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]

§ 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.

Subpart C—Registration Procedures and Requirements [Reserved]

Subpart D—Monitoring and Recordkeeping

§ 174.71 Submission of information regarding adverse effects.

(a) Any person who produces, for sale or distribution, a plant-incorporated protectant exempt under subpart B of this part, who obtains any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant must submit such information to EPA. This requirement does not apply to any person who does not produce a plant-incorporated protectant exempt under subpart B of this part. This may include, for example, researchers performing field experiments, breeders making crosses among plant varieties with the goal of developing new plant varieties, or a person who only sells propagative materials (e.g., seed) to farmers without producing the propagative materials themselves. EPA must receive the report within 30 calendar days of the date the producer first possesses or knows of the information.

(b) Adverse effects on human health or the environment for purposes of plant-incorporated protectant means at a minimum information about incidents affecting humans or other nontarget organisms where both:

(1) The producer is aware, or has been informed, that a person or nontarget organism allegedly suffered a toxic or adverse effect due to exposure to (e.g., ingestion of) a plant-incorporated protectant.

(2) The producer has or could reasonably obtain information concerning where the incident occurred.

(c) All of the following information, if available, must be included in a report.

(1) Name of reporter, address, and telephone number.

(2) Name, address, and telephone of contact person (if different than reporter).

(3) Description of incident.

(4) Date producer became aware of incident.

(5) Date of incident.

(6) Location of incident.

(d) Reports and questions should be submitted to the Office of Pesticide