GeneWatch UK reponse to the USDA APHIS consultation: Environmental Impact Statements; Availability, etc.: State University of New York College of Environmental Science and Forestry; Draft Plant Pest Risk Assessment for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (Castanea dentata) Developed Using Genetic Engineering

December 2022

This comment relates to the two new documents available on:
https://www.regulations.gov/search?filter=APHIS-2020-0030

1. 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, June 2022. Available on: https://www.regulations.gov/document/APHIS-2020-0030-8290

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), July 2022. Available on: https://www.regulations.gov/document/APHIS-2020-0030-8289

GeneWatch UK notes that:

(i) The draft Plant Pest Risk Assessment (PPRA) does not consider or address the issue raised in our previous submissions that Darling 58 genetically engineered (GE) American Chestnut trees can act as a reservoir for blight, posing a serious risk of infection to native and commercially planted trees, i.e. a plant pest risk. This failure renders this document invalid and also invalidates the Draft Environmental Impact Statement (EIS) which relies on it.

(ii) The draft Environmental Impact Statement (EIS) includes no new evidence regarding the Darling 58 GE trees or their interaction with the environment, including the target fungus (chestnut blight) and other pests, but relies solely on the previous data supplied by the applicant (cited as EIS, 2019), plus some general information regarding forest ecosystems and the role of American Chestnuts. This means that the major gaps in evidence that we identified in our previous submissions have not been addressed.

We therefore resubmit our previous submission, detailing our concerns about the proposal to deregulate these GE trees: GeneWatch UK submission to USDA APHIS re Nonregulated Status for GM American Chestnut (23rd September 2020). Available on:
http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/genewatch-uk-aphis-ge-chestnut-fin.pdf

In addition, we note that USDA's EIS has not assessed any environmental effects of migration of the GM tree across the U.S. border, despite being required to do so (NAS, 2019, page 155[1]).

We note that the largest Darling 58 GE trees alive were only about 3 years old when the evidence relied upon in the petition for deregulation was produced, and that no Darling 58 trees are yet mature enough to produce female flowers. This stands in stark contrast to the timescales over which

[1] *Forest Health and Biotechnology: Possibilities and Considerations*. (2019). National Academies Press. https://doi.org/10.17226/25221

these GE trees will impact ecosystems. Individual trees may live hundreds of years (even if they remain stunted by blight and do not become canopy trees), and the uncontrolled spread of pollen and chestnuts means they will impact ecosystems in perpetuity.

As before, we find that:

- The Petition is seriously premature, due to lack of any long-term data and the many significant gaps in the data that is available.
- Darling 58 GE American Chestnut trees can act as a reservoir for blight, posing a serious risk of infection to native and commercially planted trees, i.e. a plant pest risk.
- The applicants have not established whether the GE trees will show long-term blight tolerance or be able to survive and grow to canopy trees; however, poorly growing (or dying/dead) GE trees will still pose a plant pest risk and may remain part of ecosystems for centuries.
- Numerous long-term ecological risks have not been assessed.
- The applicants have not established whether or not GE pollen will cause allergies, despite the fact this risk may continue in the environment indefinitely if deregulated status is granted.
- There is no precedent for releasing a genetically engineered organism with an antibiotic resistance gene into natural ecosystems, as proposed. This risk has not been addressed at all in the Petition. The use of an antibiotic marker gene in these GE trees poses unnecessary risks and should have been avoided.
- Non-regulated status would make it impossible to trace and monitor the trees, or the GE chestnuts they produce. Distribution of chestnuts and pollen would not be controllable. For example, people could plant GE trees or GE chestnuts in a wide variety of ecosystems, including in countries where such plantings would be illegal. This could occur unwittingly since any chestnut picked up in a forest may turn out to be GE.
- Information provided in the petition regarding unintended pollination, due to late bagging of flowers, seriously undermines confidence in the ability of the applicants to meet permit regulations, as well as highlighting that cross-pollination can easily occur.
- GE chestnuts have yet to be approved as safe to eat, and in any case cannot be labelled if they are not traceable. This has the potential to breach GE food labelling laws and pose a threat to chestnut selling businesses, as well as posing potential risks to human and animal consumers of the chestnuts.
- Deregulation cannot be considered until the GE chestnuts are FDA-approved, as to do otherwise could put human health at risk. Approvals from the Canadian Food Inspection Agency (CFIA) and Health Canada are also necessary prior to considering granting non-regulated status, as GE chestnut trees could be introduced or spread naturally across the border once they are released.
- Even if the FDA does grant approval, it is hard to see how GE food labelling requirements can be met unless the GE trees are traceable. This means they cannot be deregulated.

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