

“Interim Progress Report for CDEA Agreement Number 15-0577-SA”

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

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Time period covered by the report: July 2016 to June 2017

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, 17. Solano County site was completely terminated on June 7, 2017. The 2016-17 “Annual” and “Volunteers Monitoring” mandatory reports for the Solano/Riverside permit were submitted to APHIS-BRS on April 8, 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. Solano field’s APHIS-BRS inspection for the Solano site was conducted on May 17, 17. In addition, a “Field Test” report for the Solano/Riverside federal permit was submitted on 6/16/17.

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 of this proposal is the management of APHIS-BRS federal permits that facilitate the field-testing of transgenic grapevine rootstock and scion varieties in California.

Objective 1. Management of existing USDA-APHIS field permits, maintenance of regulatory oversight, and compliance with permit reporting requirements.

Activity 1. Extend and amend the existing permit beyond its current March 2016, expiration date.

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

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, approved on March 8, 2016 and extended the federal permit until 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 be planted with another grape crop immediately instead to wait until the mandatory one year volunteers monitoring period is over, and 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 over a year. Solano County site was also completely terminated on June 7, 2017.

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 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 trials 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.

APHIS-BRS inspections for Solano County and Riverside County sites were conducted on May 17, 2017 and June 22, 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 (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. 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 to wait until the mandatory one-year volunteers monitoring period is over. A new APHIS-BRS federal permit application for field release of transgenic versions of the commercially relevant rootstocks 101-14 and 1103 expressing single or dual constructs, which will be field tested for their ability to protect the sensitive variety Chardonnay from PD, was also 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.

The Riverside site was terminated following the disposition protocol approved by APHIS-BRS and the site was monitored monthly for volunteers for one year. Solano County site was also completely terminated on June 7, 2017. APHIS-BRS inspections for Solano County and Riverside County sites were conducted on May 17, 2017 and June 22, 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 requirement.

Status of funds.

We have expended all the funds available for the period July 1, 2016 to June 30, 2017.

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.