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FOOD AND DRUG ADMINISTRATION
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FDA ISSUES GUIDANCE TO ENHANCE SAFETY OF SPROUTS

The Food and Drug Administration today issued two guidance documents to enhance the safety of sprouts, a product that in recent years has been implicated in at least 1,300 cases of foodborne illness. The guidance advises sprout producers and seed suppliers of steps they should take to reduce microbial hazards common to sprout production. A companion guide provides producers with the latest information about testing spent irrigation water, an important step to ensure the safety of sprouts.

"As a public health agency, FDA is committed to preventing foodborne illness associated with this product," said Jane E. Henney, MD, the FDA Commissioner. "We believe these guidances, which are based on sound science and the cooperation of many groups, represent a major step toward ensuring food safety."

The guides, entitled "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" are the latest of several FDA actions to reduce the risk of foodborne illness attributed to eating raw sprouts.

In 1997, FDA asked the National Advisory Committee on Microbiological Criteria for Food (NACMCF) to review the current literature on outbreaks of sprout-associated foodborne illness, identify the organisms and production practices of greatest public health concern, set research priorities, and recommend intervention and prevention strategies. The guidance published today is based largely on recommendations from the NACMCF report issued last May.

In August 1998, following outbreaks of Salmonella and E. coli O157 infections attributed to sprouts, FDA issued a health advisory warning high risk groups not to eat raw alfalfa sprouts. The advisory was reissued last July to include all raw sprouts and all consumers because of the continued increase in the incidence of illness attributed to sprouts.

In September 1998, FDA held a public meeting with industry, consumer groups and academia to discuss further steps to ensure the safety of sprouts. Although the meeting and other measures improved the food safety awareness within the industry, sprout-associated foodborne illness outbreaks have continued.

Raw sprouts present unique food safety problems because conditions under which they are produced -- growing time, temperature, water activity, pH (a measure of acidity) and nutrients -- are ideal for the rapid growth of bacteria. If pathogens are present on or in the seed, these conditions are likely to encourage proliferation. To counter this risk, the FDA guidance recommends seed disinfection (with solutions such as calcium hypochlorite) combined with microbial testing of used irrigation water from each batch or production lot to determine whether the pathogens Salmonella and E. Coli O157:H7 are present.

FDA will closely monitor the safety of sprouts and the adoption of prevention practices recommended in the guidance, and will consider enforcement actions against producers who do not have preventive controls in place.

Although FDA solicits public comments, it is implementing the guidances immediately because of the seriousness of the public health hazard associated with sprouts. Written comments on the guidance documents should be submitted by December 13, 1999, to be considered in the preparation of a revised document, if warranted.

The comments should be identified as Docket No. 99D-4488 and 99D-4489 and submitted to Docket Management Branch (HFA-305), 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

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