



September 3, 2010

By Electronic Submission

Docket EPA-HQ-OPP-2010-0607
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: Comments to Docket No. EPA-HQ-OPP-2010-0607 Regarding Proposed Registration Extensions for Bt corn Registrations.

The Center for Science in the Public Interest (“CSPI”)¹ hereby submits the following comments to the Environmental Protection Agency (“EPA”) regarding the issues raised in its Docket No. EPA-HQ-OPP-201-0607 regarding the proposed registration extensions for several different Bt corn products. The proper regulation of plant-incorporated protectants (“PIPs”) is important to the public and CSPI appreciates the opportunity to provide comments on EPA’s proposed decision to extend the registration of several different Bt corn products.

In the comments regarding the proposed registration decisions set out below, CSPI supports many of the proposed changes to the terms and conditions of registration for the Bt corn products as those changes will help ensure those products are safe and remain available for use by current and future generations of farmers. CSPI proposes in its comments to EPA additional terms and conditions that will help ensure compliance with insect resistance management (“IRM”) refuge planting obligations and delay the development of resistant pests. CSPI also identifies below information that should be obtained by EPA before some or all of the Bt corn products receive their renewed registration. Therefore, CSPI requests that EPA address each of the comments below before finalizing each Bt corn registration.

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.

I. CSPI Generally Supports EPA’s Proposed Scheme to Extend the Registration of Different Bt corn Products for Different Time Periods Based on their Relative Durability and their Risk of Developing Resistant Pests. However, Changes are Necessary to Make EPA’s Proposed Scheme Understandable and Based on Current Scientific Data.

In the different Biopesticide Registration Action Documents (“BRAD”) in the Docket supporting the proposed terms and conditions of registration for the different Bt corn products, EPA sets forth a reasoned approach for determining the length of time for each Bt corn’s registration. That approach is based on the determinations by EPA that (1) all the Bt corn products are no longer functionally equivalent and (2) different products have different risk levels for developing resistant pests and should qualify for different registration periods. CSPI agrees with both of those determinations and supports EPA’s decision to base decisions regarding how long to register each product on a scheme based on their relative durability and their risk of developing resistant pests.

EPA also states that its proposed scheme is reflective of two complementary principles: “first, to ensure that we apply our limited resources to the products that pose greater risk of adverse effects to the environment; and second, to conserve the resources that registrants and applicants must expend in amending the registration of products that pose less risk of adverse effects to the environment.” CSPI supports both of those complementary principles. It is imperative that EPA uses its limited resources to focus on products with the greatest relative risks. Similarly, products that pose less risk should require less regulatory review and procedure. In addition, CSPI believes that the proposed EPA scheme will give Bt corn developers an incentive to produce less risky products and phase products that pose the greater risk out of the marketplace. Having products that are more durable against the development of resistance on the market longer will help extend the use of Bt corn to future generations and prevent the “grave adverse effect” of resistance development.

While CSPI generally supports the proposed differentiation for the length of time of a particular Bt corn’s registration, the EPA scheme needs some elaboration and refining to make it understandable and scientifically defensible. First, EPA proposes that Bt corn products will be registered for either five years, eight years, twelve years, or possibly even fifteen years and links those time periods to specific characteristics of different Bt corn products. However, EPA never states why the specific time periods were picked and how those relate to the durability of the different traits within each category. Why should single PIP toxins with a 20% external refuge get a five year registration instead of a three or four year registration? Does the product with pyramided PIP toxins that are high-dose have a durability that justifies a twelve year registration? Why not a ten year registration? Those and other similar questions about the different categories, their relative durability, and the length of time proposed for the registrations are not addressed in the BRAD documents. EPA needs to scientifically justify both the lengths of time proposed for the registrations and why different Bt crop product categories (e.g. single toxin, pyramided PIPs, etc...) have a scientific risk assessment that justifies the length of time proposed for its registration. Until that occurs, the proposed

scheme reads as if EPA has randomly picked different lengths of time and matched them with products categories ranked from greatest risk of developing resistance to least likely to lead to resistance. EPA needs to include a more robust scientific justification for the proposed scheme in the Docket.

Secondly, the proposed registration scheme needs to treat any novel products or products with novel IRM compliance options, including the first few products employing the use of seed blends, on a separate case-by-case basis. Novel IRM compliance options, and seed blends in particular, are new. It is currently difficult for EPA to determine both their likelihood of preventing the development of resistance as well as how they may work in the field for farmers who adopt them that other Bt corn products. Thus, for the first few products with such novel properties, their registration lengths should be set by EPA to expire in a two or three year period of time so EPA can obtain data on how they operate in practice and then decide whether to renew their registration based on the additional information collected. For example, it is premature to determine now that seed blend PIPs can qualify for an eight, twelve or fifteen year registration period when only 20,000 acres of seed blend products have ever been grown commercially. EPA should specify that novel products or novel IRM compliance options are addressed on a case-by-case basis until there is sufficient experience to determine whether they would qualify for a longer registration of eight to fifteen years. EPA should eliminate the reference to seed blend products as qualifying for eight, twelve or fifteen year registrations as there is no scientific justification in the Docket to support such a determination at this time.

II. The Proposed Registrations for the Bt Corn Products Include New Insect Resistance Management Compliance Obligations that Should Become Legally Binding When The Registrations Are Finalized.

For each of the Bt corn products, EPA has proposed some additional insect resistance management compliance monitoring and education obligations to help ensure that the registrants and corn farmers comply with the IRM planting obligations. In recent years, compliance with the planting of the required refuge of non-Bt corn has not been good, as documented by CSPI's report entitled "Complacency on the Farm." EPA's own analysis of IRM compliance contained in the Optimum AcreMax Bt Corn Seed Blends ("AcreMax 1") decision docket (Memo from Jeannette Martinez to Mike Mendelson dated April 15, 2009) also found an unreasonable amount of non-compliance. Compliance rates need to improve and hopefully some of the new education and compliance monitoring obligations in the proposed terms and conditions of registration will help make that happen.

CSPI supports the following changes as an excellent first step that will hopefully lead to better industry-wide compliance with refuge planting requirements and protect the longevity of the different Bt corn products for future generations of farmers:

- **Including the refuge size requirement on all Bt corn seed bags or bag tags.** Putting the refuge size requirement on the corn seed bags or bag tags will remind farmers of their planting obligations, reinforce the messages given to farmers

from seed dealers and developers, and hopefully lead to better overall compliance. Providing this information is especially important now and in the future, as many of the Bt corn products have different refuge size requirements, which may be confusing to farmers. CSPI would propose, however, that EPA make it a requirement that the seed bag or bag tag include not only the refuge size requirement but also a short summary of any requirements about where the refuge is to be planted in relation to the Bt corn (i.e. adjacent to the Bt corn, in the field, within a ½ mile of the field, etc...).² Providing information on the distance obligation for refuges is as important as the size information because both lead to farmer compliance with IRM obligations and together they decrease the likelihood of the establishment of resistant pest populations.

- **Requiring the registrants to focus the majority of their on-farm assessments on regions with the greatest risk for resistance.** On-farm assessments both determine compliance and deter violations that might lead to resistance from the specific farmers being assessed as well as their neighbors and colleagues. Therefore, it makes sense to focus the majority of those assessments on regions with the greatest risk for resistance development, including areas of high concentration of adopters of Bt corn as well as areas of high pest pressure.
- **Identifying potential on-farm assessments using sales records to find growers who purchased Bt corn seed but may not have purchased refuge seed.** CSPI in the past has commented to EPA that all different information sources, including seed sale records, should be used by the registrants to target on-farm assessments. Using those records will help identify persons needing help with compliance and deter farmers who might not otherwise purchase the necessary non-Bt seed.
- **Specifying that the registrants will contract with third parties to perform on-farm assessments.** Using independent contractors with no financial ties to the registrants will provide EPA and the registrant with independent and unbiased data on actual compliance rates and deter farmers from avoiding their legal obligations. CSPI supports using those third-party assessors to “conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment” as stated in the proposed conditions of registration. However, CSPI believes that **all on-farm assessments** should be completed by third-party assessment, not just the subset identified above. This would include the “follow-up checks on growers out of compliance within three years after they are found to be back in compliance” as required by paragraph 22 (i) of the registration conditions. It would also include inspections that are the result of an “investigation or tip.” The third-party assessors should conduct all on-farm assessments, whether they occur for the first time, in the second-year, or any subsequent years.

² While the proposed terms and conditions of the registrations for the different Bt corn products call for the seed bag to identify the size requirement for the refuge, other documents in the Docket state that the seed bag or bag tag will be required to show the “refuge requirements.” For example, the updated BRAD for AcreMax 1 states on page 2 that “EPA is proposing ... a phased requirement for seed bag labeling that clearly shows the refuge requirements.” The refuge requirements in the terms and conditions of registration include both a size and a distance component. Therefore, EPA needs to make the documents in the Docket consistent and decide whether to include only the size or both the size and distance requirements to be on the seed bag or bag tag.

- **Requiring additional follow-up on-farm assessments for growers found significantly out of compliance and then in compliance.** This requirement will ensure that a farmer who was significantly out of compliance and came back into compliance the next year remains in compliance in subsequent years. All farms found significantly out of compliance should be assessed in the next year and then again sometime in the following three years to ensure that the farm remains in compliance.
- **Requiring that any second incident of significant non-compliance over a five year period results in being denied access to the Bt corn product in a subsequent year.** This changes the current obligation to deny Bt corn products only when a farmer is significantly out of compliance two straight years in a row by making it more stringent. It is a change that will help ensure that farmers comply with their IRM refuge obligations and is something that CSPI has been advocating for in comments to EPA for many years.

III. **Additional Terms and Conditions Should be Included by EPA in the Bt Corn Registrations to Help Ensure Compliance with IRM Refuge Obligations and Prevent the “Grave Adverse Effect” of the Development of Resistant Pest Populations.**

The development of resistance is described by EPA in the supporting documents in the Docket as a “grave adverse effect.” Therefore, EPA should include in the terms and conditions of registration any and all new conditions that help ensure resistance is not developed through poor compliance with IRM refuge planting obligations. EPA has proposed many important terms and conditions to achieve that goal but there are other terms and conditions that should be added which would help ensure EPA achieves its goal while not imposing a tremendous burden on developers and farmers. Thus, CSPI proposes the following additional terms and conditions, each of which will help monitoring of compliance and reduce the likelihood of the development of resistant pests:

- **EPA should require that farmers planting Bt corn annually certify to the registrant their actual compliance with IRM obligations and document how they complied.** The certification 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. CSPI has made this suggestion several times and EPA responded in the updated BRAD for AcreMax 1 that it will consider this in the future “should the compliance picture not improve.” The CSPI Report entitled “Complacency on the Farm” and EPA’s own analysis of the ABTSC compliance survey data, however, both show extremely low compliance nationwide for all the various Bt corn products. In addition, the report from ABTSC in January, 2010 did not show any improvement in compliance rates in 2009. Thus, waiting for compliance to continue to decline before instituting a certification requirement could result in the development of resistant pests from the many noncompliant farms. Therefore, there is sufficient industry-generated data to support implementing a certification requirement at this time.

- **EPA should include in its Bt product registrations specific penalties it will impose on registrants if compliance rates do not meet specific targets (such as 90%).** If the registrant does not meet the specified compliance targets, EPA should impose a significant monetary penalty on the registrant or limit the number of Bt seeds that registrant and its fully-owned subsidiaries could sell the following year. Those penalties could be imposed on a sliding scale, where the penalty increases as the compliance rate decreases. While there is no acceptable level of noncompliance, by setting targets for IRM compliance and identifying specific consequences to the registrant if those targets are not met, there will be much stronger incentives to improve compliance.
- **EPA should require compliance data for Bt corn from the industry survey and on-farm assessments to be separated into geographic regions.** The most recent industry compliance report did not break down its data into separate geographic regions. Compliance data from both the industry survey and the on-farm assessments required under the registration should be submitted for the four regions identified in the compliance analysis conducted by Jeannette Martinez on April 15, 2009.
- **EPA should require the registrants to deny Bt corn seed to any farmer the year after that farmer plants Bt corn with no refuge at all.** With ten years of education and extremely high adoption rates, all Bt corn farmers should be aware of the requirement to plant a refuge of non-Bt corn. If a farmer is found to have planted no refuge corn at all (through either an on-farm assessment or as a result of an investigation of a tip or complaint), EPA should require the registrant to deny that farmer Bt corn seed the following year. With some areas of the country reaching a point where they have almost 100% adoption of Bt corn, the pressure on developing resistance is increasing. Farmers who plant no refuge at all put the efficacy of the technology in jeopardy for everyone. EPA and the registrants need to send a strong message that complete non-compliance is not tolerated.
- **Information included on the seed bag or bag tag about the IRM refuge obligations should be reviewed and approved by EPA.** The proposed terms and conditions for Bt corn product registrations requires that registrants place information about the refuge size on the seed bag or bag tags. The proposed terms and conditions should also require that whatever the registrants do to satisfy this requirement is first submitted to EPA for its review and approval more than 60 days before its proposed use. This will allow EPA to ensure the information is both accurate and misleading or confusing.
- **On-farm assessment results should specify whether the violation is of the size or distance requirement of the product registration.** For the on-farm assessments to be as useful to EPA and the registrants as possible, the reporting from those assessments should specify whether any found violations involved the size requirement, the distance requirement, or both. This information will be useful in bringing the violating farmer back into compliance and will more generally help identify compliance issues that require changes to the educational programs instituted by the registrants. Therefore, the annual report to EPA should include a break down of the on-farm assessment data into non-compliance with the size requirement, the distance requirement, or both requirements.

IV. EPA Should Convene a Science Advisory Panel (SAP) Meeting to Address Important Scientific Issues Surrounding Current and Future Bt Corn Products and the EPA's assessment of their safety.

In previous comments to EPA addressing the conditional registration of AcreMax 1 dated June 15, 2010, CSPI stated that the agency should convene a FIFRA SAP to address several important issues regarding the registration of that product and to address issues surrounding EPA's overall scientific assessment of current and future Bt corn products. In particular, CSPI stated that

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.

In the updated BRAD for AcreMax 1 dated August 4, 2010, EPA states, when referring to its own models developed to address pest resistance, that it "will convene a public meeting of the SAP to evaluate these models in early December." CSPI supports this decision by EPA to convene a SAP meeting for that purpose. It is hoped, however, that the scope of that meeting will be broader than just the EPA models and include all three issues identified above. In particular, EPA needs to ask the SAP about whether the 10% blend for AcreMax 1 will sufficiently reduce the likelihood of developing resistant pests. The current announcement on the EPA FIFRA SAP webpage states that the meeting will address "Efficacy of PIP Seed Blends and IRM Modeling for PIP Product." Any discussion of efficacy of PIP seed blends should include AcreMax 1 as well as future products with blended refuges so that EPA gets practical scientific advice from the SAP about actual products, not just information about the concept of seed blends in general.

V. It is Premature to Extend the Conditional Registration of AcreMax 1 Until After EPA Receives the Following Information: (1) the Report of the FIFRA SAP Meeting in December, 2010; and (2) Data from Pioneer on Compliance with the Lepidopteran Refuge Requirements by AcreMax 1 Growers in 2010.

In the AcreMax 1 updated BRAD, EPA states that it proposes registering the products until September 30, 2012. Elsewhere in the BRAD, EPA states that it will convene a FIFRA SAP in December, 2010 to evaluate the EPA models – models that were integral to the EPA decision on the safety of AcreMax 1. EPA also states on its website that the scope of the SAP meeting will be "Efficacy of PIP Seed Blends and IRM Modeling for PIP Product." As the AcreMax 1 product is a PIP seed blend, the expert scientific opinions from the SAP that is convened in December will be extremely relevant to the analysis by EPA on the registration extension for AcreMax 1. Thus, EPA should

not conditionally register AcreMax 1 for 2011 and 2012 until after it has received the report from the SAP.

EPA also states in the AcreMax 1 updated BRAD that there is a concern that growers might be confused about the need to plant a lepidopteran refuge. In response to this concern, EPA writes:

Pioneer also is responsible for 2000 independent, third-party on-farm assessments to address compliance with the lepidopteran refuge requirements. Significant non-compliance with the OAM1 lepidopteran refuge requirements, if verified, could have implications for continued availability of OAM1 in 2011 and beyond.

Therefore, EPA should wait to find out the results of the 2000 on-farm assessments and their compliance with refuge requirements before it grants the registration of that product through September, 2012.

Alternatively, if EPA does not wait until getting the SAP report and Pioneer's compliance report before registering AcreMax 1, it should limit the registration to one year (2011) and defer the decision on the planting of that product for 2012 and beyond until after analyzing the reports from the SAP and Pioneer.

Conclusion

PIPs have benefitted farmers and the environment and EPA has done a reasonably good job regulating them. The proposed terms and conditions for the registration of the different Bt corn products are an improvement from the current terms and conditions in a number of ways. However, there are still additional terms and conditions that EPA should require to improve the likelihood that IRM refuge compliance will increase and to decrease the chance of developing resistant pests. In addition, EPA needs to better explain and scientifically justify its new scheme to establish different lengths of time for a registration extension based on the product's risk profile. Finally, EPA should defer its registration extension decision on AcreMax 1 certain decisions until after it receives the report of the upcoming FIFRA SAP.

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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