(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

[70 FR 13278, Mar. 18, 2005, as amended at 77 FR 61077, Oct. 5, 2012]

§ 331.20 Administrative review.

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 180 calendar days of the decision.

(c) The Administrator's decision constitutes final agency action.

[77 FR 61077, Oct. 5, 2012]

PART 340—MOVEMENT OF ORGANISMS MODIFIED OR PRODUCED THROUGH GENETIC ENGINEERING

Sec.

AUTHORITY: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

SOURCE: 85 FR 29832, May 18, 2020, unless otherwise noted.

§ 340.1 Applicability of this part.

(a) The regulations in this part apply to those organisms described in § 340.2, but not to any organism that is exempt from this part under paragraph (b), (c), or (d) of this section.

(b) The regulations in this part do not apply to plants that have been modified such that they contain either a single modification of a type listed in paragraphs (b)(1) through (3) of this section, or additional modifications as determined by the Administrator, and described in paragraph (b)(4) of this section.

(1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or

(2) The genetic modification is a targeted single base pair substitution; or

(3) The genetic modification introduces a gene known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.

(4) The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated, and follow the process in paragraph (b)(4)(i) of this section, or in response to a request made in accordance with paragraph (b)(4)(ii) of this section.

(i) *APHIS-initiated proposals for exemptions.* APHIS will publish a notice in the FEDERAL REGISTER of the proposal by the Administrator to exempt plants with additional modifications. The notice will make available any supporting documentation, and will request public comment. After reviewing the comments, APHIS will publish a subsequent notice in the FEDERAL REGISTER announcing its final determination.

(ii) *Other parties' requests for exemptions.* Any person may request that the Administrator exempt plants developed with additional modifications that could be achieved through conventional breeding. To submit a request, the person must provide, in writing, information supporting the modification(s). Supporting information must include the following:

(A) A description of the modification(s);

(B) The factual grounds demonstrating that the proposed modification(s) could be achieved through conventional plant breeding;

(C) Copies of scientific literature, unpublished studies, or other data that support the request; and

(D) Any information known to the requestor that would be unfavorable to the request.

(iii) *Timeframe for Agency review of requests for additional exemptions.* After APHIS receives all information required under paragraph (b)(4)(ii) of this section, APHIS will complete its review of the request and render a determination within 12 months, except in circumstances that could not reasonably have been anticipated.

(iv) *Denial of requests.* If APHIS disagrees with the conclusions of the request or determines that there is insufficient evidence that the modification could be achieved through conventional breeding methods, APHIS will deny the request and notify the requestor in writing regarding this denial.

(v) *Agreement with requests.* If APHIS initially determines that the modification could be achieved through conventional breeding methods, APHIS will publish a notice in the FEDERAL REGISTER and request public comments in accordance with the process set forth in paragraph (b)(4)(i) of this section. After reviewing the comments, APHIS will publish a subsequent notice in the FEDERAL REGISTER announcing its final determination.

(vi) *website posting.* A list specifying the additional modifications will be posted on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology*.

(c) The regulations in this part do not apply to a plant with:

(1) A plant-trait-mechanism of action combination that has previously undergone an analysis by APHIS in accordance with §340.4 and has been determined by APHIS not to be regulated under this part, or

(2) A plant-trait-mechanism of action combination found in a plant that APHIS determined to be deregulated in response to a petition submitted prior to October 1, 2021, pursuant to §340.6 as that section was set forth prior to August 17, 2020. All plants determined by APHIS to be deregulated pursuant to §340.6 as that section was set forth prior to August 17, 2020 will retain their nonregulated status under these regulations.

(d) The regulations in this part do not apply to plants determined by APHIS not to require regulation under this part pursuant to the ''Am I Regulated'' process. All plants determined by APHIS not to require regulation under this part pursuant to the ''Am I Regulated'' process will retain their nonregulated status under these regulations.

(e) Developers may request confirmation from APHIS that a plant is not within the scope of this part. APHIS will provide a written response (confirmation letter) within 120 days of receiving a sufficiently detailed confirmation request, except in circumstances that could not reasonably have been anticipated.

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

§340.2 Scope of this part.

Except under a permit issued by the Administrator in accordance with §340.5, no person shall move any GE organism that:

(a) Is a plant that has a plant-trait-mechanism of action combination that has not been evaluated by APHIS in accordance with §340.4 or that, as a result of such evaluation, is subject to the regulations; or

(b) Meets the definition of a *plant pest* in §340.3; or

(c) Is not a plant but has received deoxyribonucleic acid (DNA) from a plant pest, as defined in §340.3, and the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease; or

(d) Is a microorganism used to control plant pests, or an invertebrate predator or parasite (parasitoid) used to control invertebrate plant pests, and could pose a plant pest risk; or

(e) Is a plant that encodes a product intended for pharmaceutical or industrial use.

§340.3 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

Access. The ability during regular business hours to enter, or pass to and from, a location, inspect, and/or obtain