



April 15, 2015

By Electronic Submission  
Docket EPA-HQ-OPP-2014-0805  
Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001

Re: Comments to Docket No. EPA-HQ-OPP-2014-0805 Regarding the Proposed Changes to the EPA Framework for the Registration of Plant-Incorporated Protectants for Corn Rootworm.

The Center for Science in the Public Interest (“CSPI”)<sup>1</sup> hereby submits the following comments to the Environmental Protection Agency (“EPA”) Docket No. EPA-HQ-OPP-2014-0805, which addresses new requirements to increase the durability of plant-incorporated protectants (PIP) that kill corn rootworm (CRW) pests. CSPI supports both the goals of EPA’s proposal as well as the specific requirements it seeks to impose on Bt crops that target CRW pests.

Seeds engineered with Bt genes that produce toxic proteins are an effective and environmentally friendly method of protecting against CRW damage. It is crucial that EPA ensure that those seeds will achieve the same results for future farmers as they do for current farmers. When the first corn seeds engineered with Bt genes that target CRW pests were registered under FIFRA, EPA imposed on registrants and farmers the requirement to implement insect resistance management (IRM). In particular, farmers are required to plant a refuge of non-Bt corn to prevent the development of resistant pest populations. Unfortunately, those obligations have not prevented the development of resistant CRW populations throughout the Midwest. Thus, it is critical that EPA put in place additional requirements if EPA is to meet its objective of preserving Bt toxins for future farmers. Without government-imposed obligations, developers and farmers will not address preventing resistance development until it is too late.<sup>2</sup>

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<sup>1</sup> 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 900,000 member-subscribers to its Nutrition Action Healthletter and by foundation grants. CSPI receives no funding from industry or the federal government.

<sup>2</sup> As stated by Michael Owen from Iowa State University: “Unfortunately there appears to be another universal truth that suggests that agriculture, defined to include all sectors (e.g. farmers, technology agricultural retailers and technology providers) typically do not address pest adaptation (evolution) until resistance has become of great economic importance.” Owen, M. 2015. “Pest resistance: An Overview.” Iowa State Workshop on January 30, 2015. Available at:

CSPI supports all the actions proposed in EPA's letter to the Bt CRW registrants dated September 3, 2014 and recommends that EPA make those requirements mandatory through either the terms of registration or through label restrictions.

## **I. Integrated Pest Management is Necessary to Combat the Development of Resistant Pest Populations.**

Development of resistance to biological or chemical insecticides by insect pests is not a new phenomenon nor something that occurs only with genetically engineered (GE) seeds. Virtually any entomologist will explain that if one insecticide is used exclusively, resistant pest populations will develop. Those same entomologists also will state that the best way to prevent development of resistant pests is through implementing different farming practices that are part of integrated pest management (IPM). In fact, the scientific literature strongly supports IPM as necessary and critical to retain the durability of insecticides.

EPA originally approved the different Bt corn products with only an IRM requirement that farmers plant a refuge of non-Bt corn to prevent the development of resistance. EPA stated:<sup>3</sup>

Bt IRM is of great importance because of the threat insect resistance poses to the future use of Bt-plant pesticides and Bt technology as a whole. EPA considers protection of insect (pest) susceptibility of Bt to be a "public good." EPA has determined that development of resistant insects would constitute an adverse environmental effect.

While a majority of farmers have met those requirements each year, a significant minority have not.<sup>4,5</sup> In the last few years, CRW populations resistant to Cry3Bb1 have developed and now exist on numerous farms throughout the Midwest.<sup>6,7</sup> Thus, the EPA strategy that resistance can be prevented by relying solely on farmers planting a refuge is failing and will not protect the durability of the Bt toxins that kill CRWs.<sup>8</sup> In addition, "By the time the existence of pest resistance is accepted, the spread of the pest resistance complex is such that effective management is no longer a simple or inexpensive prospect."<sup>9</sup> For those reasons, EPA is justified

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[http://www.ipm.iastate.edu/files/page/files/Resistance%20Management%20Meeting%20Background%20Materials%202015\\_0.pdf](http://www.ipm.iastate.edu/files/page/files/Resistance%20Management%20Meeting%20Background%20Materials%202015_0.pdf).

<sup>3</sup> EPA. Oct. 15, 2001. EPA Registration Action Document, V12

<sup>4</sup> Martinez, J. April 9, 2014. Memorandum: EPA Review of ABSTC's 2011-2013 Corn Insect Resistance Management Compliance Assurance Program. EPA.

<sup>5</sup> CSPI. 2009. Complacency on the Farm. Available at: <http://cspinet.org/new/pdf/complacencyonthefarm.pdf>.

<sup>6</sup> Gassmann, A. J. 2012. Field-evolved resistance to Bt maize by western corn rootworm: predictions from the laboratory and effects in the field. *Journal of Invertebrate Pathology* 110:287-293

<sup>7</sup> Gassmann, A. J., Petzold-Maxwell, J. L., Clifton, E. H., Dunbar, M. W., Hoffmann, A. M., Ingber, D. A. and Keweshan, R. S. 2014. Field-evolved resistance by western corn rootworm to multiple *Bacillus thuringiensis* toxins in transgenic maize. *Proceedings of the National Academy of Sciences USA* 111:5141-5146.

<sup>8</sup> The Bt toxins that kill rootworm pests are considered "moderate" dose while the Bt toxins that kill corn borer pests are "high" dose toxins. That difference explains one of the reasons why resistance to Bt corn borer toxins has not developed and why additional IPM requirements are not needed for GE seeds with just those Bt toxins.

<sup>9</sup> Owen, 2015.

in following the recommendations by the FIFRA Science Advisory Panel (SAP) that call for establishing IPM requirements to delay resistance development.

A. Crop Rotation is an Important IPM Practice that can Delay Resistance.

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 the first year from surviving that following year. Not rotating to a different crop accelerates the likelihood of developing resistant insect populations. In fact, field research from Aaron Gassmann at Iowa State University identified resistant CRW insect populations in several locations in Iowa. In each case, the field had been planted with corn continuously for at least four years.<sup>10</sup>

Crop rotation is both an effective method to delay resistance and a common practice among farmers. According to the comments submitted to this docket by the Agricultural Biotechnology Stewardship Technical Committee, which represents the companies who have registered Bt corn products, “The primary recommendation to effectively manage CRW populations is crop rotation to a non-host crop. Crop rotation will help break the CRW cycle in addition to keeping high CRW populations in check.”<sup>11</sup> In addition, when Iowa State University conducted survey research of farmers, it found that 93% of farmers used “rotating corn and soybeans” as a management practice to prevent CRW resistance and 89% rated that management practice as either effective or very effective.<sup>12</sup>

USDA found that 11.3% of all corn acreage planted in 2010 followed corn planted on the same field for at least five years and 27% of all corn acreage planted followed corn the previous year.<sup>13</sup> If EPA wants to delay the development of resistant CRW populations, it is clear that rotating to a non-host crop needs to be a mandatory on-farm practice. EPA needs to amend the terms of registration to require that the registrants include such a requirement in their seed contracts with farmers purchasing seeds with CRW traits. EPA also needs to identify this particular requirement as a restriction on the label (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).<sup>14</sup>

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<sup>10</sup> Gassmann, 2012. This same point was reiterated in the report from a recent Iowa State resistance management meeting that found: “Field populations of western corn rootworm with Bt resistance are typically associated with a history of continuous corn cultivation and continuous use of the same Bt trait.” Owen, 2015, p. 3.

<sup>11</sup> Agricultural Biotechnology Stewardship Technical Committee (ABSTC). February 13, 2015. Letter to EPA Docket # EPA-HQ-OPP-2014-0805, Re: EPA Proposal to Improve Corn Rootworm (CRW) Resistance Management. p. 5.

<sup>12</sup> Iowa State University. October, 2013. Iowa Farm and Rural Life Poll: 2013 Summary Report. pp. 11-12. Available at: <http://www.soc.iastate.edu/extension/ifrlp/PDF/PM3061.pdf>

<sup>13</sup> FIFRA SAP. December, 2013. *A set of scientific issues being considered by the Environmental Protection Agency regarding scientific uncertainties associated with corn rootworm resistance monitoring for Bt corn plant incorporated protectants (PIPs)*. p. 26.

<sup>14</sup> The FIFRA SAP Panel noted that “BMP practices can be encouraged through **requirements** placed on the label” (emphasis added). They also stated that “not all producers will choose to use the BMPs as part of the production plan **unless required**.” (FIFRA SAP, 2013, p. 58). Therefore, the Panel acknowledges the need to mandate BMPs and to do it by placing requirements on the product label.

While some organizations or individuals may argue to EPA that such a condition is too prescriptive or burdensome, the fact is that the different registrants consider rotation as a “best management practice” that all farmers should follow.<sup>15</sup> In addition, an overwhelming number of farmers consider rotation as an effective management practice, so such a prescriptive requirement will be memorializing what the vast majority of farmers either do or should do. If rotation is not required, a minority of farmers might jeopardize a product that a majority of farmers use correctly and need as a safe and effective insecticide.

**B. Requiring Farmers to Use Multiple Modes of Action or to Rotate Their Modes of Action are Effective IPM Practices.**

After crop rotation, one of the most effective IPM practices is for farmers to rotate between insecticides with different modes of action. The FIFRA SAP supports as a “best management practice” that farmers rotate between different PIP modes of action and then to a non-BT corn with a soil insecticide.<sup>16</sup> The ABSTC comment to EPA states that after crop rotation, the next most effective “best management practice” is the rotation between different Bt traits. It recommends rotating among dual mode of action Bt corn products or using a non-Bt corn seed with a soil-applied insecticide. ABSTC even states that the same Bt corn trait should not be used in the same field for three consecutive years when farmers use only a single trait Bt corn product.<sup>17</sup> Finally, Professor Gassmann from Iowa State University recently wrote that “Rotating among a diversity of management tactics over multiple growing seasons and using non-Bt refuges will help to delay the evolution of Bt resistance.”<sup>18</sup>

Farmers also acknowledge that rotation between pesticides with different modes of action is an effective practice to prevent corn rootworm resistance. In the previously mentioned Iowa poll, 51% of farmers said they rotated between different Bt traits. In addition, 74% of the farmers surveyed stated that such a practice is either somewhat effective (17%), effective (41%) or very effective (15%).<sup>19</sup>

Similar to crop rotation, the registrants and farmers both understand the importance of rotating among different modes of action. If EPA makes such a practice a requirement, it would not be difficult to implement because many farmers already conduct that practice and the industry strongly encourages it to farmers. Therefore, EPA should mandate such a requirement in the different registration documents (such as the PIP label, the registration document, and the grower agreement between the registrant and the farmer).

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<sup>15</sup> ABSTC, 2015, pp. 7-10.

<sup>16</sup> FIFRA SAP, 2013, pp. 56-60.

<sup>17</sup> ABSTC, 2015, p. 2.

<sup>18</sup> Gassmann, A. 2015. “Resistance to Bt Corn by Western Corn Rootworm.” Iowa State Workshop on January 30, 2015. Available at:

[http://www.ipm.iastate.edu/files/page/files/Resistance%20Management%20Meeting%20Background%20Materials%202015\\_0.pdf](http://www.ipm.iastate.edu/files/page/files/Resistance%20Management%20Meeting%20Background%20Materials%202015_0.pdf).

<sup>19</sup> Iowa State University, 2013, p. 12.

C. Minimizing the Use of Single-Toxin Traits Is Important to Reducing the Likelihood of Developing Resistant Pests.

The scientific literature on Bt crops supports the EPA requirement to limit the use of single-trait Bt toxin PIPs in both the high- and low-risk areas. In a review of insect resistance to Bt crops, Tabashnik et al. found that where Bt toxins in pyramids were used and single trait varieties were eliminated, resistance pests did not develop. However, where pyramided traits were used concurrently with one-toxin plants, continued resistance developed.<sup>20</sup> Thus, EPA's decision to limit the use of single-toxin PIPs to no more than 10% in high-risk areas and no more than 20% in low risk areas is clearly supported by adequate scientific evidence. In fact, EPA's decision to allow small percentages of farmers to continue using single-toxin PIPs is fairly generous and could lead to additional resistant pest populations unless carefully implemented with other IPM measures (such as crop rotation, rotation of modes of action, etc...).

D. The Adoption Targets Proposed by EPA are Reasonable and Necessary to Achieve CRW Resistance Management.

CRW resistance to Cry3Bb was identified several years ago and additional resistant pest populations continue to develop throughout the Midwest.<sup>21</sup> There is also evidence that some of those populations show cross-resistance to mCry3A.<sup>22</sup> IRM alone has not been effective at stopping resistance from developing and additional action by EPA is warranted. The adoption targets for different IPM stewardship actions (crop rotation, multiple modes of action, non-Bt corn with a soil insecticide, and limiting the use of single-toxin PIPs) are reasonable and should be memorialized as enforceable conditions that each registrant must meet for its growers purchasing its particular Bt CRW product.

When EPA implemented its IRM program and the requirement that farmers plant refugia, it did not mandate that the registrants meet adoption targets to ensure that the vast majority of Bt corn farmers met those IRM obligations. Without any enforceable adoption rate, compliance by farmers in most years has been quite bad. According to the data available, IRM in most years had compliance as high as 70-75 % if one looks at the reported data generously for some products and regions. For some products (particularly CRW traits) and regions (particularly the South), compliance in the 50-60% range is a better estimate. See CSPI report entitled "Complacency on the Farm"<sup>23</sup> and my oral comment to EPA SAP in December 2013,<sup>24</sup> as well as the ABTSC annual Compliance Assurance Program (CAP) reports for 2010, 2011, 2012, and 2013.

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<sup>20</sup> Tabashnik, B. E., Brévault, T., & Carrière, Y. 2013. Insect resistance to Bt crops: lessons from the first billion acres. *Nature biotechnology*, 31(6), 518.

<sup>21</sup> Gassmann, 2012.

<sup>22</sup> Gassmann et al., 2014.

<sup>23</sup> CSPI, *Complacency on the Farm*, 2009.

<sup>24</sup> Jaffe, G. December, 2013. CSPI's Comments to EPA FIFRA SAP on Bt Corn and Rootworm Resistance. Center for Science in the Public Interest. Available at: <http://cspinet.org/biotech/epa-fifra-sap-2013.pdf>.

With such pitiful compliance rates for IRM obligations that did not have corresponding adoption targets, EPA cannot afford to do the same thing again for implementing IPM practices to prevent CRW resistance. The adoption targets are the proper way forward and those targets need to be memorialized in the terms of registration with each registrant. The registrants should collect information from their farmer customers about how they carry out IPM for CRW resistance on their farms and make summary data available to EPA on an annual basis. In addition, the annual IRM CAP farmer survey should include questions on compliance with IPM for CRW. Finally, the on-site third-party inspections for IRM compliance should also assess compliance with IPM approaches for CRW resistance. If a particular developer does not achieve the adoption targets for its farmer customers, financial penalties and/or restriction on seed sales should result.

## **II. Soil Insecticides Do Not Protect the Yield of BT Corn Farmers but Do Increase the Likelihood of CRW Resistance, and Should Not be Allowed.**

One practice that has become common among many Bt corn farmers is to apply a soil insecticide in addition to planting a GE seed variety with one or more Bt genes that kill rootworms. However, a number of scientific studies including one by Petzold-Maxell et al. show that the soil insecticide does not increase the yield for the Bt corn farmer but does delay emergence of those pests, which could promote mating patterns that hastens resistance evolution.<sup>25</sup> As stated by the SAP in its report:

The Panel has concerns with the recommendation to use a soil insecticide with the compromised Bt toxin as we believe this will allow resistant corn rootworm to survive by feeding on Bt expressing roots outside of the application band of the soil insecticide in the band. The Panel believes the use of soil insecticides with a Bt hybrid should not be done. (Page 21)

Use of a soil insecticide also reduces some of the benefits of Bt corn, which are reduced insecticide use as well as the cost savings from that reduced use. Those benefits were part of EPA's original risk and benefit decision to register those pesticides.

Given the environmental impact caused by the soil insecticides, the lack of a yield increase, and the potential that the practice will increase the development of Bt-resistant populations, EPA is justified in prohibiting the use of soil insecticides with Bt corn varieties with genes that target CRWs. Carrying out this IPM practice is so important that EPA needs to set forth this obligation in several different ways so the message reaches all farmers using Bt seeds that kill rootworm. It should be explicitly stated as a label condition for each Bt CRW seed variety. Also, it should be explicitly included in the terms of registration for each Bt CRW seed product. The terms of registration should prohibit the use of soil insecticides and require the registrant to memorialize that prohibition in their grower agreement, their grower use guides, and in all educational information provided to farmers. Finally, the terms of registration should

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<sup>25</sup> Petzold-Maxwell, J. L., Meinke, L. J., Gray, M. E., Estes, R. E., & Gassmann, A. J. 2013. Effect of Bt maize and soil insecticides on yield, injury, and rootworm survival: implications for resistance management. *Journal of economic entomology*, 106(5), 1941-1951.

require developers to include language setting forth the prohibition on the use of soil insecticides on the tags of seed bags.<sup>26</sup> Only by repeating this mandatory prohibition throughout the PIP registration documents and farmer educational materials will compliance be assured.

### **III. EPA Should Require Remedial Action (RA) Plans Prior to the Development of Resistance.**

The FIFRA SAP Panel clearly stated that IPM will reduce the likelihood that remediation will be necessary. However, it also stated that remediation plans should be in place for all Bt products before resistance develops. As stated by the SAP Panel:

The Panel recommends that remediation plans be in place for all licensed products taking into consideration geographical location of the field, production practice, population resistance, and species behaviors. (Page 21)

Such plans are critical to arresting resistant populations from multiplying and protecting the durability of each Bt CRW variety for other farmers. Therefore, EPA should require development of such a plan as a mandatory term of registration. The registrant should submit its remedial action plan to EPA for approval within 90 days of registration and update it on a yearly basis.<sup>27</sup>

### **IV. The Remainder of the EPA Proposal is Appropriate**

The other items in the EPA proposal are reasonable and will help EPA achieve its goal. CSPI supports the implementation of a proactive strategy to detect and remedy unexpected damage in fields. It also supports the switch from artificial diet bioassays to “on plant” assays, the elimination of random sampling in the Corn Belt, and the enhancement of remedial action plans. Those EPA proposals are reasonable and reflect the current state of scientific information available as well as the recommendations and analysis by the FIFRA SAP Panel.

### **Conclusion**

EPA’s proposal to arrest, contain, and prevent CRW resistance is well supported by current field conditions and scientific evidence. It implements the recommendations of the FIFRA SAP Panel while providing the registrants and farmers with necessary flexibility to address specific conditions that may exist in specific regions or on specific farms. However, it is also imperative that EPA learns from past experience with IRM obligations. If EPA wants IPM

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<sup>26</sup> Martinez, 2014. EPA’s recent analysis of the ABSTC’s annual survey of farmers about IRM found that the percentage of farmers who get IRM information from the bag tag has increased from 57% in 2011 to 69% in 2012 and 71% in 2013. That data strongly supports that providing information on the bag tag is an effective way to communicate to farmers about a prohibition against the use of soil insecticides.

<sup>27</sup> Since all the Bt CRW crops have existing registrations, the requirement of submitting a remedial action plan to EPA for approval should come in effect 90 days after EPA amends the current registration or 90 days after the Bt CRW products are re-registered if that occurs (some of Bt CRW products’ current registration expires on September 30, 2015).

to delay CRW resistance, it needs to make the different aspects of its proposal mandatory in the terms of registration, on the PIP label, in the grower agreements, and on the bag tags. The EPA proposal is sound and the registrants and farmers should embrace it because it protects a valuable farming tool for use now and into the future.

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,

A handwritten signature in blue ink, appearing to read "Gregory Jaffe".

Gregory Jaffe  
Director, Biotechnology Project  
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