Public Comment Period FAQs

Please consider voicing your opinion by submitting a public comment

Introduction

Since 1983, The American Chestnut Foundation's (TACF) bold mission has been to rescue the American chestnut tree from the brink of extinction and restore it to the eastern forests of the United States. Using the <u>3BUR approach</u> (Breeding, Biotechnology and Biocontrol United for Restoration) ensures multiple pathways to this goal. We are now at a critical milestone for the biotechnology approach.

A breakthrough discovery by scientists at the State University of New York College of <u>Environmental</u> <u>Science and Forestry</u> (ESF) has helped put this audacious goal within reach. A gene from wheat, known as oxalate oxidase (OxO), was engineered into the genome of the American chestnut. This gene allows the transgenic tree to tolerate blight infections. ESF has named trees with OxO "Darling," in honor of longtime supporter and NY-TACF Chapter member Herb Darling and his family. Rigorously tested for safety and efficacy, the Darling 58 tree shows tremendous promise to tolerate blight infection. Learn more about the <u>Darling 58</u>, a transgenic American chestnut tree.

Because genetically engineered plants must be approved for use by federal agencies, ESF has filed a "Petition for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (*Castanea dentata*)" with the United States Department of Agriculture's office of Animal and Plant Health Inspection Service (USDA-APHIS). This is one part of the U.S. federal government's coordinated framework that also includes the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Approval of the petition is a critical step toward planting this blight-tolerant transgenic tree in unrestricted areas as part of restoration programs.

Public comments play an important role in the review process of USDA-APHIS. We invite you to <u>participate</u> in this groundbreaking opportunity to save the American chestnut. Below are some frequently asked questions about the public comment process. You can also find a full explanation of the review and approval process <u>on this Regulatory Map</u>.

FAQs

What is USDA-APHIS?

The United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is a multi-faceted agency tasked with protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife management activities.

Why is ESF submitting the "Petition for Determination of Non-regulated Status: State University of New York College of Environmental Science and Forestry; Blight-Resistant Darling 58 American Chestnut (Docket Number: APHIS-2020-0030)" to USDA-APHIS and why do we need "nonregulated" status?

Under current rules, regulated transgenic plants can only be grown in confined permitted pots. We are asking USDA-APHIS to approve the nonregulated status of the Darling 58 transgenic tree to allow the tree to be planted in unrestricted areas and released to the public for general use in restoration programs. It is a crucial step to restore the forests, save the American chestnut from extinction and advance the science for saving tree species. An executive summary of the petition can be <u>found here</u>.

What is involved in the federal regulation process for transgenic plants?

For the transgenic American chestnut, three federal agencies will be involved: USDA-APHIS, the Environmental Protection Agency (EPA), and the Food & Drug Administration (FDA). ESF submitted a petition to USDA-APHIS first, because this review will be the broadest and most comprehensive of the three. The open public comment period is an important component of the USDA-APHIS process, during which the agency is looking for feedback or additional information from the public. After the agency considers public feedback and makes changes where appropriate, it will publish a final rule in the Federal Register whereby the agency must describe and respond to the public comments it received.

Why are public comments important?

Public comments are important because they demonstrate support or concern for a particular set of regulations. For this petition, positive public comments will bolster the efforts of thousands of volunteers, researchers and other professionals working for over five decades to save the American chestnut. Ultimately, the risk assessment and decision made by USDA-APHIS will be driven by legal, scientific, economic, and technical information. This input enables the USDA to make a fully informed decision on the petition incorporating both scientific data and public support or concerns.

Who can comment?

Anyone can submit a comment. We are enlisting support from our network of stakeholders including TACF membership, volunteers, and growers. Opinions from scientists, academic researchers, non-governmental organizations and governmental agencies are also expected. Our goal is to demonstrate wide positive support for the Darling 58 and its offspring to rescue the American chestnut. The case of the Darling 58 American chestnut is unique, as it will be the first time a petition has been evaluated for non-

profit use in environmental restoration, so it is important that the USDA hears from many enthusiastic members of the public who want to plant these trees and help restore the forests.

Is it helpful to hear from scientists?

Yes, the USDA will incorporate scientific data throughout the process, and will go through a rigorous scientific review. Professional scientists can think of public comment as a type of peer review for federal regulations. And in this process, commenters who demonstrate an expert understanding of the issue and who can support positions with substantive data are especially valuable to the agency. Public comment periods are designed to cast a wider net for collecting scientific information by encouraging participation from scientists across disciplines and sectors, as well as from knowledgeable chestnut enthusiasts without formal scientific training.

If I am a scientist, what should my comment focus on?

In order to be the most effective and useful to the agency, comments should be original and focus on the scientific arguments for accepting the petition, not a copied and pasted note or form letter. Your comment can report on scientific evidence that supports the theory behind approving nonregulated status for the Darling 58 transgenic tree. Providing additional supporting evidence helps create a stronger scientific foundation for action. <u>Click here</u> to access the full petition.

If I am not a scientist, what should my comment focus on?

It is important to tell your own story, your relationship to the American chestnut, and why you would like to see the Darling 58 tree deregulated for restoration purposes. Some effective messaging points can be found on the <u>Master Messaging Guidelines</u>.

What is the formal name and docket number of the Petition?

The official name is: Petition for Determination of Nonregulated Status: State University of New York College of Environmental Science and Forestry; Blight-Resistant Darling 58 American Chestnut **(Docket Number: APHIS-2020-0030)**

How do I submit a comment?

- 1. Click on this link.
- 2. Confirm that you have selected the **Petition for Determination of Non-regulated Status: State** University of New York College of Environmental Science and Forestry; Blight-Resistant Darling 58 American Chestnut (Docket Number: APHIS-2020-0030)
- 3. Submit your name, organization (if appropriate) and comment.
- 4. Review Public Comment Period <u>Best Practices and Sample Submissions</u> for commenting guidance.

When can I submit my comment?

The public comment period is now open and runs through Monday, October 19, 2020. You can <u>submit a</u> <u>comment</u> at any time during this period.

What kinds of testing has been done by ESF (or others) to ensure the safety and efficacy of the Darling 58 tree?

To date, ESF has conducted a multitude of studies and tests regarding the interaction between the transgenic tree and its ecosystem. <u>These tests</u> have shown no indication of adverse environmental impacts. Nutrition and composition testing has also been performed by commercial food testing labs, demonstrating that transgenic and non-transgenic chestnuts are <u>nutritionally equivalent</u>. Furthermore, test plots to study long-term effects have already been planted to gather additional data before large-scale reintroduction, and allow for any necessary modifications. Blight inoculation tests on Darling 58 have shown that, much like with Chinese chestnuts or hybrids, transgenic chestnuts can get the blight but canker damage is reduced and the trees can persist and thrive after being infected. All of these tests and more are described in detail within the petition.

What happens if the Darling 58 tree is not approved for "nonregulated" status?

The American chestnut tree is at great risk of extinction without human intervention, such as the introduction of the Darling 58 tree and its offspring. Breeding American chestnuts with blight-resistant Asian chestnut species has produced hybrids with intermediate blight resistance. Since Darling 58 retains 100% of its original traits, with only blight tolerance added, breeding Darling 58 with wild-type American chestnuts is one promising approach for rescuing the tree. In the unlikely case there is an insurmountable regulatory hurdle concerning some particular aspect of the Darling 58 tree, ESF is already working on other transgenic lines with improvements or variations that might simplify the regulatory review process.

What happens after I submit my comment?

After submitting your comment, a screen titled "Your Receipt" will appear, which contains a Comment Tracking Number. Enter your email address and click the "Email Receipt" button if you'd like a copy. Once your comment is publicly posted (usually within 24 hours of submission), you can view it online by entering the Comment Tracking Number in the search field on the homepage, or searching by keyword or submitter name. The Comment Tracking Number is also the best way to find or share your comment once it has been posted.

Can I edit a comment once it is submitted?

Comments cannot be revised once submitted. To make changes, submit another comment referring to your previous comment correcting any errors and/or re-stating your position or evidence.

How long does the review process generally take?

Once the public comment period ends (60 days after opening), the agency may initiate an optional reply comment period to allow interested parties to respond to submitted comments and facilitate a discussion. They may also choose to extend the public comment period if they are unsatisfied with the quality of feedback or if commenters requested additional time to respond. After reviewing public comments, the agency then determines whether to revise the proposed rule, abandon the proposal, or move forward to the final stage of the informal rulemaking process, generally lasting between 30-60 days. The overall USDA review process timeline for a new crop is estimated to take approximately 18 months, but the American chestnut is unique and may take longer.