

AgBiotech Planning Committee
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Andrew C. von Eschenbach, M.D.
 Acting Commissioner
 Food and Drug Administration
 5600 Fisher Lane
 Rockville, MD 20857

Dear Commissioner Eschenbach,

The AgBiotech Planning Committee (ABPC) urges immediate action to finalize draft guidance published by the Food and Drug Administration (FDA) in the Federal Register on November 24, 2004 (69 FR 68381) establishing an Early Food Safety Evaluation (EFSE) for New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use. This guidance was developed in response to policies articulated by the Office of Science and Technology Policy in 2002. The ABPC is a coalition representing farmers, merchandisers, food manufacturers and processors, and biotechnology providers that support the continued availability and marketability of agriculture and food biotechnology.

The ABPC strongly supports the approach outlined by FDA in the November 2004 guidance and urges the Agency to take final action. The ABPC has had numerous discussions with the FDA regarding this matter over the last two years and understood that the guidance was to be finalized in 2005. In May 2005, FDA's Center for Food Safety and Applied Nutrition (FDA-CFSAN) published a notice in the Federal Register (70 FR29329) requesting comments on the agency's "programs priorities" for FY 2006. Completion of EFSE by the end of FY 2005 was included as an "A-list" priority (3.1.1) in the agency's request.

While the ABPC understands that certain circumstances may have caused a delay in finalizing the guidance, its importance requires expedient attention. The FDA EFSE guidance is the cornerstone of developing a comprehensive science-based US Government system which will protect food and agricultural interests domestically, and is a necessary first step for subsequent international policy discussions to protect food and agricultural interests in export markets.

Our organizations appreciate your attention to this urgent matter and look forward to discussing it with you and your staff in the near future. In addition to working with FDA staff on the EFSE issue, our organizations also will be working closely with the U.S. Department of Agriculture to ensure that the regulatory measures governing field trials of biotech crops are rigorously enforced and monitored.

Sincerely,

American Farm Bureau Federation
 American Seed Trade Association
 American Soybean Association
 Biotechnology Industry Organization
 Corn Refiners Association
 Food Products Association
 Grocery Manufacturers Association
 National Association of Wheat Growers

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National Corn Growers Association
National Cotton Council
National Grain and Feed Association
National Oilseed Processors Association
North American Millers' Association
U.S. Apple Association
Wheat Export Trade Education Committee