



Healthy Plants • Healthy World

September , 2002

To: Office of Science and Technology Policy (OSTP)
e-mail: comments@ostp.eop.gov

Re: Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants (Federal Register, August 2, 2002 (Vol. 67, No. 149, pgs 50577-50580)

To Whom it May Concern:

The American Phytopathological Society (APS), founded in 1909, is the premiere educational, professional and scientific society dedicated to the promotion of plant health and plant disease management for the common good. The Society, representing the interests of five thousand scientists whose pivotal research advances in the understanding of the science of plant pathology and its application to plant health, respectfully submits its comments regarding the proposed federal actions to update field test requirements for biotechnology derived plants and to establish early food safety assessments for new proteins produced by such plants (Federal Register, August 2, 2002 (Vol. 67, No. 149, pgs 50577-50580)

The APS is generally supportive of updating field testing requirements of biotechnology derived food and feed crop plants and establishing early food safety assessments for new proteins produced by such plants. The details and proposed implementation of such requirements will be of interest to us, especially with regard to impact on academic research in this area. We expect that another opportunity to comment will become available when the proposed actions are published.

We raise two questions based on the proposal:

1) What is the trigger for "If a trait or protein presents an unacceptable risk or the risks cannot be determined adequately"?

Regulators likely are aware that currently there is no evidence, as opposed to conjecture, of risk to animals and humans of food and feed products produced using methods of biotechnology. Furthermore, new technology is being developed to prevent pollen dissemination from transgenic plants, and to eliminate marker genes of concern. Also, under the FDA proposal, the FDA will evaluate all proteins resulting from the expression of transgenes and comment on the acceptability of the specific transgene product(s). In formulating comment, we urge FDA to review and consider the range of proteins found naturally in plants that are consumed as food or feed, or that have been introduced into plants by conventional breeding programs. This should be used as a point of comparison, where appropriate, in determining the suitability of protein(s), resulting from expression of transgenes in plants that are to be consumed by humans or animals.

2) At what level of detection will developers be expected to test new plant materials?

One can speculate about minor proteins that may be harmful, but if such proteins already are present in plants generally consumed for food and feed they should be considered exempt from further testing unless there is evidence that they are harmful. In our opinion, the regulatory agencies should urge the corresponding research

agencies to examine questions of allergenicity of biotechnology-derived products, since this is still a major concern of introduced traits regardless of whether their introduction is by conventional breeding or by methods of biotechnology. Research agencies should also support studies of gene flow and consequences thereof, which will contribute to public understanding and evaluation of gene flow beyond that occurring with conventional plants.

We emphasize that any further oversight and regulation should be based on the best available science. We welcome additional opportunities to be of assistance in commenting on policy regarding field testing for biotechnology derived plants, about which we of the APS are concerned as both consumers and scientists.

Sincerely yours,

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