

November 9, 2020

By Electronic Submission
(Docket #: EPA-HQ-OPP-2019-0682)

Re: Comments on EPA's Draft Proposal to Improve Lepidopteran Resistance Management

The Center for Science in the Public Interest (CSPI)¹ appreciates the opportunity to comment on EPA's draft proposal to improve current insect resistance management (IRM) strategies for certain Lepidopteran pests of *Bacillus thuringiensis* (Bt) plant-incorporated protectants (PIPs) in corn and cotton. Bt PIPs are genetically engineered plants where scientists have introduced a gene from a Bt bacterium that produces a toxic protein that kills certain insects when they are exposed to it (usually from eating part of the plant). As with other chemical and biological pesticides, if the product is used regularly, resistant insects will evolve (which is the same as what happens if humans regularly use an antibiotic drug). To prolong the benefits that farmers and the environment receive from the use of Bt PIPs and to delay the development of resistant insects, EPA established science-informed IRM requirements in 2001. One IRM requirement is that farmers planting Bt crops plant a portion of their fields with non-Bt crops, called a "refuge", that generates non-resistant insects able to mate with any resistant insects to prevent inheritance of the resistance.

For more than fifteen years, CSPI has supported EPA's efforts to impose IRM requirements. CSPI agrees with EPA's decision made years ago that Bt PIP products are a "public good" and that "the development of resistance would constitute an adverse environmental effect." (EPA Registration Action Document, Oct. 15, 2001, p. VI2). We are concerned by the EPA Federal Insecticide, Fungicide, and Rodenticide Science Advisory Panel's (SAP) findings that confirm resistance has evolved in several different Lepidopteran pests, as this means that EPA's IRM requirements for registrants have not been adequately successful. CSPI believes that EPA needs to strengthen its IRM requirements with additional science-informed actions that will delay resistance development and preserve Bt PIPs for use by future generations of farmers. Therefore, CSPI recommends that EPA implement as quickly as possible (so they can be required for the 2021 growing season) the recommendations below, many of which were endorsed by EPA's SAP in 2018.²

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 over 400,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry or the federal government.

² CSPI supports EPA's use of its SAP to provide expert advice on the complex scientific issues surrounding documentation of resistant insects and the different management tools that could be used to delay resistance

I. EPA Should Eliminate the Use of Single Trait Bt Corn Products and Non-Functional Pyramids Used to Control Lepidopteran Pests as Quickly as Possible.

Information in the EPA Docket EPA-HQ-OPP-2019-0682 and the SAP report point to evidence that single trait Bt corn products and non-functional pyramids threaten resistance management for corn earworm, cotton bollworm, and other primary pests.³ The continued use of these corn products over time will reduce or even eliminate the effectiveness of the existing functional pyramids, turning them into non-functional pyramids and preventing individual Bt toxins from helping farmers control pests. To prevent resistance, registrants of Bt products have already voluntarily phased out single trait products used to control cotton pests and worked collaboratively with EPA to effectively eliminate single trait products for controlling corn rootworm. Eliminating those products and only selling pyramided products was carried out to prolong the effectiveness of the individual Bt toxins. The SAP “suggested that single gene corn products should be removed from the market.” (EPA Draft Proposal 2020). Ending the sale of single trait Bt corn products designed to control lepidopteran pests is a simple, scientifically sound risk management approach that is necessary for protecting the effectiveness of the non-resistant Bt products used by farmers and for preventing the development and spread of resistant insect populations.

The elimination of single toxin corn products and non-functional pyramided products should be completed as quickly and as completely as possible. EPA has proposed a three-year phase down for single traits and a five-year phase down for pyramided products without any justification for the lengths of time chosen. The SAP stated that field resistance for lepidopteran pests has already been found and that it is “highly likely that *H. zea* will further evolve resistance to Bt crops on a broad scale in the continental U.S.” unless further actions are taken. Every additional year that single trait and non-functional traits are used by farmers will likely lead to greater development and spread of additional resistant pest populations. CSPI proposes that EPA give registrants two years to end the sale of single traits and three years to end the same of non-functional pyramids. The Agricultural Biotechnology Stewardship Technical Committee (ABSTC) submitted information to EPA stating that there is low acreage of single trait crops targeting Lepidopteran pests currently planted nationwide, which should make eliminating them in two years practicable without significant impact on farmer preferences. In addition, EPA should require complete elimination of those products, with exceptions only for limited extenuating circumstances. EPA should identify criteria for what would constitute an extenuating circumstance and require that registrants apply for exceptions for a minimal number of acres for an agreed upon number of years.

development. EPA’s proposal incorporates some, but not all, of the SAP recommendations. EPA should heed the advice of these independent outside experts and where it does not agree, provide a detailed explanation.

³ A “single” trait product is one in which there is one Bt toxin that can kill the target pest. A “pyramid” PIP contains two or more Bt proteins, each with a different mode of action (which means that they both kill the pest but using different biological pathways). A pyramided product delays resistance because if a pest is resistant to one Bt protein, it is killed by the other protein through a different mode of action. A “non-functional” pyramid PIP product has two Bt proteins but one of them does not work effectively because of a resistant insect population to that toxin. Thus, it acts like a single trait product. Resistance is more likely to develop quicker to single trait and non-functional pyramids because if an insect develops resistance, there is not a second toxin to kill the pest.

II. To Preserve the Value of Vip3A to Manage Cotton Pests, EPA Should Prohibit its use in Corn Products in the Southern U.S.

Vip3A is a Bt protein with no known resistant insect populations to date. To preserve the value of Vip3A, the SAP unanimously recommended that EPA prohibit the use of Vip3A insecticidal proteins in corn products used in the southern U.S. where ear-feeding lepidopteran pests overwinter and cotton is grown. The SAP found that using the same toxin for both corn and cotton fields in the same geographic region imposes too much pressure for the selection of resistant insects (since those insects feed on both corn and cotton). They also found that Vip3A is more important for cotton production, where *H. zea* is a much more harmful pest, than in corn fields in the South. In addition, the SAP found that corn plants with Cry proteins other than the Vip3A protein will provide farmers with sufficient control of major corn pests while also acting as refuges for moths susceptible to Vip3A, thereby benefiting cotton fields.

EPA seems to have ignored this important recommendation in its current proposal to address resistance in lepidopteran pests and failed to explain why. CSPI believes this recommendation is scientifically sound and that prohibiting the use of Vip3A insecticidal proteins in corn products in the South is necessary to prolong the efficacy of Vip3A in cotton. Therefore, CSPI recommends that EPA adopt the recommendation from the SAP to prohibit Vip3A use on corn in the southern cotton growing region of the U.S.

III. EPA Should Increasing the Refuge in All “Refuge-in-a-Bag” Products from 5% to 10% Nationwide

EPA and the SAP both identified numerous concerns for resistance that could result from the use of refuge-in-a-bag (RIB) seed blend, especially for pests that eat corn kernels⁴. In addition, EPA and scientists have acknowledged that a 5% blended refuge is less effective than the equivalent 5% block refuge. While the EPA option to increase all corn RIB products to have 10% refuge seeds does not solve all the concerns with resistance developing when farmers use those products, a 10% refuge product will improve resistance management compared to 5%. It is also a product that farmers would be willing to purchase and grow. Therefore, CSPI supports EPA implementing that option as soon as possible. However, CSPI agrees with the SAP recommendation that EPA should: (1) prohibit RIB products in the southern corn growing regions; and (2) prohibit Vip3A from being a toxin in those seed blended products. Those prohibitions are necessary to keep the effectiveness of Vip3A for cotton farmers by preventing resistance in *H. zea* from developing due to overuse in corn fields.

IV. EPA Needs to be Creative and Use All Available Tools to Increase Refuge Compliance in the Southern U.S.

One of the risk factors EPA identified as leading to increased resistance development in lepidopteran pests is widespread non-compliance with refuge planting requirements in the

⁴ There are two different ways for farmers to plant the required refuge. First, they can take a portion of their farm and plant non-Bt seed in that area, which is referred to as a “block refuge.” EPA also allows for the use of a refuge-in-a-bag, which is a blend of both Bt and non-Bt seeds randomly mixed in the bag of seed the farmer buys from the registrant. A 5% blended refuge would have 5% non-Bt seeds in a bag with 95% Bt seeds.

southern U.S. The EPA White Paper and the SAP Report both document the seriousness of this problem, finding compliance in the last few years by farms in the southern U.S. to be extremely poor. Between 2011 and 2016, full compliance with the block refuge requirement ranged between a low of 7% in 2016 to a high of 46% in 2013 and complete non-compliance (no planted refuge) ranged between a high of 46% in 2016 and a low of 29% in 2013. (EPA White Paper, 2018). EPA acknowledges that there is a consensus among stakeholders that refuge compliance needs improvement if the development of resistant pests is to be slowed down and Bt crops are to remain effective. The SAP specifically found that the likelihood of a farmer meeting their refuge obligation is partially dependent upon the “perceived probability of receiving a sanction and the severity of any sanction from non-compliance.” (SAP Report 2018) It also found that compliance is not due to a lack of awareness of the requirement but to other barriers, such as the cost and time for farmers to plant the refuge field, perceptions by individual farmers that the refuge is not needed, and/or the lack of quality non-Bt seed.

To improve block refuge compliance and increase the longevity of Bt traits in the Southern U.S., CSPI recommends that EPA require the following:

- On-farm refuge compliance inspection visits every year to any farm growing Bt corn that requires a block refuge. Those inspections should be conducted by independent third-party entities with no financial relationship to the registrant. This is consistent with the SAP conclusion that it is problematic for the registrants to monitor their own regulatory compliance because the registrants do not want to make enemies of their customers by reporting them as violating the requirements.
- The registrants obtain from all farmers planting Bt corn in the cotton belt an annual certification stating that they are complying with IRM obligations along with documents showing how they complied. The certification and documentation should be required to be sent to the registrant in June after planting. The evidence to show compliance should include maps identifying the location of Bt and non-Bt fields and seed purchase records showing the purchase of non-Bt corn seed. This information would be forwarded to the independent inspector in preparation for their field visit.
- Each registrant should be required to withhold all Bt corn products (including RIB products) for two years from any farmer in the Southern U.S. who is out of compliance with the block refuge standard. In addition, if any farmer returns to non-compliance in the year following that two-year suspension, that farmer should be permanently barred from purchasing any of that company’s Bt corn products. A suspension should be required for any violation of the block refuge requirement that is not *de minimis*.
- Each registrant should be subject to monetary penalties if the compliance rates for block refuge standards of farmers who have purchased its Bt corn seed do not meet specific targets (such as 90% of farmers planting the required refuge). If the registrant does not meet the specified target adoption rate of block refuge compliance, EPA would impose a significant monetary penalty on the registrant and/or limit the quantity of Bt seeds that registrant and its fully-owned subsidiaries could sell the following year in that geographic area (which could be by county, state or region).

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 farmers planting block refuge and identifying specific consequences to the registrant if those targets are not met, there will be much stronger incentives for the registrants to do everything in their power to help farmers comply with block refuge obligations.

- Each registrant should incentivize the planting of the block refuge by farmers through one or more of the following discount/subsidy programs: (1) provide discounts on refuge seed; (2) provide a subsidy for planting the block refuge; (3) require a farmer to show receipt of the purchase of non-Bt seed in order to purchase Bt seed; or (4) give farmers free non-Bt seed when they purchase their Bt seed (i.e. tie the two products together at the point of sale).
- Each registrant should produce enough high yielding non-Bt corn hybrids for farmers to use for the block refuge. The SAP found that one reason for not planting a refuge was the lack of non-Bt seed varieties and that the ones that are on the market are of lower quality.

In addition, EPA should consider the feasibility and value of allowing for a community refuge option, where a group of farmers would decide which farmer would plant only non-Bt corn in their fields to provide a refuge for the remainder of the farmers planting solely Bt corn. If this option would help delay resistance development and improve refuge compliance, it would be worth EPA providing this option to the registrants and farmers.

V. Rotation of Crops and/or Pesticide Modes of Action (MOA) Must be a Part of the EPA IRM Requirements

A tried and tested method to delay resistance is to rotate the crop grown within a particular field. A farmer might plant corn one year and then switch to growing soybeans the next year. Those different crops support different insects, and the rotation helps prevent any resistant pests that survive at the end of one year from surviving the following year. Similarly, an effective resistance management tool is to rotate pesticide modes of action (MOA) in different years in the same field. This could mean a farmer plants Bt corn one year and non-Bt corn the next year (and uses chemical insecticides) or it could mean the farmer plants a different variety of Bt corn with different Bt proteins that have an alternate MOA. In EPA's White Paper in advance of the SAP meeting, EPA included among the many possible management options the rotation of Bt pyramided products (different MOAs) and the rotation to conventional corn with the use of chemical insecticides, yet neither of these options is in the current EPA proposal.

If EPA wants to prolong the effectiveness of Bt proteins throughout the country, it needs to require the use of all effective tools, including rotation. EPA's only discussion of rotation in its current proposal involves the reference to "switching to a different Bt mode of action or planting non-Bt" as one of five possible "best management options" for a farmer to use in their field if there was documented "unexpected injury" from resistant pests in that field the previous year. Rotation is not required and is probably the least likely option the farmer will choose voluntarily, because the others are easier and cheaper to implement (though probably less

effective). EPA needs to mandate either crop or MOA rotation in all fields where there is documentation of unexpected injury from target pests.

EPA also should require mandatory rotation in other places in their resistance management standards. The SAP made a consensus determination that a “trait rotation strategy... provides the best opportunity to forestall the development of resistance in lepidopteran pests in regions of high risk for resistance, in areas with historically low compliance with block refuge requirements....” To implement this recommendation, EPA could restrict registrants from selling the same Bt corn products to farmers two years in a row through a label condition (*i.e.*, “This product cannot be used two years in a row in the same field nor can any other seeds with Bt traits that have cross-resistance”). Rotating different crops or different MOAs is a common pest management practice used by many farmers, so such a requirement will be codifying what many farmers already do. If rotation is not required, a minority of farmers might jeopardize a product that most farmers use in accordance with best management practices and is needed to address pests.

CSPI appreciates the opportunity to provide these comments to the EPA and would welcome the opportunity to meet with the staff at EPA to discuss the issues addressed here in more detail.

Sincerely,

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