

ALERT

EPA Releases Draft Guidance for Mitigating Lepidopteran Resistance to PIPs

September 9, 2020

On September 8, the U.S. Environmental Protection Agency (EPA) announced that it is making available for public comment a proposed guidance document that is intended to improve "resistance management" strategies for Lepidopteran pests targeted by *Bacillus thuringiensis* plant-incorporated protectants (PIPs) in corn and cotton. The Federal Register link is available here. EPA's draft guidance, *EPA Draft Proposal to Address Resistance Risks to Lepidopteran Pests of Bt Following the July 2018 FIFRA Scientific Advisory Panel Recommendation'* is available at www.regulations.gov under the docket identification number EPA-HQ-OPP-2019-0682. EPA will accept comments on the draft guidance until November 9, 2020.

Various species of the common soil bacterium *Bacillus thuringiensis* (*B.t.*) produce substances that are harmful to pests of corn and cotton plants. These substances do not pose any risk to humans or to any organisms other than the corn and cotton pests. Technology producers have genetically engineered corn and cotton plants to express these substances, thus protecting crops from pests that cause significant damage. By growing corn and cotton plants that express these substances that are harmless to humans, farmers have avoided spraying millions of tons of chemical pesticides. Because the substances protect crops from pests, EPA regulates them as pesticides and has designated them with the term "plant-incorporated protectants" or PIPs.

While the agronomic, ecological, and environmental benefits of *B.t.* PIPs have been incalculable, the pests targeted by these PIPs can develop resistance to them. When target pests develop resistance, the crops expressing the PIPs are no longer protected from these pests. EPA requires growers to take certain measures to try to delay

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the development of resistance by target pests. These measures required by EPA have proven generally successful, but there have been recent cases of actual *B.t.* resistance that have developed in corn and cotton crops in some locations.

To address concerns regarding the development of resistance to some *B.t.* PIPs, EPA convened a FIFRA Science Advisory Panel (SAP) meeting in July 2018. This SAP meeting resulted in a number of recommendations to EPA to try to forestall the spread of insects resistant to *B.t.* PIPs. EPA has now developed a draft guidance document that incorporates recommendations by the SAP, as well as comments received from other key stakeholders. EPA will take public comment on the draft PIPs IRM guidance until November 9, 2020.

Some of the proposed changes to EPA's required IRM practices could have significant impacts on producers and uses of *B.t.* PIPs. Technology providers that produce and distribute *B.t.* PIPs, growers that plant *B.t.* corn and cotton crops, and anyone that is interested in the substantial environmental benefit attendant to the growing of *B.t.* crops should take advantage of the opportunity to comment on EPA's draft Lepidopteran IRM quidance.

(EPA's Federal Register announcement states that EPA will hold webinars on the draft guidance "in late July and August to discuss the proposal and answer questions." We have been informed that this is a mis-print, and that EPA intends to hold a webinar on the draft guidance in late September.)

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