



INTERNATIONAL SPECIALTY SUPPLY

August 2, 2004

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 2004N-0258]

Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated With Fresh Produce; Public Meeting
Objectives of the Proposed Action Plan
Objective 1: Prevent Contamination of Fresh Produce With Pathogens

It is recognized within the scientific community that the main source of contamination of sprouted products is contaminated seed. If this is the case, a logical safety measure is to reduce the risk that the seed is contaminated prior to sprout growers receiving it. The seed processor or distributor is the most logical one to do this because the entire seed lot can be done at one time. It can be done in two ways: seed screening, and seed treatment.

Seed Screening

Seed Screening is a simple approach to risk reduction. The idea is to do everything you can to determine if the seed is contaminated prior to sprouting. If it is, don't sprout it. We are one of the two largest seed suppliers in the industry. We started using the following procedures in 2000 and none of this seed has been involved in an outbreak, nor have any of the sprouters who use our seed.

1. Inspect the Seed Shipment. Look for evidence of mouse dropping on the bags, holes in the bags, insect larva, bird droppings, etc. Black light the bags for traces of urine.
2. Seed Sampling. Sample every bag and draw at least 25 grams from each bag. If the sample comes to less than 3 kg, re-sample enough bags that you get 3 kg. However, if you are sampling a full truckload (880 bags) of seed, your sample size is 22 kg.
3. Seed Inspection. The composite sample of seed is very carefully inspected for indicators of contamination with both a magnifying glass and microscope to determine its' fitness for human consumption. Again you are looking for traces of visitation by animals and insects, but in the process we have also found glass, seed that was blended with seed that had been treated with a fungicide, etc.
4. Sprouting (Enrichment). The entire sample should be sprouted using commercial sprout production methods and at temperatures that support maximum pathogen growth. The seed should not be sanitized prior to sprouting. This should be done in an area segregated from commercial sprout production. In 48 hours the pathogens for which you are testing should have increased about 1,000,000 times, substantially increasing the probability of detection.

ISS, LLC • 820 EAST 20TH STREET • COOKEVILLE TN 38501
TEL 931 526 1106, EXT 107 • FAX 931 526 8338 • sprouts@infoave.net

5. Runoff Water Sampling and Testing. At about 48 hours, a sample of the runoff water is collected using FDA procedures recommended for commercial sprout producers. The water is then enriched to make the pathogens multiply about 5 log (100,000 times) and the water is tested for salmonella, E.coli, and E.coli 0157:H7 and L. mono.
6. Documentation Each step needs to be thoroughly and accurately documented and signed by the person taking responsibility for completing each step of the process.

International Specialty Supply (ISS) has been using these procedures since 2000. We add an extra step though. Before we receive a shipment, we bring in a sample and go step by step through the above procedures. We stop at the point of rejection. That is, if the seed does not pass visual inspection, we reject it without taking the time to sprout it out. We also put an additional step of testing the seed for generic E.coli before we sprout it out and test it. It just saves us time.

Low average contamination levels in a lot make our seed screening procedures unreliable as the *only* method needed to insure sprout safety. If only one bag is contaminated at the rate of 4 cfu/kg, our chance of capture is only 9.5%. It takes 7 contaminated bags before the odds of capture are even 50%. It takes 40 contaminated bags (4.4% of those in a truckload) of seed before the odds of capture hit 98%. It takes 80 bags (9% of a truckload) contaminated at that rate before the odds of capture hit 99.97%

Though the method is not perfect, it has allowed us to avert sending out contaminated seed at least four times (2 salmonella, 2 E. coli 0157:H7). I suspect the actual number is far greater. Seed will never make it to the sprout out phase of the screening if it has urine, feces, mouse evidence, high generic E.coli (prior to sprouting), sever damage or other reasons for rejection. In other words, the worst is rejected without pathogen testing.

I know of one lot we rejected that found its way to sprouters. It was loaded with generic E.coli and never made it past our initial screening, so we did not sprout it out and test it for pathogens. We later found out it was 0157:H7.

This may not be a perfect method, but it is the best risk reduction step available.

?? No seed that has gone through this screening has ever been involved in an outbreak.

?? No sprout grower who has used seed that has gone through this screening has ever been involved in an outbreak.

Wrong Method: These procedures should not be confused with just taking a 25-gram sample and sending it to a lab. Even if every single bag were contaminated at the rate of 4 cfu/kg, the odds of capturing a pathogen for detection are only 9.5%. If 40 bags are contaminated, the odds are ½ of 1% that this method will capture it for detection. Even if the pathogen is captured, if the seed is not sprouted out, the odds of detecting it are remote. Unfortunately, this method is the most commonly practiced method in the sprouting industry. Thus contaminated seed continually makes it to sprout growers.

Seed Treatment

As I said, the seed screening method has diverted outbreaks away from us, but it is still likely that some contaminated seed will get past the screening process some time.

ISS, LLC • 820 EAST 20TH STREET • COOKEVILLE TN 38501
TEL 931 526 1106, EXT 107 • FAX 931 526 8338 • sprouts@infoave.net

I would feel more comfortable if seed screening was followed by a seed treatment, prior to shipment to sprouters. There has been some work done with ammonia, acetic acid, dry heat, irradiation, etc. and some of it is quite promising. But the focus of the research has been on disinfection, and post testing. I think it would help if the FDA stressed the importance of this step so researchers, seed companies, and the sprouting industry would focus on it.

Mung Bean Seed should be Considered Differently than Alfalfa Seed

Mung bean seed appears to be far easier to clean up than alfalfa. From what I understand, England has not had a mung sprout outbreak since the one in the 1980's. It is possible that the reason they have not is because their guidelines require 200 ppm on their mung seed. This is a number that all mung sprout growers can live with. The 20,000-ppm will damage *some* lots of mung seed. It is possible that some growers realize this and feel that "chlorine" is what is destroying their crop. Indeed, it is. But they may not be aware that at 200 ppm is an excellent step for eliminating plant pathogens such as Erwinia, Pythium and Rhizopus. If they were directed to use 200 ppm (for example) there may be 100% compliance, and bean sprouts might come off the list of dangerous foods.

No food product is 100% safe. The question is how do you minimize the risk? A two-phase approach could work.

- ?? First, having the government take an aggressive stand on seed inspection, sampling and testing to seed distributors.
- ?? Second, indicate to the seed industry that a seed treatment will be required on all sprouting seed starting in 2006 or 7. This will give researchers and the industry a focus of direction. At the moment there is none.

Ultimately you would end up with a four-step process:

1. Sample, inspect, sprout and test the seed at the processor or distributor level. (I know this might be necessary *after* the seed treatment, but the pathogens would be easier to detect prior to treatment. And if you don't detect pathogens at this stage, you certainly aren't going to find them after a seed treatment.)
2. Treat the seed that passes #1. That is, don't try to clean up contaminated seed.
3. Sanitize the seed with a reasonable yet effective amount of sanitizer. (Reduced for mung seed.)
4. Post test the sprouts

Thanks for your consideration,

Bob Rust, President
International Specialty Supply
Cookeville, TN 38501
bob@sproutnet.com
www.sproutnet.com