CENTER FOR FOOD SAFETY

January 26, 2023

Center for Food Safety & International Center for Technology Assessment

RE: Comments on Draft Environmental Impact Statement and Draft Plant Pest Risk Assessment for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (*Castanea dentata*) Developed Using Genetic Engineering

Docket No.: APHIS-2020-0030

Comments and all supporting materials listed in the References section submitted electronically to: https://www.regulations.gov/commenton/APHIS-2020-0030-8291

Center for Food Safety (CFS) and International Center for Technology Assessment (ICTA) appreciate the opportunity to comment[1] on the draft Environmental Impact Statement (dEIS)[2] and draft Plant Pest Risk Assessment (dPPRA)[3] prepared by US Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) [Docket No. APHIS–2020–0030] to assess impacts of approving the Petition for Determination of Nonregulated Status for Blight-tolerant Darling 58 American Chestnut (*Castanea dentata*) (ESF 2020 Petition).

As part of these comments, please incorporate the CFS and ICTA comment from October 19, 2020 (01 CFS Comment GE American chestnut APHIS 10-19-20.pdf at Comment ID APHIS-2020-

[1] Federal Register/Vol. 87, No. 217/Thursday, November 10, 2022/Notices; pp 67861-67862: 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; Availability of a Draft Environmental Impact Statement and Draft Plant Pest Risk Assessment for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (*Castanea dentata*) Developed Using Genetic Engineering. Extension of Comment Period, FR 79273, Dec 27, 2022: APHIS-2020-0030-11678.

[2] Draft Environmental Impact Statement: The State University of New York College of Environmental Science and Forestry Petition (19-309- 01p) for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (*Castanea dentata*), OECD Unique Identifier: ESF-DAR58-3. USDA Animal and Plant Health Inspection Service, July 2022.

[3] Draft Plant Pest Risk Assessment: State University of New York College of Environmental Sciences and Forestry Petition (19-309- 01p) for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut, OECD Unique Identifier: ESF-DAR58-3. USDA Animal and Plant Health Inspection Service, June 2022.

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0030-4295) on the Petition which includes EIS scoping [4]; and the comment-associated supporting materials (Comment ID APHIS-2020-0030-4295, 4293, 4292).

Blight-tolerant American chestnut (*Castanea dentata*) Darling 58 cultivar (D58) is genetically engineered with an oxalate oxidase (OxO) gene derived from wheat that is intended to allow offspring that receive it to survive infections from the ascomycete fungus *Cryphonectria parasitica* well enough that the trees can become dominant overstory species in forests again. This is a project to rapidly domesticate a wild species through genetic engineering and accelerated breeding, and then to put it back into ecosystems to form self-perpetuating populations (Westbrook et al 2020 at 94) – an intentional evolutionary intervention that has never been attempted before with any species. The large spatial scale throughout eastern North America (ESF 2020 at 25, 27) and long timeline of more than a century to gauge full impacts (ESF 2020 at 39-40) requires that this unprecedented experiment be carefully evaluated before deregulation by the APHIS.

The researchers at State University of New York College of Environmental Science and Forestry (ESF) who developed D58, under the direction of Prof William Powell, prepared and submitted a Petition for Determination of Nonregulated Status (Petition), which APHIS made public and available for comment (Federal Register/Vol. 85, No. 161/Wednesday, August 19, 2020/Notices: 51008-09) (ESF 2020).

Now APHIS calls for public comment on dEIS and dPPRA documents that assess impacts of approving the Petition, and Plant Pest Risks associated with environmental release of D58 (Federal Register/Vol. 87, No. 217/Thursday, November 10, 2022/Notices; pp 67861-62, deadline extension).

The evidence and conclusions in the pPPRA and dEIS do not support granting the petition, and are contrary to NEPA and the PPA's mandates to rigorously analyze all foreseeable risks and base any determination on sound science

ESF's William Powell claims that because regulation of D58 will grease the skids for genetically engineered trees to come that APHIS was "extra careful" in its review of this "most studied tree…in history".[5] (ESF 2021 at 5-6).

[4] NOI at https://www.regulations.gov/document/APHIS-2020-0030-4324: "Those who have already submitted comments on the ESF petition need not resubmit—we will consider these comments in development of the EIS."

[5] Powell states: "This will be the first restoration tree developed with the tools of biotechnology. But it won't be the last. The Darling American chestnut trees will pave the way to rescue many other threatened tree species such as the American elm and others. Therefore, the regulators are being extra careful and giving our trees extensive review. The Darling American chestnut trees will be one of the most studied variety of trees in history. By doing this, it will make it easier and faster for future restoration trees because the regulators will be much more familiar with the development of restoration trees." (ESF 2021, https://www.esf.edu/chestnut/progress-report/2021.htm at 5-6).

On the contrary, CFS has already explained how there are not enough observations and data regarding D58 in the Petition for APHIS to be able to assess plant pest risks and environmental, health and other impacts of D58 (CFS 2020). This is still the case, as the observations and data APHIS relies on in the pPPRA and dEIS for D58 growth, development, and interactions with other organisms are not substantially different from those in the Petition. APHIS has forged ahead with the deregulation process anyway, despite the requirement that it base its decision on sound science and not be contrary to the record before it.

For example, in the dPPRA and dEIS, as in the Petition, data for growth and development of D58 (CFS 2020 at 2, Petition at 82, 231), does not span key aspects of the American chestnut life-cycle necessary to assess impacts of D58.

In its dPPRA, APHIS ostensibly examined the "[p]otential spread of OxO to other Castanea species" (dPPRA at 16) to assess impacts of the spread of the transgene in D58 to related species with which it can mate. Indeed, basic information on D58's reproductive behavior in field conditions are needed to assess plant pest risks and environmental impacts. Such information is critical for determining the likelihood that D58 will mate with sexually compatible relatives, of which there are several in North America (dEIS at 4-28), and under what conditions. Reproductive behavior is also key to predicting rate of spread and thus assessing weediness (DEIS at 4-27– 4-29), restoration potential, and impacts on other species that use pollen and nuts (DEIS at 4-23 – 4-25; 4-29 – 4-30).

Yet APHIS admitted there were no data at all on pollination rates of D58, an important parameter of reproduction, nor for any other aspect of reproduction:

> There is [sic] no data on natural pollination rates for Darling 58 trees yet. However, there is no reason to expect that pollen viability, fertilization rates, or any other aspect of sexual reproduction would differ between Darling 58 American chestnut and unmodified American chestnut. (dPPRA at 16)

Thus, APHIS' unfounded conclusion that there is "no reason to expect" differences in reproductive parameters is not based on sound science (CFS 2020). This conclusion also directly contradicts the National Research Council's admonition to APHIS to cease relying on "absence of evidence" as an illegitimate stand-in for "evidence of absence" (NRC 2002, pp. 10-111, 149). It is well documented that the phenotype of each transformation event must be observed and analyzed throughout the plant's life stages in relevant environmental conditions, and it is standard practice for differences between events to be evaluated by biotechnologists before choosing particular transformation events to meet intended goals. A case in point: studies of other genetically engineered trees show unexpected impacts to flowers that would not be predicted from the intended change; for example, Sala Junior et al. 2008, cited in CFS 2020, found that sweet orange trees genetically engineered to express an antibacterial peptide had floral nectar that was significantly different in composition vis-a-via its unmodified counterpart, and discussed potential adverse effects this altered nectar could have on the GE tree's pollination and on pollinators visiting the GE tree.

APHIS under-estimated pollination distances and rate of spread from seeds using outdated and inappropriate studies, when there are more relevant data leading to the conclusion that in some realistic scenarios D58 can spread from initial plantings more quickly with greater impacts (Davis 2023 at 2-5, Mazurowski et al 2022, Stoltz and Husband 2022, Canadian Chestnut Council 2022).

Pest and disease impacts of D58 are also central to the dPPRA upon which APHIS bases its deregulation decision. But APHIS' criteria for plant pest and disease impacts of D58 are agriculture-oriented, and not fit for the purpose of restoration of a wild species to a native ecosystem such as this one (dPPRA at 7).

Even within APHIS' limited scope, data comparing pest and pathogen impacts of D58 in greenhouses and short-term field trials are not adequate to assess risks. APHIS claimed no significant differences in pests and pathogens based on vague observations in unrealistic conditions (dPPRA at 15-16: for example, "[m]odified and unmodified American chestnuts in greenhouse conditions do not appear differentially susceptible to damage from common greenhouse pests such as mealybugs, spider mites, and powdery mildew," pests that have little relevance in forests.)

Also, pest and pathogen behaviors are likely to change with tree age and variable environmental conditions and thus require observations over more time and locations for reliable conclusions of any sort (CFS 2020 at 5-6). As CFS has noted, no D58 trees grown outdoors from seed were older than a few years in studies APHIS has relied upon. APHIS stated that D58 has been grown in field trials since 2011 (dPPRA at 7), but this is a mistake. D58 was first regenerated from embryo culture in 2013 (Petition at 74). Seed-grown D58 was first planted in field trials in 2017 (Petition at 82, 231). Clearly, part of the scientific cure for lack of data should be to grow D58 for enough years and locations in regulated field trials to accumulate appropriate data to assess risks.

In addition to the above, CFS previously identified myriad problems with the science used in the Petition to assess risks (CFS 2020) that APHIS did not remedy in the dEIS and pPPRA, including: reliance on studies that use genetically engineered American chestnut events other than D58; failure to examine impacts of potential changes in tolerance to *Cryphonectria parasitica* over time including OxO gene silencing and ecology of cankers on D58; no information on other OxO-sensitive organisms in forest ecosystems that could be affected, and lack of analyses of changes to population genetics of chestnut species from D58 deregulation.

Human nature: foreseeable impacts of human-assisted dispersal and cross-fertilization are severely underestimated

In the dEIS, APHIS arbitrarily limited the scope of its analyses by only considering impacts of planting D58 for purposes of forest restoration within its historical natural range, underestimating impacts of human-caused dispersal and disregarding the likely use of D58 and its progeny in agricultural nut production and restoration schemes.

For restricting the affected environment to the historical range of American chestnut, APHIS cited the stated intentions of the petitioner to go slow in reintroducing D58 as research proceeds:

> Although the Preferred Alternative would allow for new plantings of Darling 58 American chestnut to occur anywhere in the United States the petitioner has stated their intention is ecological restoration and that initial distribution will consist of long-term research plots and relatively small-scale public horticultural plantings and will focus on areas where there are surviving small remnant American chestnut populations. For this reason, APHIS considered the affected environment for this EIS to be those areas of the United States where American chestnut was once a dominant forest tree (dEIS at iv)

In fact, ESF developers and The American Chestnut Foundation (TACF) collaborators have promoted plans to widely distribute D58 materials for propagation as soon as they get the green light from regulators, whipping up excitement in a subset of people likely to grow chestnuts. Thus there is every reason to believe that these enthusiasts will rapidly disseminate D58 progeny far and wide in a chaotic fashion. Even if, contrary to this evidence, the "initial distribution" of D58 were to be limited in scope as APHIS assumes in the above passage, the agency's assessment duty is not limited to the impacts of the most immediate of actions the developer might take (***initial*** distribution), but rather must encompass impacts of the full range of foreseeable actions a determination of nonregulated status would enable. Therefore, APHIS must consider impacts in a much larger affected environment than just the historical range, and for purposes beyond ecological restoration of American chestnut (CFS 2020, ESF 2021).

Wider impacts from humans as dispersal agents and cross-pollinators are eminently foreseeable because the developers of D58 explicitly reported (ESF 2021) that steps are already being taken to 1) intentionally cross D58 with chestnut species and varieties used in nut production for "agricultural American chestnut hybrid restoration," 2) cross D58 with the related Ozark Chinquapin species for restoration attempts using the same genes and strategies, 3) transfer OxO to European chestnut species, and 4) use different promoters with the OxO wheat gene to experiment with expression patterns. In 2021, ESF noted the following chestnut research progress:

- Pollinations occurred mainly on pure American chestnut mother trees for the primary goal of restoration, but this year we had enough pollen to perform controlled pollinations on other Castanea species and interesting agricultural varieties including Allegheny chinquapin, Bouche de Betizac hybrid, Luvall's Monster hybrid, and Bill's Chinese hybrid, to name a few. These may help in future areas of agricultural American chestnut hybrid restoration, another value of the American chestnut trees.
- Nearly 200 nuts were produced from crosses between Ozark Chinquapin mother trees and Darling 58 pollen. These nuts will begin our plan to breed OxO into blight susceptible Ozark chinquapins and help restore this closely related species that was also devastated by the chestnut blight.
- From the tissue culture lab, over 200 T2 trees were produced clonally, many of which went into holding plots for future distribution. In addition to many American chestnut

trees, some of our first American/European hybrids were also propagated for field testing. European chestnut is also susceptible to blight and this is a first step to bringing the OxO gene into that species.

- Thirteen new, diverse genotypes from the 2020 controlled crosses were successfully initiated into tissue culture. Two of these cultures include the first T1s of the wound/pathogen inducible promoter lines that help target the expression of OxO to the infection sites. We hope that some of these cultures will become pollen parents for the 2022 pollination season.

(ESF 2021 at 2, partial list, underlining ours)

Based on the stated intentions and experimental progress of ESF, TACF, and others, APHIS must consider and analyze the impacts of human-mediated crossing and dispersal of D58-derived chestnut lines and species for myriad purposes. It must also consider agency decision alternatives that would restrict any such further usage.

Instead, APHIS ignored the evidence of intent to use D58 in agriculture and stated that "no socioeconomic impacts are expected from deregulation" of D58, in part because it "is not expected to be used in commercial plantings for timber or nut production for the foreseeable future" (dEIS at vi).[6] On the contrary, the evidence cited above shows clearly that developers of D58 foresee using it and crosses thereof for agricultural purposes, necessitating consideration of all relevant impacts in the EIS and PPRA.

APHIS also failed to account for the role that intentional hybridization of D58 with related species will have on the ease with which cross-pollination will occur in the future (dEIS at vi, 4-28)[7]. In fact, flowering of intentionally produced D58 hybrids may be more synchronous with various sexually compatible relatives. Also, members of ESF, TACF and other humans routinely

[6] dEIS at vi: "No socioeconomic impacts are expected from deregulation of Darling 58 American chestnut for several reasons. As noted above, Darling 58 American chestnut is not expected to be used in commercial plantings for timber or nut production for the foreseeable future. The draft EIS considered whether Darling 58 American chestnut could impact commercial plantings of chestnut via cross pollination, especially those chestnuts produced for a biotech sensitive market. Gene flow from Darling 58 American chestnut to commercial chestnut is considered unlikely for several reasons. Darling 58 American chestnut is most likely to be planted in the native American chestnut range while the majority of commercial chestnut production (58%) occurs in states outside the native range (USDA-NASS 2019). Darling 58 American chestnut is a different species than the chestnut used for commercial production and so, successful hybridization occurs at a lower frequency than within the species (ESF 2019). Chinese chestnut also usually flowers earlier than American chestnut which decreases effective cross-pollination (Pennsylvania Chapter The American Chestnut Foundation 2006). And finally, chestnut pollen does not travel long distances. Effective pollination does not occur beyond 400 m (Forest et al. 1977; Russell 1987; Rutter 1990) so there is likely to be adequate isolation distances between Darling 58 American chestnut and chestnut orchards catering to the biotech sensitive markets. …."

[7] dEIS at 4-28: "Although chestnut species are sexually compatible, crossing efficiency in the wild between species is less efficient than within the species because flowering times often are not coincident…".

store chestnut pollen to facilitate crosses between cultivars and species that flower at different times and locations (see, for example, ESF 2021).

In determining the affected environment, APHIS must also consider the effects of climate change on the projected range of American chestnut, as well as pest and pathogen pressure and other factors that dictate where American chestnut will succeed or fail (CFS 2020 at 9, Barnes and Delborne 2020, Clark et al 2022, Gustafson et al 2022).

APHIS did not assess impacts of granting this Petition on regulation of other OxO lines

CFS asked APHIS to clarify the impacts of granting this Petition under legacy rules on the regulatory status of other blight resistant chestnuts developed using wheat OxO genes (CFS 2020 at 7-8).

APHIS briefly responded that "[a] determination of nonregulated status and this EIS would not necessarily apply to other blight tolerant American chestnut events as APHIS' regulatory practice is to review requests on a case-by-case basis." (dEIS at iv)

However, from the language of the regulations, it is clear that under the Part 340 rules operating now – 7 CFR § 340.1(c)(2)[8] – petitions granted under legacy Part 340 rules automatically create an exemption from APHIS regulation for other transformation events that are similar (same trait and mechanism of action in the same species or plants with which that species can mate), that APHIS has referred to as Plant Trait Mechanism of Action (PTMOA) combinations (https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/moa/moa-table).

For example, in 2021 Okanagan Specialty Fruits Inc requested (Okanagan Specialty Fruits 2021) and was granted (APHIS 2021) the PTMOA combination exemption (7 CFR § 340.1(c)(2)) for a genetically engineered apple tree based on a petition granted for nonregulated status of an independent transformation event in a different apple variety in 2014

[8] **Federal Register**/Vol. 85, No. 96/Monday, May 18, 2020/Rules and Regulations **29832-33. PART 340—MOVEMENT OF ORGANISMS MODIFIED OR PRODUCED THROUGH GENETIC ENGINEERING. § 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.
…
(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.

(https://www.aphis.usda.gov/biotechnology/downloads/confirmation-response/21-105-01cr.pdf):

> Type of Claim for regulatory exemption:
> We are requesting the exemption of Nonbrowning Arctic® apple Event HCR835 from regulation under USDA-APHIS article 7 CFR Part 340.1(c)(2) which states "a plant-trait-MOA combination that is the same as that in a plant of the same species APHIS determined to be nonregulated in response to a petition submitted prior to October 1, 2021, pursuant to 340.6 of the previous regulations found at 7 CFR part 340." We believe that our request qualifies under this article since USDA has previously reviewed petitions pertaining to the low PPO trait in the tree crop apple (*Malus* × *domestica*) developed by this applicant (Okanagan Specialty Fruits Inc.), and determined that nonbrowning apples modified to reduce polyphenol oxidase are unlikely to pose a plant pest risk. (21-105-01cr at 2)

Although Okanagan did approach APHIS for confirmation of the exemption, this was Okanagan's choice (§ 340.1(e)). Developers of D58-like chestnut trees who self-determine they are exempt based on this D58 Petition being granted would not have to approach APHIS at all, giving APHIS no cases to review case-by-case or otherwise.

Thus any similar future approvals may escape any APHIS oversight or analysis entirely, underscoring the importance that APHIS analyze those risks of creating this precedent with this proposed action.

Such D58-like transformation events that exist now as regulated "legacy events" (e.g., those used as surrogates for D58 in many of the environmental assessments, CFS 2020) and are also being produced under regulation as listed in the ESF 2021 Progress Report, will presumably be exempt from regulation by APHIS if the petition for D58 is granted. We presume APHIS also has records of D58-like events grown in regulated field trials over the years, including those that have not been terminated and thus would be readily available for unregulated dissemination.

The cumulative and other impacts of concurrent deregulation-by-exemption of similar OxO chestnut lines and species if this D58 Petition is granted must be assessed, as CFS discussed previously (CFS 2020 at 7: "All of these new and "legacy" OxO-engineered American chestnut trees will join the gene pool that includes Darling 58. Potential impacts of intentional or natural "stacking" of various OxO events must be considered, including increases in OxO levels with more gene copies and different regulatory elements that increase non-target exposure, or conversely, gene silencing that may reduce tolerance to blight.").

Also missing from the dEIS: a range of reasonable alternatives, and ESA consultation with appropriate agencies

APHIS shirked its duty under NEPA to consider and analyze a range of reasonable alternatives. Instead it only considered 2 alternatives, stating that its hands are tied by its finding of no plant pest risk, citing a Plant Pest Risk Assessment from 2020:

> Based on the PPRA for Darling 58 American chestnut (USDA-APHIS 2020), experience regulating organisms developed using genetic engineering, and broad general experience with plant varieties, APHIS determined that Darling 58 American chestnut trees are unlikely to pose a plant pest risk. Thus, the imposition of testing, release/planting, and/or isolation requirements on Darling 58 American chestnut would be inconsistent with the Agency's statutory authority under the plant pest provisions of the PPA, implementing regulations at 7 CFR part 340, and federal regulatory policies embodied in the Coordinated Framework. Because it would be unreasonable to evaluate alternatives absent any jurisdiction to implement them, these additional alternatives stated above were dismissed from detailed analysis in this EA. (dEIS at 3-4)

However, there is no PPRA from 2020. The current draft Plant Pest Risk Assessment is included in this 2023 comment period[9] and thus has not been finalized. Also, this is a draft EIS, not an EA. Beyond that, APHIS has plenary authority under the PPA, as shown by its discretionary decision to revise its new Part 340 regulations. This includes the ability to apply the noxious weed authority to novel proposed GE trees like this one.

Finally, APHIS did not consult with expert wildlife agencies on the potential risks to Endangered Species Act-listed species ensuing from the grant of non-regulated status to D58. Given the potential impacts over much of North America, it must do so. APHIS does not have the requisite expertise regarding listed species and their habitats. As discussed above, APHIS has also based its "no effect" determination (dEIS at 4-54) on faulty scientific information (for example, lack of data on reproductive parameters, use of events other than D58 in experiments, and other deficiencies noted in CFS 2020 and these comments).

[9] Draft Plant Pest Risk Assessment: State University of New York College of Environmental Sciences and Forestry Petition (19-309- 01p) for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut, OECD Unique Identifier: ESF-DAR58-3, June 2022.

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CFS, 2020. https://www.regulations.gov/search?filter=aphis-2020-0030, 01 CFS Comment GE American chestnut APHIS 10-19-20.pdf at Comment ID APHIS-2020-0030-4295; cited supporting materials, Comment ID APHIS-2020-0030-4295, 4293, 4292.

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