June 15, 2010

By Electronic Submission
Docket EPA-HQ-OPP-2010-0405
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: Comments to Docket No. EPA-HQ-OPP-2010-0405 Regarding Pesticide Product Registration Issuances for PIP Seed Blends.

The Center for Science in the Public Interest (“CSPI”) hereby submits the following comments to the Environmental Protection Agency (“EPA”) regarding the issues raised in its Docket No. EPA-HQ-OPP-201-0405 and the Biopesticides Registration Action Document (“BRAD”) for Optimum AcreMax 1 B.t. Corn Seed Blends (“AcreMax 1”). The proper regulation of plant-incorporated protectants (“PIPs”) is important to the public and CSPI appreciates the opportunity to provide comments on EPA’s analysis of AcreMax 1. Until each issue raised in the comments below is addressed by EPA, AcreMax 1 should not get a conditional registration to be grown in 2011 or 2012.

I. The Public Participation Process Surrounding EPA’s Decision to Conditionally Register AcreMax 1 for 2010 was Inadequate.

The Obama Administration has made transparency and public participation extremely important to government operations. EPA has embraced that initiative yet its actions surrounding its decision on AcreMax 1 show that it has not made it easy for the public to find the AcreMax 1 decision or comment on it. As stated below, when EPA makes important decisions regarding the commercial growing of any PIPs (including

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1 CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens’ interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the 800,000 member-subscribers to its Nutrition Action Healthletter and by foundation grants. CSPI receives no funding from industry or the federal government.
AcreMax 1), it needs to do more to alert the public to its decision-making process and provide the opportunity for input to EPA before any registration decision.

A. The EPA Decision to Conditionally Register AcreMax 1 Should Not Have Been Done Until After the Public Had an Opportunity to Comment.

In the BRAD, EPA admits that its current action to conditionally register AcreMax 1 qualifies as an “action for which the Agency anticipates that there will be significant public interest” and requires under EPA policy an opportunity for the public to participate before the registration decision. However, the BRAD justifies violating the EPA policy by stating that “it is in the best interests of the public and the environment to issue the registrations … without delay for the 2010 growing season.” The BRAD, however, does not support that decision. In fact, the BRAD and the history of the AcreMax 1 application support the opposite decision: that EPA should have provided the public an opportunity to participate before its conditional registration decision.

Pioneer submitted its application to register AcreMax 1 in February, 2008 and EPA finalized its conditional registration decision on April 30, 2010. It took EPA approximately 26 months after receipt of the application and almost a year after its Science Advisory Panel submitted its report on Pioneer’s application to reach its decision. With the registration process taking so long, allowing an additional month or two for public comment would have been in the public interest and would not have materially impacted the environment. If “it is in the best interests of the public and the environment to issue the registrations … without delay,” then EPA should have moved more quickly and issued its conditional registration months or even years ago so farmers could have planted AcreMax 1 in 2009 and 2010. The BRAD does not explain how its current action is in the best interest of the public now, instead of after the conclusion of a short public comment period.

Contrary to EPA’s assertion, rushing to conditionally register AcreMax 1 on April 30, 2010 without public comment and in violation of EPA new policy will have no positive material impact on the environment. The BRAD states that USDA predicts that 90 million acres of corn will be grown in the US in 2010 and Pioneer estimates that at most, 0.077% of that corn will be AcreMax 1. That amounts to approximately 69,000 acres of AcreMax 1 corn out of approximately 56 million acres of Bt corn that could be grown in 2010. While the AcreMax 1 corn acres will have reduced pesticide use and have 100% corn rootworm IRM compliance, the total environmental impact will be so small that it does not justify rushing the conditional registration decision and compromising EPA policy on transparency and participation. In addition, in discussions with CSPI, Pioneer employees have stated that Pioneer is not selling any AcreMax 1 seed to farmers for the 2010 growing season but only providing seed to farmers with demonstration plots that were already contracted for before the conditional registration was announced. Therefore, there is no environmental benefit to justify EPA’s decision to violate its participation policy.
B. EPA Should Announce in a Published Federal Register Notice All Proposed or Final PIP Registration Decisions and Provide an Opportunity for Public Comments on those Actions.

EPA stealthily released its Biopesticides Registration Action Document (“BRAD”) for AcreMax 1 and its supporting documents on April 30, 2010. EPA did not issue a press release nor did it announce its decision on the main EPA web homepage, its Pesticides Office web homepage, or its PIP web homepage. It did not publish a notice in the Federal Register announcing the decision or the fact that there was a 30-day public comment period. It did establish a docket at Regulations.gov and announce that fact in an alphabetical list of pesticides on its webpage entitled “Pesticide Registration Application Status.” However, EPA did not inform the public that a decision on this application was imminent so unless stakeholders had looked at that page regularly, they would not have been aware of the public comment period. In fact, CSPI only became aware of the public comment period because Pioneer issued a press release about EPA’s decision which received press coverage.

To ensure transparency and public participation, all PIP registration decisions should provide for a public comment period and those comment periods should be announced in the Federal Register. They should also be clearly announced on key EPA web pages, including the EPA homepage, the Pesticides Office homepage and the PIP web homepage. Hiding the announcement on an obscure webpage on the EPA website will not lead to the transparency and public participation EPA claims it wants to achieve.

C. All Registered PIPs Should be Listed on the EPA Website within a week of the release of the Registration Decision

EPA completed the BRAD for AcreMax 1 seeds on April 30, 2010. That document registered AcreMax 1 for general use until September 30, 2010. However, it took EPA more than five weeks before it included AcreMax 1 on its website in its list of “Current and Previously Registered Section 3 PIP Registrations.” See http://www.epa.gov/oppbppd1/biopesticides/pips/pip_list.htm. That list is an excellent source of information for farmers, interested stakeholders, and even foreign government officials because it identifies genetically engineered crops that are currently registered and can be commercially grown in the United States. While it may not be possible to update that list on the day a BRAD is released and a new PIP is registered, EPA should update the list within a week of every new registration. Clearly, EPA is not being as transparent as it should be when it takes five weeks before the AcreMax 1 decision and its corresponding documents were identified on that list.
II. EPA’s Analysis of Benefits in the BRAD Should Consider Overall IRM Compliance and Should Not Just Focus on Corn Rootworm Compliance for AcreMax 1 Fields.

The BRAD states in its benefits analysis that there will be “increased grower compliance with IRM requirements for the corn rootworm active ingredient.” While this may be true and benefit the environment, the analysis EPA has undertaken is too simplistic and narrow. Instead, EPA should assess what is the likely compliance by AcreMax 1 farmer for all of their IRM obligations as well as the impact of AcreMax 1 on overall nationwide farmer compliance with EPA IRM obligations for all Bt corn products.

AcreMax 1 is a stacked product with corn borer protection in addition to rootworm protection, so farmers will need to plant a 20% refuge of non-Bt corn borer corn in order to comply with EPA’s registration of AcreMax 1. The BRAD does not discuss overall AcreMax 1 compliance with IRM requirements; it only discusses compliance with the corn rootworm portion of the IRM obligations. Farmers planting AcreMax 1 actually may believe the seed blend solves all of their IRM obligations and either forget or neglect to plant the 20% non-Bt corn borer refuge. The compliance by AcreMax 1 farmers for the 20% corn borer refuge could be the national average of approximately 75% (see CSPI’s “Complacency on the Farm”) or it could be significantly lower. Either way, poor compliance in planting a corn borer refuge might lead to resistant pest populations and reduce or eliminate the identified environmental benefit from the corn rootworm IRM compliance. EPA needs to assess the likely farmer compliance with all of EPA’s registration requirements for farmers planting AcreMax 1 before it can state whether AcreMax 1 IRM is a net “significant benefit” to the environment from its easy corn rootworm IRM compliance.

AcreMax 1 is just one of many Bt corn products in the seed market available to US farmers. Farmers can buy corn varieties with only Bt corn borer protection or corn varieties with only Bt corn rootworm protection. They can buy varieties with stacked genes giving both corn borer and corn rootworm protection or varieties with multiple genes that target a particular pest (e.g. SmartStax). For each of those products, as well as AcreMax 1, EPA has established different IRM obligations, making it confusing and sometimes difficult for farmers to meet their IRM obligations (especially if they plant different Bt varieties on the same farm). CSPI’s recent report “Complacency on the Farm” documented significant decreases in IRM compliance from 2005 through 2008, a time when the different Bt corn options for farmers greatly increased. The trends were clear -- farmer compliance with IRM obligations decreased as the number of different Bt corn varieties with different IRM obligations increased.

For any analysis of the benefit of AcreMax 1 on IRM compliance, EPA should consider not only AcreMax 1 compliance but also the potential impact that AcreMax 1 might have on the compliance of farmers planting other varieties of Bt corn. Some farmers may learn about AcreMax 1 from their seed dealer, literature, or advertisement and think they are buying and planting it, but actually plant a Bt variety that needs a
separate corn rootworm refuge. Some farmers may talk to their neighbors about IRM compliance and follow what they do even though they did not purchase the same AcreMax 1 seeds that their neighbor purchased. In 2010 through 2012, AcreMax 1 will only be a small percentage of the total Bt corn acreage in the United States so its compliance benefit may not be more significant than a resulting decrease in compliance by other Bt corn farmers. Therefore, before EPA can find that AcreMax 1 is a “significant benefit” due to its easy corn rootworm IRM compliance, it needs to assess what impact there will be to overall Bt corn IRM compliance nationwide from having AcreMax 1 and its blended refuge available in the seed market. AcreMax 1 could lead in the short run (2010 to 2012) to lower overall Bt corn farmer compliance, even though farmers planting it will be 100% compliant for the corn rootworm IRM obligations.

III. EPA Should Convene a Science Advisory Panel (SAP) Meeting to Address Important Scientific Issues Surrounding AcreMax 1 Before It Registers that Product for 2011 and/or 2012.

EPA states in the BRAD that “having the refuge in the bag of seeds is a novel approach.” While the FIFRA SAP found that a seed blend methodology could be a successful control and mitigation strategy to prevent resistant corn rootworms from developing, it did not find any support for a 5% blended product. It did not review and give an opinion about the data that supports a 10% blended product, nor did it review and analyze the EPA Model used to analyze the comparative durability of the 10% blend. The SAP did not review whether the previous determination of 15 years with no resistance is a reasonable goal given the current products commercially grown and/or in development and the current level of adoption nationwide. Those are all important issues that need a full scientific review before AcreMax 1 is registered to be grown after the 2010 growing season. Therefore, EPA should not conditionally register AcreMax 1 past 2010 without convening a meeting of its FIFRA SAP to give its technical analysis and opinion about: (1) whether the 10% blend is protective and is supported by data; (2) whether the EPA Model should be used and whether it provides a good analysis of AcreMax 1; and (3) what should be the durability goal for AcreMax 1 and other Bt corn products going forward.

IV. EPA Should Impose Additional Conditions on the AcreMax 1 Registration to Ensure Pioneer and Farmers Growing AcreMax 1 Meet the IRM Requirements.

The AcreMax 1 conditional registration generally imposes the same compliance and monitoring obligations for the corn borer refuge requirements that EPA has imposed on other corn borer protected products in the past. CSPI’s report entitled “Complacency on the Farm” documents significant non-compliance with those obligations. In addition, EPA’s own analysis of IRM compliance contained in the AcreMax 1 decision docket (Memo from Jeannette Martinez to Mike Mendelson dated April 15, 2009) found an unreasonable amount of non-compliance. Therefore, EPA should change the compliance and monitoring obligations to ensure better rates of compliance. In particular, EPA
should add the following obligations to the conditional registration and any future registrations relating to AcreMax 1 (and other PIPs involving Bt genes):

- **The label for the PIP should require that the seed bags sold to farmers are labeled with information about the proper use of the regulated article, including the IRM obligations.** Putting a label, stamp or tag on the seed bag identifying the IRM obligation (in this case, stating that a 20% or 50% non-Bt corn borer refuge needs to be planted within ½ mile of the AcreMax 1 corn) would increase compliance and reinforce messages given to farmers from seed dealers and developers. It would serve as a reminder of the obligation at the time of planting as many farmers buy seed and sign grower agreements months before they actually plant the seed.

- **The registration should require that all on-farm assessments for AcreMax 1 be conducted by independent third parties with no financial relationship to the registrant.** Such assessment would provide EPA and Pioneer with independent and unbiased data on actual compliance rates and deter farmers from avoiding their legal obligations.

- **The registration should require that farmers planting AcreMax 1 annually certify to Pioneer their actual compliance with IRM obligations and document how they complied.** This should be required in June after planting and provide evidence of compliance, such as a map of Bt and non-Bt fields and seed purchase records.

- **The registration should require compliance data for AcreMax 1 from the industry survey and on-farm assessment to be separated into geographic regions.** The most recent industry compliance report did break down its data into some geographic regions. AcreMax 1 compliance data required under the registration should be submitted for the four regions identified in the compliance analysis conducted by Jeannette Martinez on April 15, 2009.

V. If The Regulatory Rationale for Conditionally Registering a PIP Involves Sales Projections for the PIP, Then the Registration Should Limit The Sale of the PIP to Those Projections.

Throughout the BRAD, EPA relies on the sales projections from Pioneer in determining whether AcreMax 1 can be conditionally registered for the 2010 growing season. It also states that “our modeling analysis combined with the Pioneer sales projections for the 2011 and 2012 growing seasons support continued registration … for 2011 and 2012.” Thus, it is clear that EPA’s analysis and its modeling is based on the fact that only a certain number of acres of AcreMax 1 will be grown in a given year. If significantly more were grown, the analysis and its potential impact on the environment might be different. Therefore, if EPA relies on sales projections, as it has for the conditional registration of AcreMax 1, it should require in the registration that the company not sell any more seed than its projection.
Conclusion

PIPs have benefitted farmers and the environment and EPA has done a reasonably good job regulating them. However, the EPA regulatory process needs to be transparent and participatory. For AcreMax 1, EPA has not followed its transparency and participation policy and has failed to provide legitimate justification for such inactions. It has also failed to solicit advice from its SAP about the novel scientific issues raised by this PIP. In addition, its analysis of the benefits from AcreMax 1 does not assess compliance with corn borer IRM obligations nor how AcreMax 1 will impact overall national Bt corn farmer compliance. Finally, the conditional registration does not impose simple conditions that will improve compliance with EPA’s IRM requirements. Therefore, before EPA allows AcreMax to be grown past the 2010 growing season, it should correct each of those deficiencies.

If EPA would like more information about the issues raised in these comments, I would be happy to meet with you at your convenience.

Sincerely,

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