



September 27, 2001

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

Re: *Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments; Docket No. 98N-0359*

Dear Sir/Madam:

The American Crop Protection Association (ACPA) is submitting these comments in response to the program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for 2002, as published in the *Federal Register* on July 18, 2001. 1/

ACPA is a not-for-profit trade organization representing the major manufacturers, formulators and distributors of crop protection, pest control, and biotechnology products. ACPA member companies produce, sell and distribute virtually all the scientific technology products used in crop production by American farmers. Since ACPA members are heavily involved in the development and use of modern biotechnology methods in the initial stages of the "agri-food chain", they are vitally interested in the application of guidance to all foods developed using recombinant DNA technology.

ACPA commends the Food and Drug Administration (FDA) for thorough and transparent stakeholder involvement in the regulatory process. We provided comments to the FDA earlier this year in response to the voluntary labeling guidelines and the pre-biotechnology notification (PBN) proposed rule. We endorse adding the finalization of these emerging areas to the "A" list for 2002 under Strategy 3.4 – *Emerging Areas*. We also support development of a consumer education program on biotechnology emphasizing the safety and benefits of foods and ingredients developed through biotechnology.

ACPA strongly believes that food safety issues should continue as CFSAN's first priority. In the context of modern biotechnology, the adventitious presence 2/ (AP) of

1/ 66 Fed. Reg. 37480 (2001).

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protein or DNA is considered de minimis from either a safety or marketing (quality) standpoint. It is critical that the US regulatory agencies responsible for food biotechnology address and resolve the issue of AP in food, especially the presence of those events for which the regulatory review process is pending.

ACPA also strongly urges FDA to maintain adequate funding and staff expertise for the Pesticide Residue Monitoring Program, carried out by the Center for Food Safety and Applied Nutrition. This program provides a valuable service to safeguard the nation's food supply against misuse of pesticides on food crops, through monitoring for pesticide residues. Regulatory monitoring, incidence monitoring, and the total diet survey are important portions of this program. Consideration should be given to closer cooperation with the Office of Pesticide Programs within the Environmental Protection Agency, and the Pesticide Data Program operated by the Department of Agriculture, to determine how modifications to the Pesticide Residue Monitoring Program could make its data more useful in pesticide risk assessments.

ACPA is committed to working with FDA and other stakeholders in developing scientifically -sound regulations for products of crop biotechnology to achieve food safety. We hope these comments are useful in this regard.

Sincerely,

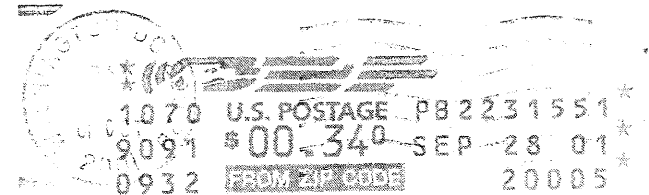


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Senior Director, Biotechnology & Trade

2/ Adventitious presence is defined as the unintentional presence of genetically modified DNA or protein occurring in seed, grain, or food products at trace levels through naturally occurring pollen flow or unintended comingling during harvest, transportation or storage.

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