

## **“Interim Progress Report for CDEA Agreement Number 17-0420-000-SA”**

**Project Title: Management of the federal permit for field testing transgenic grapevine rootstocks in California.**

### **Principal Investigator (PI)**

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### **Cooperators**

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**Time period covered by the report:** July 2017 to February 2018

### **Introduction**

The major objective of this project is management of the APHIS-BRS federal permits that facilitate the multi-investigator testing of transgenic grapevine rootstock and scion varieties in California. A renewal application for the Solano/Riverside federal permit with an end date of March 31, 2016 was filed with APHIS-BRS on October 10, 2015, approved on March 8, 2016 and extended until March 8, 2019. The Riverside County site was completely terminated following the final disposition protocol approved by APHIS-BRS on June 9, 2016; the site was monitored monthly for volunteers over a year. Riverside “Field Termination”, “Field Test” and “Field Volunteer Monitoring” mandatory reports were submitted to APHIS-BRS on December 8, 2016. APHIS-BRS final inspection for the Riverside terminated field was conducted on June 22, 2017, and the Riverside “Final Volunteer Monitoring Report” was submitted on September 18, 2017. The Solano 2016-17 “Annual” and “Volunteers Monitoring” mandatory reports for the Solano/Riverside permit were submitted to APHIS-BRS on April 8, 2017. Solano County site was completely terminated on June 7, 2017, APHIS-BRS inspections for the Solano terminated field was conducted on May 12, 2017 and on September 27, 2017. The Solano/Riverside permit’s final disposition protocol was modified, to allow the terminated Solano field to be planted with another grape crop immediately instead to wait until mandatory one-year volunteers monitoring period is over, and a permit amendment application was filed on May 16, 2017 and approved on August 4, 2017. In addition, Solano County site “Field Termination”, “Field Test” and “Field Volunteer Monitoring” reports were submitted to APHIS-BRS on November 17, 2017.

A new federal permit application for field release of transgenic rootstocks expressing single or dual constructs was submitted on February 22, 2016. The new Solano APHIS-BRS federal permit was approved with an end date of June 17, 2019. The Solano site was expanded to begin field-testing transgenic versions of the commercially relevant rootstocks 101-14 and 1103 for their ability to protect the sensitive scion variety Chardonnay from Pierce’s disease (PD). The first “Annual” and “Volunteers Monitoring” reports for the new Solano permit were submitted to APHIS-BRS on July 17, 2017. “Annual”, “Planting”, “Volunteer Monitoring”, “Field Test”, and “Field Termination” mandatory reports for each federal permit are submitted in a timely manner to comply with the APHIS-BRS requirements.

### **List of objectives**

The major goal is to manage the APHIS-BRS permit that facilitates field-testing of transgenic grapevine rootstock and scion varieties in California.

Objective 1. Manage the existing USDA-APHIS field permits 15-282-118r and 16-053-101r, and maintain regulatory oversight and compliance with permit reporting requirements.

Activity 1. Manage the documentation and submission processes for the federal permit that enables field-testing at the ‘ePermits’ website.

Activity 2: Maintain regulatory oversight and compliance with reporting requirements and regulatory compliance inspections at both field locations.

**Description of activities conducted to accomplish each objective, and summary of accomplishments and results for each objective**

**Activity 1. Extend and amend the existing permit beyond its current March 2016 expiration date.** The Solano and Riverside County field APHIS-BRS federal permit with end date of March 31, 2016 was transferred from Professor Alan Bennett to Professor Abhaya Dandekar in January 2014. A permit renewal application was filed with APHIS-BRS on October 10, 2015. This permit action was approved on March 8, 2016, extending the end date of the federal permit to March 8, 2019. The final disposition protocol for the current Solano/Riverside APHIS-BRS federal permit was modified, to allow the use of the terminated field to enable the planting with new grapevine transgenics immediately instead of waiting a mandatory one year required for 'volunteer monitoring' period. A permit amendment application was filed on May 16, 2017. The Riverside site was terminated following the final disposition protocol approved by APHIS-BRS on June 9, 2016; the site was monitored monthly for volunteers for over a year. The Solano County site was terminated on June 7, 2017; the site will be monitored monthly for volunteers for one year or until a new grape crop is planted.

The Solano site was expanded to the North to begin field-testing of single and dual transgenic versions of the commercially relevant rootstocks 101-14 and 1103 for their ability to protect a sensitive variety like Chardonnay from PD. A new federal permit application for field release of transgenic rootstocks expressing single or dual constructs was submitted on February 22, 2016. The new Solano APHIS-BRS federal permit was approved on June 17, 2016 with an end date of June 17, 2019.

**Activity 2: Maintain regulatory oversight and compliance at both field locations, including reporting requirements and regulatory compliance inspections.**

Personnel from the Dandekar laboratory are maintaining regulatory oversight of the field trial sites. The issues requiring regulatory oversight compliance are listed in the permit. Timely reporting and inspections are conducted to maintain compliance with specific APHIS-BRS federal permit performance standards and conditions. Regulatory compliance is enforced by working closely with the participant investigators, the two field coordinators, and their crews. PD field trial activity information is updated quarterly using the PI's activity monitoring logs. Two individuals from the Dandekar laboratory are entrusted with the tasks of documentation, training, and inspection to ensure regulatory compliance with the APHIS-BRS permit conditions (USDA- APHIS-BRS 2012a and 2012b). This includes monitoring the increased activity at the Solano site due to the two federal permits and monitoring the terminated Riverside site. "Field Annual", "Planting", "Volunteer Monitoring", "Field Test", and "Field Termination" mandatory reports for each federal permit are submitted in a timely manner to comply with the APHIS-BRS requirements.

Riverside County site "Field Termination", "Field Test" and "Field Volunteer Monitoring" reports were submitted to APHIS-BRS on December 8, 2016. The "Field Test" report provides methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment observed during the trial lifetime. The "Field Termination" report provides the final status, methods of observation and resulting data for each location. The "Field Volunteer Monitoring" report contains the dates when the field site and perimeter zone were inspected for volunteers, the number of volunteers observed each month during one-year period. Solano/Riverside 2016-17 "Annual Report" and "Volunteer Monitoring Report" were submitted to APHIS-BRS on April 8, 2017. The "Annual Report" reflects the status and observation for each location during a one-year period. New Solano 2016-217 "Annual Report" and "Volunteer Monitoring Report" were also submitted to APHIS-BRS on July 19, 2017. Solano County site "Field Termination", "Field Test" and "Field Volunteer Monitoring" reports were submitted to APHIS-BRS on November 17, 2017.

APHIS-BRS inspections for Riverside County on June 22, 2017 and for Solano County sites on May 17 and September 27, 2017, respectively. The purpose of the inspections was to verify that the field trials were in compliance with APHIS-BRS performance standards and permit conditions. The inspections included visiting the field trials and related facilities (e.g., buildings for equipment, seed storage, processing, disposal, etc.) and reviewing associated records for each field trial.

**Publications produced and pending, and presentations made that related to the funded project.**

Dandekar, A.M., A.M. Ibanez and A. Jacobson. 2017. Field testing transgenic grapevine rootstocks expressing chimeric antimicrobial protein and polygalacturonase-inhibiting protein. Research Progress Reports: Pierce's Disease and other Designated Pests and Diseases of Grapevines. December 2017. California Department of Food and Agriculture. pp. 20-28.

Dandekar, A.M., A.M. Ibanez, and A. Jacobson. 2016. Field testing transgenic grapevine rootstocks expressing chimeric antimicrobial protein and polygalacturonase-inhibiting protein. Proceedings of Pierce's Disease Research Symposium held at December 12-14, 2016 at the Marriot Courtyard Hotel San Diego California. pp. 35-42.

Dandekar, A.M. 2016. Field testing transgenic grapevine rootstocks expressing chimeric antimicrobial protein and polygalacturonase-inhibiting protein. Oral presentation at the Pierce's Disease Research Symposium. December 13, 2016, San Diego California.

Dandekar, A.M., D. Gilchrist, P. Rolshausen, A.M. Ibanez, A. Jacobson D. Dolan, R. Just and H. Gouran. 2015. Chimeric antimicrobial protein and polygalacturonase-inhibiting protein transgenic grapevines filed trial. Research Progress Reports: Pierce's Disease and Other Designated Pests and Diseases of Winegrapes. December 2015. pp. 18-26.

Dandekar, A.M. D. Gilchrist, T. Miller, A.M. Ibanez, D. Dolan and H. Gouran. 2014. Chimeric antimicrobial protein and polygalacturonase-inhibiting protein transgenic grapevines filed trial. Proceedings of Pierce's Disease Research Symposium held December 15-17, 2014 at the Sheraton Grand Sacramento Hotel, Sacramento, California. pp. 106-117.

**Research relevance statement, indicating how this research will contribute toward finding solutions to Pierce's disease in California.**

The objectives described in this proposal directly address the number 1 RSAP priority outlined in the, "Accelerate regulatory process". Establish and facilitate field trials of current PD control candidate vines / endophytes / compounds in multiple locations" handout released in the December 2009 Pierce's Disease Research symposium that outline the "Top 5 to 10 Project Objectives to Accelerate Research to Practice". This document updates the priority research recommendations provided in the report "PD/GWSS Research Scientific Review: Final Report" released in August 2007 by the CDFA's Pierce's Disease Research Scientific Advisory Panel.

**Layperson summary of project accomplishments.**

An APHIS-BRS federal permit with an end date of March 31, 2016 to conduct field trials of transgenic grapevines at two locations in Solano and Riverside Counties was obtained and managed by PIPRA until 2012, then by Professor Abhaya Dandekar since January 2014. A permit renewal application was filed on October 10, 2015, and approved on March 8, 2016, that extends the federal permit until March 8, 2019. An amendment application for the current Solano/Riverside federal permit was filed with APHIS-BRS on May 16, 2017 since the permit final disposition protocol was modified to allow the use of the terminated field to be planted with another grape crop immediately instead of waiting the mandatory one-year volunteers monitoring period. A new APHIS-BRS federal permit application was submitted February 22, 2016, approved on June 17, 2016, with an end date of June 17, 2019. This new permit is for a field site adjacent and North of the current site and is for testing single and dual transgenic versions of the constructs commercially relevant rootstocks 101-14 and 1103, which will be field tested for their ability to protect the sensitive variety Chardonnay from PD. The Riverside site was terminated following the disposition protocol approved by APHIS-BRS and the site was monitored monthly for volunteers for one year. The old Solano County site (adjacent and South of the new site) was completely terminated on June 7, 2017. APHIS-BRS inspection for Riverside County and Solano

County terminated sites were conducted on June 22 and September 27, 2017, respectively. The purpose of the inspections was to verify that the field trials were in compliance with the APHIS-BRS performance standards and permit conditions. The inspections included visiting the field trials and related facilities, and reviewing associated records for each field trial.

Timely reporting and inspections are conducted to maintain compliance with APHIS-BRS federal permit conditions. Regulatory compliance is enforced by working closely with the participant investigators, the two field coordinators, and their crews. PD field trial activity information is updated quarterly using the PI's activity monitoring logs. Two individuals from the Dandekar lab are entrusted with the tasks of documentation, training, and inspection to ensure regulatory compliance with the permit conditions (USDA-APHIS-BRS 2012a, 2012b). This includes monitoring the expanded activity at the Solano site under the two federal permits, monitoring the terminated Riverside site for volunteers, and preparing "Annual", "Planting", "Volunteer Monitoring", "Field Test" and "Field Termination" mandatory reports for each permit which are submitted in a timely manner to comply with the APHI-BRS permit requirements.

**Status of funds.**

We have expended all the funds available for the period July 1, 2017 to Feb 28, 2018. Funds being carried over are for the period remaining; March 1, 2018 through June 30, 2020.

**Summary and status of intellectual property associated with the project.**

No IP involvement in this project.

**Literature cited**

USDA-APHIS-BRS. 2012a. Permit User's Guide with Special Guidance for ePermits. V.5/30/2012. USDA-

APHIS-BRS. 2012b. ePermits BRS Reports and Notices User Guide. V.1.5.