



International Sprout Growers Association

2150 N. 107th St., #205, Seattle, WA 98133-9009 USA

Tel: 206-367-8704 Fax: 206-367-8777 Toll-free: 800-572-3015 (US and Canada) www.isga-sprouts.org E-mail: office@isga-sprouts.org

President
Bob Sanderson
Jonathan's Sprouts
P.O. Box 128
Marion, MA 02738

Secretary
Bob Rust
International Specialty
Supply
820 E. 20th Street
Cookeville, TN 38501

Treasurer
Tim Frame
Pacific Coast Sprout
Farms, Inc.
5640 Warehouse Way
Sacramento, CA 95826

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

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To Whom it May Concern:

This letter is being submitted as the International Sprout Growers Association (ISGA) comment on the FDA's "Action Plan to Minimize Foodborne Illness Associated With Fresh Produce."

This comment letter will focus primarily on Question #1 of the suggested Action Plan Questions: "What concepts or underlying principles should guide the 2004 Produce Safety Action Plan? Are the seven objectives in the working draft appropriate for achieving the overarching goal to minimize foodborne illness associated with the consumption of fresh produce?"

The 1999 FDA guidance documents relating to growing sprouts, "Reducing Microbial Food Safety Hazards For Sprouted Seeds and Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" are cited in the Draft Action Plan as a possible model for other commodities. In order to evaluate the effectiveness of this Guidance, it needs to be asked whether there has been an adequate improvement in the sprout safety situation as a result of its being issued. The answer seems unclear; there may have been some improvement, but there still appear to be serious problems.

Furthermore, in trying to understand any slight improvement, it is difficult or impossible to determine the relationship between this improvement and either one of the guidance recommendations, or both combined, since a number of other variables also may have changed at about the same time as the issuance of the Guidance; for example, some changes in seed suppliers' procuring practices, geographical seed production areas, etc.

One consequence of this lack of analysis is that different assumptions can be made, based more on predisposition than on any scientific measurement, about which change, if any, has had a beneficial impact. Conclusions can be drawn which may have little connection to reality. There are different interpretations and emphasis of the Guidance, not only among growers, but among regulators as well, and in certain retail markets, these differences in regulatory emphasis can have life-or-death influence on individual producers, with selectively interpreted "compliance" being used by some growers for marketing purposes. This unfortunately feeds into distrust and cynicism.

In the relatively uncontrolled situation that existed in the sprouting industry prior to the issuance of the Guidance in 1999, it may have been felt necessary to take drastic steps in order to provide immediate solutions. However in the ensuing five years, there is still considerable, if not increasing, confusion about the specific effectiveness of each recommendation, concern with

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the difficulties and risks of implementation to producers, and inconsistencies with international standards and organic production practices.

These confusions have resulted in a number of fracture lines within the sprouting industry. Many feel that the Guidance recommendations lack a convincing science-base, and so are perceived as arbitrary. This has had a demoralizing effect on the industry, and puts obstacles in the way of effective cooperation, information sharing, and problem solving.

The ISGA would welcome a review of the 1999 Guidance, with the objective of determining whether the problematic aspects are optimum in achieving the desired effect, which is the drastic reduction, and hopefully, elimination, of sprout-related illness. We ask particularly that assumptions about benefits which are modeled on accepted practice for other foods be closely examined as to their appropriateness for sprouts.

It needs to be emphasized that intervention costs, either for materials or training or labor, that can be justified to retail buyers, and therefore which can command a reasonable premium, do not constitute a burden to growers. The price-sensitivity of sprout products is almost entirely a matter of competition between growers for retail accounts, where, in the absence of regulatory support, there is an incentive to cut every penny in costs, including safety-related costs.

The ISGA also would like the FDA's involvement in developing a standard protocol for seed sampling and testing, significantly more thorough than existing sampling protocols for agricultural seed, and consistent with what is known about optimum pathogen detection in sprouts. The cost of taking relatively large seed samples, like other costs of effective safety intervention, can be justified if they have strong regulatory acknowledgment.

Although the sampling and testing procedure can be done by individual growers, there would be advantages in having it be done by seed suppliers, so that seed lots which gave positive test results would never get into sprouting facilities, but be diverted to non-food uses. The FDA's acknowledgment of the possible value of this procedure would help justify a premium for seed suppliers' willingness to provide this service.

Finally, the ISGA would very much like to move as rapidly as possible to a situation where all seed destined for sprouting was grown under GAP's for food. A rigorous sampling and testing protocol for seed would go a long way toward bringing this about, since the costs and logistical problems of dealing with contaminated seed lots are great, and it could be expected that seed grown with GAP's would present fewer such problems.

The ISGA would like to thank the FDA for this opportunity to submit comments to the 2004 Action Plan. We have recently established a Technical Review Board (TRB) with capable technical resources and expertise, which is available to cooperate in bringing about needed improvements in sprout safety regulatory policy.

Respectfully,



Robert Sanderson

Interim President, ISGA