AMERICAN SEED TRADE ASSOCIATION, INC.

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October 5, 2001

VIA FACSIMILE

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Program Priorities in CFSAN; Docket No. 98N-0359

Dear Sir or Madam:

The American Seed Trade Association (ASTA) is pleased to have this opportunity to respond to the Food and Drug Administration's (FDA's) above-captioned notice in the Federal Register. 66 Fed Reg. 37480 (2001). FDA requests comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2002 (i.e., October 1, 2001 through September 30, 2002). Our comments focus primarily on food plant products and other foods that are produced through the use of modern biotechnology, although seed and grain are also discussed.

By way of background, founded in 1883, ASTA is one of the oldest trade organizations in the United States. Its membership consists of about 900 companies involved in seed production and distribution, plant breeding, and related industries in North America. Its mission is to enhance the development and free movement of quality seed worldwide. Many of ASTA's members, large and small, are engaged in research and development activities designed to enhance the quality, variety, productivity, and availability of agricultural seeds. Some of this research involves the use of molecular and other new techniques for genetic modification, although the industry still relies heavily on traditional breeding methods such as hybridization to produce new plant varieties and to otherwise accomplish desirable genetic changes. The Association remains committed to the development and commercialization of all genetically altered plants that comply with applicable federal and international laws and regulations.

Using the format of the 2001 Work Plan as a guide for the development of the 2002 Work Plan, the three priority areas that ASTA has identified for FY 2002

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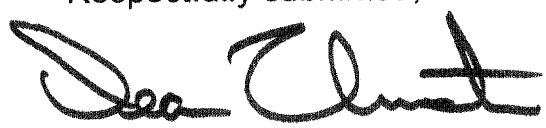
involve FDA's Mandatory Premarket Notification Proposal (PBN) (66 Fed. Reg. 4706 (2001)), Draft Guidance for Voluntary Labeling of Food That Have or Have Not Been Developed Using Biotechnology (id. 4839), and the development of agency policy on the subject of adventitious presence (AP). Strategy 3.4, entitled "Emerging Areas," of CFSAN's 2001 Program Priorities already appropriately lists several biotechnology initiatives as part of the 'A' List. FDA's goal is to fully complete at least 90% of the 'A' List activities within the relevant fiscal year. The two activities currently on the 'A' List for FY 2001 regarding the PBN proposal and Draft Guidance for Labeling should be the subject of follow-through between the 2001 and 2002 Work Plans, as FDA notes in seeking comment on FY 2002 program priorities. We agree that these areas should be a high priority for completion of final documents in FY 2002. See 66 Fed. Reg. at 37481. Completion of these activities in FY 2002 is important to different segments of the entire food chain, including growers, seed companies, grain handlers, and food companies.

With regard to Adventitious Presence (AP), we understand that a number of agencies or departments of the federal government, such as the United States Department of Agriculture, FDA, and the Environmental Protection Agency, are currently developing policies or other programs to address the subject. AP involves the accidental, inadvertent presence of very low levels of modern biotechnology-produced plant materials, such as protein or DNA, in conventionally-derived or other products, including seed, grain, and processed food. AP may occur from pollen flow or commingling or by other means that result in accidental or inadvertent presence. We have urged in the past and continue to do so here that this is a very important area in need of regulatory resolution; therefore, it should be a class 'A' priority for the agency during FY 2002. As FDA is well aware, the establishment of such an allowable level, or threshold, is essential to the continued distribution of modern biotechnology-derived and conventional seed, grain, and processed or raw agricultural food products, both domestically and internationally.

We further urge in this regard that FDA manage this issue in the context of the entire food chain. In the past, the agency seems to have been oriented around addressing only processed foods or grain dedicated to food uses. This orientation, which is understandable given the agency's jurisdiction over foods, nonetheless is incongruous with the fact that seeds essentially are at the beginning of the food chain. Setting levels of AP or other adulteration/ misbranding standards for products at the end of the food chain, without taking into account seed levels, ignores the reality that allowable levels in foods do not necessarily correlate with levels in seeds. The establishment of AP levels in, particularly, processed foods, therefore can result in unobtainable standards being placed on the seed industry. We therefore urge FDA and other agencies or departments to continue to evaluate the AP issue in the context of the entire food chain, not just one segment.

We hope these comments are useful in addressing FY 2002 program priorities. If we can provide any further information, please do not hesitate to contact us.

Respectfully submitted,



Dean Urmston
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