



**CPDC Quarterly Report
July
2013**

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Quarterly Activity Update

- EPA's pending expansion of the clothianidin label to bearing citrus has been delayed until mid-December due to litigation filed by several environmental and pollinator advocacy groups.
- At its July meeting, the CRDF Board authorized Third Party Registrations to lead an effort to prepare and submit a FIFRA Section 18 Emergency Use Exemption petition. This petition would allow grower access to clothianidin targeting application on five to nine foot trees in Florida.

Issues and Gaps

- All stakeholders must be comfortable that the Section 18 process addresses their needs and concerns.
- Stakeholder coordination will be essential to develop needed information in support of the Section 18 petition, as well as to conduct a communication outreach program.
- CRDF will be working with TPR, FDACS and industry on a stewardship program that emphasizes strict grower compliance with label instructions for neonicotinoid products.

Performance to Milestones

- Imidacloprid label expansion was approved in the fall 2012, on track with milestones established in the September 2012 Quarterly Report.
- Clothianidin target of mid-December for PRIA approval is a slip of six months from the March 2013 Quarterly Report projection.
- The March report projected late fall Thiamethoxam 24 (c) SLN submission date to FDACS, about eight months later than the January projection. That time period is increasingly problematic due to escalating concerns over pollinator protection and pressures from beekeepers and environmental groups.

CRDF Project Roadmap: Neonicotinoid Label Modification

What	Who	Start	End	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Submit 24(c) package for Imidacloprid	Bayer	Sep'12	Sep'12	█															
Imidacloprid approval	FDACS	Oct'12	Oct'12		█														
Submit 24 (c) package for Thiamethoxam	Syngenta	Nov'13	Nov'13		S			→		J									M, JI
Thiamethoxam approval	FDACS	Dec'13	Dec'13			S		→		J									M, JI
Clothianidin Section 3 approval	EPA	Dec'13	Nov'13							S		→		J, M					JI
Clothianidin 24(c) approval	FDACS	Dec'13	Dec'13								S		→	J, M					JI
Additional data collection	Team	Apr'13	2014																█
Additional label changes	Team	2013	2014																█

Quarterly Activity Report

- The Research Agreement for follow-on work on InnoCentive™ dsRNA molecules that have demonstrated high toxicity to ACP was signed by CRDF and UF in April.
- The USDA patent office has provisionally approved the Invention Disclosure by Dr. Bob Shatters (USDA-ARS, Fort Pierce) for preparation for a patent application. The Invention Disclosure was submitted on a subset of the InnoCentive™ materials.
- Current USDA CRADA with Monsanto is being modified to allow Monsanto to synthesize large quantities of two of the dsRNA gene targets associated with the InnoCentive™ follow-on research project for greenhouse and field testing.

Issues and Gaps

- USDA Office of Licensing must finalize a patenting approach for InnoCentive™ materials.
- USDA and CRDF need to leverage the CRADA relationship to help develop a long term commercial relationship with Monsanto.

Performance to Milestones

- The start of research under the CRDF-funded research agreement is roughly in line with the March Quarterly Report, and a two month slippage from the January Quarterly report.

Project Roadmap: Psyllid Control RNAi

What	Who	Start	End	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	2H'13	'14	'15	'16	'17	'18+	
InnoCentive Challenge awards selected	Turpen	Aug'12	Aug'12	█																	
Comm research proposals submitted	Powell/Shatters	Aug'12	Sep'12		█																
Approve proposal for follow-on development	CPDC/BoD	Sep'12	Oct'12			█															
Conclude Research Agreement	CRDF staff/UF	Apr'13	Apr'13																		
Begin Research Project (First Year)	Powell/Shatters	May'13	May'13																		
Company partnership explorations	CPDC/Companies	2013+	Ongoing																		
Regulatory roadmap	Companies	2013+	Ongoing																		
Partnerships for commercialization	Companies	2013+	Ongoing																		
Develop and optimize products	Companies TBD	2015+	Ongoing																		
Regulatory approvals (exogenous, synthetic)	Companies TBD	2016+	Ongoing																		
Regulatory approvals (plant incorp. protectant)	Companies TBD	2018+	Ongoing																		
Commercial availability	Companies	'17-'19	Ongoing																		

Quarterly Activity Update

- Upon CPDC recommendation, in April CRDF Board approved a Research Services Agreement (RSA) and revised Research Agreement created out of a follow-on research project involving 11 InnoCentive™ Challenge-winning antimicrobial compounds. Dr. Charles Powell of UF serves as PI.
- Upon CPDC recommendation, RSA evaluations using a graft-based assay are in progress for efficacy against HLB involving both InnoCentive™ and third party (company) provided compounds. The timeframe for individual evaluations is six months.
- Upon CPDC recommendation, in April CRDF Board also approved RSA with Dr. Nian Wang of UF CREC to evaluate soil-based microbials against HLB. Work is underway with soil samples taken from areas surrounding several “escape” trees, as well as one commercial product.
- Upon CPDC recommendation, CRDF Board approved in July an RSA for Dr. Eric Triplett to provide rapid turn-around evaluation of up to 1200 promising antimicrobial compounds against HLB using the *L. crescens* assay. Evaluations are in progress.
- Upon CPDC recommendation, CRDF Board approved funding in July for field trials during 2013-2014 to evaluate efficacy against HLB of promising antimicrobials and soil-based microbials, as well as a GLP residue study for EPA product registration.


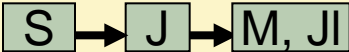












Issues and Gaps

- The focus of effort is on accelerating the path to commercial antimicrobial products to address HLB, balancing the need to leave “no stone unturned” while focusing resources on the most promising compounds and taking them to field trials and commercial partnerships.
- This involves identifying additional candidate commercial partners, targeting compounds with lower regulatory barriers, potential label changes, and pre-registration visits with EPA to better understand requirements.

Performance to Milestones

- Other than addition of *L. crescens* assay approval, there are no roadmap changes from those provided in the March Quarterly Report.

Project Roadmap: Antimicrobials

What	Who	Start	End	3Q'12 4Q'12 1Q'13 2Q'13 3Q13 4Q13 2014 2015 2016 2017+
InnoCentive™ challenge awards selected	Turpen	Aug	Aug'12	
Approve amended Powell research proposal (1 Yr)	UF/Powell	April'13	Apr'13	
Approve RSAs (Powell, Wang), RA (Powell)	CRDF/UF	Apr'13	Apr'13	
Approve RSA (Triplett)	CRDF/UF	Jul'13	Jul'13	
Source candidate compounds	CRDF	Jan'13	Ongoing	
Screen compounds with various assays	UF/TBD	Jul'13	Ongoing	
Grower-led field experiments	CPDC/ Growers	Fall'13	Ongoing	
Powell research in greenhouse/field (Y1)	UF	Apr'13	Apr'14	
Regulatory roadmap	TBD	2014+	Ongoing	
Secure Commercial Partners	CRDF	2014+	Ongoing	
Develop and optimize products	Companies	2015+	Ongoing	
Regulatory approvals (anti-bacterials)	Companies	2016+	Ongoing	
Regulatory approvals (antibiotics)	Companies	2017+	Ongoing	
Commercial availability	Companies	2016+	Ongoing	

Quarterly Activity Update










- Dr. Janice Zale has accepted the position of MCTF Coordinator and came on board mid-July. Dr. Zale brings experience in plant molecular biology, breeding, plant pathology and genetic transformation of crops and model species. CRDF staff met with her in mid-July to discuss the “go forward” roadmap.
- With a lab coordinator in place, we will be in a position to establish a Steering Committee, define objectives, create an operational plan, and begin work on mature transformation of commercially important citrus scion and root stock cultivars.

Issues and Gaps

- Formation of a Steering Committee to provide oversight and support to the MCTF Coordinator
- Finalize arrangements with Dr. Leandro Pena to provide valuable support in ensuring facilities, tools, protocols, and work plan are in place

Performance to Milestones

- Securing and having in place a new MCTF Coordinator, and associated activities of establishing a steering team, establishing resource requirements and budgets, and associated protocols and operational planning has slipped about three months from March projections. Long term projections remain unchanged.

What	Who	Start	End	3Q'12 4Q'12 1Q'13 2Q'13 3Q13 4Q13 '14 '15 '16 '17 '18 '19 '20 '21 '22+
<u>MCTF Ramp</u>				
Interim MCTF Oversight	CREC	Sep'12	Jul'13	
Secure new MCTF Manager	CREC	Jul'13	Jul'13	<pre> graph LR J1[Jul'13] --> M1[Mar'14] M1 --> JI1[Jan'15] J2[Jul'13] --> M2[Mar'14] M2 --> JI2[Jan'15] J3[Jul'13] --> M3[Mar'14] M3 --> JI3[Jan'15] </pre>
Establish Steering Comm	CREC/CRDF	Aug'13	Aug'13	
Establish resource requirements/budgets	MCTF/Steer Comm	Aug'13	Sep'13	
Ongoing operations	MCTF/Steer Comm	4Q'13	Ongoing	
<u>Commercialization</u>				
Mature tissue transformation into commercial cultivars	MCTF	4Q'13	Ongoing	 ▲
First raw materials with desired canker traits	MCTF	2017+	Ongoing	
Field evaluations/wide area testing	CRDF/Com Partners	2017+	Ongoing	
Regulatory studies, permits	CRDF/Com Partners	2014	Ongoing	
Achieve deregulation of first new line	CRDF/Com Partners	2021	Ongoing	
New cultivar budwood to nurseries	CRDF/Com Partners	2022	Ongoing	
Strategic partnerships	CRDF/Steer Comm	2014	Ongoing	

Quarterly Activity Update

- With the finalization of the licensing agreement with UF, SGC continues its process of tree growth and assessment moving forward, with focus on performance and risk management as it executes its roadmap.

Issues and Gaps

- The key go-forward issues relate to execution of SGC's roadmap. Performance, cost and risk management are paramount to success.

Performance to Milestones

- No changes from the January Quarterly Report

Advanced Citrus Production and Harvesting Systems

Quarterly Activity Update

- This project remains on hold until USDA has received and committed funding to the SCRI program.

Issues and Gaps

- Once CRDF staff has better visibility on the timing, size and scope of the USDA SCRI program, and the impact on DR. Burks' plans for proposal submission, it c ant at that point revisit the CRDF Board letter of support and funding commitments.

Performance to Milestones

- No changes in the projected milestones established in the March report that included projections of a late 2013/early 2014 possible timeframe for the SCRI program.

What	Who	Start	End	3Q'12	4Q'12	1Q'13	2Q'13	3Q'13	4Q'13	1H'14	2H'14
CRDF BoD decision on \$1.5 million cost-share commitment	CRDF BoD	Aug'12	Aug'12								
Informal Notification to ACPHS team	Browning	Aug'12	Aug'12								
Meeting with ACPHS to align expectations	Dukowitz/ Burks	Nov'12	Nov'12								
SCRI Program funded at USDA	Congress/ USDA	4Q13	1Q14								
ACPHS team proposal submitted to SCRI	Burks	1Q14	1Q14								
CRDF formal commitment letter	CRDF BoD	1Q14	1Q14								
CRDF cost-match commitment takes effect.	CRDF/ Burks	2H2014	Ongoing								

Quarterly Activity Update

- J&K Canine Academy is continuing its focus on nursery inspections. It has conducted several inspections and has landed a six month, once a week inspection contract.
- J&K applied for a grant in California, but was turned down, apparently being told that Canker, HLB and Black Spot were not sufficiently large problems to warrant canine scouting.
- J&K is continuing its education programs for growers at meetings and expos.

Issues and Gaps

- J&K faces the normal market acceptance and risk management challenges of an entrepreneur creating a new business in an established industry.

Performance to Milestones

- No changes in roadmap from March.

Project Roadmap: Canine Scouts

What	Who	Start	End	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	2H2013	2014
Industry awareness progs	J&K	July'12	Ongoing														
Validate market demand	J&K	July'12	Mar'13														
Initial nursery projects	J&K	Aug'12	Mar'13	<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 2px;">1</div> <div style="border: 1px solid black; padding: 2px;">2</div> <div style="border: 1px solid black; padding: 2px;">3</div> </div>													
Marketing roll-out	J&K	2013	Ongoing														
Meet with UF Profs re HLB, Black Spot	J&K, UF	1Q'13	1Q'13														
New market development	J&K	Sep'12	Ongoing														
Quality Assurance Certification program	J&K	2013	2013														
Business model evolution	J&K	2013	Ongoing														

Quarterly Activity Update

- On May 23 CRDF received notice from USDA, ARS Office of Technology Transfer that CRDF's license application to USDA for the Diaprepes pheromone patent has moved forward with a Federal Register Notice of Intent to Grant Exclusive License to CRDF.
- The notice was posted in the Federal Register on July 2, and comments must be received on or before August 1, 2013.
- Comments received in the Federal Register Notice should help CRDF determine the extent of commercial interest in the technology.

Issues and Gaps

- CRDF has communicated to USDA that the current market is small because it is geographically limited, with a relatively slow diffusion rate due to quarantine; that there are no company commitments at this point to co-fund the Lapointe research in return for an option to sub-license the technology; and that there must be multiple, simultaneous paths and concurrent closing of the licensing, CRADA and agreements with participating companies.
- There will be "go/no go" hurdles and decision points along the way, and CPDC and the Board will be kept informed. Any commitments will require prior CPDC and board approval.

Performance to Milestones

- The timing of the posting of the Federal Register Notice slipped an additional three months from the projections in the March Quarterly report, and a total of nine months from the projections in the September 2012 report.

