

AMERICAN SEED TRADE ASSOCIATION



May 5, 2010

Docket No. FDA-2010-N-0085
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Rm 1061
Rockville, MD 20852

www.regulations.gov (Subject Line: Docket No. FDA-2010-N-0085)

RE: FDA-2010-N-0085 Preventive Controls for Fresh produce; Request for Comments

The American Seed Trade Association (ASTA) is pleased to provide comments on issues related to the potential role of seed in food borne human pathogen outbreaks associated with the production, harvesting, and marketing of fresh fruits and vegetables. Founded in 1883, ASTA, located in Alexandria, Virginia, is one of the oldest trade organizations in the United States. Its membership consists of more than 730 companies which are involved in seed production and distribution, plant breeding, and related industries in North America. As an authority on plant germplasm, ASTA advocates science and policy issues of industry importance. The mission of ASTA is to enhance the development and movement of quality seed worldwide.

In response to the 2006 outbreak of E.coli 0157:H7 on spinach in California, ASTA formed a Food Safety Pathogen Working Group (WG) to evaluate the possible role of seed in outbreaks of food borne human pathogens in commercial field and greenhouse vegetable production environments. The WG concluded that seed, at that point in time, was not a clear pathway and there was no significant value in testing seed lots for the presence of human pathogens. These conclusions were based on discussions with researchers, a thorough review of research literature, and a review of practices in use for the production and marketing of seed intended for fresh vegetable production. In July of 2008, ASTA articulated these conclusions with its "ASTA Statement on Field and Greenhouse Planted Seeds and Human Pathogens" position paper (available on the ASTA website at www.amseed.org/newsDetail.asp?id=167) This ASTA statement is in the process of being revised to indicate that, after continued monitoring of scientific literature and information following outbreaks of food borne human pathogens, the conclusions in the original statement remain valid. The updated statement will be formally presented to the ASTA Board of Directors for adoption on July 1, 2010.

The Food and Drug Administration (FDA) has recognized the potential risk of seed used for the production of sprouts in transmitting human pathogens, and has issued several alerts to the public recently to discontinue eating sprouts until further assessment of the specific causes and sources of inoculum can be determined. In addition, the FDA has

released guidance documents to the sprout industry, urging implementation of properly recognized sanitation practices, testing of irrigation water and seed, traceability of products through the production chain, and documentation and recordkeeping practices. ASTA fully supports FDA's responses to food borne human pathogen outbreaks associated with sprout production and guidance to the sprouting industry for preventing outbreaks. This guidance appears to be adequate and new standards for sprout production need not be included in this ASTA initiative. ASTA urges the FDA to continue to distinguish between seeds used in fields and greenhouse vegetable production versus seeds used for the production of sprouts in the development of future policies, standards, and guidance documents.

In summary, ASTA believes that seeds used in fields and greenhouses for the production of fresh produce do not contribute to outbreaks of human pathogens. ASTA will continue to monitor the scientific literature and future outbreaks of human pathogens associated with the production of fresh produce, and provide leadership to its members to ensure that seed does not contribute to future outbreaks.