow diagram - Incoming material control - Packaging control - Production preparation - Product coding control - Process control - Labeling control - Deviations and corrective actions - Verification of product safety 				
G2	Does the firm have written procedures for incoming material controls? (including incoming seed control?)				Document
I3d	Are production lines and equipment dedicated to one seed type where allergens are present?				Inspection
G3	Does the firm have controls in place to prevent the presence				Document

	of undeclared allergens, including prevention of cross-contamination or carry-over?				
G4	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)?				Document
G5	Are packaging materials new (or sanitized if reusable), clean and non toxic, posing no threat to the safety and suitability of sprouts under specified conditions of storage and use?				Document
G6	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				Document
G7	When defects occur or limits of acceptability are exceeded, does the firm have written procedures to identify, isolate and evaluate affected products.				Master document
G8	Does the firm have written procedures for corrective actions following any deviation that include:				
	<ul style="list-style-type: none"> -Investigation to determine the cause of the deviation -Preventative measure to prevent recurrence of deviation -Verification of the effectiveness of the corrective action taken 				Master document
G9	Does the firm use supplementary methods of evaluation to verify the conformance and effectiveness of controls affecting product safety. Methods of verification may include:				
	<ul style="list-style-type: none"> - Review all specifications for incoming ingredients and materials as well as letters of agreement at an adequate frequency. - Development of a sampling plan to ensure the consistent collection of samples (e.g., spent irrigation water) - On-site assessment of the monitoring procedures - Review of records for completeness - Review of deviation records to ensure that appropriate corrective actions are taken - Independent external or internal audits - Analysis of consumer complaint trends 				Master document? Covered in individual sections?

H: Control of Seed Supplier Sources

H1	Does the firm have a letter from each of its seed suppliers stating that they obtain their seed from growers following Good Agricultural Practices for growing and harvesting?				Document
H2	Does the firm have documentation from each of its seed suppliers that the growers are storing and distributing the seeds under Good Manufacturing Practices				Document
H3	Does the firm have confirmation that each seed supplier has a documented food safety program?				Document
H4	Does the firm have a letter from each of its seed suppliers stating that they are planning to, or have already obtained annual 3 rd party audits for GMPs?				Document
H5	Does the firm have documentation of seed supplier testing results as part of a certificate of analysis (COA) from the seed supplier for every seed lot received?				<u>Document</u>

I. Control of sprouting operations

I.1. Seed Receiving and Storage

#	Questions	Yes	No	Doc	Comment
I1a	Does the firm have a written SOP for seed receiving and storage?				<u>Document</u>
I1b	Does the firm have written procedures for visual evaluation of seed shipments when seeds reach the sprouting facility? For example, black light or visual examination of bags for evidence of rodents.				<u>Document</u>
I1c	Does the firm maintain a seed log with seed lot used on each day to track seed (and lot #) through receipt, use, shipping or return to suppliers?				<u>Document</u>
I1d	How are seeds stored?				
	Is storage area dry and clean?				<u>Inspect</u>
	Is there a dedicated seed storage area?				
	Stored off the floor and away from walls?				
	Are opened bags of seed stored in containers?				
	Are containers emptied and sanitized between lots?				
	Are seed lot numbers clearly marked on storage containers?				
	Are seed storage containers covered/closed?				
	Sanitary?				
I1e	Are seed lots ever mixed? During Storage?				<u>Document</u>
	Production?				
	If so, are records kept?				

I.2. Seed Disinfection/Treatment

#	Questions	Yes	No	Doc	Comment
I2a	Does the firm have written seed disinfection procedures?				Document
I2b	Does the firm have written seed disinfection logs?				Document
I2c	Does the firm have copies of invoices for disinfection chemicals purchased that approximate their written disinfection procedures?				Document
I2d	Is at least one effective antimicrobial treatment applied to seeds immediately before sprouting? This treatment must be from a list of treatments suggested by industry, published in the scientific literature, peer reviewed and accepted by a review panel made up of scientists expert in the field.				Document – Reservation; we must have a list approved by the expert panel, adequate for different seeds and different companies before this draft is finalized, or some other wording until the list is acceptable.
I2e	Have the firm re-create an actual seed disinfection process from mixing of chemicals to actual disinfection of seeds while you observe and record data.				
		Inspect			
	a. Describe process and observations				
	b. Test the strength of the solution				
	c. What volume of seed to what volume of solution is used?				
	d. Is the seed/solution agitated during treatment?				
	e. Method of agitation?				
	f. How long is the treatment?				
	g. Potable water being used?				
	h. Are seeds pre-rinsed, prior to any antimicrobial treatment?				
	i. Rinse after treatment?				
	j. Method of disposal of sanitation material?				
I2f	Obtain the following information on antimicrobial treatment(s) used by the firm for each seed type:				
	Type of seed	Document			
	Biocide (include brand)				
	Concentration				
	Treatment method				
	Duration of treatment				

I2g	Is the firm able to demonstrate that the concentration of the solution was within the established target range?				<u>Inspect</u>
I2h	How often does the firm check to verify that the concentration of antimicrobial was prepared according to the firm's SOP and is within the target range established by the firm? (daily, weekly, etc.)	<u>Document</u>			
I2i	What method and procedures are used by the firm to check the concentration (e.g., test strips)? Include brand, model and test range.	<u>Document</u>			
I2j	How are the disinfected seeds transferred/transported to sprout production?	<u>Inspect</u>			

I.3. Sprout Production

#	Questions	Yes	No	Doc	Comment
I3a	Does the firm have a written SOP for sprout production?				<u>Document</u>
I3b	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?				
I3c	What types of seeds are sprouted at the facility? List all:				
I3e	What is the source of water used for irrigation (e.g., municipal, well)? Potable water?				
I3f	Is there a microbial control program for irrigation water? Is it chlorinated or otherwise disinfected by the firm? If yes, what level of chlorine is used? (note: chlorination of irrigation water may affect microbial testing of spent irrigation water)				
I3g	Does the firm capture and reuse spent irrigation water? If so, does it have adequate treatment to prevent cross-contamination?				

I.4. Post harvest washing, dehulling, and dewatering

#	Questions	Yes	No	Doc	Comment
I4a	Does the firm have a written SOP for the dehulling, washing, and dewatering processes?				<u>document</u>
I4b	Is the wash water recycled? If so, is the sanitizer level tested prior to use?				<u>document</u>

I.5. Packing & Labeling

#	Questions	Yes	No	Doc	Comment
I5a	Does the firm have a written SOP for packing finished product?				document
I5b	Is the packing area clean and protected from potential cross contamination?				inspect
I5c	Does the firm have controls in place to ensure that labels are complete and accurate?				Document
I5d	Are sprouts labeled with the statement “Keep refrigerated”?				Inspect
I5e	Are pre-packaged sprouts identified with sell-by, use by or best before on the label or container to allow the identification of product in the event of a recall?				inspect
I5f	Is the list of ingredients complete for each product?				Inspect
I5g	Is it clear from the name on the main identification panel what is in the product, based on the list of ingredients or the actual ingredients? (ie. labels are not misleading)				Inspect

I.6. Spent Irrigation Water Testing for Pathogens

#	Questions	Yes	No	Doc	Comment
I6a	Does the firm have a written SOP for microbial sampling and testing of spent irrigation water?				Document
I6b	Are there separate and appropriate spent irrigation water sampling procedures for drum grown, tray grown, or bin grown sprouts?				Document
	<ul style="list-style-type: none"> 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? 				
	<ul style="list-style-type: none"> If sprouts are grown in a rotary drum, is water sampled from each of the quads? 				
	<ul style="list-style-type: none"> If sprouts are grown on trays, is water sampled from each of the trays in the tower? 				
I6c	If the firm is growing sprouts in soil, is there a sampling protocol in place for soil grown sprouts or microgreens?				Document
I6d	Is the firm using sterile soil?				Document
I6d	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				Document
I6e	Are soil grown sprouts or microgreens tested in a regular				Document

	hold and release program?					
16c	Does the firm have written microbial testing logs? If yes, review test records for last year				Document	
16d	Does the firm collect spent irrigation water for microbiological testing? If yes, describe the procedure					
	<ul style="list-style-type: none"> Is spent irrigation water collected for microbiological testing for all sprouts grown every day? If not, comment which batches are not and how often. Does the firm sample/test every homogenous production batch (ie. drum, rack of trays, bin, etc.) individually? (Pooling seed lots in less than production size batches up to 50 lbs of raw seed is considered acceptable.) Are spent irrigation water samples collected after 48 hours of sprouting start? If not, note the firm's justification for other time frame? What is the volume of spent irrigation water collected per sample? Are sampling containers clean, sterile and free of anti-microbials? Is neutralizing chemical (e.g., sodium thiosulphate) added in the sampling container (this is needed if chlorinated water is used for irrigating sprouts)? How are samples stored prior to testing? (Include temperature) What are the minimum and maximum amounts of time these samples are stored before arriving at the lab? How are the samples transported to the testing lab? Are samples clearly marked for tracking? Are samples shipped refrigerated? 				Document	
16e	Does the firm have sampling records that confirm the above answers?				Automatic Failure	
16f	Is spent irrigation water tested for: <i>E. coli</i> O157:H7 <i>Salmonella</i> spp. Others? Specify.					
16g	Is the initial microbial testing of spent irrigation water				Document	

	performed by a contract laboratory or the firm's in-house lab?				
I6h	If contract laboratory, is there documentation that the lab is A2LA and/or ISO 17025 certified?				Document
I6i	Does contract lab participate in the American Proficiency Institute "check sample program"?				Document
I6j	Does the lab confirm they did the testing?				Automatic Failure
I6k	If firm's in-house lab, is the lab certification on file?				Document
I6l	Is the in-house technician certified to perform the tests?				Document
I6m	Method used for initial testing? (FDA BAM method, rapid test kits, PCR, other?)	This is for comment only. Are rapid test kits valid for hold and release?			
I6n	If rapid test kits are used, list brand name for each test - <i>Salmonella</i> - <i>E. coli</i> O157:H7 - Other (specify)				
I6o	Did the firm have any presumptive positive results?				
I6p	Is a confirmation test done when a preliminary positive test result is received? If yes, check lab report results to verify				
I6q	Is the original enrichment media used for confirmation testing? Spent irrigation water should not be used.				
I6r	If positive or unconfirmed presumptive positive, are there records to confirm proper disposition of all product in that batch of seeds?				Fatal flaw
I6s	Does the firm keep hold and release records adequate to ensure no contaminated product has gotten into the marketplace?				Document
I6t	Does the firm notify seed suppliers of positive results?				document

J. Storage and Distribution

#	Questions	Yes	No	Doc	Comment
J1	Does the firm cool their sprouts to 45 degrees Fahrenheit or below, prior to distribution? Check the core temperature of the sprouts that were placed under refrigeration at the end of the previous day's shift.				Inspect
J2	Are sprouts being cooled under sanitary conditions?				Inspect
J3	Is the cooler temperature checked at least twice a day?				Document
J4	Is the truck refrigeration temperature recorded on the truck log, monitoring device or invoices, etc.?				document
J5	Does the firm distribute sprouts under refrigeration?				Inspect

K. Traceback and Recalls

#	Questions	Yes	No	Doc	Comment
K1	Does the firm have written procedures for the recall of product?				Document
K2	Has the firm tested its traceback and recall system twice a year at a minimum? Confirm with documentation.				Document
K3	Was all of the product accounted for in the recall test?				Document
K4	Was the traceback successful to the seed supplier and from the supplier to the farmer?				Can we trace back to the field yet?

L. Food/Facility defense (security) program [Do we need this?](#)

M. Training

#	Questions	Yes	No	Doc	Comment
M1	Is management trained in GMPs?				Document
M2	Is management trained in HACCP?				Document
M3	Are personnel and supervisors responsible for the sanitation program trained to understand the principles and methods required for effective cleaning and sanitation?				Inspect
M4	Does the firm have a training program for personnel and supervisors to have adequate technical knowledge and understanding of the operations and procedures to maintain the safety of sprouts?				Inspect
M5	Does the firm have an appropriate training program in personal hygiene and hygienic handling of food?				Document
M6	Does the firm have training materials for:				
	seed sanitizing?				Document
	Every Batch Testing?				
	Hold and Release programs?				
M7	Are there proficiency criteria to show that the training was actually understood and retained by employees?				Inspect
M8	Does the firm have signed records of training sessions?				Document
M9	Does the firm have training records for recent hires?				Document
M10	Does the firm have training records for regular refresher training for all employees?				Document
M11	Are all training programs routinely reviewed and updated?				Document
M12	Does the firm have records documenting regular self-audits?				Document