DRAFT FOR DISCUSSION

QUARTERLY REPORT TO THE COMMERCIAL PRODUCT DEVELOPMENT COMMITTEE OF THE CITRUS RESEARCH AND DEVELOPMENT FOUNDATION

FOR THE PERIOD ENDING JUNE 30, 2012

Prepared by
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Project Monitoring and Reporting System Overview

This first quarterly report to the CPDC is a "strawman" for discussion at our July 24 Committee meeting. It is a key element of the Project Monitoring and Reporting System we are implementing to provide the Committee with quarterly reports, monthly updates and ongoing access to information on the performance of projects to established milestones, timelines, and, as appropriate fiscal and contractual obligations to CRDF. Preparation of these reports involves identifying a key stakeholder associated with each project to serve as "communications leader" to ensure reporting accountability and that proper information is captured on reports. These individuals will also serve as points of contact for me to query to respond to questions regarding the status of Committee projects.

My task will be to ensure all project reports are updated at least monthly; provide quality control; go back with questions and requests for additional information; serve as point of contact for CPDC on questions related to project status; help position communications regarding the work of the projects in a way that best serves the needs of CPDC decision-makers; and prepare monthly update reports as well as quarterly reports for communication at CPDC meetings.

We are using a standard reporting format for the reports to ensure that key project management issues are addressed in a consistent manner. Some of the reports will be longer than others. Initial reports on projects less familiar to the committee will receive more detailed attention in a first report, which will serve as a base document. Subsequent project reports will be shorter and track progress since the last report. The goal is to make the committee reports as concise as possible to provide the information you need as a committee to make informed decisions.

The committee currently has eight projects

- **Psyllid Control (Neonicotinoid Label Modification)**
- **Disease Detection: Canine Scouting**
- **Diaprepes Root Weevil Control**
- Psyllid Control (RNAi)
- Antibacterials
- Genetic Disease Resistance
- Citrus Gene Therapy
- Advanced Citrus Production Systems

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The first three projects, highlighted in bold type, are contained in this first report. Other projects will be added over the next 1-2 months and the next quarterly report will include all projects.

Please review the materials in this report and be prepared to discuss whether the level of detail, content and process meets your needs as a committee member. Based on your feedback, we'll make needed adjustments.

Thank you very much.

Jim Dukowitz, PhD
Commercial Product Manager

UPCOMING MEETINGS AND EVENTS

July 24	**CPDC Meeting and CRDF Board Meeting**
August 28	**CRDF Board of Directors Meeting**
September 7	**Target date to announce CATP12 RFP and open system for receipt of pre-proposals**
September 25	**CRDF Board Meeting**
October 8	**Deadline for receiving CATP12 proposals.**
October 23	**CRDF Board Meeting**

PROJECT REPORTS

Neonicotinoid Label Modification
Disease Detection: Canine Scouting
Diaprepes Root Weevil Control

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Psyllid Control: Neonicotinoid Label Modification

Goal

The goal of this project is to expand labeling on Imidacloprid, Clothianidin and Thiamethoxam to include a second soil application during a calendar year at the current maximum labeled per tree rate to protect young trees up to 5-9 feet tall (transplants/replants to 5 years of age). At project conclusion, a major commercial product involving each of the above active ingredients will have received regulatory approval for label changes.

Description

Research at the University of Florida and other locations has indicated a need for changes in the use pattern of Neonicotinoid insecticides to facilitate control of the Asian Citrus Psyllid (ACP) on mature trees under Florida production practices. With the increased annual application rates, this would afford protection to the leaf flushes from feeding by the Asian Citrus Psyllid (ACP), and will result in a more comprehensive management scheme across all trees in commercial groves.

The project has been divided into four phases. Phases 1-3 were in the first year agreement, and Phase 4 is a recommended additional phase contained in the project extension proposal.

Phase 1: Identify and select the most efficacious treatment program for ACP utilizing neonicotinoid insecticides. This involved scheduling meetings with primary researchers and key grower representatives to develop the proposed labeling and use patterns, which were then circulated to representative growers and the registrants to ensure consensus and support.

Phase 2: Work with primary registrants of the "neonic(s)" selected to determine the feasibility of label changes and any impediments to obtaining those changes. This included addressing any concerns over environmental non-target impacts. Meetings were held with each of the registrants of the active ingredients in the treatment scheme, along with follow-up correspondence, to establish an agreed-upon final course of action.

Phase 3: Development of labels and registration documents, submission and supporting the review and final decision process at the state and federal level. This involved development and oversight of any research necessary to obtain appropriate use labels requested, preparation of documentation and support for a 24(c) label package for FDACS, support during the review, and coordination of any implementation efforts required upon registration

Phase 4: Provide stewarding of the needed information development and submissions to accomplish additional label changes, including more definitive use instructions as to timing and additional work to support increased rates for the larger tree classifications.

Targeted Completion
Phases 1 and 2 are complete. Completion of Phase 3 is anticipated by the end of calendar year 2012, although the regulatory approvals could slip into 1Q2013. Phase 4 work is expected to continue through the bloom season of 2013 with data collection and analysis during the spring of 2013 with proposed label modification to be submitted in late spring 2013.

Available Resources
TPR/FFVA: Dan Botts (lead consultant and principal communications contact); Mike Aerts, Mike Stuart
IFAS/CREC: Michael Rogers (collaborating researcher)
FDACS: Dennis Howard
Bayer Crop Science (Imidacloprid): Steve Olsen, Alan Ayers
Syngenta (Thiamethoxam): John Abbott, John Taylor
Valent (Clothianidin): Jeff Smith

Status
The first two phases of the project are complete, and the team is in the process of completing its first 24 (c) label package for Imidacloprid. This will serve as a template for the other two submissions.

- During January and February 2012, the project team met with Bayer Crop Science, Syngenta and Valent and in February, and initiated data collection from existing trial work.
- In April the team met with FDACS, Tallahassee and with EPA in Washington DC.
- In May through the present the team has focused on developing data summaries, economic information and the registration package.
- The team has targeted August 1 to complete the 24(c) label package for Imidacloprid, with submission to FDACS shortly thereafter. This is about 45 days behind the schedule presented at the April CPDC meeting, and could lead to corresponding delays in the other two applications. The delay was due to many factors, including additional time to obtain analytical information, and the need to address additional issues raised by participating companies during the process. FDACS approval for Imidacloprid could come in a matter of weeks, which would coincide with the timeframe that Bayer would have adequate supplies of Imidacloprid to meet increased demand.
- For Thiamethoxam, the 24(c) submission is projected for the September/October time frame with Clothianidin coming 2-3 weeks later.
- A typical 24(c) time frame for approval is 60 to 90 days once the application package is completed and in the hands of the state. The actual time period is anticipated to be shorter than normal due to the dialogue and cooperation with FDACS and EPA during label development. Clothianidin will require review under the label expansion process of PRIA, with approval likely during first quarter of 2013.

Issues and Gaps

There are no major issues or gaps other than normal challenges of organizing many stakeholders around a common goal. The Imidacloprid team is working very well together, and issues are being resolved efficiently and effectively. One issue resolved during the July 13 conference call was who should submit the 24(c) registration package. The team determined that Bayer should submit the package, with supporting letters from key stakeholders in the Florida industry.

Roadmap

2012-13 Project Roadmap: Neonicotinoid Label Modification

What	Who	Start	End	Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun
Meet with FDACS Tal	Team	Apr	Apr	
Meet with EPA DC)	Team	Apr	Apr	
Develop 24(c) package for Imidacloprid	Team	May	July	
Submit 24(c) package for Imidacloprid	Bayer	Aug	Aug	
Develop 24(c) package for Thiamelthoxam	Team	July	Sep	
Submit 24 (c) package for Thiamethoxam	Syngenta	Sep	Sep	
Develop package for Clothianidin	Team	Aug	Oct	
Submit package for Clothiandin	Valent	Oct	Oct	
Approvals Imidacloprid Thiamelthoxam Clothianidin	FDACS/ EPA	Nov Dec Jan	Nov Dec Jan	
Additional Label Changes	Team	Mar	Jun	

Fiscal Reporting($)

FY2012 Budget	41,400
Invoiced	31,488
Residual (Phase 3)	9,912
Phase 4	18,400
FY 2013 Budget	**28,312**

Disease Detection: Canine Scouting

Goals

The goals of this project are to assist in developing a commercialization plan and roadmap, provide Florida citrus industry feedback, and provide other support, as appropriate, to facilitate the commercialization of canine scouting for detection of citrus canker. Currently the European Union (EU) does not allow Florida grapefruit and other citrus to be imported unless the grove is certified canker-free, and the fruit is inspected by the USDA and no canker is found. Growers are finding it increasingly difficult to find a grove with no canker. The use of canine scouts could potentially increase the number of certified canker-free groves, with favorable economic impact to the industry. Plans are also underway to expand canine scouting to HLB and potentially other plant diseases.

Description

Research on detection of citrus canker using canine "scouting" has progressed to the point where it is ready to be commercialized. Dr. Tim Gottwald has conducted research over the past 12 years that demonstrates that dogs can reliably detect the smell of volatile compounds being given off by canker-infected citrus foliage and fruit. Field and packinghouse trials conducted in 2010-2011 showed greater than 98% detection accuracy. The majority of the errors were false negatives due to such factors as being downwind from infected trees, and the presence of infected foliage or fruit at the location on a previous run. Temperature was also found to be a factor in packinghouse trials, as panting reduced detection accuracy. A more recent 16 acre trial produced positive results, although results are not yet released.

J&K Canine Academy, the dog training company involved in the citrus canker research program, is actively preparing a business plan and rollout to reach nurseries, growers and packers. J&K wants to initiate a pilot project with a grower that is seeking a Harvesting Permit to export fresh fruit to EU, and would be willing to pay a reduced fee for services on a longer-term contract. The goal is to self fund the launch of this business through service contracts.

Certification is an issue to ensure service quality, and Dr. Gottwald has developed a testing protocol (See Appendix for more details). The details of the certification program, including who would "own" the program, needs to be worked out.

Because this is a new and potentially important approach to citrus disease control, CPDC can provide valuable feedback and other appropriate assistance to the commercialization process. The commercialization success ultimately rests on the level of commercial interest from growers, and whether the pilot program achieves desired performance standards.

Additional details on the research, commercialization and certification issues is contained in the Appendix to this document.

Targeted Completion
The goal is to complete the pilot program on citrus canker by November-December 2012 and launch the business by the year end.

Available Resources
Tim Gottwald, USDA/Ft. Pierce
Pepe Peruyero, CEO of J&K Canine Academy
CPDC assistance, as appropriate, including project coordination and facilitation by program manager.

Status
J&K is ready to move now to a full pilot program for citrus canker, followed by commercial launch. It has developed the protocol for a four month pilot program covering 500 to 800 acres in which four dogs and two handlers would cover the entire area in a 30 day period, then repeat the process three more times. "Level 1" dogs would be used for the first pass, with "Level 2" dogs used for passes two through four. After each pass, the grower will, as appropriate, prune, defoliate or remove the identified diseased trees, leaves or branches. At the end of the pilot program, the grove will seek certification as a canker-free grove required for fresh fruit exports to EU.

Issues and Gaps (Citrus Canker)
- **Market Demand Validation**: target markets, level of interest, citrus industry risks, needs and priorities (surveys, focus groups, etc.) This would include an assessment of likely continuation of EU import restrictions.
- **Value proposition**: Preparation and communication of cost-payback models for citrus industry.
- **Competition:** Cost and performance comparisons with alternative approaches, including full costs of human scouting, equipment, copper, total man hours involved. J&K has requested CRDF support this information gathering effort.
- **Disease Management:** how canine scouts might be used as part of an overall disease management program for citrus canker?
- **Dog Supply**: Present and projected business capacity for delivery of trained canines
- **Underlying Science Support**: What additional scientific research is needed related to canine scouting for citrus canker? How will it be funded?
- **Awareness Campaign** (e.g. APHIS Plant Management Network, PR, marketing materials, grower channels
- **Finalize Business Model**: pricing, contract services vs. lease, etc.
- **Intellectual Property Protection**: How to protect proprietary training methodology, possible CRADA
- **Certification Program**: One avenue for exploration is who will take financial and management responsibility for the certification program. This might be a good thing for the growers to control.

HLB Research
Concurrent with growing the citrus canker detection business, J&K plans to support Tim Gottwald's ARS lab to launch a research and training program on HLB detection. This

will require external funding. A key question is to what extent pre-symptomatic detection will be possible while the disease is still latent. (See Appendix for more detail.)

2012-3 Project Roadmap: Canine Scouts

What	Who	Start	End	Jul Aug Sep Oct Nov Dec Jan Feb+
Validate Market Demand	J&K	Aug	Oct	
Ramp up Canine Supply	J&K	Sep	Ongoing	
Secure partner	J&K	Aug	Aug	
Launch Pilot Program	J&K, Grower	Sep	Dec	
Govt. Inspection and Harvesting Permit	FDACS	Dec	Dec	
Finalize Business Model	J&K	Aug	Oct	
Industry Awareness/ Marketing	J&K, Growers	Aug	Ongoing	
Establish Certification Program	J&K, Growers	Sep	Dec	
HLB Research Program	ARS			
Funding Applications		Aug	Nov	
Bootstrap/Other Funding		Aug	Feb	
CRDF Funded Program		Feb	1 year	

The **Appendix** provides additional detail on research, commercialization and certification programs

Appendix: Canine Scouting

Citrus Canker Research

USDA/Ft. Pierce researcher Tim Gottwald began initial research efforts in 1999 to determine a dog's ability to detect minute concentrations of citrus canker volatile/aromatic compounds with a focus on grapefruit. He successfully trained a criminology dog to correctly identify a canker scent based on air samples captured on cotton pads through a Scent Transfer Unit with 98% accuracy. That research was discontinued following the events of September 2001 when the dog was diverted to explosive detection.

In the 2005 time frame, Gottwald began a second effort with APHIS/USDA agriculture detector dogs, teaching them both recognition and response (to sit) when detecting the citrus canker infected fruit and small infected trees in blind boxes. There was no consistency in the training due to the dogs being shipped out to ports to detect agricultural products in baggage, so the training was discontinued.

In the third and on-going attempt, Gottwald has used a commercial training facility, J&K Canine Academy of High Springs Florida, to train canines for the detection of canker infected grapefruit trees using a new training approach called "self discovery". J&K Canine Academy, led by CEO Pepe Peruyero, has an ongoing commercial business training detector dogs (PepeDogs) and is known for work in detecting bedbugs, termites, search and rescue and cadaver tracking. Through a combination of internal USDA and ARS funding, J&K support, and a $50,000 grant in 2009-10 from FCPRAC, Gottwald and J&K have conducted field and packinghouse trials that have further demonstrated the ability of canines to detect canker infected grapefruit with high reliability.

Four field trials were conducted between July 2010 and May 2011 using plot sizes of 100 grapefruit trees in a 4X25 row design. Ten replications were conducted in which the proportion of diseased trees ranged from 2 to 10%. Infected trees were randomly distributed. Results showed average detection accuracy of 98.3%, with false negatives at 1.2% and false positives at 0.5%. Analysis of the data suggested that the incidence of higher false negatives was due to two factors: tree proximity downstream from other "positives", and the tree was found "positive" in a prior run.

Packing house trials on grapefruit conducted over two days in April 2011 showed average detection accuracy of 98.2%, with false negatives of 1.3% and false positives of 0.5%. Analysis of the data suggested that error rate increased with temperature due to the dogs panting. During the trials, the dogs identified two boxes with canker fruit missed by human trained technicians.

More recently, a 16 acre field trial on grapefruit trees was completed, also with favorable results. This data is being analyzed and will be publicly reported when complete.

Commercialization (Citrus Canker)

J&K Canine Academy is interested in self-funding a canine detection business for citrus diseases with initial focus on citrus canker to serve growers, packers and nurseries. Initial targeted customers for citrus canker include growers that seek to export fresh fruit internationally, especially to the EU. They must comply with EU health import requirements that citrus fruit imports be sourced from groves where, since the beginning of the last cycle of vegetation, no symptoms of citrus canker were observed in the field of production or its immediate vicinity. Any grove, block or sub-block and a surrounding buffer must be inspected no more than 120 days prior to the beginning of harvest and found to be free of citrus canker. Those that pass an FDACS inspection receive a fresh fruit Harvesting Permit, which is valid for the remainder of the harvesting season. Any grove block found positive for canker will be disqualified for EU markets for the remainder of that harvesting season. The harvesting permit number(s) must be recorded on the trip-ticket(s) to verify the grove block has been surveyed and found free of citrus canker.

This EU requirement provides an opportunity to use canine scouts to go into the grove prior to a government inspection for a harvesting permit, removing detected citrus canker fruit and trees/foliage.

J&K's preferred business model is to provide contract inspection services to clients over an extended period. The goal is to cover the end-to-end process from pre-planting inspection of fields and plants, to grove inspections and inspection at packers.

J&K is seeking to launch its program by conducting a pilot program with a grower who plans to obtain a fresh fruit permit for EU export. In exchange for a long-term services contract, this grower would receive a special discounted rate for services provided during and after the pilot program. J&K's goal would be to fund the commercialization of the canker detection business through revenues from service contracts. J&K is also beginning a market awareness program through podcasts and media interviews.

Certification (Citrus Canker)

There is legitimate concern that unscrupulous companies will make unfounded claims and secure contracts with ill-trained dogs and handlers. As a result, there will be a need for a certification process to ensure quality at highest level is maintained. There are existing models used in other dog detection industries, e.g. pest management, narcotics detection, and "port of entry" customs inspections. The tests are generally very straight forward, with simple "pass-fail" outcomes.

USDA will provide the selection process that will be required for any individual, business and/or entity which is planning to supply the industry with citrus detection canines. The planned protocol includes the following:

- Three separate areas of evaluation that include five runs for each area;
- A 95% or higher detection of infected plants (controlled identification), fruit (packing houses) and trees (groves) must be obtained to pass the canine trainer evaluation process.

- The process shall also require a 5% or less false and/or miss rating to pass
- Pass or fail results will be provided at the completion of the process upon compiling the test data from each area evaluated by qualified USDA personnel.

Areas to be completed for the selection process will consist of:

- Five runs of 100 trees during each run, in a field setting, where randomly generated numbers and location of infected plants are placed that the team must detect.
- Five runs of 100 boxes of fruit during each run, inside a fruit packing house, where a randomly generated number and location of infected fruit are placed that the team must detect; and
- Five runs of a five acre plot, containing mature trees, in an actual grove, where upon completion, USDA inspectors will confirm or deny alerts with due diligence and their (qualified USDA inspectors) results will be final.

Upon failing to meet the listed standards, entities will not be eligible for re-test for a six month period from the date of the final test results being presented.

Details of how this program would be implemented must be developed.

HLB Research

The plan includes launching an aggressive research and training program to move to detection of HLB. A first stage HLB research program framework has been jointly defined by Tim Gottwald and Pepe Peruyero as follows: 4 dogs, 2 trainers, 4 days a week for six months. To conduct the research and training, J&K will move dogs close to Gottwald's ARS lab and rent a warehouse with concrete floors for training.

At this stage, there is ongoing discussion between ARS and J&K regarding research priorities between canker and HLB; whether additional research should first be completed on canker detection before launching the HLB research program; whether to seek alternative (non-CRDF) near term funding, or bootstrap the HLB research until funding becomes available. If J&K could secure a pilot program contract for canker detection, a portion of those proceeds could be used to help fund an HLB research and training program.

Whatever option is selected, the plan will include submitting a research proposal to CRDF during the fall 2012 call for proposals.

Diaprepes Root Weevil Control

Goal
The goal of this project is to take the lead in commercialization planning for pheromones associated with Diaprepes root weevil control. This will include supporting continued testing through 2014, obtaining a license on the Intellectual Property from USDA, and identifying 2-3 companies to co-fund development and sub-license the technology

Description
Dr. Stephen Lapointe at the U.S. Horticultural Research Laboratory/Fort Pierce has discovered an aggregation pheromone and host plant volatiles (kairomones and allomones) that induces arrestment behavior in the Diaprepes root weevil. The pheromone development has advanced through research and is close to commercialization. Ongoing CRDF sponsored research is addressing this potential. While not directly related to HLB, root injury by weevils is part of the complex interaction that leads to tree health decline, and the impact is greater in the presence of HLB.

The Technology Transfer Coordinator at USDA has contacted CRDF to consider playing a lead role in commercialization planning for pheromones associated with Diaprepes root weevil control. There is a patent pending on this work, and USDA may consider licensing the technology to CRDF, which will, in turn, sub-license the technology to companies to incorporate with their own delivery technologies and complete the commercialization process. These companies would be part of a co-development investment pool by each taking out an option to sub-license the technology incorporate into their own delivery systems.

The goals of this project are to continue to support a field testing program through 2014 and, in parallel, to establish licensing terms, negotiate agreements with participating companies, and monitor contract performance to ensure the interests of USDA and CRDF are protected. This is an important contractual and structural precedent for how the Foundation does business in the future.

Targeted Completion
Proposed field testing program through 2014.

Available Resources
USDA/Ft. Pierce: Steve Lapointe.
CRDF: Tom Turpen, Jim Dukowitz
Potential sub-licensee companies that have expressed interest

Status
Lapointe has submitted a development budget to CRDF for a 2 year field-testing program. CRDF Program Manager has spoken with three companies about creating a consortium to co-fund this next phase with CRDF matching funds. CRDF would be the exclusive

licensee and CRADA party while each of the companies would have access through a sub-license from CRDF to combine with their own delivery technologies.

Issues and Gaps.
One of the key issues is to establish a valuation for the patent for purposes of licensing/sublicensing. Another is finalizing the model and negotiating agreements for flow of royalties from companies as sub-licensees to CRDF to USDA. This project can represent a major level of effort, particularly during set up and negotiations, and we recommend that both Tom Turpen and Jim Dukowitz be involved during key parts of the process.

2012-2014 Project Roadmap: Diaprepes Root Weevil Control

What	Who	Start	End	Aug Sep Oct Nov Dec 2013 2014
Submit license application to USDA/OTT	Dukowitz	Aug	Nov	
Notice of Intent in Fed Register (Secure license)	CRDF	Nov	Nov	
Negotiate consortium company option	Turpen/ Dukowitz	Aug	Nov	
Secure option	CRDF	Nov	Nov	
Negotiate CRADA/license agreement with USDA	Turpen/ Dukowitz	Aug	Nov	
Secure agreements with USDA	CRDF	Nov	Nov	
Conduct field study	Lapointe	2013	2014	