

§ 340.5

7 CFR Ch. III (1–1–23 Edition)

plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, would pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparator(s), based on the following factors:

(i) The biology of the comparator plant(s) and its sexually compatible relatives;

(ii) The trait and mechanism-of-action of the modification(s); and

(iii) The effect of the trait and mechanism-of-action on:

(A) The distribution, density, or development of the plant and its sexually compatible relatives;

(B) The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;

(C) Harm to non-target organisms beneficial to agriculture; and

(D) The weedy impacts of the plant and its sexually compatible relatives.

(2) APHIS will complete the initial review within 180 days of receiving a request for a regulatory status review that meets the requirements specified in paragraph (a)(4) of this section, except in circumstances that could not reasonably have been anticipated. If APHIS does not identify a plausible pathway by which the GE plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the GE plant is not subject to the regulations in this part. APHIS will post the plant, trait, and general description of the MOA on its website.

(b)(3)(i) If APHIS does identify a plausible pathway by which the GE plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the requestor may apply for a permit and/or request that APHIS conduct an evaluation of the factor(s) of concern identified in the initial review to determine the likelihood and consequence of the plausible increased plant pest risk. APHIS may request additional information as needed to evaluate the factor(s) of concern.

(ii) For those GE plants for which such an evaluation is conducted, APHIS will publish the results of the evaluation in the FEDERAL REGISTER

and will solicit and review comments from the public. Except in circumstances that could not reasonably have been anticipated, APHIS will complete these steps within 15 months of receiving a request for a regulatory status review that meets the requirements specified in paragraph (a)(4) of this section.

(iii) If APHIS finds that the GE plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the GE plant is not subject to this part. APHIS will publish its evaluation of the plant-trait-MOA combination in a subsequent FEDERAL REGISTER document and will also post it on the APHIS website. If APHIS does not make such a finding, the GE plant will remain regulated under this part, and its movement will be allowed only under permit in accordance with § 340.5.

(c) This section is applicable beginning April 5, 2021 for GE corn, soybean, cotton, potato, tomato, and alfalfa, and on October 1, 2021 for all GE plants.

(Approved by the Office of Management and Budget under control number 0579–0471)

§ 340.5 Permits.

(a) *Permit requirement.* A permit from APHIS is required for the movement of all GE organisms subject to the regulations under this part.

(b) *Permit application requirements.* All applications for permits must be submitted in accordance with the requirements of this section. The responsible person must apply for and obtain a permit through APHIS' website. The application must also include the following information:

(1) *General information requirements for all permit applications.* All permit applications must include the name, title, and contact information of the responsible person and agent (if any); the country (or countries) and locality (or localities) where the organism was collected, developed, manufactured, reared, cultivated, and cultured (as applicable); the organism's genus, species and any relevant subspecies and common name information; the intended activity (*i.e.*, importation, interstate

movement, or release into the environment of the GE organism); and information on the intended trait and the genotype of the intended trait. All permit applications must be signed by the responsible person.

(2) *Information requirements for permit applications for interstate movement or importation.* Applications for permits for interstate movement or importation of GE organisms must include the following additional information:

(i) The origin and destination of the GE organism, including information on the addresses and contact details of the sender and recipient, if different from the responsible person;

(ii) The quantity of the GE organism, the method of shipment, and means of ensuring the security of the shipment against unauthorized release of the organism; and

(iii) The manner in which packaging material, shipping containers, and any other material accompanying the organism will be disposed of to prevent unauthorized release.

(3) *Information requirements for permit applications for release into the environment.* Applications for permits for release of GE organisms into the environment must include information on all proposed environmental release sites, including land area (size), Global Positioning System coordinates, addresses, and land use history of the site and adjacent areas; and the name and contact information of a person at each environmental release site, if different from the responsible person. In the event that additional release sites are requested after the issuance of a permit, APHIS will evaluate and amend permits as appropriate, in accordance with paragraph (1) of this section.

(c) *Exemption for GE *Arabidopsis thaliana*.* A permit for interstate movement is not required for GE *Arabidopsis thaliana*, provided that it is moved as a secure shipment, the modified genetic material is stably integrated into the plant genome, and the modified material does not include the complete infectious genome of a plant pest.

(d) *Exemption for GE *disarmed Agrobacterium* species.* A permit for importation or interstate movement is not required for any GE *disarmed Agrobacterium* species, provided that it

is moved as a secure shipment, the modified genetic material is stably integrated into the genome, and the modified material does not include the complete infectious genome of a plant pest.

(e) *Exemption for *Drosophila melanogaster*.* A permit for importation or interstate movement is not required for GE *Drosophila melanogaster*, provided that it is moved as a secure shipment and that any introduced genetic material is not designed to propagate through a population by biasing the inheritance rate.

(f) *Exemption for certain microbial pesticides.* A permit is not required for the movement of any GE microorganism product that is currently registered with the Environmental Protection Agency (EPA) as a microbial pesticide, so long as the microorganism is not a plant pest as defined in § 340.3.

(g) *Exemption of certain plant-incorporated protectants.* A permit is not required for the movement of any GE plant modified solely to contain a plant-incorporated protectant that is currently registered with EPA as a pesticide product pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*, FIFRA) or that is currently exempted from FIFRA pursuant to 40 CFR 174.21.

(h) *Administrative actions—(1) Review of permit applications.* APHIS will review the permit application to determine whether it is complete. APHIS will notify the applicant orally or in writing if the application is incomplete, and the applicant will be provided the opportunity to revise the application. Once an application is complete, APHIS will review it to determine whether to approve or deny the application.

(2) *APHIS assignment of permit conditions.* If a permit application is approved, the Administrator will issue a permit with conditions as described in paragraph (i) of this section. Prior to issuance of a permit, the responsible person must agree in writing, in a manner prescribed by the Administrator, that the responsible person and all agents of the responsible person are aware of, understand, and will comply with the permit conditions. Failure to

comply with this provision will be grounds for the denial of a permit.

(3) *Inspections.* All premises associated with the permit are subject to inspection before and after permit issuance, and all materials associated with the movement are subject to sampling after permit issuance. The responsible person and agents must provide inspectors access to premises, facilities, release locations, storage areas, waypoints, materials, equipment, means of conveyance, documents, and records related to the movement of organisms permitted under this part. Failure to provide access for inspection prior to the issuance of a permit will be grounds for the denial of a permit. Failure to provide access for inspection following permit issuance will be grounds for withdrawal of the permit.

(4) *State or Tribal review and comment.* The Administrator will submit for notification and review a copy of the permit application, without confidential business information (CBI), and any permit conditions to the appropriate State or Tribal regulatory official. Timely comments received from the State or Tribal regulatory official will be considered by the Administrator prior to permit issuance.

(5) *Approval or denial of a permit.* Except in circumstances that could not reasonably have been anticipated, APHIS will approve or deny the permit within:

(i) 45 days of receipt of a complete application for a permit for interstate movement or for importation; or

(ii) 120 days of receipt of a complete application for a permit for release into the environment.

(iii) The 120-day period may be extended if preparation of an environmental assessment or environmental impact statement is necessary.

(i) *Permit conditions.* The standard conditions listed in this paragraph (i) will be assigned to all permits issued under this section. The Administrator may assign supplemental permit conditions as deemed necessary to ensure confinement of the GE organism. Prior to issuance of a permit or an amended permit, the responsible person will be required to agree in writing or electronically that he or she and his or her

agents will comply with the conditions of the permit, as described in this paragraph (i). If the responsible person does not agree to the conditions, the amendment will be denied.

(1) The organism under permit must be maintained and disposed of in a manner so as to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

(2) The organism under permit must be kept separate from other organisms, except as specifically allowed in the permit.

(3) The organism under permit must be maintained only in areas and premises specified in the permit.

(4) The identity of the organism under permit must be maintained and verifiable at all times.

(5) Authorized activities may be engaged in only while the permit is valid; the duration for which the permit is valid will be listed on the permit itself.

(6) Records related to activities carried out under the permit must be maintained by the responsible person and must be of sufficient accuracy, quality, and completeness to demonstrate compliance with all permit conditions and requirements under this part. APHIS must be allowed access to all records, to include visual inspection and reproduction (*e.g.*, photocopying, digital reproduction). The responsible person must submit reports and notices to APHIS, containing the information specified within the permit, at the times specified in the permit. At a minimum:

(i) Following an environmental release, environmental release reports must be submitted for all authorized release locations where the release occurred. Environmental release reports must contain details of sufficient accuracy, quality, and completeness to identify the location, shape, and size of the release and the organism(s) released into the environment. In the event no release occurs at an authorized location, an environmental release report of no environmental release must be submitted for all authorized locations where an environmental release did not occur. Unauthorized releases must be reported in accordance with paragraph (i)(9) of this section.

(ii) When the environmental release is of a plant, reports of volunteer monitoring activities and findings must be submitted for all authorized release locations where an environmental release occurred. If no monitoring activities are conducted, a volunteer monitoring report of no monitoring must be submitted indicating why no volunteer monitoring was done.

(7) Inspectors must be allowed access, during regular business hours, to all locations related to the permitted activities.

(8) The organism under permit must undergo the application of measures determined by the Administrator to be necessary to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

(9) In the event of a possible or actual unauthorized release, the responsible person must contact APHIS as described in the permit within 24 hours of discovery and must subsequently supply a statement of facts in writing no later than 5 business days after discovery.

(10) The responsible person for a permit remains the responsible person for the permit unless a transfer of responsibility is approved by APHIS. The responsible person must contact APHIS to initiate any transfer. The new responsible person assumes all responsibilities for ensuring compliance with the existing permit and permit conditions and for meeting the requirements of this part.

(j) *Denial or withdrawal of a permit.* Permit applications may be denied, or permits withdrawn, in accordance with this paragraph.

(1) *Denial of permits.* The Administrator may deny, either orally or in writing, any application for a permit. If the denial is oral, the Administrator will then communicate, as promptly as circumstances allow, the denial, and the reasons for it, in writing. The Administrator may deny a permit application if:

(i) The Administrator concludes that the proposed actions, *e.g.*, movements under permit, may not prevent the unauthorized release, spread, dispersal, and/or persistence in the environment of the organism; or

(ii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply with any material provision of this part, any other regulations issued pursuant to the Plant Protection Act (7 U.S.C. 7701 *et seq.*) or the Plant Protection Act itself;

(iii) In addition, no permit will be issued if the responsible person and his or her agents do not agree in writing, in accordance with paragraph (h)(2) of this section, to comply with the permit conditions or, in accordance with paragraph (h)(3) of this section, to allow inspection by APHIS.

(2) *Withdrawal of permits.* The Administrator may withdraw, either orally or in writing, any permit that has been issued. If the withdrawal is oral, the Administrator will communicate, as promptly as circumstances allow, the withdrawal, and the reasons for it, in writing. The Administrator may withdraw a permit if:

(i) Following issuance of the permit, the Administrator receives information that would have provided grounds for APHIS to deny the original permit application;

(ii) The Administrator determines that actions taken under the permit have resulted in the unauthorized release, spread, dispersal, and/or persistence in the environment of the organism under permit; or

(iii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any material provision of this part or with any other regulations issued pursuant to the Plant Protection Act (7 U.S.C. 7701 *et seq.*). This includes failure to comply with the conditions of any permit issued.

(k) *Appeal of denial or withdrawal of permit.* Any person whose permit application has been denied or whose permit has been withdrawn may appeal the decision in writing to the Administrator.¹ The applicant must submit in

¹The Office of the Administrator, as established in §371.2 of this chapter, will review appeals involving the denial or withdrawal of a permit. Appeals may be sent to Office of the Administrator, United States Department of Agriculture, Jamie L. Whitten
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writing an acknowledgment of the denial or withdrawal, and a statement of intent to appeal, within 10 days after receiving written notification of the denial or withdrawal. The applicant may request additional time to prepare the appeal. The appeal must state all of the facts and reasons upon which the person relies to assert that the permit was wrongfully denied or withdrawn. The Administrator will grant or deny the appeal in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict.

(1) *Amendment of permits*—(1) *Amendment at responsible person's request.* If the responsible person determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, the responsible person must request the amendment by contacting APHIS directly. The responsible person will have to provide supporting information justifying the amendment. APHIS will review the amendment request, and will amend the permit if APHIS determines that relatively minor changes are necessary. Requests for more substantive changes will require a new permit application. Prior to issuance of an amended permit, the responsible person will be required to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the amended permit. If the responsible person does not agree to the conditions, the amendment will be denied.

(2) *Amendment initiated by APHIS.* APHIS may amend any permit and its conditions at any time, upon determining that the amendment is needed to address plant pest risks presented by the organism or the activities allowed under the permit. APHIS will notify the responsible person of the amendment to the permit and, as soon as circumstances allow, the reason(s) for it. The responsible person may have to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the amended permit before APHIS will

issue it. If APHIS requests such an agreement, and the responsible person does not accept it, the existing permit will be withdrawn.

(m) *Shipping under a permit.* (1) All shipments of organisms under permit must be secure shipments. Organisms under permit must be shipped in accordance with the regulations in 49 CFR part 178.

(2) The container must be accompanied by a document that includes the names and contact details for the sender and recipient.

(3) For any organism to be imported into the United States, the outmost container must bear information regarding the nature and quantity of the contents; the country (or countries) and locality (localities) where collected, developed, manufactured, reared, cultivated, and cultured (as applicable); the name and address of the shipper, owner, or person shipping or forwarding the organism; the name, address, and telephone number of the consignee; the identifying shipper's mark and number; and the permit number authorizing the importation. For organisms imported under permits by mail, the container must also be addressed to a plant inspection station listed in the USDA Plants for Planting Manual, which can be accessed at: https://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/plants_for_planting.pdf. All imported containers of organisms under permits must be accompanied by an invoice or packing list indicating the contents of the shipment.

(4) Following the completion of the shipment, all packaging material, shipping containers, and any other material accompanying the organism will be devitalized consistent with supplemental permit conditions, or disposed of to prevent unauthorized release.

(n) *Applicability date:* This section is applicable beginning April 5, 2021.

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§ 340.6 Record retention, compliance, and enforcement.

(a) *Recordkeeping.* Responsible persons and their agents are required to

Building, Room 312–E, 1400 Independence Ave. SW, Washington, DC 20250.