



CFSAN/Office of Plant and Dairy Foods

August 19, 2004

Note to Firms that Grow, Condition, Store, or Distribute Seed for Sprouting and to Firms that Produce, Pack, or Ship Fresh Sprouts

This letter is intended to make you aware of the Food and Drug Administration's concern regarding continuing outbreaks of foodborne illness associated with the consumption of raw and lightly cooked sprouts, and the actions we recommend that your industries take to enhance the safety of these products.

Since 1996, the Food and Drug Administration (FDA) has responded to 27 outbreaks of foodborne illness for which raw or lightly cooked sprouts were the confirmed or suspected vehicle. These outbreaks account for an estimated 1636 reported cases of illness. Although the sprouts associated with outbreaks in the U.S. have been primarily alfalfa, clover, or mung bean sprouts, FDA is concerned about the risk associated with all types of raw and lightly cooked sprouts. The sprouts have been generally of U.S. origin while the seeds from which the sprouts have been produced are of both U.S. and non-U.S. origin. To date, the causative agents have been *Salmonella* and *E. coli* O157. Because fresh vegetables, including many types of sprouts, are commonly consumed in their raw state without processing to reduce or eliminate pathogens, the manner in which they are produced, packed, and distributed is crucial to ensuring that the potential for their microbial contamination is minimized, thereby reducing the risk of illness to consumers.

In 1998, FDA issued a "Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables" (available at <http://www.foodsafety.gov/~dms/prodguid.html>), which discusses recommended good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers, and shippers can undertake to address common risk factors in their operations and thereby, minimize food safety hazards potentially associated with fresh produce.

Within the fresh produce category, sprouts present a special challenge because the conditions that promote sprouting of the seed (e.g., temperature, humidity, available nutrients) also promote the growth of pathogens if pathogens are present. FDA believes that the seed is the source of contamination in most of the foodborne illness outbreaks associated with sprout consumption. However, insanitary conditions at the sprouting facility can exacerbate any problems.

In October 1999, FDA issued "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds," which recommends preventive controls to assist all parties involved in the production of sprouts (seed producers, seed conditioners and distributors, and sprout producers) to reduce the risk of sprouts serving as a vehicle for foodborne illness. Specific recommendations in this guidance include the development and implementation of GAPs and GMPs in the production and handling of seeds and sprouts, seed disinfection treatments, and microbial testing of spent irrigation water before product enters the food supply. FDA also issued a second guidance, "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" to assist sprout producers in implementing one of the principal recommendations in the broader sprout guidance, i.e., that producers test spent irrigation water for two pathogens before allowing the product to enter the food supply. (These guidance documents are available from: <http://www.cfsan.fda.gov/~dms/sproug1.html> and <http://www.cfsan.fda.gov/~dms/sproug2.html>.)

Since publication of the two guidance documents for sprouts, FDA has worked to promote the recommendations in the guidances and to advance the scientific knowledge applicable to enhancing the safety of sprouts. FDA also served as a technical consultant to the California Department of Health Services (CDHS), who, in cooperation with industry, developed a video to assist the sprout industry to produce a safer product (<http://www.cfsan.fda.gov/~dms/sprouvid.html>).

For several years following release of FDA's two guidance documents, foodborne illness outbreaks associated with alfalfa and clover sprouts appeared to diminish. However, between 2000 and 2002, we have seen an emergence of

Salmonella illnesses associated with consumption of raw and lightly cooked mung bean sprouts. In 2002, FDA issued an updated consumer advisory to include recent outbreaks associated with mung bean sprouts (available at <http://www.cfsan.fda.gov/~lrd/tpsprout.html>). More recently, alfalfa sprouts appear to be reemerging as a significant vehicle for foodborne illness as reflected in the five outbreaks in 2003 and two outbreaks by mid-2004 involving alfalfa sprouts.

In view of continuing outbreaks associated with raw and lightly cooked sprouts, FDA strongly encourages firms in your industries to review their current operations in light of the agency's existing guidance for reducing microbial food safety hazards for sprouted seeds, as well as other available information regarding pathogen reduction or elimination on fresh sprouts and seeds destined for sprout production. We further encourage your firms to consider modifying operations to be consistent with FDA's guidance to ensure that you are taking appropriate measures to provide a safe product to the consumer. Because the seeds used in sprout production are the likely source of contamination in most outbreaks, we recommend that firms from the farm level (seed production) through the distribution of finished product (sprouted seed) undertake these steps. We have observed that damage to seed during harvest or conditioning, and chemical or physical treatments that scarify the seed coat to promote more uniform germination of seed, increase the risk of internalization of pathogens in seed, which makes disinfection of the sprout seed more difficult.

FDA intends to continue monitoring the safety of sprouted seeds and seed destined for sprouting and to continue encouraging the use of good agricultural and good manufacturing practices and preventive controls, such as seed treatment and microbial testing. As you are aware, food produced 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 will consider enforcement actions against firms and farms that grow, condition, produce, or pack sprouted seeds and seed destined for sprouting under insanitary conditions.

On June 18, 2004, FDA released a plan, "Produce Safety from Production to Consumption: A Proposed Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption" (<http://www.cfsan.fda.gov/~dms/prodplan.html>). The overarching goal of this proposed plan is to minimize foodborne illness associated with the consumption of fresh produce. The proposed plan includes steps that could contribute to the achievement of this objective. FDA expects that implementation of the produce safety action plan will include actions to ensure progress towards the goal of reducing foodborne illness associated with the consumption of raw and lightly cooked sprouts.

We recognize and appreciate the efforts that your industries have taken to date to improve the safety of sprouted seeds, and we are confident that you will continue to work actively to pursue this goal.

Sincerely,

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