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Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville MD 20857

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May 1, 2009

Dear Seed Suppliers, Distributors, and Sprouters:

This letter is intended to make you aware of the Food and Drug Administration's (FDA's) serious concern with the continuing outbreaks of foodborne illness associated with the consumption of raw and lightly cooked sprouts. Since 1996, there have been 30 reported outbreaks of foodborne illness for which contaminated sprouts were implicated as the cause. These outbreaks resulted in about 1,800 cases of illness caused by the bacterial pathogens *Salmonella* species and *E. coli* O157.

Sprouts are often consumed raw (or lightly cooked in the case of bean sprouts) without processing to reduce pathogens that may be present. Therefore, the manner in which they are produced, packed, and distributed is crucial to minimizing microbial contamination, thereby reducing the risk of illness to consumers. In 1999, the FDA issued two guidance documents to industry concerning sprout safety. These documents were entitled "Reducing Microbial Food Safety Hazards for Sprouted Seeds," available at www.cfsan.fda.gov/~dms/sprougd1.html (Appendix A), and "Sampling and Microbial Testing of Spent Irrigation Water during Sprout Production," available at www.foodsafety.gov/~dms/sprougd2.html (Appendix B). These guidance documents recommend good practices that seed suppliers, distributors, and sprouters should undertake to address common risk factors in their operations, and thereby minimize food safety hazards potentially associated with raw and lightly cooked sprouts.

We have worked in partnership with the sprout industry since the release of our sprout guidance documents in 1999 to promote adoption of our recommendations and to advance the scientific knowledge applicable to enhancing the safety of sprouts. We recognize and appreciate the efforts that academia and some industry members have taken to date towards the safety of sprouts, and we are confident that you will continue to work actively to pursue this goal. However, in light of continuing outbreaks, it is clear that more needs to be done.

In view of continuing outbreaks associated with sprouts, we are issuing this letter to strongly encourage firms in your industry throughout the supply chain – from seed production and distribution through sprouting – to review their current operations in light of the agency's previously issued guidance documents. We also encourage you to consider other available information regarding the reduction or elimination of pathogens on fresh produce, and to modify your operations accordingly to ensure that you are taking the appropriate measures to provide a safe product to the consumer. In 2004, FDA issued its "Produce Safety from Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with the Consumption of Fresh Produce" (Produce Safety Action Plan, available at www.cfsan.fda.gov/~dms/prodpla2.html). There are four general objectives set out in the Produce Safety Action Plan: prevent contamination of fresh produce; minimize the public health impact when contamination occurs; improve communication between all parties; and facilitate research relevant to the contamination of fresh produce. For each objective, the plan identifies steps or actions by the industry as well as regulators that could contribute to the achievement of the objectives. We believe that many of the steps set out in the Produce Safety Action Plan are relevant to the goal of reducing foodborne illness caused by pathogens associated with sprouts.

As you are aware, seeds are considered the most likely source of contamination in most sprout-associated outbreaks. Therefore, it is important that sprout growers source their seeds from suppliers with an appropriate program to screen their seeds for potential contamination with pathogens.

FDA is aware that the California Department of Public Health (CDPH) recently issued a letter to the sprout industry in California (Appendix C). Sprout producers may find CDPH's letter useful. Additional information about the safer production of sprouted seed set out in an educational video produced by FDA and CDPH can be found at: www.cdph.ca.gov/pubsforms/Documents/fdbIRfrm01.pdf.

FDA stands ready to continue to engage and assist in these endeavors. As you are aware, food prepared, packed, or held under insanitary conditions whereby it may be rendered injurious to health is adulterated under § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act ((21 U.S.C. 342(a)(4)). FDA is investigating regulatory options and may consider enforcement actions against firms and farms that grow, condition, produce, or pack sprouted seeds and seed destined for sprouting under insanitary conditions.

Sincerely,

Stephen F. Sundlof, D.V.M., Ph.D.
Director
Center for Food Safety
and Applied Nutrition

Enclosures

Appendix A
www.cfsan.fda.gov/~dms/sprougd1.html

Appendix B
www.foodsafety.gov/~dms/sprougd2.html

Appendix C
CA Letter to Sprout Industry

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