Appendix A: Comments on the Sprout-Specific Safety Audit draft:

1. Are all aspects of a comprehensive sprout food safety program covered in the checklist? Are key recommendations provided by international food safety guidelines being considered?
2. Does the checklist cover all aspects of sprouting facilities and sprouting activities?
3. Does the checklist clearly point out the critical control points important in minimizing the risk of microbial contamination of sprouts?
4. Are key elements of Good Manufacturing Practices covered?
5. Are the questions for document review clear and easy to understand?
6. Are questions related to record review complete and easy to understand?
7. Are questions related to facility inspection clear and easy to understand?
8. Are the points assigned appropriate? Any suggestion for different points?
9. Is the audit fair to small and large sprout growers alike?

KR: Kathleen Rajkowsyy - Comments:

After reading and reviewing the audit, questions (1-8) in the covering e-mail are answered in the affirmative. However, there may be a concern with the small sprout growers, who have one or two operating the growing facility. These growers most likely are the ones who grow and sell at a "farmer's market" where they bring the tray of sprouts and sell from there (no prepackaging) – particularly in California. There is nothing in the audit to state that the tray of sprouts was transported to a market for direct sale. Would this be a concern? The audit documents, as it is now, address the larger producers who sell to major retailer and restaurants. These small sprout growers may also classify themselves as "organic" growers. There is no statement in the audit for larger grower, who have applied for the "organic" status. Should this be addressed?

BS: Bengt Schumacher – Comments:

The food industry in Canada continues to see further interest and adoption of food safety programs that are benchmarked against the Global Food Safety Initiative (GFSI) standards such as BRC and SQF. These programs are already accepted by the food industry and are proven to work. Other benefits to adopting a format similar to one of the GFSI benchmarked standards are that it would help provide a format more familiar to auditors and it would help to establish a checklist with more meaningful weighting. It may still be worth considering adopting one the GFSI benchmarked food safety programs. With regards to the scoring, considerable changes are suggested. The scoring for section A. Documentation and Records and section B. Site Inspection has been all lumped together as seen on page 23. Section A and B scores should be separated. I have included a chart below that separates this out to help make the following comments more understandable.

	DOCUMENTATION and RECORDS		SITE INSPECTION	
1	Overview of Documents	230	20	Overview of Documents
2	Sprout Production Facility and Equipment	45	155	Sprout Production Facility and Equipment
3	Cleaning and Sanitation	265	115	Cleaning and Sanitation
4	Pest Control	30	120	Pest Control
5	Waste Management	5	15	Waste Management
6	Personal Hygiene	135	145	Personal Hygiene
7	Control of General Operations	160	45	Control of General Operations
8	Control of Seed Supplier Sources	40		Control of Seed Supplier Sources
9	Control of Sprouting Operations			Control of Sprouting Operations
	seed receiving and storage a.	45	95	a. seed receiving and storage
	seed disinfection and treatment b.	80	40	b. seed disinfection and treatment
	sprout production c.	55	50	c. sprout production
	post harvest washing, dehulling and dewater d.	20	30	d. post harvest washing, dehulling and dewater
	packing and labelling e.	25	35	e. packing and labelling
	spent irrigation water testing for pathogens f.	165	215	f. spent irrigation water testing for pathogens

10	Storage and Distribution	20	35	Storage and Distribution
11	Traceback and Recalls	110	25	Traceback and Recalls
12	Food/Security Defence Program	145	50	Food/Security Defence Program
13	Training	130	65	Training
		1705	1255	

As an example of how section A and B are different and should be separated, major non-conformance of operational issues requires immediate action but generally there can be a more relaxed schedule for document improvements/additions.

One of the first things that is evident in the scoring system is that there are a lot more points for documentation and records, than there are for site inspection. What this division indicates is that documentation is more important than what takes place during sprout production. Thinking of recent examples, both Maple Leaf Foods and the Peanut Corporation of America had very well documented food safety programs, but both had major flaws in their operational procedures causing some major food safety issues. Clearly, what firms are actually doing (site inspection) is more important than the documents and records and the scoring should reflect that.

One way to improve the scoring is to have each section worth a certain percentage of the total score based on risk. This is essentially a two level scoring system which allows one to make changes to sections without changing the overall percentage value of a section. For example, if one scored 200 out of 265 on the cleaning and sanitation (section A) and this section was deemed to represent 5% of the risk. The score would be 200/265 X 5 = 3.77 out of a possible 5. This technique overcomes the difficulty of having sections with lots of details (high score) but little risk and sections with low scores but high risk. Some work will be needed to assess the proportional risk of each section.

There may be a benefit to having an actual score for the sections marked “automatic failure” instead of nothing. This helps to reflect that firms that are doing a very good job can also rightfully have a very high score.

The "Overview of Documents" is really a measure of management commitment. In some food safety programs it would be considered a separate section.

In terms of the weightings assigned within the current audit checklist, it appears that in some sections, that the weighting across requirements is virtually the same (take Cleaning and Sanitation, Seed Disinfection as examples). Does this seem realistic based on risk?

Is there a plan for overall score ratings? Pass/Fail or different levels? What score would need to be achieved to pass? How high a score would you need to be considered very good?

RW: Richard Whiting – Comments:

Introduction purpose—I might add record management and traceability into that paragraph. They’re important for the new food law.

The checklist is extensive and complete; I don’t have much to add.

The scoring system is somewhat unusual. If the items that fall under the ‘automatic failure’ criterion are met, then what is the significance of those that contribute to the point total?

I’ve mentioned record keeping several times above, the pages ‘to the Sprout Grower’ add further guidance on record keeping (page 26-27).

GP: Gale Prince – Comments:

There appears to be a lot of duplication of comments throughout the document. I have a problem with the point distribution with a de-emphasis on the importance of such a critical area as the control of the seed supplier and source of seed. Also on the post harvest washing, dehulling and dewatering with on 50 point value. There is not enough in this document on evaluation of equipment design, construction and maintenance of the food contact equipment and adjoining surfaces. This equipment can be a major source of contamination due to design and maintenance. This includes materials used, hollow frame or the wrong stainless steel used for food contact surface.

DS: Dick Spezzano – Comments

1. Are all aspects of a comprehensive sprout food safety program covered in the checklist?**Yes, but not at the GFST level.**

Are key recommendations provided by international food safety guidelines being considered? **Yes on a lower level to allow the small growers to comply**

2. Does the checklist cover all aspects of sprouting facilities and sprouting activities? **Yes, but not at the GFSI level.**

3. Does the checklist clearly point out the critical control points important in minimizing the risk of microbial contamination of sprouts?**Yes, two ccp's are the sanitizing and test hold and release.**

4.Are key elements of Good Manufacturing Practices covered? **Yes, but should be a higher standard (GFSI). The retailers will be looking for higher standards and especially the larger ones. Wal-Mart is already asking for much higher standards in order to put the product back into the stores and most of the larger chains usually follow their lead.**

5. Are the questions for document review clear and easy to understand? **Yes**

6. Are questions related to record review complete and easy to understand? **Yes, but not the same detail as GFSI.**

7. Are questions related to facility inspection clear and easy to understand? **Yes**

8. Are the points assigned appropriate? Any suggestion for different points? **Yes**

9. Is the audit fair to small and large sprout growers alike? **They are on a lower scale than some the growers use. BPP is requiring all of their growers to be GFSI certified. This audit is made for the smaller growers to pass. Food safety standards either recommended or required must be high enough to protect the general public and be acceptable to all retailers. In many of the food safety incidents both with sprouts and other fresh produce items it has been the smaller grower who have had the incident and the entire industry shares the pain. There are many smaller growers that will benefit from this audit because they are using nothing at the present. It is by no means acceptable to the larger retailers as they would want higher standards and more detail on documentation. and tighter facility standards.**

It is our recommendation that these efforts should be only Phase one and that once these are published that a general audit among all growers be conducted to review compliance. At the conclusion of the audit a committee be reconvened to review progress and at that time develop Phase two recommended standards that would be higher.

LB: Larry Beuchat – Comments

BSt: Bob Strong – Comments

I have a few general questions to ask

1. Is this proposed as an addendum to a GFSI audit or are you going to submit to GFSI to be approved as a recognized scheme? This is very detailed to be an addendum but it is not detailed enough to be approved as a stand-alone GFSI scheme. If you are only recommending that Growers have an GFSI audit then you cannot have a score against not doing this see A1 f.
2. Is the scoring All or nothing for each audit line item?
3. Will you be developing guidelines for each audit line item so as to help Growers and Auditors understand the full intent of an audit line item so full compliance is demonstrated? Without it some line items will bring with them subjectivity vs. objectivity.

KW: Keith Warriner – Comments
A Glossary of terms would be useful at the start of the auditors checklist . This is especially relevant with regards the difference between validation and verification.
More comments by Keith Warriner:

1. Are all aspects of a comprehensive sprout food safety program covered in the checklist? Are key recommendations provided by international food safety guidelines being considered?

The main aspects of the food safety guidelines have been considered although there is a deficiency in the guide. This specifically relates to procedures to perform, validate and verify seed decontamination procedure – one of the most important food safety measures within the sprout production process. For years there has been a focus on the application of hypochlorite despite the clear limitations of the sanitizer. In addition, there is yet to be a standardized protocol to test different approaches seed decontamination procedures that is a key barrier to providing a list of alternatives. The 2 log reduction criteria is unsuitable given that even low levels of residual survivors can proliferate during the early stages of sprouting. A more appropriate approach would be to inoculate seeds, subject to seed decontamination, sprout the seeds and screen for pathogens.

2. Does the checklist cover all aspects of sprouting facilities and sprouting activities?

Additional points to consider:-
The validation/calibration of thermometers in cold rooms.
Minimizing mixing of seed lots for sprout production.
The frequency of wash water re-charging and monitoring of sanitizer concentration (for example, Oxidation Reduction Potential).
Minimize introduction of utensils and materials into the plant without being sanitized.

3. Does the checklist clearly point out the critical control points important in minimizing the risk of microbial contamination of sprouts?

The CCP's could be made more prominent rather than buried within the audit. A generic HACCP model for sprout production the includes flow diagrams, decision tress, monitoring procedures, corrective actions and verification should be provided with the audit.

The audit puts a heavy emphasis on spent irrigation water testing even though this cannot be considered a CCP. In reality, the CCP's are seed sourcing, seed sanitation and post-harvest washing. Spent irrigation water testing should be used as a verification method that could be performed periodically as opposed to every batch. There is no evidence that spent irrigation water testing has prevented an outbreak although there is work published on limitations of the screening method.

4. Are key elements of Good Manufacturing Practices covered?

Key elements are included although additional points could be included. Specifically:-

Elements of Standard Operating Procedures
Notices instructing workers on how to perform procedures (for example, hand washing)
Selection of sanitation zones to focus on key areas.
Frequency of sanitizer rotation.

5. Are the questions for document review clear and easy to understand?

Some questions require further clarification (see audit comments).

6. Are questions related to record review complete and easy to understand?

See Audit Comments. For example, "Is the management trained in HACCP?" HACCP training is very broad and it would be more appropriate include "What is the basis for selecting identified hazards and what is the justification for the selection of critical limits".

7. Are questions related to facility inspection clear and easy to understand?
See audit comments.

8. Are the points assigned appropriate? Any suggestion for different points?
See audit comments. There should be a revision of some points.

9. Is the audit fair to small and large sprout growers alike?
No, the audit checklist is focused on large sprout producers and is too lengthy, in addition to being too costly to implement. The main cost will be with respect to the extensive microbial testing required and hold-and-release policy. Although microbial testing is important it cannot be relied upon to ensure a safe product. Resources directed towards improvement in facility construction would be more productive.

Expecting the manager of a small plant to be an expert in HACCP is over optimistic. Nevertheless, it would be anticipated that the producer would be aware of the potential hazards and this can be provided in the form of a generic HACCP plan – similar to the format of the HACCP Advantage program here within Ontario.

SH: Susan Harlander – Comments
Armand and TJ. The following comments on the Sprout Specific Safety Audit are submitted by The Vista Institute. We have not been involved with the Sprout Safety Task Force in the past, so we do not have the history of this document. Perhaps it is intended to fill a perceived void for sprouting operations that have not been required by their customers to comply with some kind of audit system. Sprouters associated with Brassica are required to incorporate a GFSI-approved audit system (as demanded by some of their customers) which is highly redundant to significant portions of this Sprout Specific Safety Audit checklist. For those sprouting companies who have already instituted a GFSI audit system, the addition of a "sprouting addendum" that focuses specifically on those operations unique to a sprout operation (i.e., seed chlorination, irrigation water testing, seed receiving and handling, etc.) seems to be the best option.

JS: - Jenny Scott CFSAN
Scoring
The assignment of points is unclear. It would appear to be a combination of both A and B, but there is not a direct correspondence of the sections. It would be better to identify major non-conformances in some way other than by the number of points if there are scores that are different from the points (e.g., the mock recall score is the percentage of product accounted for, whereas the points is listed as 25; this could confuse someone reviewing the audit.
With respect to the major non-conformance, why is someone given 30 days for "immediate corrective action" of a critical deficiency the first time? Why is this then 14 days once "you are credited"? (And what does this mean?)

Part 1, Documentation and Records:
Section 9 (Control of Sprouting Operations/ Seed disinfection and treatment) b/iii

Bob Sanderson: The requirement for a 2-log reduction does not take into account the fact that there is presently no standard protocol by which this, or any other log reduction can be demonstrated as being valid for disinfection of naturally contaminated seed.

The published reports of survival and recovery of pathogens following sanitization treatments, including reports on the effectiveness of the 20,000 ppm calcium hypochlorite seed treatment recommended in the FDA Guidance, indicate that log reductions observed with inoculated seed may be significantly greater than the actual log reduction that occur with the same treatment, used on naturally contaminated seed.

It may seem obvious that if multi-log-reductions are achieved with high inoculum levels, then probably the relatively low numbers of pathogens on naturally contaminated seed will be completely eliminated in most cases. But since the correlation between log reduction and inoculation level slopes continually down, it would be useful to be able to estimate more accurately the probable reductions on naturally contaminated seed. One possible way of doing this would be to graph log-reductions starting with high levels of inoculum, and move progressively toward lower levels of inoculum, using the same disinfection treatment at each level. Once there were enough points on the graph, the shape of the graph might

suggest a mathematical approach to extrapolating to probable reductions at the low levels of pathogens observed on naturally contaminated seed.

Another possible approach toward better understanding of what a given treatment is achieving by way of log reduction on naturally contaminated seed would be to do more research with naturally contaminated seed. Since the sprout seed industry has naturally tried to obtain seed from fields that would have the least likelihood of being contaminated- i.e. not close to feed lots or contaminated water sources- it seems reasonable that if the criteria for obtaining seed samples were to find sources that are close to contamination sources, considerably more naturally contaminated seed could be obtained, and observations of the effectiveness of sanitization treatments with this contaminated seed would provide a better indicator of real-world effectiveness of these treatments.

Until there is a more accurate way to assess the effectiveness of a seed disinfection treatment, than extrapolating a linear relationship from studies using inoculated seed, the assumed log reduction will be guesswork.

One danger with this uncertainty is that there will be an assumption of greater effectiveness at reducing risk to the consumer than is actually the case.

Another is that, in the context of the 5-log reduction standard, a treatment or combination of treatments that provide a 5-log reduction in studies using inoculated seed may seem to reduce or eliminate the need for every-batch spent irrigation water sampling and testing. This will not only constitute a risk to the consumer, but will also result in a significant economic advantage to the producers doing less sampling and testing than their competition.

A third problem is that the more precedents are set assuming that log reductions with inoculated seed are equivalent to reductions that can be expected with naturally contaminated seed, this will tend to act as a disincentive to do sanitization research, particularly in the case of privately funded research, since the results using improved protocols may appear to be inferior in comparison with results achieved in past studies, even if these results are in fact better.

Part 2, Site Inspection:
Section 8 Control of Sprouting Operations a/ii

Bob Sanderson: “Documentation of seed supplier pathogen testing results” is so vague that it will provide an incentive to the seed suppliers to do the minimum.

It has been recognized for a long time that the methods by which raw seed is sampled and tested have a very significant influence on the likelihood of the sampling and testing being able to detect pathogens if present.

The reason why there is so little emphasis on the value of seed sampling and testing is, largely, that in the many epidemiological investigations following sprout-related outbreaks, sampling and testing on implicated seed lots have rarely isolated pathogens. But this failure is largely due to the use of ineffective methods. There is some reason to believe that this continues to be the case with the present FDA BAM method for sampling and testing seed.
(http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm070149.htm)
The unfortunate result of this is a self-fulfilling prophecy that seed sampling and testing is of marginal value.

The fact that sampling and testing of implicated seed lots, even using less-than-optimum methods, has on a number of occasions isolated pathogens, is very strong evidence that if this sampling and testing had been done prior to the use of the seed for sprouting, these seed lots would have been diverted to non-sprout uses, and the outbreaks caused by the use of those seed lots would not have occurred.

Although sampling and testing of seed can’t be 100% effective,

seed supplier certification of sampling and testing, using the method described at:
http://www.sproutnet.com/Research/iss_seed_screening_procedures.htm
should be a minimum requirement for acceptance of seed lots at the sprouting facility. Requiring at least this degree of pre-production seed sampling and testing can provide an important margin of safety for the consumer, and possibly spare sprout producers considerable costs and headaches.

International Specialty Supply

ISS Seed Screening Procedures

We have been asked by many, including the International Sprout Growers Association, to make our seed screening procedures available to other seed companies and sprout growers. We are pleased to do so in the interest of food safety within the sprout industry.

1. Inspect Shipment. Quarantine the seed and inspect the bags for evidence of contamination. Such things would include mouse droppings, dead insect parts, holes in the bags that appear to have come from rodents or insects, etc. In dim light, inspect the bags under black light for traces of urine. Examples of urine under black light can be found in any men's restroom. Record any findings.
2. Sample Seed. Sample 1/1000th of every bag using a seed trier or other procedures described by the ISTA Handbook on Seed Sampling, Second Edition, January, 2004, International Seed Testing Association. In a large shipment, this may be 20-22 kg. If the composite sample, which is 1/1000th of the shipment or lot, does not come to 3 kg, start over and collect additional samples until the composite sample equals at least 3 kg. Record lot information and sampling information.
3. Inspect the Composite Sample. Visually inspect the seed for damage and for evidence of contamination. Such things would include dirt, mouse droppings, glass, metal, live or dead insects or animals, etc. Then do the same using a magnifying glass. A 2X magnifying glass is a good start, but using several different powered magnifying glasses is preferable. Pull out anything that is suspicious and inspect it more thoroughly under a microscope. Record any findings.
4. Sprout the Composite Sample. Sprout the sample, without sanitizing it, using the rotary drum or tank method.
5. Test Runoff Water. Collect two 1-liter samples of the runoff water at approximately 48 hours. Record production and collection times and methods. Enrich and test both samples for Salmonella, Generic E.coli, E.coli 0157:H7. Inspect the sprouts for quality and possible presence of plant pathogens. Record lab findings and results of inspection. If there is Salmonella or E.coli 0157:H7 reject the seed and contact the company that sold you the seed.

The first three steps are just to help a person make an educated decision about the safety of the seed. If, for instance, a seed lot were full of mouse droppings it would be rejected regardless of the results of a pathogen test. But it is not practical to reject a lot if there are a few damaged seeds, or a dead insect stuck to the outside of a paper bag. This information is reviewed and the risk evaluated.

The above is where we started in the year 2000 and not necessarily the procedures used on any given lot. Our procedures are continually changed and improved as we learn more about seed screening. When purchasing a lot of seed, please ask for a copy of the current seed screening protocol.

Susan Harlander: B.8.a.ii: Is it the intention of the Sprout Safety Task Force to provide a list of validated methods for seed supplier pathogen reduction treatments, sampling, and testing methods to be included in COAs? ISS provided the method they use. Have they also shared the results of these studies? Has the sampling method been validated by the Task Force or FDAs sampling experts? Will the Task Force be recommending sampling methods, especially for large seed lots? We are aware of at

least two methods being used by seed suppliers to reduce the microbial load of seeds. Have these treatments been validated and approved by FDA and/or the Task Force? Sampling is a very critical issue as it is highly likely that contamination will not be uniform in seed lots.

Sprout grower needs to get some form of Certificate of conformance that the seed has been grown and handled in accordance with specific requirements.

Part 2, Site Inspection:
Section 8, Control of Sprouting Operations f/i

Bob Sanderson : It isn't clear whether the maximum amount of seed that can be included in a single sample is 50 lbs, or, as much as can be included in a "homogenous production batch." If a producer starts a batch by soaking 100 lbs of seed in a tub, this would seem to be a homogenous batch. If he then drains the seed and transfers it to 2 racks, is it still a homogenous batch? If so, then there will be a strong incentive to start the crop out in the biggest possible container. If not, then given the high costs of testing, there will be an incentive to design the largest possible "drum, rack, bin, etc."
The costs of testing are significant. If a grower can do 20 tests a week, instead of 40, there may be a savings of well over $50,000 per year to spend on re-designed "single-batch" equipment.

Without a means of quantifying detection probabilities from specific contamination levels and batch sizes, specifying an amount of seed to include in one sample is somewhat arbitrary, and may have the unintended consequence of inhibiting research into more sensitive detection methods.