# The nuances of biotech field trials and permitting.

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**The Appalachian Fruit Research Station (AFRS),**
**Kearneysville, WV**

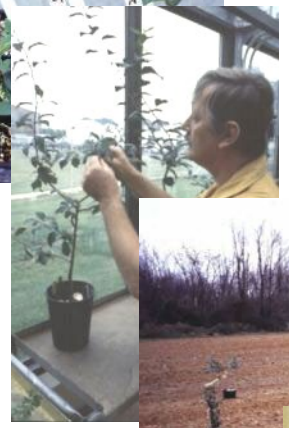
United States Department Of Agriculture
Agricultural Research Service

# AFRS has continuously been performing field tests on GE trees since 1995.

- **‘HoneySweet’ Plum – virus resistance**
- Disease resistance
- Dwarfing rootstocks
- Root architecture
- Tree architecture
- Dormancy
- Bloom time
- Fruit ripening
- Seedless
- Pitless

1990 1995 2002 2009

Initial genetic engineering 1990



Greenhouse testing for resistance
1992-1995

U.S. field test
1995 - 2011

Determination of the resistance mechanism
1995-2006

EU field plantings 1996

Ralph Scorza

Field test PPV resistance
horticultural performance
risk assessments
1996-present

# Navigating the APHIS Permitting Process for GE Field Releases

- The application process
- Permit conditions
- Reporting and Monitoring
- Inspections
- Post-trial activities
- Examples
- Tips and Advice


- **Know your organism and your germplasm**
  - Sexually compatible species and distribution.
  - Fertility and mechanism of pollination.
  - Seed and non-seed mechanisms of dispersal.
  - Environmental interactions.
  - Commercial and hobbyist plantings near you.

- **Know your gene and mechanism of action (as much as possible)**
  - Literature
  - Pleotropic phenotypes
  - Fitness

- **Reach out to others who have done field trials with your species.**
  - Copies of supplemental permit conditions can be extremely useful.

- **Talk to APHIS**
  - Schedule a pre-application meeting to discuss what, why, when, and how you want to trial.

# Permit Application Information

- The Applicant
- Organism details
- Suppliers/developers
- Construct/event information
  - Intended Trait
  - Genotype information and source of genes/genetic elements
- Location details (GPS coordinates)

United States Department of Agriculture

Authorization No. AUTH - 0000441468
CBI Copy

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICE
**PERMIT UNDER 7 CFR 340**
*(Genetically Engineered Organisms or Products)*

This permit was generated electronically via the eFile system

Enclosed is the BRS Permit Application

| | | | |
|---|---|---|---|
| **PERMITTEE NAME:** | Timothy Artlip | **PERMIT NUMBER:** | 124-PGW9UCC |
| **TITLE:** | Plant Physiologist | **DATE ISSUED:** | 09-25-2025 |
| **ORGANIZATION:** | USDA ARS AFRS | | |
| **ADDRESS:** | 2217 Wiltshire Road, Kearneysville, West Virginia, 25430 | **EFFECTIVE:** | 10-28-2025 |
| | | **EXPIRES:** | **10-28-2028** |
| **PHONE:** | (304) 725-3451 | | |
| **Fax:** | | **MOVEMENT TYPE** | Release |
| | | **PERMIT TYPE** | Standard |
| **RELEASE:** | WV | **PURPOSE OF PERMIT** | Traditional |

Under the conditions specified, this permit authorizes the following:

**Organism:** Prunus domestica

# STANDARD PERMIT CONDITIONS

United States Department of Agriculture

Authorization No. AUTH - 0000441468
CBI Copy

**Standard Permit Conditions for the Introduction of an Organism**

**(7 CFR 340.4(f))**

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.
(2) All packaging material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner as to prevent the dissemination and establishment of plant pests.
(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit.
(4) The regulated article shall be maintained only in areas and premises specified in the permit.
(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article.
(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation.
(7) The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article.
(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the administrator to be necessary to prevent the spread of plant pests.
(9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.
(10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or

# Supplemental Permit conditions


- Specific to your situation.
- Includes details about duration, confinement, monitoring, equipment cleaning, termination and devitalization, records, and reporting.

# Reporting Requirements

*Types and specifics of reporting depend on type of authorization*

- Pre-Planting (Environmental Release) Notice*
- Planting (Environmental Release) Report
- Report of No Planting/Release (Optional)
- Pre-Flowering Notice*
- Flowering Report*
- Annual Field Test Report*
- In-season Annual Volunteer Monitoring Report*
- Pre-Harvest/ Termination Notice*
- Final Field Test Report
- Post-termination Volunteer Monitoring Reports, Interim And Final
- Return To General Use Notice (Dedicated equipment and storage facilities)
- Reporting Of Possible Or Actual Unauthorized Release
- Reporting Of Regulated Article With Characteristics Substantially Different Or If It Suffers Any Unusual Occurrence

https://www.aphis.usda.gov/sites/default/files/report-and-notices-guide.pdf

# Monitoring and Reporting


- Regular monitoring for potential escapes
  - Flowering periods
  - Volunteers
  - Changes in nearby sexually compatible species
- Regular reporting on activities
  - Changes to planting (plant removal/death, replant, other non-GE plants in block, etc.)
  - Tissue collections and removals
    - Tissue types, method of removal and transport, etc.
  - Management of propagules (flowers, pollen, seeds, cuttings, etc.)
    - Mowing, spraying, and other farm activities that could spread.
  - Devitalization of materials
  - Staff training
- Incidence reporting – severe storms, hurricanes, tornadoes, hail, downed trees, flooding, etc.
- Unusual occurrence reporting

- **Example Template for Flowering Report Attachment.**

# Flowering Report Template

- Indicate the dates you monitored the field trial and other monitored locations, as applicable.
- Indicate the location(s) you monitored, including the field trial (with any perimeter zone and border row areas), and any other areas where in-season volunteer monitoring is required.
- Indicate if flowering was observed. If yes, provide D to I:
- Indicate any dates upon which you identified flowers (if different than dates monitored)
- Number of flowers observed. If more than 100 flowers were identified, follow an estimation strategy and provide an estimate of the number.
- Whether any unusual flowering, early flowering, out-of-season flowering, or overabundance of flowering occurred.
- The developmental stage of any flowers at the time of destruction (e.g., reproductive structures, visible flower buds, open flowers, pollen or seed)
- Any actions and dates of actions taken to remove or destroy flowers.
- Indicate if you have submitted a report indicating any unusual, early, out-of-season, or overabundance of flowering.

# Unusual Occurrence Report

Hi xxxxx,

I have an unusual occurrence to report for AUTH – 0000328685, Block 19. Trees from two different constructs are in bloom. The constructs are xxx construct (2019-5C in the AUTH) and xxx construct (2019-3C in the AUTH). Included is a PowerPoint file illustrating the occurrence, with images taken from the surrounding areas not under our control (nothing in bloom). I have attached a Block map, with the blooming trees outlined in thick outside borders. The trees are found in Row 2, spaces 1-3, Row 3, spaces 30-32, Row 4, spaces 12-14, and Row 4, spaces 20-22. The xxx genes are involved in dormancy and flowering, and these two constructs inactivate two different genes via a hairpin driven by 35S; gene A is from peach (Prunus persica), and Gene B is from European plum (Prunus domestica).

Please feel free to contact me with any questions.

Woods adjacent to AFRS property – no sexually compatible trees in bloom
Block 19 11/16/2025

| Block 19 | | | = planted Oct. 11, 2023 | | | | |
|---|---|---|---|---|---|---|---|
| Rows 16', trees 6' | | | = planted Mar. 26, 2024 | | | | |
| Planted Oct 28, 2022 | | | | | | | |
| | | | Dam5 Si-19 #2 | Dam5 Si-20 #1 | | | Dam6 Ii-15 |
| | 50 | 7C#2 3 | Dam5 Si-19 #3 | Dam5 Si-20 #2 | | | Dam6 Ii-15 |
| | 49 | 7C#2 8 | Dam5 Si-19 #1 | Dam5 Si-20 #3 | Dam6 Ii-27 #3 | | Dam6 Ii-15 |
| | 48 | NcRNAi # L1-3 | 5E#13 4 | DAM4-3c # L5-3 | Dam6 Ii-27 #1 | | Dam5 SE-1 |
| | 47 | NcRNAi # L1-2 | 5E#131 | DAM4-3c # L5-2 | Dam6 Ii-27 #2 | | Dam5 SE-1 |
| | 46 | NcRNAi # L1-1 | DAM3-3i # L3-3 | DAM4-3c # L5-1 | DAM6-6e # L13-3 | | Dam5 SE-1 |
| | 45 | DAM4-4i # L2-3 | DAM3-3i # L3-2 | 7C#4 2 | DAM6-6e # L13-2 | | Dam6 Ii-20 |
| | 44 | DAM4-4i # L2-2 | DAM3-3i # L3-1 | 7C#4 9 | DAM6-6e # L13-1 | | Dam6 Ii-20 |
| | 43 | DAM4-4i # L2-1 | DAM6-6e # L12-3 | DAM3c # L10-3 | DAM4-4i # L6-3 | | Dam6 Ii-20 |
| | 42 | 7C#3 5 | DAM6-6e # L12-2 | DAM3c # L10-2 | DAM4-4i # L6-2 | | Dam5 Si-11 |
| | 41 | 7C#3 1 | DAM6-6e # L12-1 | DAM3c # L10-1 | DAM4-4i # L6-1 | | Dam5 Si-11 |
| | 40 | DAM3- Control-3 | 7C#5 9 | NcRNAi # L3-3 | 7C#6 1 | | Dam5 Si-11 |
| | 39 | DAM3- Control-2 | 7C#5 8 | NcRNAi # L3-2 | 7C#6 3 | | Dam5 SE-1 |
| | 38 | DAM3- Control-1 | DAM4-4e # L2-3 | NcRNAi # L3-1 | NcRNAi # L4-3 | | Dam5 SE-1 |
| | 37 | DAM6-8c # L1-3 | DAM4-4e # L2-2 | DAM4- Control-3 | NcRNAi # L4-2 | | Dam5 SE-1 |
| | 36 | DAM6-8c # L1-2 | DAM4-4e # L2-1 | DAM4- Control-2 | NcRNAi # L4-1 | | Dam5 Si-5 |
| | 35 | DAM6-8c # L1-1 | NcRNAi # L5-3 | DAM4- Control-1 | DAM3-3e # L4-3 | | Dam5 Si-5 |
| | 34 | 7C#6 6 | NcRNAi # L5-2 | 7C#2 10 | DAM3-3e # L4-2 | | Dam5 Si-5 |
| | 33 | 7C#6 8 | NcRNAi # L5-1 | 7C#2 6 | DAM3-3e # L4-1 | | Dam6 Ii-32 |
| | 32 | DAM3-3e # L1-3 | 7C#4 6 | DAM3-5c # L3-3 | 7C#2 11 | | Dam6 Ii-32 |
| | 31 | DAM3-3e # L1-2 | 7C#4 5 | DAM3-5c # L3-2 | 7C#2 4 | | Dam6 Ii-32 |
| | 30 | DAM3-3e # L1-1 | NcRNA/4C # L2-3 | DAM3-5c # L3-1 | DAM6-8c # L7-3 | | Dam5 SE-1 |
| | 29 | DAM4-3c # L2-3 | NcRNA/4C # L2-2 | DAM3-3e # L3-3 | DAM6-8c # L7-2 | | Dam5 SE-1 |
| | 28 | DAM4-3c # L2-2 | NcRNA/4C # L2-1 | DAM3-3e # L3-2 | DAM6-8c # L7-1 | | Dam5 SE-1 |
| | 27 | DAM4-3c # L2-1 | DAM6-8c # L2-3 | DAM3-3e # L3-1 | NcRNA/4C # L4-3 | | 7C#2 1 |
| | 26 | 7C#4 11 | DAM6-8c # L2-2 | 7C#5 7 | NcRNA/4C # L4-2 | | 5E#13 3 |
| | 25 | 7C#4 3 | DAM6-8c # L2-1 | 7C#5 10 | NcRNA/4C # L4-1 | | 5E#13 6 |
| | 24 | NcRNAi # L10-3 | 7C#2 9 | DAM3- Control-1 | 7C#4 8 | | 7C#3 3 |
| | 23 | NcRNAi # L10-2 | 7C#2 2 | DAM3- Control-2 | 7C#4 7 | | 7C#4 4 |
| | 22 | NcRNAi # L10-1 | DAM3-3i # L2-3 | DAM3- Control-3 | DAM4-3c # L12-3 | | 7C#6 2 |
| | 21 | DAM4-4e # L1-3 | DAM3-3i # L2-2 | DAM4-4e # L4-3 | DAM4-3c # L12-2 | | 7C#6 4 |
| | 20 | DAM4-4e # L1-2 | DAM3-3i # L2-1 | DAM4-4e # L4-2 | DAM4-3c # L12-1 | | 7C#6 5 |
| | 19 | DAM4-4e # L1-1 | DAM6-6e # L10-3 | DAM4-4e # L4-1 | NcRNA/4C # L3-3 | | 7C#5 2 |
| | 18 | Fox hole | DAM6-6e # L10-2 | 7C#6 9 | NcRNA/4C # L3-2 | | 7C#5 5 |
| | 17 | empty | DAM6-6e # L10-1 | 7C#6 11 | NcRNA/4C # L3-1 | | 7C#5 1 |
| | 16 | DAM3- 3i # L1-3 | NcRNA- Control-3 | DAM4-3c # L4-3 | 7C#5 3 | | DAM3-3i # |
| | 15 | DAM3-3i # L1-2 | NcRNA- Control-2 | DAM4-3c # L4-2 | 7C#5 4 | | DAM3-3i # |
| | 14 | DAM3-3i # L1-1 | NcRNA- Control-1 | DAM4-3c # L4-1 | DAM3-5c # L5-3 | | DAM3-3i # |
| | 13 | DAM4- Control-3 | 7C#6 7 | DAM6-8c # L4-3 | DAM3-5c # L5-2 | | DAM4-4e # |
| | 12 | DAM4- Control-2 | 7C#6 10 | DAM6-8c # L4-2 | DAM3-5c # L5-1 | | DAM4-4e # |
| | 11 | DAM4- Control-1 | DAM3-3e # L2-3 | DAM6-8c # L4-1 | NcRNAi # L8-3 | | DAM4-4e # |
| | 10 | 7C#5 11 | DAM3-3e # L2-2 | 5E#13 5 | NcRNAi # L8-2 | | 7C#2 7 |
| | 9 | 7C#5 6 | DAM3-3e # L2-1 | 5E#13 2 | NcRNAi # L8-1 | | 7C#2 5 |
| | 8 | DAM6-6e # L6-3 | DAM4-4i # L3-3 | DAM3c # L8-3 | 7C#3 4 | | DAM4-3c # |
| | 7 | DAM6-6e # L6-2 | DAM4-4i # L3-2 | DAM3c # L8-2 | 7C#3 2 | | DAM4-3c # |
| | 6 | DAM6-6e # L6-1 | DAM4-4i # L3-1 | DAM3c # L8-1 | NcRNA- Control-3 | | DAM4-3c # |
| | 5 | NcRNA/4C # L1-3 | 7C#3 6 | NcRNAi # L2-3 | NcRNA- Control-2 | | DAM3-5c # |
| | 4 | NcRNA/4C # L1-2 | 7C#3 7 | NcRNAi # L2-2 | NcRNA- Control-1 | | DAM3-5c # |
| | 3 | NcRNA/4C # L1-1 | DAM3-5c # L2-3 | NcRNAi # L2-1 | DAM4-4i # L4-3 | | DAM3-5c # |
| | 2 | empty | DAM3-5c # L2-2 | empty | DAM4-4i # L4-2 | | empty |
| | 1 | empty | DAM3-5c # L2-1 | empty | DAM4-4i # L4-1 | | empty |
| | | | | | | | |
| space # | | ROW 1 | ROW 2 | ROW 3 | ROW 4 | | ROW 5 |

# Compliance Inspections

- Know your surroundings.
- Ensure knowledgeable people available to meet and answer questions.
- Send materials in advance (lists, maps, reports, etc.)

# Sample Pre-inspection Information Request

- Training record – **Attached (2025 transgenic plants combined training record_Kearneysville)**
- Material transfer form (if applicable) – **Attached as an Excel file starting with "717"; also included the Interstate Movement Permits**
- Equipment cleaning record (if applicable) – **N/A due to juvenile trees**
- In-season field monitoring record – **Attached (Block 45 Field Inspection, Block 45 Plant Loss & Injury)**
- List of planted lines/events/constructs (if it is different from those submitted to eFile) – **N/A**
- Permit number(s) of other biotech trial(s) planted in the same field or nearby fields (if applicable) - **AUTH – 0000328685 (Permit 124-3959EW5-A1), Prunus domestica, Blocks 7 and 19; AUTH – 0000341250 (Permit 124-CKCX8XX), Malus x domestica, Block 1B**
- Field map outlining the trial location within the research station or area (e.g., a marked Google map showing the trial field boundary) with GPS coordinates for all four corners (excluding the fallow zone) – **Attached (Field Map 7.0 – KV)**
- Information of the personnel attending the inspection, including the name(s), job title(s), affiliation(s), and functional role(s) associated with this field trial – **Dr. Chris Dardick, Lead Scientist; Dr. Andrea Kohler, post-doctoral research associate running the project; Ms. Kamryn Viands, Field Agent; Dr. Timothy Artlip, permit holder**

# Post-trial monitoring -

After you terminate the environmental release at each planted release site, you must monitor for, remove, and devitalize or destroy any volunteer plants to prevent the regulated article from being released without authorization, spreading, dispersing, and/or persisting in the environment

- Survivors, sprouts, volunteers, root suckers, propagules, etc.
- Numbers of volunteers
- Actions taken to destroy volunteers

# Examples

# Plum Tree Field Trials - 1995

*Then*: cover all flowering trees to prevent pollen spread.

- We submitted a pollen flow monitoring scheme.

*Now*: Open pollination approved based on the absence of sexually compatible species.

# Plum Tree Field Trials - 1995

*Then*: Harvest and destroy all fruit not analyzed in the lab.

- Provided data/info on field seed germination rates.

Now: Fruit are allowed to drop and decay in the block.

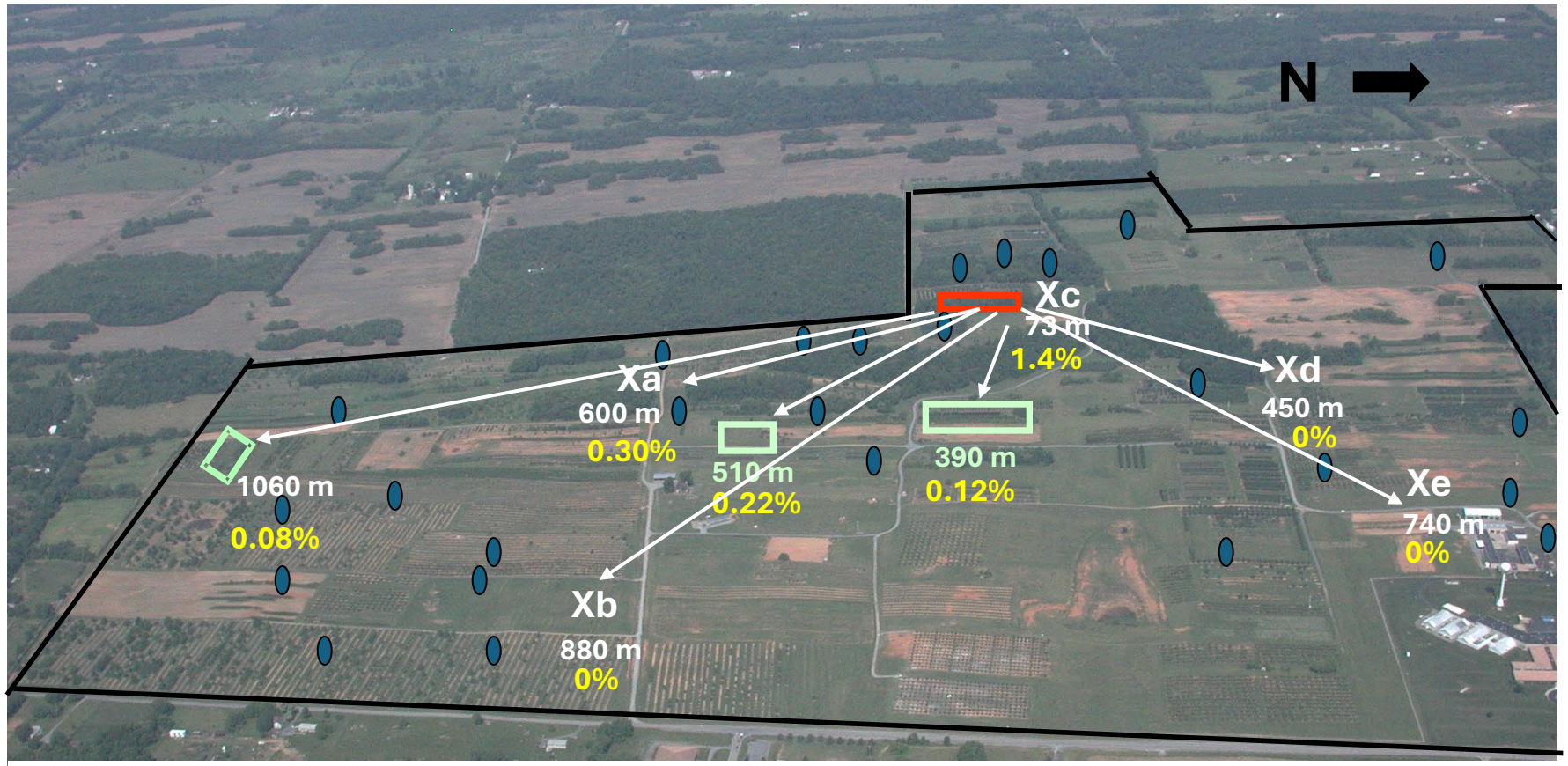
# Plum Tree Field Trials - 1995

## *Then:* Required devitalizing all prunings

- Provided data along with alternative propagule control and monitoring plans.

*Now:* prunings are left in the block to decay.

# Results of monitoring pollen flow from GE plum trees 1999-2009 (>11,000 seeds)




= CP transgenic plums

= existing non-transgenic P. domestica blocks

X = sentinel sampling sites

% of GUS positive (GE) hybrid seed

= bee hives

## Current permit conditions

- Monitor annually in a 1600m radius for trees not under our control that are being grown in a seed orchard.
- Monitor biannually in a 400m radius for any sexually compatible trees not under our control.

# Applying GE pollen to apple trees in the field

# GE Poplar Field Trials

- Open field plot
- No Flowering due to wind pollination and presence of sexually compatible species (remove trees prior to maturity)
- Block design with very wide borders to prevent risk of root escape
- Specialized weed control due to root stock suckering
- Post-monitoring trial specifications

# Tips for successful GE field trials

- Talk to APHIS at early stages of product development. Try to think ahead and anticipate/mitigate obstacles to conducting field trials.
- Obtain data about your organism to identify risks and strategies to minimize risk and reduce restrictions.
- Be creative – think outside the box on how to conduct experiments and still meet APHIS requirements.
- Develop institutional expertise to effectively manage permits.
  - Staff training.
- Make monitoring and reporting activities part of your routine research activities to help ensure compliance and minimize workload.
- Be proactive about reporting.
- Think long term. Gather data as you go to make it easier in the future. Working as a research community is even better (and publish).

# Compliance is Critical


- Ceasing activities
- Additional supplemental conditions
- Negative consequences to your industry and stakeholders
- Can make it more difficult not just for you, but for others too.

https://www.aphis.usda.gov/sites/default/files/report-and-notices-guide.pdf

# THANK YOU