"Interim Progress Report for CDFA Agreement Number 15-0577-SA"

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

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Time period covered by the report: July 2016 to March 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 current 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. This permit was modified to facilitate the field-testing of additional transgenic genotypes and a permit amendment application was filed with APHIS-BRS on February 24, 2017. The Riverside County site was terminated following the final disposition protocol approved by APHIS-BRS and the site will be monitored monthly for volunteers over the next year and a half. Riverside "Field Termination", "Field Test" and "Field Volunteer Monitoring" mandatory reports were submitted to APHIS-BRS on December 8, 2016. 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 "Field Planting' report of 101-14 and 1103 transgenic rootstocks was submitted to APHIS-BRS on October 14, 2016. Field annual, field planting, field 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.

<u>Description of activities conducted to accomplish each objective, and summary of accomplishments</u> 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 until March 8, 2019. The current APHIS-BRS federal permit was modified to accommodate additional constructs currently in the transformation pipeline and a permit amendment application was filed with APHIS-BRS on February 24, 2017. The Riverside site was terminated following a disposition protocol approved by APHIS-BRS and the site will be monitored monthly for volunteers over the next year and a half. 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 the single and dual constructs was also submitted on February 22, 2016. The new 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 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 lab 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. Riverside "Field Termination", "Field Test" and "Field Volunteer Monitoring" mandatory reports were submitted to APHIS-BRS on December 8, 2016. The first "Field Planting' report of 101-14 and 1103 transgenic rootstocks was also submitted to APHIS-BRS on October 14, 2016. The 2016-2017 "Field Annual" and "Field Volunteer" mandatory reports for the Solano/Riverside and the New Solano federal permits will be submitted to APHIS-BRS on April and July 2017, respectively.

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.

<u>Layperson summary of project accomplishments.</u>

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. This current APHIS-BRS federal permit was modified to accommodate additional constructs currently in the transformation pipeline and a permit amendment application was filed with APHIS-BRS on February 24, 2017. The Riverside site was terminated following the disposition protocol approved by APHIS-BRS and the site will be monitored monthly for volunteers for the next year and a half. 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 APHIS-BRS federal permit was approved on June 17, 2016, with an end date of June 17, 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 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 field annual, field planting, field 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. The first "Field Planting' report of 101-14 and 1103 transgenic rootstocks was also submitted to APHIS-BRS on October 14, 2016. Riverside "Field Termination", "Field Test" and "Field Volunteer Monitoring" mandatory reports were submitted to APHIS-BRS on December 8, 2016.

Status of funds.

We have expended all the funds available for the period July 1, 2016 to March 31, 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