

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

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

Principal Investigator (PI)

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Time period covered by the report: Jan 2017 to June 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 federal permit application 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) was submitted on February 22, 2016. The Solano APHIS-BRS federal permit was approved on June 17, 2016 with an end date of June 17, 2019. The first “Annual” and “Volunteers Monitoring” reports for this Solano permit were submitted to APHIS-BRS on July 17, 2017. In order to expand the Solano site from 3.4 acres to 5.4 acres we submitted a Solano permit amendment application to APHIS-BRS, but following the recommendation of the APHIS-BRS staff inspector, the APHIS-BRS Solano permit was withdrawn and a new permit application was submitted. The new federal permit application for field release of transgenic rootstocks expressing dual and single constructs was submitted on December 13, 2017. The new Solano APHIS-BRS federal permit was approved on March 16, 2018 with an end date of March 31, 2021. “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, 16-053-101r and 17-347-101r, 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.

A permit amendment application was filed on May 16, 2017 to modify the final disposition protocol for the current Solano/Riverside APHIS-BRS federal permit, to allow the use of the terminated field to enable the planting with new transgenic grapevines immediately instead to wait a mandatory one year required for 'volunteer monitoring' period. 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 was monitored monthly for volunteers for one year.

A federal permit application 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) was submitted on February 22, 2016. The Solano APHIS-BRS federal permit was approved on June 17, 2016 with an end date of June 17, 2019. In order to expand the Solano site from 3.4 acres to 5.4 acres we submitted a Solano permit amendment application was submitted to APHIS-BRS, but following the recommendation of the APHIS-BRS staff inspector, the APHIS-BRS Solano permit was withdrawn and a new permit application was submitted.

A new federal permit application for field release of transgenic rootstocks expressing dual and single constructs was submitted on December 13, 2017. The new Solano APHIS-BRS federal permit was approved on March 16, 2018 with an end date of March 31, 2021.

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. The final “Field Volunteer Monitoring” for the terminated Solano field will be submitted to APHIS-BRS in August of this year. New Solano 2016-2017 “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 on December 17, 2017, approved on March 16,

2018, with an end date of March 31, 2021. This new permit is for an 5.4 acres field that includes the current field (2.0 acres) and an adjacent field site (3.4 acres) 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 new Solano permit conditions (USDA-APHIS-BRS 2012a, 2012b). This includes monitoring the terminated Riverside and Solano sites 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 APHIS-BRS permit requirements.

Status of funds.

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