CITRUS RESEARCH & DEVELOPMENT FOUNDATION

GROWER RESEARCH REPORT

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Progress in Pursuing Emergency Registration of Bactericides Targeting Huanglongbing (HLB)

CRDF continues to support the development of treatments that target the elements of HLB, the vector insect, the host plant, and the bacterium, *Liberibacter asiaticus.* Progress on all topical areas is reported regularly at CRDF meetings, in seminars and grower meetings, and through a range of other outreach activities. One of the priorities that has received considerable attention is evaluation of bactericides.

How bactericidal candidates are evaluated

A range of bactericide candidates have been evaluated over recent years, using a standardized assay system shown below to determine best candidates for advancement to field trials.

Best candidates in the assay system move into small scale field trials, where the primary objectives are to evaluate efficacy and obtain information on phytotoxicity. In addition, these first level trials can begin to assess formulations and application methods.

The next step is to advance candidates into multi-year field evaluation during which the impact of treatment can be measured, including reduction of bacterial titer, plant health response, and following season-long treatments, yield and fruit quality data, and can be compared with untreated controls. Candidate bactericide materials that have been evaluated in field tests include representatives of several groups, including biopesticides, plant essential oils and agricultural bactericides used in other cropping systems for disease control.

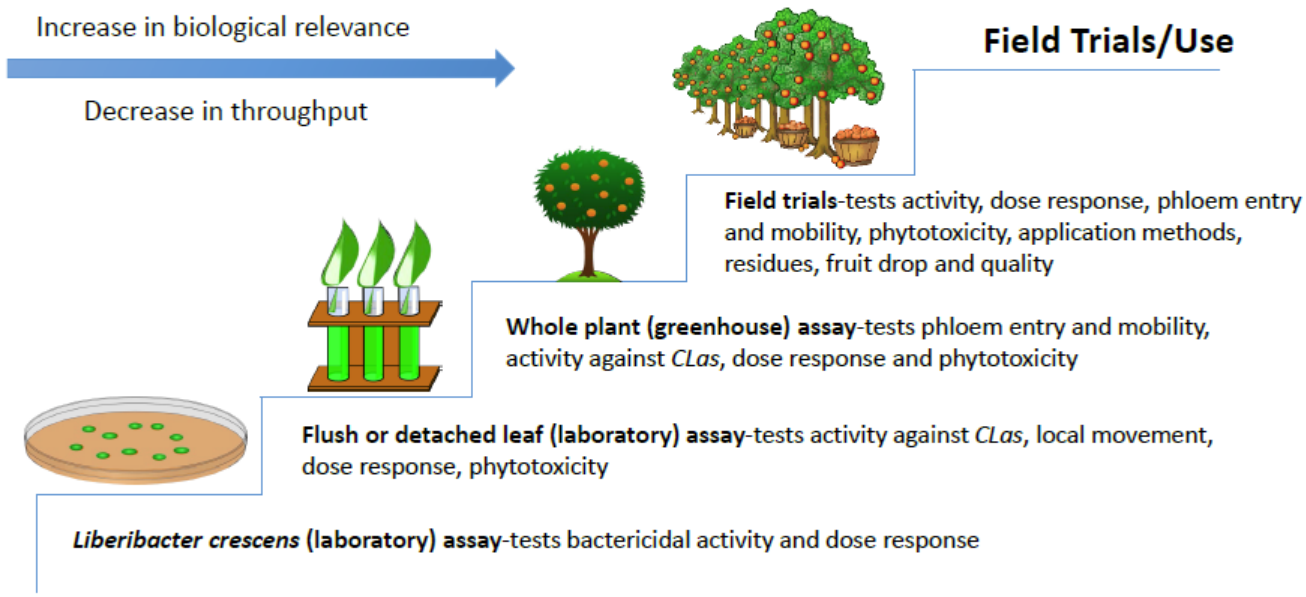
The most expansive evaluation is represented by full-scale field trials conducted by registrants, and these trials are multi-site evaluations of activity, dose , application methods and residues following treatment.

Upcoming Board and Committee Meetings

Most meetings are held in Ben Hill Griffin Hall at the UF-IFAS, CREC campus in Lake Alfred, Florida

October 27 - Board of Directors	9:30 am

Stepwise Assay System for Bactericides



(Slinski 2015)

Three active ingredients are currently used in U.S. agriculture:

- Streptomycin
- Oxy-Tetracycline
  - Above materials used for decades in vegetable and tree fruit crops
- Kasugamycin—Emergency approval for use in Cherries, full label pending

What is the status of moving streptomycin and oxy-tetracycline to field use?

CRDF has supported research to accelerate the development of streptomycin and oxy-tetracycline. Registrants associated with these active ingredients were already at work in Florida conducting trials to determine the ability of these materials to suppress *CLas* titer in infected trees. With additional support from CRDF, this work was accelerated and full residue studies were initiated to support a federal label application.

Products associated with two U.S. registrants are being evaluated as follows:

AgroSource International

- Firewall® 50 WP Streptomycin
- Fireline® 17 WP Oxy-tetracycline

Nufarm Americas

- Mycoshield® 17 WP Oxy-tetracycline

Field research in 2014 and 2015 is providing data on efficacy, tree health response and evaluation of residues when applied as a foliar spray during the growing season. These data provide the basis for establishment of a field use pattern and to determine the contribution that they might make to HLB management.

Based on results provided in updates to CRDF, it is time to determine if enough evidence for efficacy is available to consider Section 18 Emergency Exemption for one or more of the products.

The work to secure the information to develop petitions for use of bactericides in a management system for improvement of tree health for citrus infected with Huanglongbing under a Section 18 Specific Exemption in Florida has followed a specific process. This process was described by Dan Botts of Florida Fruit and Vegetable Association (FFVA) several months ago to the Commercial Product Delivery Committee, who has oversight of development and delivery of bactericides, and the process was outlined specifically in a report to the committee. Direct communication with representatives of Nufarm Americas, Inc., AgroSource, Inc., CRDF, and the Florida Department of Agriculture and Consumer Services (FDCAS) was held to discuss the data needs and process that would be followed to assure the registrants that their request for independent development of the supporting package was followed. The plan calls for assembly of the data from field research conducted by the registrants for each material, and an evaluation of the strength of evidence for each product based on its supporting evidence.

Third Party Registrations, Inc. (TPR) then provided an outline of the specific requirements under CFR Title 40, Part 166, annotated with the information needed to complete each of the sections for a complete petition to be submitted to FDACS and EPA. This document was discussed with FDACS and registrants with particular attention on the data needed from the registrants to be able to finalize the justification and economics sections of the petition. **The basis for consideration of a Section 18 Emergency Exemption includes a clear understanding of the use patterns being proposed, the status of the magnitude of expected residues, and the underlying efficacy data supporting the expected positive results on declining tree health.** The justification, expected impacts and economic arguments are developed once the above information is collected, analyzed and appropriate documentation developed. Assignments were made regarding FFVA, TPR , the entity responsible for assembling the petition on behalf of the citrus industry, and the registrants, whose data will support the request. This included a rigorous timeline to move this activity forward as quickly as possible.

During September, TPR and CRDF were notified that a petition for a Section 18 for use Mycoshield ® had been developed by the Indian River Citrus League for submission to FDACS independently. Follow-up communication has taken place to integrate the materials submitted to FDACS with the continued process that was outlined by FFVA and CRDF.

Coordination with FDACS is continuing as we move this process forward. It is anticipated that once we have a complete picture of what will be requested of EPA, an overview of the pending petition will be provided to EPA to assure the most efficient review possible. FFVA (TPR) has extended its good

working relationship with EPA over recent years to potential HLB solutions and with CRDF, has provided periodic updates and conducted technical discussions of various HLB interventions, including bactericides.

What are some of the elements that must be considered for a Section 18 Emergency Exemption?

- Existence of emergency pest/disease situation
- Measure of economic loss to warrant emergency consideration
- Lack of alternative solutions
- Evidence of effectiveness of intervention and economic benefit of its use
- Field use pattern established (draft use label)
- Supporting data for claims
- Residue data to establish crop tolerance or exemption
- Expert letters supporting strength of evidence
- Support from industry needing solution

Where are we in the Section 18 process?

Work with FFVA is advancing to complete assembly of packets on efficacy and use pattern for the three products: Firewall® streptomycin; Fireline® oxy-tetracycline; and Mycoshield® oxy-tetracycline. Evaluation of the strength of evidence of effect and economic impact of each product has been initiated and will continue with scientific experts asked to independently review the evidence. A decision to support application of a portfolio of HLB suppression products as a treatment series will emerge from the evaluations and determination of the strength of evidence. Considering the seriousness of HLB in Florida citrus and the difficulties in suppressing bacteria within citrus tissue, this process is considering the strategy and value of rotation of materials to benefit from multiple active ingredients if the data supports this approach which could lead to improved efficacy and resistance management within both the target *CLas* bacteria and also within plant and soil microbial communities which might also be exposed to the treatments.

The proposed timeline for this process as presented by FFVA to CRDF in August is aggressive and it will be necessary to follow this timeline if the endpoint of approval for use in early spring 2016 is to be realized.

September 2015:	Assembly of evidence in data submission
September 2015:	Evaluation of strength of case for each product
October 2015:	Submission of petition for best cases
Late 2015:	Approval by FDACS, submission to EPA
March 2016:	Approval by EPA and consideration for use

The consideration for approval of multiple tools for suppression of HLB in Florida citrus in the timeframe proposed is only possible with full cooperation of the growers, registrants, FFVA, and state and federal regulatory agencies. Section 18 Emergency Exemption requests are a valuable tool that can be accessed during emergency situations, but the granting of such uses only comes when a strong case is made. The Florida industry has a strong relationship with FFVA in these matters, as they have provided the leadership for previous label changes for neonicotinoid insecticides in citrus, and has been central to the industry's interactions with FDACS and EPA.

In fact, FFVA has served the Florida agricultural industries in this capacity for over 30 years, working closely with FDACS and EPA. The registrants as well are critical in this process. While the industry is the party who takes these requests forward, it is based on the data resident with the registrants, who have conducted the tedious research. Finally, the regulatory agencies involved at both state and federal levels must be engaged, and we are very fortunate that FDACS has been closely involved in each step as this process has proceeded.

CRDF is confident in the process which has been developed, and in the strength of looking at the evidence for all three of these products. We believe that this effort as organized and driven by FFVA has the best chance of putting a tool into the hands of Florida citrus growers in early 2016.

Quarterly and Final Progress Reports submitted by PI's on CRDF-funded research projects can be found at **citrusrdf.org/growers**