

## EPA's Plant-Incorporated Protectants (PIPs) Exemption Rule Fact Sheet

*EPA is issuing this fact sheet to help biotechnology developers exercise the full benefits of the exemptions available under the recently issued PIPs exemption rule.*

In May 2023, the U.S. Environmental Protection Agency (EPA) released a final rule exempting two categories of plant-incorporated protectants (PIPs) created using genetic engineering from registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and from the food or feed residue tolerance requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA).

This rule ensures that human health and the environment are protected while reducing costs for the regulated community, consistent with the September 2022 [Executive Order 14081 on Advancing Biotechnology](#). The rule may also result in increased research and development activities, commercialization of new pest control options for farmers, and reduced use of conventional pesticides.

The final rule reflects the biotechnological advances made since 2001, when the Agency first exempted PIPs derived through conventional breeding from FIFRA registration and FFDCA tolerance requirements, but did not at that time exempt PIPs created through biotechnology. Specifically, the final rule exempts PIPs derived through genetic engineering from FIFRA registration and FFDCA tolerance requirements in cases in which the PIPs are essentially equivalent to those exempted by the 2001 rule.

The rule contains conditions for exempting:

- 1) PIPs in which genetic engineering has been used to insert a gene from a sexually compatible plant or to modify a gene to match a gene found in a sexually compatible plant. This category of PIPs requires EPA confirmation of eligibility for the exemption.; and
- 2) Loss-of-function (LoF) PIPs, in which a gene is modified through genetic engineering to reduce or eliminate the activity of that gene. The loss of the activity of that gene then results in the pesticidal effect. For this category of PIP, biotechnology developers can make a self-determination that their PIP meets the exemption criteria, which requires notification but no EPA review, or request EPA confirmation of eligibility for the exemption.
- 3) EPA also indicated in the preamble to the rule that EPA would consider exempting additional categories of PIPs from both FIFRA registration and FFDCA tolerance requirements and expanding the categories of PIPs that are allowed the option to self-determine and do not require EPA confirmation of eligibility for the exemption.

EPA anticipates it will take a biotechnology developer less than 30 minutes to complete the self-determination process. EPA anticipates it will take the biotechnology developer a few hours to complete a request for EPA confirmation and should not require additional testing or data

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gathering (which could take months or years, if the PIP was required to undergo FIFRA registration rather than being exempted). This request would be submitted under PRIA category M009 and has minimal cost (about \$3000 or 1% of the full FIFRA registration cost).

The final rule is effective on July 31, 2023.

### Resources to Help with PIPs Exemption Rule

EPA is providing additional information and clarification to assist developers with exemption qualification and compliance under the PIPs exemption rule.

#### PIP Exemption Examples:

High precision genetic engineering tools can create modifications in plants that are indistinguishable from what could have been created through conventional breeding, but also has the capability of creating modifications outside the scope of this rulemaking (e.g., *Bt* corn).

EPA is providing illustrative examples of genetic modifications that could qualify under the PIPs exemption categories. These examples should not be interpreted to represent the entire universe of genetically modified PIPs that may be eligible for these exemptions. Specific questions regarding whether a genetic modification in a plant would constitute a PIP, and therefore be subject to FIFRA regulation, can be submitted to the Agency under the PRIA category M009.

#### ***“PIPs created through genetic engineering from a sexually compatible plant”***

The examples below are considered PIPs created through genetic engineering from a sexually compatible plant and may be exempt if they meet the criteria under 40 CFR 174.26.

- An insect resistance trait is moved through genetic engineering from one variety of corn into another variety of corn.
- A commercial potato variety is genetically engineered to match a variation found in a wild potato, resulting in disease resistance.

#### ***“Loss of function PIPs”***

The example below is considered to be a loss-of-function PIP and may be exempt if it meets the criteria under 40 CFR 174.27.

- A tomato has been genetically engineered to turn off the function of one of its genes. The loss of function of this gene results in a plant virus being unable to enter the tomato, resulting in disease resistance.

Additional more technical examples of exempt PIPs can be located at:

<https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/pesticides-exemptions-certain-plant-incorporated-0>

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### Notification Process

#### ***Self-Determination***

Developers can make a self-determination for the loss-of-function PIP exemption and submit an electronic notification to EPA. The exemption is effective upon EPA notification, which occurs immediately since it is automated through EPA's CDX portal. There is no cost associated with the notification of self-determination for this exemption category, and it is expected to take approximately 30 minutes to complete.

Refer to EPA's training webinar to help with the self-determination.

#### ***Request for EPA Confirmation of Eligibility for Exemption***

Developers can submit a request for EPA to make a determination of whether a PIP qualifies for exemption under either 40 CFR 174.26 or 174.27. To make this determination, EPA requests certain information such as plant biology, pesticidal trait, molecular characterization, history of safe use (could be in form of statement and reference to existing information or literature). EPA anticipates it will take the biotechnology developer a few hours to complete a request for EPA confirmation and should not require additional testing or data gathering. This request would be submitted under PRIA category M009.

Refer to EPA's sample submission forms to help with the request for confirmation.

### Training Webinars

On June 28 and July 19, 2023, EPA conducted two training webinars to provide compliance assistance and answer questions related to the PIPs exemption rule.

Additional information on EPA's PIP exemption rule webinars can be located at:

<https://www.epa.gov/pesticides/epa-hosts-webinars-final-rule-related-use-plant-incorporated-protectants>

### Sample Submission Documents

On July 18, 2023, EPA posted five sample submission documents to assist developers' notification and request for EPA confirmation of exemption eligibility for the PIPs exemption rule.

Additional information on EPA's sample submission documents can be located at:

<https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/electronic-submission-portal-resources-pips-rule>

### **Next Steps: EPA Clarification on Plant Regulator PIP Scope and Exemption Proposal**

In 1994, EPA published a draft policy outlining a proposed scope that defined plant regulator PIPs. Although EPA has since made product specific determinations as to whether a plant contains a plant regulator PIP (e.g., a plant regulator PIP in a corn plant genetically engineered to be smaller in stature through the reduced production of a hormone), the draft policy was never finalized and there remains uncertainty in the regulated community as to how the plant regulator

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definition applies to PIPs. EPA will consider clarifying the scope of plant regulator PIPs and proposing a new exemption for plant regulator PIPs covered by FIFRA that are not eligible for existing exemptions.

More information on the 1994 EPA draft policy proposal for plant regulator PIPs can be located at: <https://www.govinfo.gov/content/pkg/FR-1994-11-23/html/94-28822.htm>.