



August 6, 2008

Stephen Howie
Hazard Assessment Coordination and Policy Division (7202M)
Office of Science Coordination Policy
Office of Prevention, Pesticides and Toxic Substances
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Plant-Incorporated Protectants; Potential Revisions to Current Production
Regulations (EPA-HQ-OPP-2006-1003)

Dear Mr. Howie:

The American Seed Trade Association and the Biotechnology Industry Organization ("Commenters") are pleased to submit these additional comments as a supplement to those originally submitted by both organizations in response to the Advance Notice of Proposed Rulemaking ("ANPRM") published by the Environmental Protection Agency ("EPA" or "Agency") on April 4, 2007 (72 Fed. Reg. 16312).

Commenters remain supportive of the EPA's stated intention to amend existing regulations to better address apparent differences between plant-incorporated protectants ("PIPs") and chemical pesticides in the application of the production and production-related requirements found in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). In our view, achieving that objective will require ensuring that the appropriate information is available to the EPA while striking a careful balance between the Agency's traditional enforcement prerogatives and the unique operational elements of the seed industry and production agriculture.

Our PIP registrant members have offered to make the relevant records available to EPA as a condition of each PIP registration and, as you know, PIP registrants have been successfully keeping records for EPA as a condition of their registrations since 1995. In addition to records maintained directly by PIP registrants, EPA also appears to be interested in records that, in many cases, are maintained by a registrant's licensees and by growers who produce seeds for the licensees. Because registrants typically would not have access to such records for commercial reasons, we have attempted to identify other means by which they could be made available to the Agency.

For those records maintained by licensees and their growers, registrants could contractually require their licensees to ensure that such records would be made available to EPA on request, either directly or through the registrant, as appropriate. This approach is similar to that used successfully for several years now by Bt corn registrants, who enter into commercial agreements with their growers that provide for adherence to the insect resistance management ("IRM") requirements that are a condition of the Bt corn registrations.

In our earlier comments on the ANPRM, we agreed with the basic concept that would have EPA propose a rule requiring PIP registrants, as a condition of registration, to ensure that the relevant PIP records are maintained and made available to the Agency on request. We also urged that those records should, to the greatest extent possible, be the same as those currently maintained for PIPs pursuant to EPA's direction under FIFRA Sections 3 and 5. Further, we offered specific suggestions regarding the types of information that would be most relevant to the Agency in performing its FIFRA oversight responsibilities. Finally, we agreed that the rule should recognize the unique nature of PIPs and rely on FIFRA Section 25(b) to exempt PIPs from any unnecessary FIFRA requirements.

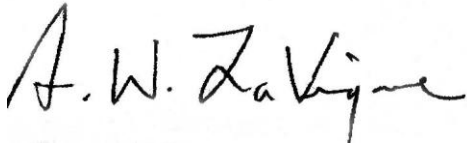
In order to ensure, to the greatest extent possible, that the Agency has the ability to enforce recordkeeping requirements applicable to PIPs in the same manner and to the same extent as those that apply to chemical pesticides under FIFRA Section 7, we would propose that EPA issue the PIP rule under the authority of Section 3(a) as well as Section 7. As you know, FIFRA Section 12(a)(2)(S) makes it unlawful for any person to violate a regulation issued under Section 3(a).

Proposing a rule with the foregoing elements would recognize the ability of registrants to contractually require their licensees to maintain and make available the requisite records to EPA, but would stop short of making those licensees or their growers subject to EPA inspection and enforcement. Just as with IRM and other current PIP requirements, the ultimate responsibility for compliance would rest with the PIP registrant, but with the added enforcement authority provided by a Section 3(a) rule. This approach would facilitate adoption and implementation of a meaningful recordkeeping program while avoiding difficult legal and policy issues. If the Agency decides that this approach has

merit and meets its objectives, we do not believe it would be necessary to address the treated article issue at this time.

We look forward to hearing from you with regard to these additional comments.

Sincerely,

A handwritten signature in black ink that reads "A. W. LaVigne". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

Andrew W. LaVigne
President and CEO
American Seed Trade Association

A handwritten signature in black ink that reads "Sharon Bomer Lauritsen". The signature is highly stylized and cursive, with a large, looping initial "S" and a long horizontal flourish at the end.

Sharon Bomer Lauritsen
Executive Vice President
Biotechnology Industry Organization