

with FIFRA requires immediate action, EPA may take such action, including enforcement, without first informing the submitter of an eligibility review.

(f) *Extension of exemption.* An exemption can be extended in one of two ways. First, if the exempted plant-incorporated protectant is moved through conventional breeding to other plants, the exemption is extended to the subsequent plant-incorporated protectant. Second, to extend the exemption of the plant-incorporated protectant to subsequent genetic engineering events in other plants, the following exemption-specific criteria apply:

(1) *Plant-incorporated protectant created through genetic engineering from a sexually compatible plant.* An exemption extends to a plant-incorporated protectant when that plant-incorporated protectant is genetically engineered by the submitter into another variety of that same plant species, the substance produced is identical to the substance produced in the original recipient plant, and no new modifications were made to the regulatory regions.

(2) *Loss of function plant-incorporated protectant.* An exemption extends to a plant-incorporated protectant when that plant-incorporated protectant is genetically engineered by the submitter into another variety of that same plant species and the same native gene is targeted to create the loss-of-function PIP.

(g) *No duplication necessary.* A developer is not required to submit duplicative requests for eligibility determination or self-determination under both §§174.541(c) and 174.21(d), if it has already been submitted for purposes of determining eligibility under §174.21(d).

§ 174.91 Submitting a letter of self-determination.

To self-determine eligibility for the exemption of a plant-incorporated protectant listed under §174.90(a)(2), a developer must comply with all of the following requirements.

(a) *When to submit a letter of self-determination.* A letter of self-determination for an exemption must be submitted to EPA prior to engaging in any activity

that would be subject to FIFRA absent an exemption.

(b) *Contents of a letter of self-determination.* The letter of self-determination must:

(1) Provide the name and contact information for the submitter (including telephone number and email address), company name, or other affiliation.

(2) Identify the plant-incorporated protectant by providing: the identity of the recipient plant (genus and species), a unique identifier for the native gene from the National Center for Biotechnology Information (NCBI) at the National Library of Medicine of the National Institutes of Health (NLM) at the National Institutes of Health (NIH) (i.e., Entrez GeneID), the trait type (e.g., insect resistance), and cite the paragraph under §174.90(a)(2) that indicates that the plant-incorporated protectant is eligible for self-determination.

(3) Complete and submit the certification statement provided in the electronic submission portal. The statement must be dated and signed by the certifying official identified in the certification statement.

(c) *EPA response.* EPA will provide electronic confirmation of receipt immediately. Electronic confirmation of receipt shall be equivalent to written confirmation of receipt.

(d) *Effective date of exemption.* The exemption does not apply until EPA confirms receipt of the letter of self-determination.

§ 174.93 Requesting EPA confirmation.

To request EPA confirmation of eligibility for exemption of a plant-incorporated protectant listed under §174.21(d), a developer must comply with all of the following requirements.

(a) *When to submit a request for EPA confirmation.* Unless the developer has received confirmation of receipt of a letter of self-determination, the request for EPA confirmation must be submitted prior to engaging in any activity that would be subject to FIFRA absent an exemption.

(b) *Contents of a request for EPA confirmation of exemption eligibility.* The request must contain information as specified in §174.91(b) and supporting