Unintentional International Movement of GE Trees: Regulatory Response Scenarios

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Presentation Outline

- General Concepts
- Domestic and International Obligations
- Introduction to the Scenarios
- Scenario 1 – Blight Resistant GE Chestnuts
- Scenario 2 – Low Lignin GE Poplar
- Conclusions
Each country must comply with both their respective domestic regulations and international obligations.

Each country prevents the entry of plant pests and animal diseases through domestic regulations and a border presence.

While some GE trees have been commercialized, they have all been developed as purpose-grown trees.

There have been no examples to date of unconfined releases of GE trees into wild lands.

GE chestnut has the potential to be the first GE tree intentionally released into the wild, with establishment and persistence as an objective.

Some voluntary forest certification systems exclude use of GE trees.

More than 2/3 of Canadian forests are certified by such systems.

These systems could complicate the scenarios presented today.
Asynchronous vs Asymmetric Approvals

- **Asynchronous Approval** – An approval for commercial cultivation of a GE organism in another country in cases where *APHIS has received a petition* for a determination of nonregulated status.

- **Asymmetric Approval** – An approval for commercial cultivation of a GE organism in another country in cases where *APHIS has not received a petition* for a determination of nonregulated status.

Asynchronous approvals can result in transient trade issues.
- There are currently no asynchronous approvals for unconfined environmental release between the United States and Canada.

Asymmetric approvals can result in enduring trade issues.
- Asymmetric approvals for GE trees could result in international disputes.
The Trilateral Technical Working Group (TTWG) is comprised of agricultural biotechnology regulators from the United States, Canada, and Mexico.

The TTWG meets annually face-face and conducts quarterly conference calls.

Each country provides updates on their respective regulatory actions.

The three countries are well aware of each country’s GE crop approvals and GE crop development pipelines.

During 2018, the TTWG will visit a confined field trial (CFT) of GE American chestnut.
APHIS Domestic Obligations

**APHIS-Biotechnology Regulatory Services (BRS)**

- 7 CFR Part 340
  - Regulates the introduction of certain GE plants which may be plant pests.
  - When a “Determination of Non-Regulated Status” is granted, the GE plant may be moved and planted without APHIS oversight.

**APHIS-Plant Protection and Quarantine (PPQ)**

- 7 CFR Part 319
  - Regulates the introduction of plants that may harbor plant pathogens.
    - Many plant species are “prohibited” from entry into the United States.
- 7 CFR Part 360
  - Regulates the introduction of plants that may be noxious weeds.
The International Plant Protection Convention (IPPC)

- The purpose of IPPC “is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control”.
- The protection it affords extends to natural flora and plant products, and includes both direct and indirect damage by pests, including weeds.


- A standard for Pest Risk Analysis (PRA) of living modified organisms (LMOs) was adopted in 2004.
  - However, not all LMOs will present a pest risk.
  - APHIS PRA procedures for GE organisms are consistent with the IPPC guidance.

The North American Plant Protection Organizations (NAPPO)

- Cooperation among member countries to prevent the entry, establishment and spread of quarantine pests and to limit the economic impact of regulated non-quarantine pests while facilitating international trade in plants, plant products and other regulated articles.
**Scenarios – General Thoughts**

**Scenario**

- A GE tree is approved for release in one country (country #1), but not in a neighboring country (country #2).
- The GE tree is fully fertile and is capable of persisting in the wild.
  - Concerns about the spreading of GE trees could be mitigated with traits that alter fertility (ex. male sterility).
- Without human assistance, the GE tree spreads from country #1 to country #2.
- Because the GE tree has not been authorized for release in country #2, some type of science-based regulatory review would occur.
- The response, if any, would depend on the review and the legal authority, obligations and flexibility of federal or local authorities.
Potential actions will depend on the results of science-based risk assessments.

In the United States, the APHIS-BRS assessment could include:
- A Plant Pest Risk Assessment (PPRA) and an Environmental Assessment (EA).
  - For some GE trees, an Environmental Impact Statement (EIS) may be needed.
  - For GE trees, APHIS-BRS collaborates with the US Forest Service during the preparation of technical documents.
- The environmental analysis (EA or EIS) would address EO 12114 – Environmental Effects Abroad of Major Federal Actions
  - Includes environmental effects that may occur outside the United States.

In the United States, the APHIS-PPQ assessment could include:
- A Pest Risk Assessment (PRA) and/or a Weed Risk Assessment (WRA).

In Canada, the CFIA assessment could include an environmental risk assessment conducted by Environment Canada.

Both countries analyze potential weediness of the GE plant, potential weediness of related plants following gene flow, and impacts on beneficial organisms.
Scenarios – Potential Actions

- **Quarantine and Mitigation**
  - Quarantine may include monitoring of the restricted area and restrictions on movement of plant material from the affected area.
  - Mitigation may include destruction of the unauthorized GE trees.
  - Potential actions would be communicated to the US Forest Service and to State Plant Regulatory Officials in the affected area.

- **Granting Approval (i.e., making it legal).**
  - APHIS could request that the developer of the GE tree submit a petition for a determination of nonregulated status.
  - Alternatively, APHIS has the option of conducting a determination in the absence of a petition.
Project Overview

- American Chestnut (*Castanea dentata*) was once a dominant member of North American hardwood forests, but has been widely eliminated by the accidental introduction of chestnut blight from Asia.
- In 1990, the State University of New York’s College of Environmental Science & Forestry (ESF) and the New York chapter of The American Chestnut Foundation (TACF) began a collaboration to develop GE chestnut with resistance to chestnut blight.
- The objective is the restoration of an entire ecosystem.

Biology of Chestnut

- Mostly outcrossing.
- No long distance pollen or seed dispersal.
- Vegetative reproduction by stump sprouts.
Scenario 1 – Natural Range of American Chestnut

- The American chestnut tree once reigned over 200 million acres of eastern woodlands from Maine to Florida.

- An estimated 4 billion American chestnuts, up to 1/4 of the hardwood tree population, once grew within this range.

Source

The American Chestnut Foundation
https://www.acf.org/
Gene of Interest: Oxalate oxidase derived from wheat
Current Field Tests: Over 18 acres authorized at sites in NY, VA, GA, and SC
Regulatory: APHIS anticipates receiving a Petition for a Determination of Nonregulated Status in 2018.

The developers are also preparing regulatory submissions for EPA and FDA.
The GE chestnut has not yet been field tested in Canada.
  However, the developers have been in contact with Canadian regulators.

Considerations

- May provide a variety of ecosystem services.
- May have positive impacts on endangered species.
- May allow the rescue of surviving American chestnut genetic diversity.
If USDA-APHIS “de-regulated” GE Chestnut:

- The PPRA associated with the deregulation would address the potential for impacts on plant health, weediness and invasiveness.
- The environmental analysis (EA or EIS) associated with the deregulation would address:
  - Impacts on land use, air quality, soil resources, water resources, wildlife, insect and disease pests, biological diversity, and threatened and endangered species.
  - EO 12114 – “Impacts outside the United States” could be analyzed.
- USDA regulators and Canadian regulators routinely share information on regulatory actions during bilateral and trilateral meetings.
  - There would be no surprise when the GE chestnut arrived in Canada
- If this were an asynchronous approval, there would typically be only 1-3 years before the Canadian review was completed.
If the GE Chestnut were approved only in Canada, and later found growing in the United States:

- The USDA-APHIS-BRS response could include:
  - A PPRA and an environmental analysis (EA or EIS).
  - Potential impacts to endangered species would be analyzed.
  - **Most likely action:** Quarantine and mitigation.

- The USDA-APHIS-PPQ response could include:
  - A pest risk assessment and/or a weed risk assessment.

- The US EPA may regulate the blight resistance trait as a Plant Incorporated Protectant (PIP).
  - Chestnuts from the GE trees may require a tolerance (maximum residue level) or a tolerance exemption to be legally sold as food in the United States.

- FDA may have a regulatory role if any GE chestnuts are placed on the market.
Scenario 2 – Low Lignin GE Poplar

- Poplars (*Populus* spp.) are among the most frequently planted trees.
- Field testing of GE poplars has been ongoing for 20 years.
- Traits in development include: altered or decreased lignin content, growth rate, insect resistance, root sucker inhibition and altered fertility.
- Insect resistant GE poplar has been in production in China since 2001.

**Biology of Poplar**

- Obligate outcrossing has produced many natural hybrids.
- Long distance pollen and seed dispersal.
- Extensive vegetative reproduction by root suckers.
Scenario 2 – Natural Range of *Populus tremuloides*

- Trembling aspen (*P. tremuloides* Michx.) comprises over 80% of the merchantable poplar timber in Canada.
- Known as a “pioneer species” because it is one of the first to appear in disturbed habitats.
- Poplars hybridize so frequently in nature that many hybrids have common names.
- Until recently, poplar was considered a “weed tree”.

[Map of North America showing the natural range of *Populus tremuloides*.]

Scenario 2 – Development Status of GE Poplar

- **Gene of Interest:** Caffeic acid o-methyltransferase (COMT)
- **Current Field Tests:** Over 75 acres planted at sites in 13 states
- **Regulatory:** Petition for Determination of Nonregulated Status not anticipated soon.
  - GE poplars have been field tested in Canada for the past 10 years.
  - Regulatory submissions to EPA and FDA not anticipated.

*Considerations*
- Would the trait reduce fitness and survival?
- Would the trait affect susceptibility to plant pests and diseases?
- Would the trait impact delivery of ecosystem services?
Scenario 2 – Spread into Canada

If USDA-APHIS “de-regulated” GE poplar:

- The PPRA associated with the deregulation would address the potential for impacts on plant health, weediness and invasiveness.
- The environmental analysis (EA or EIS) associated with the deregulation would address:
  - Impacts on land use, air quality, soil resources, water resources, wildlife, insect and disease pests, biological diversity, and threatened and endangered species.
  - EO 12114 – “Impacts outside the United States” could be analyzed.
- USDA regulators and Canadian regulators routinely share information on regulatory actions during bilateral meetings.
  - There would be no surprise when the GE poplar arrived in Canada
- If this were an asynchronous approval, there would typically only be 1-3 years before the Canadian review was completed.
If the GE Poplar were approved only in Canada, and later found growing in the United States:

- The USDA-APHIS-BRS response could include:
  - A PPRA and an environmental analysis (EA or EIS).
  - *Most likely action:* quarantine and mitigation.

- The USDA-APHIS-PPQ response could include:
  - A pest risk assessment and/or a weed risk assessment.

- The US EPA would have no regulatory role since the low lignin trait is not a PIP.

- FDA would not have a regulatory role unless the GE poplar trees were used in animal feed.
Conclusions

- Routine communication between agricultural biotechnology regulators in the United States, Canada and Mexico ensures that any unauthorized movement of GE trees would not come as a surprise.
- Developers of GE trees should be encouraged to proactively communicate their plans to regulatory authorities in neighboring countries.
- Whenever possible, developers should seek simultaneous regulatory review in neighboring countries.
- If it appears that a neighboring country will not approve the GE tree, abandoning the project may be advised.
- Mechanisms to reduce gene flow (male sterility, etc.) may significantly mitigate concerns about international movement of GE trees.
Time for Questions