LOUIE FOODS
INTERNATIONAL

1587 S JUN 14 P1:39

June 8, 2005

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: **Sprout Safety Public Meeting**
[Docket No. 2005N-0147]

Dear Sir or Madam:

Pursuant to your notice of public meeting, enclosed please find written comments to the above reference Docket. Enclosures include two copies and a CD of my comments.

Very truly yours,

JAY R. LOUIE
President

Enclosures

2005N-0147

C1

471 South Tollman Avenue Fresno, California 93706 Telephone 559 264 2745 Fax 559 266 4046 LouieFoods@aol.com

To: **Food and Drug Administration**

From: **Jay R. Louie**
Louie Foods International

1588 5 JUN 14 P1:40

Re: **Sprout Safety Public Meeting**
[Docket No. 2005N-0147]

Date: **June 8, 2005**

Sprouting and Professional Background:

I currently manage a family business that has been producing sprouts since 1950, over 50+ years. I have personally been involved in all phases of production for over 30 of those years. Our company has been a member of the International Sprout Growers Association (ISGA) since 1990. I have been active in the ISGA, either as an officer and as a member of the Board of Directors for many of those years. I was the ISGA president from 1999 to 2002. I have a BA in Economics from the University of California at Berkeley, and a Juris Doctor degree from Loyola University of Los Angeles, School of Law. I was admitted to the California State Bar in 1975.

My involvement in the safe production of sprouts began in October 1996, at the invitation of the California Department of Health Services, Food & Drug Branch, and the United States Food & Drug Administration. As an industry, we were challenged to address the sanitation and microbial problems related to sprouts. In response to this challenge a California Sprout Working Group was formed to work with various public agencies. As a group, we developed a "Voluntary California Sprout Grower Guidelines" to ensure that sprouts remain a healthy choice for California consumers.

In May 1998, I was invited to join the "Microbial Education & Training Program Advisory Group." The purpose of this group was to determine the best way to design and deliver a meaningful microbial food safety and training program to the California food processing industry. The work of this group led to the production of a training video entitled "Safer Processing of Sprouts."

Shortly after the release of the Sprout Guidance Documents in October 1999, I attended the "Sprout Summit – Best Practices and Recommendations for the Production of Safer Sprouts from Seeds" in Summit-Argo, Illinois (11/99). This summit allowed me to ask questions on the new guidance documents and to learn first hand, the new microbial testing of spent irrigation water during sprout production. The sprout guidance documents described a sampling program, but it was primarily appropriate for the production of green sprouts, and not for production of bean sprouts. In 2001, I submitted a sampling procedure for bean sprouts to the FDA. The bean sprout sampling procedure was also published in the ISGA newsletter in 2001.

In November 2002, the ISGA formed a Technical Review Board, TRB. The mission of the TRB was to "Provide the technical review and research voice for the Sprout Industry and regulatory agencies and develop a consensus of allowable and good practices within the international community." I have been a participant since its inception.

Pursuant to your Notice of Public Meeting, you sought public comments focusing on questions relating to the microbial safety of seeds destine for sprouting. I have addressed my comments to the questions set forth in the notice.

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

When dealing with minimally processed food products, there is no absolutely safe food product. There is a level of risk that must be acceptable to balance with the nutritional health benefits associated with minimally processed food products.

The common sense approach of examining the process from farm to table has been overshadowed by demands for scientific verification and validation. Research has opened our eyes to numerous issues, but has left many unanswered questions. In the meantime, food safety concerns should proceed, and not be limited by the lack of reliable research data. Common sense approach should not be ignored.

Under the current guidelines for seeds for sprouting, sprout growers are encouraged to use 20,000 ppm of calcium hypochlorite solution to disinfect seeds for sprouting. This practice is not only unsafe for the sprout grower, it is also has negative impact to our environment. (Has an environmental impact report ever been performed?) It was once stated in a public meeting that the 20,000 ppm chlorine treatment of seeds for sprouting was like "going deer hunting with a cruise missile."

The treatment of seeds for sprouting demonstrated a risk reduction validated by research. However, research also demonstrated that it was not an absolute solution. Nevertheless, research continued to work toward seeking an ideal solution, the proverbial silver bullet.

Very little research has been published on finding the source of the problem, how seed for sprouting become contaminated in the first place. Because of the difficulty in disinfecting seeds for sprouting, it becomes even more important that steps be taken to prevent illness-causing bacteria from contaminating the seed.

An assumption has been made that **ALL** seeds for sprouting is contaminated. Most research articles incorporate in the intro that "seed appears to be the source of contamination in most of the foodborne illness outbreaks associated with sprout consumption." No published research has determined how the seed for sprouting become contaminated, and if it is contaminated, what is the level and nature of the contamination.

An inordinate amount of attention has been focused on the sprout growing operation, and not the source of the problem, i.e., the production and processing of seeds for sprouting.

There appears to be some assumption that there is no way to control the production of seeds for sprouting. I use to believe that you cannot change the way sprout growers grow sprouts. Times have changed, and attitudes toward food safety have raised awareness levels. It would appear to be the appropriate time to establish some sort of requirement or practice that seeds for sprouting must be certified for usage as a food product. This would represent the next logical step to improve the safety of sprouts. I am a sprout grower, not a seed producer. Those who are in the business of producing seeds for sprouting can best address the issue whether seeds for sprouting can undergo a process where there is some assurance that the seeds are grown and processed in such a manner that the risk of pathogen contamination have been minimized and the seeds could be certified as a food product, that is, the seed is intended to be use as food for human consumption.

Please note that seeds are certified as a food product, not certified as safe. No minimally processed food is absolutely safe for human consumption. If a seed producer knows that his seeds will ultimately be used as a food product with minimal processing, certain safeguards could be taken (GAP) to prevent or minimize foodborne contamination. It would be unrealistic to require seed suppliers to certify seeds for sprouting as safe. There are events beyond the control of the seed producer that could cause contamination, i.e., field animals and other wild life.

2. **Which practices primarily contribute to the contamination with harmful pathogens of seeds used for sprouting? Which intervention strategies can help prevent, reduce, or control this contamination of seeds used for sprouting? Where appropriate, identify barriers to adopting effective preventive controls for this contamination, and, if possible, suggest mechanisms to overcome these barriers.**

Best answered by those familiar with the production and processing of seeds for sprouting.

3. **Which practices primarily contribute to the contamination with harmful pathogens of sprouts? Which intervention strategies can help prevent, reduce, or control the contamination of sprouts? Where appropriate, identify barriers to adopting effective preventive controls for this contamination, and, if possible, suggest mechanisms to overcome these barriers.**

Inspections have led to GMPs:

By simply following GMPs, the production of sprouts should not be a source of harmful pathogens. I believe major growers in the sprouting industry have made significant changes to their production practices. The industry has come to accept that

they are food processors, and not farmers. Because sprouting facilities have come under frequent inspection by health regulators, many sprouting facilities have implemented changes to maintain sanitary conditions and practices. By continuing regular inspections by health regulators, an unsanitary condition at sprouting facilities is less of a factor in foodborne contamination.

However, it should be noted that there are many small sprout growers that grow sprouts undetected and are not inspected by any health regulatory agencies. Unsanitary conditions may exist in these facilities, and adequate controls to prevent contamination may not be in place, or they may not be aware of the risks involved in producing sprouts.

Seed Disinfection:

Not having pathogen-contaminated seeds in a sprouting facility should be the primary line of defense in a sprout growing facility. Once contaminated seeds enter the sprout production process, seed disinfection would be the next line of defense. Depending on the degree and nature of the contamination in the seeds, seed disinfection is an effective tool.

Seed disinfection or seed treatment has been a tool to sprout growers long before seed disinfection for human pathogens became an issue. Sprout growers have been treating seeds for sprouting with disinfectants to prevent the spread of plant pathogens. Plant pathogens affect the yield and the quality of sprouts. The treatment of seeds for sprouting with a solution of calcium hypochlorite was a practice readily accepted and adopted by sprout growers. What was objectionable, and still is a barrier to overcome, is the strength of the calcium hypochlorite solution.

There are different seeds for sprouting, and the seeds of a particular variety can differ in the rate of germination, and vitality. This can differ from year to year depending on weather conditions for growing seed. Poor weather can weaken the seed. Seed for sprouting is sensitive to the level of calcium hypochlorite used to disinfect it. Only with practice, can a sprout grower determine the concentration level of the calcium hypochlorite solution that a particular lot of seed can tolerate. The FDA sprout guidance documents were inflexible in this regard. The use of a 20,000 ppm solution of calcium hypochlorite to disinfect all seeds across the board is not a practical solution and therefore not received well by sprout growers.

Research on the effectiveness of disinfecting seed for sprouting with a solution of calcium hypochlorite has varying results. Concentration levels of 20,000 to 2000 ppm have been tested on artificially inoculated alfalfa seeds, and the results led to a standard for **ALL** seeds. Much of the research was done under the erroneous assumption that artificially inoculated alfalfa seed is equivalent to naturally contaminated seed. Researchers have not identified how seeds for sprouting become contaminated. Therefore, the methods used to inoculate seeds could only lead to questionable results. The research may have been conducted in the most scientific manner, but these assumptions led the sprout growing industry to give very little credibility to the results.

The scientific community is not in agreement on how to inoculate seeds with pathogens to be used for testing. Inoculation methods range from spraying a pathogen laden solution on alfalfa seeds, to soaking seeds in a pathogen solution followed by drying of the seed. The latter method is most often used in published research articles. By wetting the seed coat, one is initiating the germination process. The seed coat is expanded by the moisture, allowing the pathogen to be adsorbed by the seed coat, and perhaps penetrating the seed coat itself. The contaminated seed then goes through a drying process, which shrinks the seed coat embedding the pathogen in the re-dried seed coat. These artificially inoculated seeds are then used to test the effectiveness of seed disinfection.

It is unrealistic to assume that the accepted method on inoculating seeds, alfalfa seeds in most cases, simulates naturally contaminated seeds. The apparent objective is to load up a seed with as much pathogens as possible and see if a disinfection process can reduce the pathogen level. An argument can be raised that by embedding pathogens in the seed coat, you have artificially encapsulated the pathogen in the seed coat, and protected the pathogen from being disinfected under any method. This artificial method of inoculating seed leads to an artificial result, in this case, strong support toward the usage of a chlorine solution of 20,000 ppm.

Simply rinsing seeds for sprouting with plain potable water is an effective seed disinfection process. It may be that a chlorine solution as low as 200 ppm is all that is necessary to disinfect naturally contaminated seed for sprouting.

4. Do the preventive controls recommended in the FDA's sprout guidances need to be expanded or otherwise revised? If yes, please describe generally the areas that need expansion or other revision.

Guidance Documents Only Fit Alfalfa Sprout Production:

As soon as the guidance documents were issued, it was evident that the guidance documents were designed primarily for the production of alfalfa sprouts. Of the two major sprouts grown in the United States, alfalfa sprouts and mung bean sprouts, the guidance documents appeared applicable only to alfalfa sprout operations, where sprouts are often grown in rotating drums.

The guidance document detailing the sampling and microbial testing of spent irrigation water was ingenious. As water permeates through a crop of sprouts in a rotating drum, it picks up a representative sample of the bacterial load on the sprouts. By testing this water sample for particular pathogens using rapid testing kits, results could be obtained before the sprouts are distributed to consumers. For drum grown sprouts, this was a very valuable validation tool.

However, the person who designed this testing protocol appears to have had limited knowledge of how mung bean sprouts are grown. The processes are completely

different. Mung bean sprouts are not grown in drums, but large vessels whose bottom is essentially a large screened drain. The rate of irrigation in alfalfa sprouts is a single digit gallon per minute. Bean sprouts are irrigated at a rate closer to 100 gallons per minute. We have a dilution factor that significantly reduces the detection of pathogens. Although this distinction was pointed out soon after the guidance documents first came out, the process by which changes to the guidance documents could be made never took place.

Through publications in the International Sprout Growers Association newsletter, bean sprout growers were advised to modify the sampling collection method to best collect a representative sample of the bacterial load in their crop without diluting the detection level. However, health regulators who visited bean sprouting facilities failed to understand the principle behind the sampling process. They took the irrigation water literally, and perhaps, requested bean sprout growers to follow their example. What you end up with is a highly diluted water sample and a cold shower.

The Guidance Document is Inflexible to Technological Advancement:

The only seed treatment or seed disinfection method described in the guidance document is the use of a calcium hypochlorite solution of 20,000 ppm. As indicated above, that level of chlorine usage was based on questionable research assumptions. Other seed treatments have been proven to be as effective as calcium hypochlorite, but because of the inflexibility of the approval process for alternative seed treatment, no alternative is permitted to be used.

In 1999, the FDA was of the opinion that out of the many rapid test kits for Salmonella and E. coli O157:H7, only a few test kits were worthy for consideration, and specifically identified four certain test kits for the testing of Salmonella and E. coli O157:H7. Since this publication in 1999, several newer test kits or testing methods have been developed that are just as effective, or better.

The cost to perform spent irrigation water testing as described in the guidance document is prohibitive to many medium to small producers. Although contrary to the testing protocol described in the guidance documents, many sprout growers pool samples to perform a single test rather than to perform a test for each drum or bin. With the cost running around $100 for a set of tests (Salmonella and E. coli O157:H7), performing a test for each drum or bin on a daily basis can be substantial. Even with pooling, which most sprout growers practice, the cost is still high. With five crops a week, daily testing could amount to over $26,000 per year, enough to cause many sprout growers to choose not to perform the test, or have it done incorrectly at a lower cost. Those who do not perform the test have become more profitable than those who do. Economic market forces discourage testing. The larger sprout growers, who pool large crops, stand in a better economical position over small or medium growers.

Spent irrigation water testing, if performed correctly, is equivalent to testing 100% of a crop. No other food product requires that high of a level of testing. Testing

frequency must be made equitable for both small and large companies. As an example, require one set of tests for every 10,000 pounds of sprouts.

Health Regulators Do Not Trust the Guidance Documents:

In the most recent series of sprout recalls taking place around June 2004, I have been informed that several sprout growers were requested to recall and did recall sprouts grown from a certain seed lot that was suspected of being contaminated. Evidently, an epidemiological study on a foodborne outbreak, associated the outbreak to the consumption of raw sprouts. They traced the outbreak to one particular lot of seeds and tracked down other sprout growers using that same numbered lot of seeds. Notwithstanding the fact that a sprout grower followed the guidance document, using the described seed treatment, and verified by negative spent irrigation water test results, health regulators, nevertheless, sought voluntary recalls of raw sprouts merely on the grounds that they were grown from a seed lot suspected of being involved in an outbreak.

If the original epidemiological study that associated the seed lot to a suspected outbreak was, in deed, correct, this incident is clear evidence of the effectiveness of the guidance documents. Based on information that I am aware of, none of the sprout growers who were requested to recall raw sprouts had any incidents of foodborne illnesses in their distribution territory. They had documented evidence that they followed the guidance documents with seed treatment, and the product distributed had negative spent irrigation water test results for salmonella and E. coli O157:H7. Furthermore, none of the recalled sprouts were found to be contaminated.

It is also curious to note that at no time was supplier, lot number, or country of origin of the allegedly contaminated seed was ever identified and publicized in any of the several recall notices. If the seed supplier and lot number had been publicized at the outset, sprout growers who were subsequently identified to possess that lot of seed, could have discontinued using that seed lot, and avoided a costly and damaging recall. Instead, we see a series of FDA precautionary recall notices identifying several different sprout growers on 6/4, 6/10, 6/17, 6/18, and 6/23/04. Not one recall notice mentions the identity of the seed supplier or seed lot number. The cumulative effect of all these notices not only damaged the reputation of the identified sprout grower, but the reputation of the entire sprout industry.

Finding a lot of seed that is naturally contaminated is a research opportunity. If this particular lot of seed is, in deed, naturally contaminated, I hope health regulators use this opportunity to test and research this seed lot thoroughly. Find out how the seeds were grown, and where and how the seeds could have become contaminated with pathogens. Further research should confirm whether the seeds are truly contaminated, and the degree and nature of the contamination. There are unanswered theories that contamination of seeds is localized and not randomly distributed. Preservation of a naturally contaminated seed lot for research would be invaluable.

4. **Although FDA's current recommendations address practices by all parties, efforts to promote adoption of effective preventive controls have focused largely on sprouting facilities. What can or should be done to increase the involvement of producers of seeds for sprouting and seed distributors to ensure the safety of sprouts?**

In the past, there was a concern that if too many rules and regulations were imposed on seed producers, they could simply abandon that segment of the market. Speaking as a person not familiar with production and processing of seed, the market has changed where tight controls and regulations on pest control usage, crop variety purity, etc., that additional regulations or standards would not be a great imposition.

We hear again and again, that seed appears to be the source of contamination in most of the foodborne illness outbreaks associated with sprout consumption. It would appear logical to put the focus at the source of the problem.

There are but a handful of seed supplier to the sprouting industry. There are hundreds of sprout growers in the United States. Of the hundreds of sprout growers, only the more visible sprout growers are subjected to regulatory inspections. Hundreds remain below the radar and un-inspected. In my city alone, I am aware of four sprout growers. Regulatory inspector has inspected only two of us. It is practically impossible for health regulators to identify, locate, and inspect all sprout growers. Furthermore, there are many consumers who grow their own sprouts, and are completely unaware about seed treatment, sanitation, and testing.

If there are to be any new significant changes to the sprouting industry, the change should focus on the seed for sprouting. If there were a process where seed producers must follow certain guidelines to produce relatively safe seed and certify the seed as a food product, we could substantially reduce the risk of producing contaminated sprouts. By merely requiring seed suppliers to only sell seed for sprouting that has been certified as a food product, and sprout growers are required to grow sprouts only from seeds certified as a food product, the industry would enter a higher threshold of food safety.

5. **Is a regulation likely to be an effective means of achieving the goal of minimizing foodborne illness associated with the consumption of sprouts? If not, what is likely to be an effective approach?**

The effectiveness of regulations is only as good as its enforcement. Enforcement would mean regular inspections of sprout facilities to educate the sprout grower on the new regulations, and enforce the regulation with corrections when applicable. While a majority of sprout growers may get inspected, hundreds will continue to operate unregulated and un-inspected. Effective enforcement would also mean extensive training of inspectors on the many variations of growing sprouts. Not all inspectors would adsorb or understand all aspects of a sprouting operation. Inequitably enforcement and rule interpretation would be a major problem with regulations.

Before imposing rules on sprout growers, it would appear to be more logical to correct the source of the problem, before trying to regulate sprout growers that have no control over the source of their seed supply. The nature and variety of sprout growing practices can lead to a complex series of regulations.

Once rules are implemented, how flexible are they to changes in technology? There may be a seed treatment around the corner that will resolve all food safety issues, but may not be permitted to be used by sprout growers because rules cannot be changed in a timely manner. Or there could be a less expensive, and more effective testing procedure for sprouts. Rules must undergo continual evaluation and modifications in order to reflect the continuing technological changes that become available. If the guidance document is an example of the rules to come, flexibility to changes are practicably non-existent.

6. **How can progress toward the overarching goal (to minimize foodborne illness associated with sprout consumption) be effectively measured?**

Current epidemiological practices are biased against sprouts and other food products classified as high risk. Because of the public advisories on the risk associated with consuming raw sprouts, sprouts have become a "usual" suspect in any outbreak. Evidences of this bias are epidemiological survey forms that specifically identify high risk food products, including sprouts. Another evidence of biased epidemiological practice includes an incident where alfalfa sprout product is distributed over a wide territory, yet the cluster of foodborne illness is limited to a localized area. If a sprout crop is indeed contaminated with pathogens, incidents of foodborne illness should reflect the entire distribution territory.

The apparent bias toward sprouts in epidemiological studies raises credibility issues of whether, in fact, certain outbreaks are truly associated with the consumption of raw sprouts.

Epidemiological studies are the only measuring device that has been used, short of actually finding contaminated sprouts. Most charts merely list the number of people sickened in an outbreaks associated with the consumption of raw sprouts. These charts should, perhaps, be further refined. Mere epidemiological association is a statistical finding. For each statistical finding there is a level or degree of reliability. If raw contaminated sprouts were actually found, that reliability would be high, or close to 100%. If, however, only a small cluster of illness were reported in a sprout grower's larger distribution territory, the level of reliability would be very low.

Charts that implicate sprouts to outbreaks of foodborne illness should be re-examined. The chart should specify a degree of reliability for each identified outbreak, i.e., rating of 5 for high degree of reliability, to a 1 for low degree of reliability.

7. **There is broad variation within the seed and sprout industry, including variations in size of establishments, the types of seeds and sprouts produced, the practices used in production, and, possibly, variations in the vulnerability of a particular type of seed or sprout to microbial hazards or in the effectiveness of particular interventions. How, if at all, should the actions to improve the safety of seeds for sprouting be structured to take into account such variation? For example, should there be different sets of interventions for identifiable segments of the seed industry? Similarly, how, if at all, should the actions to improve the safety of sprouts be structured to take into account such variation? For example, should there be different sets of interventions for identifiable segments of the sprouts industry? If yes, please describe.**

It would be very difficult to pigeonhole various sprout growers and their methods into specifically defined categories. Many individual sprout growers devised and built their own sprout growing and processing equipment. Each individual sprout grower knows the specific of his or her own operation better than any regulatory agency. It would take a year or two just to identify all sprout growers in the US. As indicated above, there are many sprout growers that operate completely unregulated or un-inspected.

The best approach is to require a HACCP program analysis for each type of sprout production. With each variety of sprouts, the grower can identify or define various intervention practices that are applicable for that variety of sprout. It should be recognized that there is no intervention practice presently known that would completely eliminate the risk of foodborne contamination. For each intervention step, we are merely reducing the risk of foodborne contamination. The more intervention steps that become available through research, the lower the risk of foodborne contamination. Guidelines could be established to identify the many types of intervention practices that show positive results from research. It would be up to the individual sprout grower to identify and use the particular intervention steps that best suit his or her product.

Intervention steps can then be followed up with validation testing on a per 1000 or 10,000 pound basis, depending on the size and volume of the sprout product. Lot sizes can vary from one grower to another. To require a set of costly spent irrigation water tests for each lot would be cost prohibitive to a small grower, but very feasible to a large volume producer. The scales of economy would be neutralized if a lot is tested for every set amount of sprout produced. Since mung bean sprouts are heavier than alfalfa sprouts, the threshold amount should be adjusted accordingly.

If all sprout growers were required to use only seeds certified as a food product, and the certification process is actually implemented and inspected, risk of foodborne illness associated with sprout consumption could be drastically reduced. Enforcement on the sprout grower level would be very simple. Health regulators need only examine the growers' HACCP program and verify the first critical control point, which would be the receipt of seeds certified as a food product. A HACCP program should be diagramed for

each variety of sprouts, if there is a significant variation, and all critical control points and intervention steps identified and validated. Health inspectors need not concern themselves with the uniqueness of each variety of sprouts, but whether a valid HACCP program was properly prepared and documented for each variety of sprouts.

Requiring sprout growers to use only seeds certified as a food product will result in some significant changes in the seed producing industry. The burden, however, should be no different than producing seeds certified as organic.

With respect to those sprout growers who are so small and not identifiable, and to consumers who grow their own sprout; the risk of producing contaminated sprouts could be impacted in a positive manner. They would be purchasing their seeds from a limited number of seed suppliers. The seed suppliers who knowingly sell seeds destine to be used to grow sprouts, should be selling them only seeds certified as a food product. The likelihood of a consumer using an intervention step is highly remote, however, the risk of inadvertently growing contaminated sprouts is reduced by the mere fact that the seeds he or she is using have been grown and produced in a manner consistent with other food producing practices.

8. Are there existing food safety systems or standards (such as international standards) that FDA should consider as part of the agency's efforts to minimize foodborne illness associated with the consumption of sprouts? Please identify these systems or standards and explain how their consideration might contribute to this effort.

Based upon the many years I have become acquainted with growers and regulators from outside the United States, the foremost criticism of the US method is the usage of high levels of chlorine as an intervention step to disinfecting seed for sprouting. This method is not acceptable internationally, and it is illegal in most foreign countries. It is not only dangerous to use, it is also environmentally damaging.

Research validating the use of high concentration of chlorine to disinfect alfalfa seeds is based on the assumption that artificially inoculated seed, loaded with pathogens, is consistent with naturally contaminated seeds. This assumption must be re-examined.

The international community has neither adopted nor promoted the use of 20,000 ppm calcium hypochlorite solution to disinfect seeds for sprouting, yet the number of outbreaks in the international community is not statistically higher than the US. Since the guidance documents were first issued in late 1999, there has been a significant drop in foodbourne illness outbreaks associated with sprout consumption, but not eliminated. Additionally, many domestic sprout growers were subjected to periodic inspections by health regulators to confirm compliance with the guidance documents.

In the international community, the awareness of the risk associated with the consumption of sprouts was recognized, and may have led to increased inspections by food safety regulators. However, the international community has not compelled sprout

growers to use any of the methods outlined in the guidance documents. One would expect a significant difference or change in reported outbreaks associated with the consumption of sprouts between the United States and the international community.

Conclusion:

Before considering the implementation of a complex series of regulations, the sprouting industry and health regulators should explore the possibility of improving seed production and processing first. Currently, there is no practice in place and validated, that confirms that seeds used for sprouting have been produced under "good agricultural practices." Significant changes to the sprouting industry can be accomplished simply by having a system in place where seed for sprouting are actually produced under good agricultural practices, and validated accordingly. If sprout growers are required to use only seed certified as a food product, and seed suppliers, who know that seeds are destined to be used to grow sprouts, must only supply seed certified as a food product, significant improvement in food safety can be achieved.

Most conscientious sprout growers have already initiated a form of HACCP program in the production of sprouts. Most major purchasers of sprouts require it. To impose such a requirement would not be a hardship to the industry.

Instead of inspecting hundreds of sprout growers across the United States, inspecting a handful of seed suppliers and their seed source, would be a more effective use of limited resources. The reported source of contamination in most foodborne illness outbreaks associated with sprout consumption is the seed. Our attention should be focused on that source, the seed. If this translates into higher cost for the production of seeds, the added cost is far exceeded by the savings in seed intervention expenses.

Respectfully submitted,

JAY R. LOUIE
President

Louie Foods International
471 So. Teilman Avenue
Fresno, CA 93706

(559) 264-2745
(559) 266-4046 Fax
LouieFoods@aol.com

Revised 06/08/05