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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0030]

State University of New York College of Environmental Science and Forestry: Determination of Nonregulated Status for Blight-Tolerant Darling 54 American Chestnut (*Castanea dentata*)

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that Darling 54 American Chestnut (*Castanea dentata*), which was developed using genetic engineering for tolerance to the fungal pathogen, *Cryphonectria parasitica*, is no longer considered regulated. Our determination is based on our evaluation of information and data submitted by the State University of New York College of Environmental Science and Forestry in its petition for a determination of nonregulated status, available scientific data, a plant pest risk assessment, and public comments received in response to previous notices announcing the availability of the petition for nonregulated status and a draft plant pest risk assessment. This notice announces the availability of our written determination and supporting documents.

DATES: This change in regulatory status is recognized as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may read the petition, our determination referenced in this notice, and supporting documents by any of the following methods:

- Federal eRulemaking Portal: Go to www.regulations.gov. Enter APHIS-2020-0030 in the Search field.
- Our reading room, located in 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to

4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Alan Pearson, Biotechnology Regulatory Services, APHIS, USDA, 5601 Sunnyside Ave, AP100, Beltsville, MD 20705; (301) 851-3944; email: alan.pearson@usda.gov.

SUPPLEMENTARY INFORMATION:

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701-7772, 7781-7786) and the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," APHIS regulates, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340.

On January 21, 2020, APHIS received a petition (APHIS Petition Number 19-309-01p) from the State University of New York College of Environmental Science and Forestry (ESF) seeking a determination of nonregulated status for Darling 58, which was developed using genetic engineering to be tolerant to the fungal pathogen, *Cryphonectria parasitica*. The petition provided information in support of petitioners' position that Darling 58 is unlikely to pose a plant pest risk and therefore should not be regulated under APHIS' regulations in 7 CFR part 340.

As part of our decision-making process regarding the organism's regulatory status, APHIS prepared a draft plant pest risk assessment (PPRA) to assess the plant pest risk of the organism.

On August 19, 2020, APHIS published the ESF petition in the *Federal Register* seeking public comment for a period of 60 days (85 FR 51008-51009; Docket No. APHIS-2020-0030). APHIS received 4,337 total comments on the petition, of which 4,321 were posted to the docket.[1] APHIS received comments from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, Tribes, and unaffiliated individuals. Of the 4,321 comments posted to the docket, the majority were in favor of deregulation of blight tolerant American chestnut, many were in opposition to deregulation, and several were out of scope.

On August 6, 2021, APHIS published a Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) in the *Federal Register* seeking public comment for a period of 30 days (86 FR 43160-43162; Docket No. APHIS-2020-0030). APHIS received 3,968 total comments on the NOI, of which 3,964 were posted to the docket. APHIS received comments from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, Tribes, and unaffiliated individuals. Of the 3,964 comments posted to the docket, a large majority were opposed to the deregulation of blight tolerant American chestnut, many were in favor of the deregulation, and one was out of scope.

On November 10, 2022, APHIS published the draft PPRA and draft EIS in the *Federal Register* (87 FR 67861-67862; Docket No. APHIS-2020-0030) and accepted public comments for a period of 45 days. APHIS extended the comment period for an additional 30 days (87 FR 79273; Docket No. APHIS-2020-0030). APHIS received 30,455 total comments on the draft PPRA and draft EIS, of which 9,289 were posted to the docket. APHIS received comments from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, and unaffiliated individuals. Of the 9,289 comments posted to the docket, the majority were in

[1] Each comment posted on Regulations.gov is assigned a comment ID. Users have the option to indicate whether their comment includes multiple comment submissions. If the user answers in the affirmative, the uploaded comment is given one comment ID but will count as multiple comments under Regulations.gov's tally of "Comments Received". Therefore, Regulations.gov tracks both the number of comments posted and the total number of "Comments Received".

favor of deregulation of blight tolerant American chestnut, many were in opposition to deregulation, some were out of scope, one was an extension request, and three were submitted by EPA stating that "EPA did not identify significant environmental concerns to be addressed in the Final EIS."

Subsequently, in August 2024, ESF submitted a revised petition (APHIS Petition Number 19-309-01p-amended) to provide additional clarifications and corrections about the chestnut event. ESF's original January 2020 petition referred to Darling 58 instead of Darling 54. These two lines were produced at the same time, using the same transgenes in the same genetic background, so they express the same protein products. Multiple analyses in 2023 revealed that essentially all the offspring from the initial crosses were derived from Darling 54, due to a labeling error in 2016. Because nearly all of the phenotypic information in the original petition was generated from Darling 54 offspring, ESF submitted a revised petition to correct the line name and provide updates on Darling 54 chestnuts based on data collected since the original submission. As a result of the revised petition, APHIS evaluated the new information provided on Darling 54 and revised the draft EIS and draft PPRA.

On June 6, 2025, APHIS published a revised draft EIS and draft PPRA in the *Federal Register*, along with the revised petition, seeking public comment for a period of 45 days (90 FR 24090-24091; Docket No. APHIS-2020-0030). APHIS received 174,116 total comments on the revised petition, revised draft EIS, and revised draft PPRA, of which 4,115 were posted to the docket. APHIS received comments from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, and unaffiliated individuals. Of the 4,115 comments posted to the docket, the large majority were in opposition to the deregulation of Darling 54 American Chestnut, many supported deregulation, and several were out of scope.

However, on August 18, 2025, APHIS published a withdrawal of the NOI (90 FR 40050; Docket No. APHIS-2025-0029). Therefore, consistent with this August 18, 2025 *Federal Register* notice, APHIS terminated work on the EIS.

Based on APHIS' evaluation in the PPRA, of information and data submitted by ESF in its revised petition, available scientific data, and public comments received in response to the original and revised petitions and draft PPRAs, APHIS has determined that Darling 54 is unlikely to pose a greater plant pest risk than the nonmodified comparator and therefore is no longer subject to our regulations in 7 CFR part 340 governing the introduction of certain organisms developed using genetic engineering.

Copies of the signed determination, PPRA, and response to comments, as well as the previously published petitions (original and revised) and supporting documents, are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

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

Done in Washington, DC, this 24th day of August 2026.

Sarah Helming,

Acting Administrator, Animal and Plant Health Inspection Service.

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