EFFECTIVE DATE NOTE: At 88 FR 34776, May 31, 2023, §174.3 was amended by adding in alphabetical order definitions for ''Gene'', ''Genetic engineering'', ''Loss-of-function plant-incorporated protectant'', ''Native allele'', and ''Native gene'' and revising the definition of ''Sexually compatible'', effective July 31, 2023. For the convenience of the user, the added and revised text is set forth as follows:

§ 174.3 Definitions.

* * * * *

Gene, and other grammatical variants such as ''genic,'' means a unit of heritable genetic material that is comprised of the genetic material necessary for the production of a substance.

Genetic engineering means the modification of the genome of an organism using recombinant, synthesized, or amplified nucleic acids or other techniques excluded from the definition of conventional breeding.

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Loss-of-function plant-incorporated protectant means 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.

Native allele means a variant of a native gene that is identified in the genetic diversity of plants sexually compatible with the recipient plant.

Native gene means a gene that is identified in the recipient plant or source plants that are sexually compatible with the recipient plant. It does not include genes introduced through genetic engineering from a source organism that is not sexually compatible with the source plant.

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Sexually compatible, when referring to plants, means plants must be capable of forming a viable zygote through the union of two gametes through conventional breeding.

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§ 174.9 Confidential business information claims for plant-incorporated protectant submissions.

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information (CBI), a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant. (See part 2, subpart B of this chapter.) To assert such a claim, the submitter must comply with all of the following procedures:

(a) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

(b) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the points listed in §2.204(e)(4) of this chapter in the substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing information claimed as CBI that are not accompanied by substantiation, and will suspend any applicable review of such submissions until the required substantiation is provided.

Subpart B—Exemptions

§ 174.21 General qualifications for exemptions.

A plant-incorporated protectant is exempt from the requirements of FIFRA, other than the requirements of §174.71, if it meets all of the following criteria:

(a) The plant-incorporated protectant meets the criteria listed in at least one of the sections in §§174.25 through 174.50.

(b) When the plant-incorporated protectant is intended to be produced and

used in a crop used as food, the residues of the plant-incorporated protectant are either exempted from the requirement of a tolerance under FFDCA (as amended, 21 U.S.C. 321 *et seq.*) as codified at §§174.507 through 174.508, or no tolerance would otherwise be required for the plant-incorporated protectant.

(c) Any inert ingredient that is part of the plant-incorporated protectant is on the list codified at §174.705. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

[66 FR 37814, July 19, 2001, as amended at 72 FR 20434, Apr. 25, 2007]

EFFECTIVE DATE NOTE: At 88 FR 34776, May 31, 2023, §174.21 was revised, effective July 31, 2023. For the convenience of the user, the revised text is set forth as follows:

§174.21 General qualifications for exemptions.

A plant-incorporated protectant is exempt from the requirements of FIFRA, other than the requirements of §174.71, if it meets the exemption criteria in paragraphs (a) through (d) of this section. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

(a) The active ingredient of the plant-incorporated protectant meets the exemption criteria listed in at least one of the sections in §§174.25 through 174.50.

(b) When the plant-incorporated protectant is intended to be produced and used in a crop used as food, the residues of the active ingredient of the plant-incorporated protectant are either exempted from the requirement of a tolerance under FFDCA (21 U.S.C. 321 *et seq.*) as listed in subpart W of this part, or no tolerance would otherwise be required.

(c) Any inert ingredient that is part of the plant-incorporated protectant is listed as an approved inert ingredient in subpart X of this part.

(d) For plant-incorporated protectants listed in the subparagraphs below, the exemption applies only if the developer is compliant with the general recordkeeping requirements specified in §174.73 per sections 8 and 9 of FIFRA, 7 U.S.C. 136f and 136g, and only after compliance with the relevant eligibility determination procedures specified in §174.90:

(1) Plant-incorporated protectant created through genetic engineering from a sexually compatible plant.

(2) Loss-of-function plant-incorporated protectant.

§174.25 Plant-incorporated protectant from sexually compatible plant.

A plant-incorporated protectant is exempt if all of the following conditions are met:

(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient plant.

EFFECTIVE DATE NOTE: At 88 FR 34777, May 31, 2023, §174.25 was amended by revising the section heading and the introductory text and adding paragraph (c), effective July 31, 2023. For the convenience of the user, the added and revised text is set forth as follows:

§174.25 Active ingredient of a plant-incorporated protectant from a sexually compatible plant created through conventional breeding.

The active ingredient is exempt if all of the following conditions are met:

* * * * *

(c) The genetic material is transferred from the source plant to the recipient plant only through conventional breeding.

§174.26 Active ingredient of a plant-incorporated protectant created through genetic engineering from a sexually compatible plant.

The active ingredient is exempt if the conditions in paragraphs (a) and (b) of this section are met.

(a) The active ingredient is characteristic of the population of plants sexually compatible with the recipient plant and is created through genetic engineering from either an insertion of a native gene into the recipient plant as specified in paragraph (a)(1) of this section or a modification of an existing native gene in the recipient plant as specified in paragraph (a)(2) of this section.

(1) *Insertion.* A native gene is inserted into the genome of the recipient plant and produces a pesticidal substance identical in sequence to the pesticidal substance identified in the source plant. The regulatory regions inserted as part of the native gene must be identical in nucleic acid sequence to those