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ALERT

# Five Key Takeaways From EPA's Biotech PIPs Exemption Proposed Rule

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On October 9, the U.S. Environmental Protection Agency (EPA) published for public comment its long-awaited proposed rule to exempt from most requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) plant-incorporated protectants (PIPs) that are based on sexually compatible plants and created through biotechnology.

EPA has opened a 60-day comment period on this proposed rule, and will accept comments until December 8, 2020. EPA has also scheduled a webinar on the proposal to take place on October 14. The exemption for sexually compatible biotech PIPs may expand the number of technology developers that create and market new ag biotech products. There are a number of important aspects of the proposed rule, however, that EPA has not resolved conclusively. Interested stakeholders must take advantage of the opportunity to comment on the proposed rule to provide useful input to EPA as it develops the final rule. Below are five key takeaways from the proposed rule that highlight its potential importance to technology producers going forward:

1. **The Proposed Rule Could Significantly Streamline the Process of Developing Certain new PIPs.**

   Currently, EPA's regulations exempt from the requirement of FIFRA registration PIPs from sexually compatible plants that are moved through conventional breeding. Plants developed through biotechnology are expressly excluded from that exemption. Significant advances in biotechnology techniques now make it possible for EPA to conclusively conclude that such biotech plants pose no greater risk to human health and

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the environment than plants produced through conventional breeding. EPA estimates that the incremental cost saving of exempting qualifying PIPs from the requirement of registration and associated tolerance actions to be $444,000 – $459,000 per product. This cost saving may result in more research and product development in this segment of the ag biotech market. Of the genetically engineered registered PIP products currently in commerce, none would qualify for the proposed exemption. EPA hopes to jump start this market segment by reducing regulatory costs.

2. **However, the Subset of PIPs That Would Qualify for the Exemption is Limited.**

   The criteria for EPA's proposed sexually compatible PIPs Exemption are very stringent. The intent of the proposed criteria is to ensure that any PIP that qualifies for the exemption cannot possibly produce a novel substance in the newly developed plant as a result of the genetic manipulation. Technology developers would be required to identify both the source and recipient plants, and demonstrate that the source plant and the modified plant are sexually compatible. In addition, technology producers must maintain records that (1) describe the pesticidal trait and how the trait was genetically engineered into the recipient plant; (2) identify the nucleotide sequence of the PIP and the expressed amino acid sequence in the recipient plant; (3) confirm that expression of the new protein does not exceed upper limits and that the PIP is not expressed in tissues or during developmental stages different than in a plant that is sexually compatible with the recipient plant. These requirements will limit the number of genetically engineered plants that will actually qualify for the exemption.

3. **The Proposed Rule Permits Technology Developers to Self-Certify, But EPA Indicates that It is Open to Considering Less (or More) Burdensome Approaches.**

   The proposed PIPs Exemption rule allows a technology developer to submit either (1) a letter to EPA stating that it has self determined that a PIP meets the criteria for the exemption or (2) a request that EPA confirm that their PIP meets the exemption criteria. The proposed rule also allows a product developer to both submit a self-determination letter to EPA and to either simultaneously, or at a later time, request EPA to confirm that the subject PIP meets the requirements of the exemption. The proposal identifies data and information that must be submitted to EPA with requests for EPA determination of eligibility. EPA is requesting comment on whether it should consider other approaches for confirming that a newly developed PIP qualifies for the exemption.

4. **EPA's Proposed Rule is Consistent with USDA's Recent Action Exempting Certain Genetically Engineered Plants from Regulation Under the PPA.**

   The proposed PIPs Exemption rule is consistent with the recent final rule promulgated by the U.S. Department of Agriculture (USDA) amending its regulations at 7 C.F.R. Part 340, which regulate the movement of certain genetically engineered organisms. The USDA rule exempts genetically engineered plants from regulation under Part 340 if these plants could otherwise be produced through conventional breeding. EPA and USDA concur that any plant that meets the criteria for the proposed PIPs exemption would also meet the exemption criteria for USDA's rule. USDA's Part 340 rule also allows technology developers either to self determine eligibility for the USDA exemption, or to seek

USDA confirmation of eligibility.

5. **EPA Specifically Requests Comments on Key Issues.**

   The public may comment on any aspect of EPA's proposed rule. EPA has requested comment on certain specific issues, including certain definitions in the proposed exemption; whether EPA should expand the definition of inert ingredients that it included in the 2001 rule exempting sexually compatible PIPs produced through conventional breeding; what process should EPA use to provide notice that either a previously exempt plant no longer qualifies for the exemption or that a self-determination of eligibility was incorrect; and should EPA issue a separate exemption for loss-of-functions modifications?

EPA's proposed PIPs Exemption rule could significantly reduce the regulatory burden applicable to the defined category of PIPs, thus reducing a critical barrier to market entry. With the advent of new breeding techniques that make it easier to genetically engineer organisms (kudos to Drs. Charpentier and Doudna!), technology developers should take advantage of the opportunity to comment on and perhaps shape EPA's final rule.