

December 13, 1999

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

**Re: Guidance for Industry: Reducing Microbial
Food Safety Hazards for Sprouted Seeds and
Guidance for Industry: Sampling and Microbial
Testing of Spent Irrigation Water During Sprout
Production
Docket Nos. 99D-4488 and 99D-4489
64 Fed.Reg. 57893 (October 27, 1999)**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration's (FDA's) guidance documents on minimizing the food-safety hazards associated with sprouts. CSPI is a non-profit consumer advocacy organization that focuses largely on nutrition and food-safety policies. We accept no industry or government funding and are supported almost entirely by the nearly one million subscribers to our *Nutrition Action Healthletter*. CSPI has been actively involved in efforts to improve the safety of sprouts, a food that poses unique safety problems and concerns.

I. Introduction

CSPI applauds the Food and Drug Administration for taking steps to encourage sprout producers to adopt measures that should reduce the microbial contamination of sprouts. While scientists still need to develop an effective elimination treatment for microbial contamination of sprout seeds, protective measures must be taken in the interim. CSPI supports FDA's decision to recommend microbial testing of irrigation water from each batch of sprouts to reduce the likelihood that contaminated sprouts will reach consumers. While batch testing is not the ideal

99D-4488
99D-4489

C41

solution to the problem, it is a necessary measure at this time given the lack of an effective treatment to eliminate microbial contamination of seeds.¹ As soon as an effective intervention is developed, however, FDA should implement a mandatory hazard analysis and critical control point (HACCP) program for sprouts.

Although FDA's guidance documents contain much useful information for sprouters, they suffer from a significant shortcoming: they are purely voluntary. FDA states that it intends to use its authority under the Federal Food Drug and Cosmetic Act (FFDCA) to ensure compliance with its recommendations for sprout safety, but those recommendations are not binding on sprout producers because the agency has opted to publish them in guidance documents rather than as mandatory regulations. That is unwise; the hazards posed by contaminated sprouts are too dire for the agency to rely solely upon sprouters' voluntary adoption of practices suggested by the agency. Instead, FDA should immediately promulgate its recommendations as mandatory regulations. It should also add teeth in the form of aggressive enforcement provisions. Until the agency subjects the entire sprout industry to tough, mandatory safety regulations, there is no reason to believe that sprout safety will improve across all segments of the industry.

In addition, until an effective intervention step is developed and implemented as part of a mandatory HACCP system for sprout safety, FDA should maintain its advisory to consumers that there are health risks associated with eating raw sprouts and that susceptible consumers should avoid raw sprouts altogether. That advisory should, however, be bolstered by a mandatory label on all sprout containers or packages that informs consumers about the risks of eating raw sprouts.

The foregoing recommendations, as well as other, more specific comments on the two guidance documents, are discussed more fully below.

II. The Recommendations in FDA's Guidance Documents Should Be Mandatory

As long as the guidance documents are voluntary, they will not assure that sprout safety improves. FDA concedes that even though the agency has worked with the industry, "not all industry segments have been reached."² Unless the good agricultural practices, seed disinfection

¹ Department of Health and Human Services, Food and Drug Administration, "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds and Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," *Federal Register*, Vol. 64, No. 207 (1999), p. 57894 [hereinafter cited as *Guidance for Sprout Industry*]; Peter J. Taormina et al., "Infections Associated with Eating Seed Sprouts: An International Concern," *Emerging Infectious Diseases*, Vol. 5, No. 5 (1999), available at <<http://www.cdc.gov/ncidod/eid/vol5no5/taormina.htm>>Internet [hereinafter cited as *Infections Associated with Eating Seed Sprouts*].

² *Guidance for Sprout Industry*, p. 57894.

treatments, and testing requirements are made mandatory, some sprouters will likely continue to ignore FDA's recommended practices. Such sprouters could be responsible for the next large outbreak, whether it be from contaminated seeds or unhygienic sprouting practices.

In its *Federal Register* notice, as well as in statements to the trade press, FDA has stated that it will consider enforcement actions under the FFDCA for those sprouters who do not have effective controls -- particularly microbial testing programs -- in place. CSPI is pleased that the agency appears to be willing to deem adulterated sprouts not produced under its guidelines. However, as FDA explicitly notes in both the notice and the guidance documents themselves, the documents do not "create or confer any rights for or on any person and [do] not operate to bind FDA or the public." That is consistent with the fact that the guidance documents are not binding regulations developed by means of notice-and-comment rulemaking.

To ensure that the entire sprout industry complies with the critically important safety measures in the guidance documents, and to stave off any challenge to the agency's authority to enforce those measures, FDA should immediately undertake notice-and-comment rulemaking to promulgate the guidelines as mandatory regulations. In addition, the agency should specify in its regulations the enforcement actions that it will take against sprouters that fail to comply. Sprout safety is far too important a public-health issue to justify reliance on voluntary recommendations alone.

In addition, to enable it to identify all sprouting facilities for inspection and monitoring purposes, FDA should require in the regulations that all facilities register with the agency and document their safety procedures so that government inspectors can ensure that proper safety practices are being followed at all times, not just during inspections.

III. Until an Effective Pathogen Reduction Step is Developed and Mandated, Sprouts Should be Labeled as High-Risk Foods

At this time, FDA's guidance documents cannot guarantee the safety of sprouts. No single treatment, nor set of treatments, will completely eliminate, or even substantially reduce, pathogens in sprout seeds. Therefore, sprouts will continue to pose serious health risks even if FDA's recommendations are universally adopted, especially for those consumers who are most at risk of developing foodborne illness.

Until a treatment step that effectively eliminates pathogens from seeds is developed and implemented as part of a mandatory HACCP program that includes appropriate pathogen-reduction performance standards, labels on sprout packages stating that they are high-risk foods should be required. While FDA should, of course, maintain its recommendation that at-risk

persons avoid eating raw sprouts,³ effective package labeling also should be required to maximize the likelihood that all consumers learn about the risk posed by sprouts. In developing a package label, the agency should be guided by the following principles:

- *The message should be concise so consumers can read the message quickly.* Studies on the effectiveness of labels show that too much information causes consumers to filter out key elements of the message.⁴
- *A signal word such as "warning," "danger," or "caution" should precede the statement and should be in bold type.* Consumers must notice the label for it to be effective. The words should be in a single, easy-to-read type style and in type size no smaller than 8 point. The label should be enclosed by a box rule with adequate space around the statement and the words should be printed in a dark color on a light background.⁵
- *The label should be prominently placed on the front (or top) of the sprout package.*
- *The label should include a graphic symbol to improve consumer retention of the message.* To maximize the label's effectiveness, it should use a graphic symbol, such as the exclamation point inside a triangle. This symbol would serve as a reminder that sprouts may contain harmful bacteria and should be avoided by vulnerable consumers. Ideally, the symbol should be understandable to consumers who cannot read or understand English.

The agency should conduct consumer surveys to facilitate the development of an effective package label.

³ US Department of Health and Human Services, Food and Drug Administration, "Consumers Advised of Risks Associated with Raw Sprouts," *HHS News*, P99-13, July 9, 1999, available at <<http://www.fda.gov/bbs/topics/NEWS/NEW00684.html>>Internet.

⁴ Mark Lehto and James Miller, *Warnings: Fundamentals, Design, and Evaluation Methodologies, Vol. 1*, (Ann Arbor, MI: Fuller Technical Publications, 1987), pp. 61-68.

⁵ See, e.g., 21 CFR 867(e) (specifications for olestra warning label).

IV. Once an Effective Decontamination Method is Developed, a HACCP System Should Be Required for Sprouts

Unfortunately, as stated above, there is no single intervention, or set of interventions, currently available that will eliminate the hazards associated with sprouts.⁶ That fact impairs FDA's ability to require a HACCP system for sprout safety. However, FDA should encourage the development of such interventions and the responsible agency (i.e., FDA or the Environmental Protection Agency) should expedite their approval.

Once an effective pathogen-elimination technology is available, FDA should develop a mandatory HACCP program for sprout safety. Under such a program, sprouters should be required to achieve a public-health-based performance standard for pathogen reduction, using the new technology or any other intervention that affords an equivalent level of protection. By relying upon performance standards rather than mandating a particular intervention technology, FDA would protect public health without stifling innovation in the sprout industry.

V. Specific Comments on "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds"

A. The Guidelines in the "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds" Are Vague

Although the guidance document provides appropriate instructions on how sprout producers should handle seeds, many of the recommendations are too vague or overly permissive. For instance, the guidance provides that "[a]n alternative approach may be used if such approach satisfies the requirement of applicable statutes and regulations."⁷ That language does not specify *how* an alternative approach is to be judged as satisfying the governing law and regulations. The guidance should be revised to require any pathogen-control system that differs from those outlined in the guidance documents to be validated by FDA as affording an equivalent level of protection against pathogenic contamination.

Following are other examples of recommendations in the guidance that are too vague:

- Under *Seed Conditioning, Storage, and Transportation*, the guidance gives specific recommendations on storage, but omits specific information on seed conditioning or transportation.

⁶ *Guidance for Sprout Industry*, p. 87894.

⁷ *Ibid.*, p. 57895.

- Under *Sprout Production*, the guidance says “sprouters should maintain facilities and equipment in a condition that will protect against contamination.”⁸ Though the section later refers sprouters to 21 CFR Part 110, more detailed information about what is meant by this recommendation should be provided in the guidance document itself, especially if it is made mandatory.

B. All Relevant Documents Cited in the Guidance Should be Easily Accessible

The guidance refers to several different documents that contain important information concerning sprout safety. Those documents should be made readily available to sprouters in one location. For sprouters with access to the Internet, all the relevant documents should be placed in one easily accessible website. Sprouters without Internet access should be able to obtain all the relevant documents in one package from a single office, preferably by means of a toll-free telephone number. These sources should be well publicized by FDA so that the entire industry learns about them. FDA could take steps to inform all pertinent trade associations about how to obtain the information, so that they can pass it along to their individual members.

VI. Specific Comments on “Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production”

A. The Testing Guidance Document is Very Technical and Designed for Someone with Scientific Training.

In this guidance document, FDA recognizes that aseptic collection is difficult to do without training, and that sprout facility employees might have to collect irrigation water. Therefore if sprout companies collect their own samples, FDA should require that samples be collected only by personnel who have been trained and *certified* as able to collect samples aseptically. It would be difficult or impossible for a person lacking scientific training to understand the instructions without attending a training course.⁹

In addition, certain recommendations in the guidance are confusing or inconsistent. Some examples follow:

⁸ *Ibid.*, p. 57895

⁹ CSPI supports the development of the educational video of sprout practices described on p. 57895 of the *Federal Register* notice. However, if it includes instruction on how to aseptically collect water and sprout samples, viewers who will be performing these tasks should be required to pass a test to ensure that they have mastered the procedures.

- “Sterile gloves should be put on in a manner that does not contaminate the outside of the glove.”¹⁰ The directions need to be more explicit, especially for sprout growers not familiar with aseptic techniques.
- “Samples or sampling equipment should not be exposed to unfiltered air currents.”¹¹ If that is the case, then sprouting facilities should be required to have filtered air currents. The guidance omits such a recommendation.
- The guidance gives very specific instructions on how to handle sampling containers (i.e., “If collecting samples in a container with a lid, the lid and container should be held in one hand while collecting the sample.”¹²), but it does not give instructions or examples on how to sample the irrigation water (i.e., with a sterile pipette).¹³
- The guidance recommends that the lab run positive controls to ensure the tests are being performed accurately, but it does not give specific instructions on how to do this.¹⁴ Since positive controls involve pathogens that could contaminate the environment, including sprouts if the testing facility is near the sprout-production facility, it is crucial that they be handled in a cautious and appropriate manner. FDA should provide explicit instructions on how to run a positive control, and should certify that laboratory personnel are able to perform this procedure correctly and safely.

B. Until a Pathogen Elimination Step is Developed, the Seed Disinfection and Testing Methods Proposed by FDA Should be Required for the Industry

CSPI agrees with FDA that a critical step in preventing future sprout-associated foodborne-illness outbreaks is a pathogen elimination step for seeds. That fact is underscored by recent outbreaks where, in most cases, sprouters “...were not using approved seed disinfection treatments, or were not using them consistently, and were not testing for microbial contamination

¹⁰ *Guidance for Sprout Industry*, p. 57898.

¹¹ *Ibid.*

¹² *Ibid.*, p. 57898.

¹³ *Ibid.*

¹⁴ *Ibid.*, p. 57899.

during sprout production.”¹⁵ Some of those outbreaks may have been prevented if FDA’s recommendations had been followed. Since FDA’s seed-treatment recommendations have not been followed by all sprouters, the only guarantee of compliance with FDA’s current recommendations is to make them mandatory and to aggressively enforce them. Though the recommended treatment is not fail-safe, it is the best method available at this time and should be required for all sprout seeds. At the same time, an effective pathogen elimination treatment for sprouts is critically needed and should be made a top research priority by FDA.

CSPI also agrees that, at this time, batch testing for *E. coli* O157:H7 and *Salmonella* is crucial to improving sprout safety, especially since a well-designed program would assure that test results are available before the growing period is finished.¹⁶ Again, batch testing should be made mandatory and the sampling plan should be approved by FDA.

However, a long-term system for sprout safety should not rely on microbial testing alone to assure safety. CSPI agrees with FDA that as better seed treatment methods are developed, testing should evolve into a system for verifying that pathogen interventions are effective. Again, CSPI sees the evolution from batch testing to verification testing in the context of developing a HACCP system for sprouts.

As to the specific recommendations regarding microbial testing in the guidance document, CSPI also agrees with FDA that sprouts should be tested only if irrigation water cannot be tested. However, even if thorough irrigation water testing is conducted, FDA should also require random testing of sprouts as an additional layer of protection, especially since testing of irrigation water is not 100-percent effective.

CSPI agrees that batch testing should be done by “an external, qualified, independent laboratory,”¹⁷ but feels these laboratories should be certified by FDA as satisfying the criteria outlined by the agency. CSPI disagrees that sprouters should be allowed to conduct testing at their own facilities, considering the risk of contamination of sprouts. If FDA allows the sprouter to do its own testing, FDA should certify that the laboratory meets the same criteria as an independent laboratory.

If any laboratory uses a testing method other than those recommended in the guidance document,¹⁸ FDA should be notified and the agency should determine that the testing method is equivalent to the recommended methods before allowing the alternative method to be used. In

¹⁵ *Ibid.*, p. 57894; see also *Infections Associated with Eating Seed Sprouts*, Table 2.

¹⁶ *Guidance for Sprout Industry*, p. 57896.

¹⁷ *Ibid.*, p. 57897

¹⁸ *Ibid.*, p. 57898.

addition, all laboratories should run positive controls for *every* batch tested, not periodically as recommended in the guidance document.¹⁹ USDA's meat and poultry HACCP rule recommends that three controls (*S. typhimurium*, *S. senftenberg* and an uninoculated media control) be analyzed for each *Salmonella* test on a meat or poultry product.²⁰

D. A Corrective-Action Plan Should be in Place Before a Positive Sample is Detected

CSPI agrees that sprouters should develop and test a plan to effectively recall and destroy a batch of sprouts that tests positive for *E. coli* O157:H7 or *Salmonella*. If a presumptive positive test is found, then a confirmed negative test result using FDA's Bacteriological Analytical Manual (BAM) Method should be required before the sprouts can be released from the sprouting facility.

If a positive sample is found, then a general recall should be implemented for all sprouts from that seed lot. All venues where the sprouts have been sold should be notified and the sprouts should be recalled. CSPI also agrees that any seeds from the same lot in the sprouter's possession should be destroyed. In addition, the supplier of the seeds should be notified in case seeds from a contaminated lot were sent to other sprouters, as has occurred in several outbreaks.²¹ FDA should be notified as well so the agency can monitor potential outbreaks and sprout contamination rates. FDA should also conduct a traceback all the way back to the farm to determine the source of contamination, if possible.

In addition, FDA should expand its guidance or provide instruction in other documents on how to sanitize a sprouting facility after a batch of sprouts has tested positive. After sanitization, environmental testing should be conducted for *Salmonella* and *E. coli* O157:H7. The sprouter should not be permitted to resume operations until test results are negative and FDA approves the sanitation measures and any changes in preventative controls made by the sprouter to address the contamination problem.

¹⁹ *Ibid.*, p. 57899.

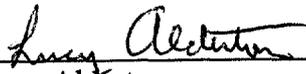
²⁰ Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point Systems; Final Rule," *Federal Register*, Vol. 61, No. 144 (1996), p. 38924.

²¹ See e.g. Centers for Disease Control and Prevention, "Outbreaks of *Escherichia coli* O157:H7 Infection Associated with Eating Alfalfa Sprouts -- Michigan and Virginia, June-July 1997," *Morbidity and Mortality Weekly Report*, Vol. 46, No. 32 (1997), pp. 741-744.

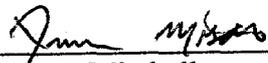
VII. Conclusion

FDA's guidelines for sprouters are an important step toward assuring the safety of sprouts. However, the precautionary measures and testing program set forth in the guidance documents will not be universally adopted by the sprout industry unless the agency makes its recommendations mandatory by undertaking the requisite notice-and-comment rulemaking process. FDA should immediately initiate that action, and should amend its recommendations as suggested above. The agency should also conduct and fund further research into effective interventions against sprout seed contamination with the ultimate goal of developing a mandatory HACCP system for all sprouters.

Respectfully submitted,



Lucy Alderton
Project Coordinator, Food Safety Program



Darren Mitchell
Staff Attorney, Food Safety Program