My name is Bob Sanderson; I'm the President of the International Sprout Growers Association. My wife Barbi and I own Jonathan's Sprouts in Massachusetts, which has been producing sprouts for the New England market for nearly 30 years

I would like to thank Dr. Brackett, Dr. Beru, Dr. Smith, and the Center for Food Safety and Applied Nutrition for arranging this public meeting on sprout safety.

Dr. Smith suggested that I provide an overview of the sprout industry's strengths, weaknesses, needs, and desires

So, my talk is not going to be the ISGA's comment, per se. That will be submitted prior to the July deadline I will try to talk about more general aspects of the sprout producer's relationship with product safety requirements.

In discussing the sprout industry's strengths and weaknesses, there is the product itself to consider, and there are the people who are involved in producing sprouts.

Any discussion of the strengths and weaknesses of the people in the sprout industry has also got to factor in the kinds of rules and regulations under which we operate- whether they are clear, consistent, and effective in achieving their intended purpose.

The product itself is remarkable in some obvious ways: sprout producers may plant from one to several crops a week, 52 weeks a year, with an interval of from 4 to 10 days between beginning the process, and shipping the product to the market.

What happens during this 4 to 10 day period is a combination of very rapid chemical and biological processes which transform a mostly unpalatable seed into a nutritious food

In addition to being nutritious, it appears that many, if not all, varieties of sprouts have high levels of one or more phyto-chemicals which may have significance to human health. The understanding of these properties is still in the early stages.

The very rapid growth of sprouts, and the conditions in which they are grown, presents unique challenges in terms of food safety, as well as some unusual opportunities, which I'll come back to.

Regarding the people who grow sprouts; they are a very diverse group

The largest, in terms of numbers of producers and amount of sprouts produced in the US, are those involved in the growing of mung bean spouts, which have been a staple food in Asia for thousands of years

The other main group consists of companies which, beginning about 40 years ago began to introduce a variety of sprouts that historically have not been widely used as human food.

In the US, and increasingly in other parts of the world, more and more sprout producers are combining the growing of both the traditional sprouts, and the more recently developed varieties

So the industry consists of a mix of people from very different cultures, some of whom are carrying on with a family business which may have been started generations earlier, and others who have introduced entirely new products to the market

The increase in concern with sprout safety seems to have coincided with the appearance on the market of the newer types of sprouts

So there may be some feeling on the part of the producers of the more traditional sprouts that they have been caught up in someone else's problem.

After all, if these traditional types of sprouts have been grown for many generations, wouldn't we have known about safety problems long ago?

Although it may be argued that different types of sprouts, which are used in different ways, may require different risk reduction strategies-

Its not quite accurate to say that any particular type of sprout is traditional, because the nature of the market, consumer preferences, and production methods continue to change very rapidly

This is true both for the producers of bean sprouts, and the newer, green-

leaf sprouts, since both are functioning in the context of increasing food safety concerns, and both have to deal with continually increasing regulatory and 3rd party inspection requirements, as well as changes in the nature of the market and consumer dietary preferences.

There are other groups and priorities within the sprouting community

The ISGA is an international organization, with members from many different countries, who have quite different perspectives

Since the ISGA core membership is made up of US growers, the Association tends to have a focus on FDA regulations and food safety, which some growers operating outside the US seem to view as a kind of negative fixation

The ISGA was started primarily to promote the positive aspects of sprouts, not to be talking about safety all the time, and furthermore sprouts seem not to be considered such a high risk food in many countries.

But the issue is not simple because of differences in types of sprouts, how they are usually consumed, total volumes sold, as well as differences in available public health monitoring and epidemiology

The FDA's recommended 20,000 ppm chlorine seed treatment is generally considered very excessive by growers from other countries, where in some cases, the use of this treatment would not be allowed.

Even among US growers, it would be high on the wish list to have an approved treatment which did not create such an irritating and hazardous working environment

It would also be a good thing for the ISGA as an international association to have a single, internationally acceptable set of safety practices, or at least, an agreement on underlying principles

This isn't to say that sprout growers all around the world would apply the same procedures equally, but that at least we could have a common frame of reference

Another point of debate in the sprout industry, which exists inside the US, as well as between the US and the rest of the world, is the status of organic

sprout production, again primarily relative to the 20,000 ppm chlorine seed treatment recommendation.

Although some organic certifiers have allowed the use of 20,000 ppm chlorine seed soaks, the basis for this allowance is felt by many to be quite a stretch with organic production standards, and is based on the need for organic standards to take second place to FDA safety regulations in situations where there may be a perceived conflict

This is entirely appropriate and necessary, but unfortunately there is not presently a clear way to evaluate the effectiveness of risk reduction strategies which might be more consistent with organic production methods

So the ISGA's wish list might also include, if possible, the allowance of safety protocols which were more consistent with organic standards

This is not to suggest that safety criteria should be diluted in order to be acceptable to different groups, but that if possible, safety requirements should be based on end product criteria rather than on any specific method of getting there.

One aspect of sprouts which many consider to be their greatest drawback, is that they have proved to be extremely resistant to treatment-based approaches to assuring their safety. This is because with sprouts, any seed sanitizing step is followed by four or more days of growth at room temperature.

However, the same characteristics which make sprouts difficult to sanitize may also make them accessible to more thorough sampling and testing than is possible with most foods

The sampling and testing of seed lots prior to use in sprouting, with seed which tests positive for pathogens being diverted to non-food uses, is a common sense preliminary step. The fact that in several instances, sampling and testing have isolated pathogens from implicated seed following outbreaks clearly suggests that if the same sampling had been done prior to the use of that seed lot for sprouting, those outbreaks would never have occurred.

Bob Rust is going to go into more detail on the best ways to carry out this

initial screening of seed lots.
Since sprouts emerged as a significant health concern in the late 90's, there have been dozens of attempts by leading food-safety researchers to develop effective sanitizing interventions

These investigations continue into the present. It may be that in the near future, a truly effective seed sanitizing procedure will be developed which is affordable, and which does not entail significant risks to sprout workers or have other serious drawbacks.

Possibly such a procedure already exists, and if so, then one can only hope that it will get a speedy regulatory approval

In the event of the discovery and allowance for such a treatment, one question which would need to be addressed is whether the use of this treatment would eliminate or significantly reduce the present need for every-batch spent irrigation water testing?

I don't know of anyone who is proposing that this should be expected, at least in the near future

This is an important question - because testing is very expensive, and if you introduce the idea of intermittent or periodic testing, in a very competitive market there will be a significant economic incentive to minimize it,

This may lead to even more confusion about what constitutes compliance, and who is in compliance and who isn't, which will not help the overall level of confidence in the market

So while we are waiting for improved treatment interventions, and even if we find them, it seems worthwhile to consider how effective the recommended testing procedures are.

The 1999 FDA Guidance recommends that the spent irrigation water from all production batches be tested, in duplicate, for the two pathogens of concern, and that negative test results be back in-house before any product is shipped from the facility

In preparing for this meeting I've tended to assume that my company's testing program could be duplicated by other sprout producers. But we are

fortunate in being an hour away from a qualified testing lab which is very responsive, and which charges us very reasonable rates for its services.

For other growers, I have heard that lab costs per test can be much greater, and some may have to overnight ship samples, which will add a full day before they can get lab results back. This will add significant problems to inventory control, as well as hold-and-release programs.

For this reason, validation studies on the use of newer, faster, and more accurate testing methods for sprouts, which might cut a day off the time presently required for testing, could provide options to growers to shop around for the best rates, and help level the playing field in the very competitive sprout market.

If every-batch testing is going to be a necessity until some significantly better treatment method is developed, then things like cost per test, how responsive a lab is, how long it takes to get the sample to the lab, and how long it takes to get the sample results back, are very important.

To put this in perspective, if my competitor and I are both doing all the required tests, but he is doing duplicate testing and I am only doing single samples for each test, I will save enough money on testing alone to offer a price which will allow me to take my competitor's business, and at the same time make more money at the lower price than I'm making now.

This testing is very expensive, and one thing on many growers' wish list is that the required testing could be significantly reduced.

One bean sprout grower from outside the US told me that if he tried to do the kind of testing recommended in the FDA Guidance, he could not remain in business

I feel its important to come back to the question: do we need to do this testing? It seems that until some treatment comes along which clearly indicates that we can cut back on our testing, we need to do it, and so we have to focus on how to make it more effective, and consistent.

High testing costs are frequently mentioned as a burden to sprout producers, but I think this concern needs to be looked at in context.

Are they a burden because the retail price of sprouts is as high as it can be, and consumers will just stop buying them if the price goes up? Or are they a burden because every grower is trying to survive in a very competitive market, and a difference of pennies per package can be a determining factor in obtaining or keeping an account with a supermarket customer?

In talking about the costs of a testing program, I'm talking about something in the range of ten cents per package, wholesale cost.. If you ask a sprout producer what his bottom line would look like with an extra dime per package coming in, I think you'd see quite a reaction. In my own company, this would finance an entirely new facility, and give everyone a raise to boot.

One important question about the burden of testing costs is, is the price sensitivity of sprouts inherent in the product, or is it dependent on perceived value, so that if this value goes up, the customer will readily pay the extra amount? There is good evidence that customers will pay more for sprouts if they have reason to believe they're getting a better, or safer, product

When the FDA Guidances were issued in 1999, sprout products were redefined. They still looked and tasted the same as they always had, but the costs of producing them to an acceptable standard had increased substantially.

At the same time, it was left up to the industry, or the individual producer to convince the customer that the new, improved product which looked and tasted just like the old one was worth the increase in price.

Since the supermarket buyer is under considerable pressure to buy the least expensive product, its the producer's job to justify his higher production and safety costs

But neither the supermarket buyer, nor the consumer, has any way to evaluate the safety claims of the producer. This can encourage marketing strategies which play upon the customer's insecurities

In the present Guidances, the recommended treatment and testing protocols are preceded with the qualifier "e.g." meaning "for example"
which suggests that what is recommended is only one option out of several.

But in practice these Guidance recommendations are very strictly

interpreted, and have acquired the force of regulations.

Deciding what, if anything, might be considered “e.g.” is a difficult thing to do, partly because it isn’t clear what the treatment referred to actually accomplishes

The sprout industry obviously would like treatment and testing options to be based on the best available science, and we want, if possible, for them to be flexible, so that “e.g.” can allow for a range of approaches, provided they achieve an acceptable end result

There was an attempt several years ago for the ISGA to take responsibility for setting safety standards, by way of a seal program.

Two problems were encountered: one was that at the time the seal program was being developed, there had not been a very thorough inquiry into the effectiveness of the safety protocols which were then available

The other was that the ISGA was not in a position to effectively police compliance with the requirements of the seal program- as it would not be, today

Whether we have a Guidance recommendation, or a regulation, whatever the structure, it needs to be responsive to developments in treatment and testing technologies, and as flexible to the needs of individual companies as possible. But obviously the FDA can’t immediately review every new idea that comes along.

Is it worthwhile to evaluate safety methods for a small industry that might be different from what is used with most foods? Of course it’s worth it to the sprout industry to solve its problems and to prosper. But are the sprout industry’s challenges relevant to other areas of food safety or research generally?

If we consider the testing challenge in its simplest form to be the challenge of quickly and accurately telling friend from foe in the microbial world, this would seem to connect the sprouting industry’s needs with many other important research efforts in other areas.

Therefore the industry needs to continue to work with people in government

and academic research who have qualifications and review capabilities necessary to develop effective sprout safety standards and procedures. The ISGA Technical Review Board can provide a framework for this effort.

Allowing for flexibility in safety protocols has got a number of interrelated parts. There is the question of how well something works in a research setting, and how well it would translate into a production setting. This has repeatedly come up in the case of the 20,000 ppm chlorine treatment, with some arguing that lab results using inoculated seed suggest a very high level of effectiveness in the real world, and others arguing just the opposite.

Another challenge is, how can compliance with a number of different methods be evaluated by food safety and 3rd party inspectors? It is certainly simpler for an inspector to evaluate a single treatment and testing protocol for all producers in a given category, than to evaluate several which might differ from company to company.

And it becomes even more difficult when, as in most cases, the sample leaves the building and is delivered or overnight mailed to a lab.

Is there a way the grower, and his food safety auditor, can be assured that the lab is doing the testing in a way which will provide the best likelihood of detection of pathogens, if present in the sample?

This may require skills which are not within the safety inspector’s usual job description

The challenges of developing good sampling protocols, assuring the best testing methods, and providing adequate inspection criteria is another area where the ISGA Technical Review Board can provide a significant contribution, by working with growers to develop appropriate inspection check-lists for treatment and testing options.

So, as long as we have the need for a lot of expensive testing, we might as well look at it as an opportunity, and make sure its being done as effectively as possible

If the playing field is as level as possible, and the methods are as good as possible, the added costs may actually benefit the entire industry, by raising the standard of acceptance in the market.

In the meantime, we can hope that treatment interventions are developed which will make the sprout producer's life much simpler, perhaps some day requiring only a minimal amount of microbiological monitoring

Most sprout growers are acutely aware of the microbial hazards which are possible with their products. Not through any choice, one of the greatest strengths of the sprouting industry is our collected awareness of microbial risk, and our growing knowledge of food safety safety.

This may not only be our best resource for our industry's future, but may also provide opportunities for learning which would be relevant to many other areas of the food industry as well

Although the past year is a good indicator of significant improvements, we need to focus our energies on how to increase our margins of safety, restore confidence in sprouts, and make the sprouting industry a model for food safety.

Thank you