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ALERT

EPA FIFRA SAP to Address Lepidopteran Pest Resistance to *B.t.* Plant Incorporated Protectants

March 6, 2018

The U.S. Environmental Protection Agency (EPA) this week took two more aggressive steps to address pest resistance to agricultural pesticides when it announced a June 17 meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider a draft document addressing the development of resistance by lepidopteran pests[1] to *Bacillus thuringiensis* (*B.t.*) plant incorporated protectants (PIPs), and invited nominations for members of the review panel. *FIFRA Scientific Advisory Panel; Notice of Public Meeting and Request for Nomination of Ad Hoc Expert Members*, 83 Fed. Reg. 9307 (March 5, 2018). EPA also announced its plan to hold a preparatory webinar to "consider and review the clarity and scope of the meeting's draft charge questions," but did not set a date for that event.

This meeting should be of particular interest to agricultural biotechnology companies, PIP registrants, growers, and researchers. In recent years, EPA has ratcheted up requirements for insect resistance management (IRM) and its efforts to address the development of insect resistance to *B.t.* PIP crops. The SAP meeting could be a precursor to even more stringent IRM proposals and requirements.

EPA is accepting nominations for ad hoc members of the SAP to serve on the panel for the July 17-20 meeting until April 4, 2018. EPA is accepting comments on both the preparatory webinar and the FIFRA SAP meeting until May 10, 2018.

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Potentially impacted companies should take advantage of these opportunities. The Agency gives great weight to SAP recommendations. The SAP is authorized under Section 25(d) of FIFRA to provide EPA with expert advice, and by Section 25(e) of FIFRA to provide peer review "with respect to the design, protocols, and conduct" of scientific studies conducted by EPA under FIFRA. Participation in this SAP meeting could be critical to influencing future EPA action on *B.t.* crops.

The paper to be addressed at this SAP meeting is titled *Resistance of Lepidopteran Pests to Bacillus thuringiensis (Bt) Plant Incorporated Protectants in the United States: EPA's Analysis of Scientific Uncertainties Related to Resistance Management and Options to Enhance the Current Insect Resistance Management Program*.

B.t. PIPs are generally described as crops (e.g., corn, cotton, and soybeans) that have been genetically engineered to express proteins that are non-toxic to humans and other animals, but that are lethal to specific crop pests. *See* http://www.ncsl.org/documents/capitolforum/2015/onlineresources/FIFRA-FFDCA-PIPs-12-8-15.pdf , slides 4-6. Non-toxic *B.t.* insecticidal proteins are among the few pesticides approved for use on organic crops, and genetically engineering plants to produce them has revolutionized agriculture in both the developed and developing world. *See, e.g.*, http://www.pnas.org/content/109/29/11652 ; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5033197/.

But, a concern exists that target pests will develop resistance to the lethal effects of the *B.t.* proteins. Almost from the beginning of registering *B.t.* PIP crops, EPA has required *B.t.* PIPs registrants to take steps to mitigate such resistance. EPA required *B.t.* PIPs registrants to work with growers to implement IRM strategies. Initially, for example, the primary IRM strategy was to require growers to plant "refuges," i.e., areas in their fields that were planted to non-*B.t.* versions of their crops. The idea behind refuges is that the non-*B.t.* plants growing in the refuges would not provide selection pressure for resistant insects, and that there would be sufficient non-resistant insects coming out of the refuges to suppress the development of resistant insect populations.

EPA now is concerned that previous efforts to suppress populations of resistant insects have proven to be inadequate. This issue has already been identified as to distinct populations of the western corn root worm, which have developed resistance to at least two *B.t.* proteins. EPA's new notice states that there have been subsequent reports of resistance developing in additional lepidopteran pests, such as fall armyworm, corn earworm, western bean cutworm, and southwestern corn borer. EPA intends to discuss during the July 17-20 FIFRA SAP meeting pest insect *B.t.* toxins resistance factors and "the feasibility of mitigating field resistance for Lepidopteran pests."

In 2016, EPA proposed to require registrants of *B.t.* PIPs corn products to develop integrated pest management (IPM) procedures for corn rootworm and to work with growers to see that these procedures were implement in their fields. Requirements identified by EPA included rotation of corn crops to non-corn crops, prohibition on planting of single-trait *B.t.* corn, requiring rotation to alternate *B.t.* corn products, and requirements not to plant *B.t.* corn. *See* https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/framework-delay-corn-rootworm-resistance.

When these measures were announced, there were concerns that EPA was overstepping its authority and micromanaging farm practices. There is also a concern that EPA is overstepping its authority in mandating how *B.t.* PIP corn registrants may market, sell, and distribute their products. It is far from clear, for example, that it is appropriate or lawful for EPA to declare that a *B.t.* toxin newly developed by an agricultural technology company "serves the public good" and on that basis to impose restrictions on whether and how the company can sell its product to willing buyers. For EPA to attempt to impose restrictions and requirements on pesticide registrations for reasons that have nothing to do with product safety or the product's potential to cause any adverse effects to human health and the environment raises serious questions.

With EPA now seeking to address additional instances of *B.t.* PIP pest resistance, it is possible the Agency will seek to go even further in managing use, sale, and distribution of these crops. *B.t.* PIP registrants and product developers, and other pesticides producers whose products may face the development of resistant pests, should promptly engage EPA on this issue and participate in the upcoming SAP process.

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[1] Lepidoptera are primarily moths and butterflies. As pests, they are primarily of concern during the crawling stage of their life cycles when, as worms and caterpillars, they are voracious eaters.