

*1. What concepts or underlying principles should guide efforts to improve the safety of sprouts?*

The concept or underlying principle of improving the microbial safety of most foods appears to be that a kill-step is applied which is known to have a high likelihood of reducing the organisms of concern to acceptable levels. Immediately following this treatment, there is some procedure to maintain the food with as nearly as possible the same microbial levels as what has been attained by the treatment. The function of sampling and testing then becomes primarily to determine if the kill-step has been applied properly, and has worked to its expected level of effectiveness.

The safety protocols for the production of safe sprouts, as recommended in the 1999 FDA Guidances, have been designed according to this model, even though in several basic respects the model is inappropriate. From the first observations of the effectiveness of 20,000 ppm calcium hypochlorite seed soaks, it has been obvious that this treatment did not achieve an acceptable reduction. This is because, due to the nature of the sprouting process, the only acceptable reduction is complete elimination.

Since the FDA Guidance recommendations were issued, there have been many attempts to develop a sanitizing treatment which will reach this “acceptable” level, defined as a 5-log reduction of pathogens. The rationale for this 5-log reduction, provided with the Guidance treatment recommendation, argues that even with a contamination level considerably higher than anything which had been observed on naturally contaminated seed, the 5-log reduction would reduce the likelihood of surviving pathogens to a very low level.

The research which has been undertaken to measure log reductions on contaminated seed, using the recommended 20,000 ppm calcium hypochlorite and many other sanitizing agents, has used seed which was inoculated to exponentially higher levels than the example provided in the rationale for the 5-log reduction. It may have been assumed that substantial reductions at high starting levels will assure comparably high reductions at the low levels observed on naturally contaminated seed. However, the reductions achieved have been roughly proportional to the starting level of inoculum. If the reduction curve is followed to the level of contamination which has been observed in naturally contaminated seed, the actual reduction may be 1 log or less.

Putting a 1-log reduction instead of a 5-log reduction into the example provided in the “rationale” results in a near inevitability of some survival of pathogens in production batches using naturally contaminated seed.

In the few research examples of the effectiveness of 20,000 ppm calcium hypochlorite seed soaks on naturally contaminated seed, there appears to be a reduction of 1 log or less. (Stewart et al. Growth of *Salmonella* during Sprouting of Alfalfa Seeds Associated with Salmonellosis Outbreaks Journal of Food Protection, Vol 64, No. 5, 2001, Pages 618-622)

The most often observed log reduction using inoculated seed is about 2 ½ logs. (“Analysis of Published Sprout Seed Sanitization Studies Shows Treatments Are Highly Variable”, JFP, Vol. 67, No.4, 2004, Pages 758-765) However, there is no good evidence that this is accurate, and some amount of evidence that it’s considerably inflated, because of the high inoculum levels used.

Its clear that, in the six years since the Guidances were issued, no treatments have come close to reducing pathogens by 5 logs, or to an “acceptable” level. For this reason, every-batch spent irrigation water testing is strongly recommended.

Presently there are a number of treatments being promoted which may provide a considerably greater log reduction than 20,000 ppm chlorine. The fact that to-date a lot of research has been done using models which may not represent what is actually achieved in a production setting, plus wide variation in the characteristics of individual seed lots, suggests that its not easy to state with any degree of confidence what a treatment is actually accomplishing.

For this reason its important to consider how alternative treatments will be compared to the 20,000 ppm chlorine, and to each other. The fact that the 20,000 ppm chlorine recommendation has become a requirement in some markets, simply because it is “recommended” by the FDA, and not because of any solid evidence of what it actually accomplishes, could be an indication of the confusion in the market which may ensue as different treatment providers, and different sprout producers, compete to win retail accounts in a market which is more and more concerned with possible litigation related to outbreaks of illness.

It is an understatement to say that sprout marketing efforts aimed at convincing retail buyers of higher levels of safety based on greater effectiveness of different safety interventions is a dismal prospect.

Compliance with expensive every-batch spent irrigation water testing also has to be considered in the context of claims of effectiveness of different treatments. No one has yet suggested openly that a given treatment will obviate the need for every-batch testing, and yet the sprout market is so competitive that a difference of pennies a package can win or lose a major retail account.

For these reasons, it may make sense to focus any revision of the 1999 Guidance on developing, monitoring, and enforcing standard methods of seed and production sampling and testing, and to de-emphasize the treatment.

An emphasis on sampling and testing might be perceived by producers as onerous at first- and if some suppliers and some growers are doing thorough sampling and testing, and others aren’t, the ones who aren’t will be able to offer considerably lower prices. However, with consistent monitoring, and a helpful attitude by inspectors to get

producers on-line, the whole sprouting industry may in time become considerably stronger.

There are other possible advantages to an emphasis on sampling and testing. Since any seed lot or production batch which tests positive will have to be discarded, there will be a strong incentive to keep contaminated seed out of sprout production. This incentive will move upstream, putting pressure on seed suppliers to carefully screen all seed before selling it to sprout producers, and since positive seed test results at the supplier level will result in seed lots having to be diverted from the sprouting market, it will be in the interests of seed suppliers to require seed producers to use farming methods which minimize the introduction of pathogens at the farm level.

A treatment-based safety protocol, in contrast, will not provide any incentive for producing safe seed, and will instead tend to provide a counter-incentive to efforts to address the problem of sprout contamination at the source.

The underlying objective of any risk reduction strategy is to minimize risk. In considering which combination of treatment, sampling, and testing, is most effective toward reaching this goal, it is crucial that the highest priority be put on the safest method or combination of methods, whether or not these methods are consistent with established approaches to ensuring the safety of other foods.