

“Renewal 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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Time period covered by the report: June 2018 to June 2019

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 federal permit application for new Solano field release of all transgenic rootstocks expressing different constructs 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. “Field Test” and “Volunteers Monitoring” reports for this Solano permit were submitted to APHIS-BRS on July 17, 2017. The new Solano site was expanded to begin field-testing transgenic versions of the commercially relevant 101-14 and 1103, and a new federal permit application 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. The first “Annual Volunteers Monitoring” and “Annual Field Test” reports for this Solano permit were submitted to APHIS-BRS on April 30, 2019 and May 1, 2019, respectively. APHIS-BRS first inspection site was conducted for the new Solano County on November 29, 2018. “Planting” reports were submitted on September 13, 2018, November 11, 2018 and July 12, 2019.

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 and maintain regulatory oversight and compliance with permit reporting requirements and conditions.

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. A renewal application for the Solano and Riverside County fields APHIS-BRS federal permit with end date of March 31, 2016 was submitted to APHIS-BRS on October 10, 2015. This permit action was approved on March 8, 2016 with an end date of 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 County and Solano sites were completely terminated on June 9, 2016 and June 7, 2017, respectively. “Final Field Test” and “Final Volunteer Monitoring” reports for each field were submitted in a timely manner to comply with the APHIS-BRS requirements.

A federal permit application for field release of transgenic rootstocks expressing single or dual constructs 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 new Solano site was expanded to begin field-testing transgenic versions of the commercially relevant 101-14 and 1103, and a new federal permit application was submitted on December 13, 2017. The current 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 approved permit and permit conditions. 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 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). Annual or final "Field Test", annual or final "Field Volunteer Monitoring" and "Planting" mandatory reports are submitted in a timely manner to comply with the APHIS-BRS requirements.

The "Field Test" and "Volunteer Monitoring" reports for the new Solano trial were submitted to APHIS-BRS on July 19, 2017, April 30, 2019 and May 1, 2019. 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. "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. APHIS-BRS first inspection for the new Solano County site was conducted on November 29, 2018. The purpose of the inspections is to verify that the field trials are in compliance with APHIS-BRS performance standards and permit conditions. The inspections included visiting the field trial and related facilities (e.g., buildings for equipment, greenhouses, processing, disposal, etc.) and reviewing associated records for the field trial. "Planting" reports were submitted to APHIS-BRS on September 13, 2019, November 11, 2018 and July 12, 2019. Planting reports provide either planting and construct data or no-planting data for the Solano site.

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

Dandekar, A.M., A. Jacobson, A.M. Ibáñez, H. Gouran, D.L. Dolan, C.B. Agüero, S.L. Uratsu, R. Just and P.A. Zaini. 2019. Trans-graft protection against Pierce's disease mediated by transgenic grapevine rootstocks. *Front. Plant Sci.* 10:84.

Dandekar, A.M., A. Jacobson and A.M. Ibáñez. 2018. Field testing transgenic grapevine rootstocks expressing chimeric antimicrobial protein and polygalacturonase-inhibiting protein. *Proceedings of Pierce's Disease Research Symposium* held at December 17-19, 2018 at the Kona Kai Resort and Spa, San Diego California. pp. 22-29.

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.

A new expanded Solano County 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 original field site (2.0 acres) and an adjacent field site (3.4 acres) for testing all transgenic versions of the constructs in commercially relevant rootstocks 101-14 and 1103, which will be field tested for their ability to protect the sensitive variety Chardonnay from PD development. "Annual Volunteer Monitoring" and "Annual Field Test" reports for the new Solano trial were submitted to APHIS-BRS on April 30, 2019 and May 1, 2019, respectively. APHIS-BRS first inspection was conducted on November 29, 2018. "Planting" reports for the new Solano County permit were submitted on September 13, 2018, November 11, 2018 and July 12, 2019.

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 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 included monitoring the new Solano site, planting, volunteers monitoring, and preparing "Field Test", "Planting", and "Volunteer Monitoring" mandatory reports, 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, 2018 to June 30, 2019. Funds being carried over are for the period remaining; July 1, 2019 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.