Hypothetical Examples of Genetic Modifications that Would Meet the Exemption Criteria

To aid developers in complying with the 2023 rulemaking exempting certain genetically engineered plant-incorporated protectants (PIPs), which goes into effect July 31, 2023, EPA is providing hypothetical examples of genetic modifications that would meet the exemption criteria. As the hypothetical genetic modifications in this document are only examples, they should not be interpreted to represent the entire universe of PIPs.

Loss-of-function PIPs

Per EPA's recent rulemaking, "loss-of-function PIP" is defined to mean "a plant-incorporated protectant in which the genetic material of a native gene is modified to result in a pesticidal effect through the reduction or elimination of the activity of that gene. For purposes of loss-of-function plant-incorporated protectants, the active ingredient and pesticidal substance are one and the same and are defined as the genetic material that has been modified to create the pesticidal trait (i.e., modification of the sequence of nucleic acids). Loss-of-function plant-incorporated protectants do not include instances where the reduction or elimination of the activity of the modified native gene results in the intentional increase of activity of another pesticidal gene." 40 CFR 174.3. Given that some loss-of-function edits may not qualify as loss-of-function PIPs, EPA is providing the below clarifying examples to assist developers in determining whether they a loss-of-function PIP and therefore qualify for the self-determination option that requires no EPA review.

Examples of PIPs considered to be loss-of-function PIPs

- Disease resistant tomato: A tomato has been genetically modified by disrupting a gene that encodes for a plant virus receptor. The disruption causes a loss-of-function of the receptor, so that the virus is unable to infect the tomato and cause disease.
- Disease resistant potato: A potato has been genetically modified by deleting part of a gene encoding for a transcription factor. Although the exact mode of action is not known, as transcription factors can result in the up or down regulation of other genes, the deletion in the gene for the transcription factor results in disease resistance in the potato.
- The two above examples are considered to be loss-of-function PIPs and may be exempt if they meet the criteria under 40 CFR 174.27 and the developer can make a self-determination that requires no EPA review.

Example of a PIP not considered to be a loss-of-function PIP

- Insect resistant blueberry bush: A blueberry bush has been genetically modified by deleting part of a repressor gene that controls production of a pesticide substance. Loss-of-function of the repressor activity directly results in the increased expression of a known gene which encodes a pesticidal substance, conferring insect resistance.
- Although the above example is not considered to be a loss-of-function PIP, it is still a PIP and may be exempt if it meets the criteria under 40 CFR 174.26.

PIPs created through genetic engineering from sexually compatible plants

EPA's rulemaking also identified another category of PIPs which qualify for exemption, titled "PIPs created through genetic engineering from sexually compatible plants." To further aid developers in interpreting the exemption criteria, EPA is providing the below examples.

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- Squash is genetically engineered to replace the coding region of a gene with the coding region (i.e., only exons, no introns) of an allele found in a wild squash variety, resulting in increased insect resistance.
- Banana is genetically engineered to edit the regulatory region of an R gene to match a polymorphism identified in another variety of banana, resulting in increased expression of the R protein and disease resistance.
- The above examples may be exempt if they meet the criteria under 40 CFR 174.26 and/or 40 CFR 174.541.