STDF Standards and Trade Development Facility

PROJECT: STDF/PG/ 436 LATIN AMERICA PESTICIDE RESIDUE DATA GENERATION PROJECT

LATIN AMERICA: STRENGTHENING REGIONAL CAPACITY TO MEET PESTICIDES EXPORT REQUIREMENTS BASED ON INTERNATIONAL STANDARDS

FINAL REPORT

[JANUARY 30, 2017]

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PROJECT INFORMATION

Title Latin America Pesticide Residue Data Generation Project: Strengthening regional capacity to meet pesticides export requirements based on international standards
Implementing Agency: Inter-America Institute for Cooperation on Agriculture, supported by the United States Department of Agriculture
Partners: National pesticide regulatory and research authorities of participating countries, the Food and Agriculture Organization, IR-4/Cornell University and Rutgers University, pesticide manufacturers (Dow and Sumitomo)
Start Date : 1 October 2013
End Date 30 September 2016
Beneficiary National pesticide regulatory authorities, farmers, agri-food industries, and consumers.
Budget Project value: US$ 1,195,416 Approved STDF contribution: US$ 374,116

LIST OF ABBREVIATIONS

ASEAN	:	Association of South East African Nations
CCPR	:	Codex Committee for Pesticides Residue
EPA	:	Environmental Protection Agency
EU	:	European Union
FA	:	Financing Agreement
FAO	:	Food and Agriculture Organization
FAS	:	Foreign Agricultural Service
GAP	:	good agricultural practices
GC-MS-MS	:	Gas Chromatography/Mass Spectroscopy
GLP	:	Good Laboratory Practice
IDB	:	Inter-American Development Bank
IICA	:	Inter-American Institute for Cooperation on Agriculture
IR-4	:	Inter-Regional Research Project Number 4
JMPR	:	Joint Meeting on Pesticide Residues
LC-MS-MS	:	Liquid chromatography/Mass Spectrometry
MRLs	:	Maximum Residue Limits
OECD	:	Organisation for Economic Co-operation and Development
PSC	:	Project Steering Committee
QA	:	Quality Assurance
SOP	:	Standards Operating Procedures
SPS	:	Sanitary and Phytosanitary
SSA	:	Special Services Agreement
STDF	:	Standards and Trade Development Facility
USA	:	United States of America
USDA	:	United States Department of Agriculture
WTO	:	World Trade Organization
WHO	:	World Health Organisation

1. EXECUTIVE SUMMARY

The Project was initiated by the United States Department of Agriculture (USDA) in collaboration with the Inter-America Development Bank (IDB) in 2012 with the aim to assist Latin American countries in enhancing their capacity to meet pesticide-related export requirements based on international (Codex) standards and to enhance global market access of Latin American agricultural commodities. Initial consultation meetings were supported by the IDB in Peru (Andean countries) and El Salvador (Central American countries) to share the concept of the project and gain country buy-in. As the primary technical assistance delivery organization in the region, the Inter-American Institute for Cooperation on Agriculture (IICA) was requested by participating countries to manage this project and submit, on their behalf, a STDF Project Proposal to collaborate on pesticide residue data generation.

With the support from the Standards and Trade Development Facility (STDF), the project was initiated on October 1, 2013 and completed on September 30, 2016 with the following four studies carried out:

1. Pyriproxyfen/Pineapple: Panama
2. Pyriproxyfen/Banana: Costa Rica and Guatemala
3. Spinetoram/Avocado: Colombia
4. Spinetoram/Banana: Bolivia

Field trials and laboratory analysis work has been completed for all four studies. Costa Rica, with Guatemala data included, submitted the data package and label documentation for pyriproxyfen on banana to Sumitomo in January 2017. Panama submitted a data package and label for pyriproxyfen on pineapple to Sumitomo in November 2016. Colombia submitted a data package and label for spinetoram on avocado to Dow in September 2016, and Dow submitted the data package to JMPR in November 2016, including it with other data packages from the sister ASEAN STDF project.

Considering the overbooked work schedule of the FAO/WHO JMPR in 2017, the review for pyriproxifen was rescheduled to 2018. Data packages and labels for pyriproxifen have been completed on schedule, shared with Sumitomo, and will be submitted to FAO/WHO JMPR in late 2017 during the next review cycle. This includes the studies on banana from Costa Rica and Guatemala, and pineapple from Panama.

The Bolivian study for spinetoram on banana was originally planned to be linked and coordinated with a study in Uganda. However, Dow was not able to support this study in Uganda. Bolivia completed their study, but unfortunately the data could not be utilized as the samples from the three studies were not analyzed.

Overall, the project provided good lessons for participating countries by delivering theoretical and practical experiences in conducting field trials, laboratory analysis by exposure to practice, techniques, and know-how of GLP studies. It improved the capability of participating countries to generate quality data for establishing MRLs based on international guidelines; e.g., OECD-GLP, EPA-GLP, FAO Manual (2009). The implementing partners, IICA, USDA, and IR-4/Cornell University and Rutgers University, also learned and shared experiences on the coordination of work sharing and efforts among different countries, including government regulatory officials, laboratory and field technicians, as well as the pesticide industry.

The success of the project is due to the good collaboration and partnership among the partnering countries, USDA, IR-4, contributing pesticides manufacturers and IICA who all made dedicated commitments towards carrying this project through.

Moving forward from the success of the project, it is expected that partnerships among

IR-4 and participating countries will continue in future to support regional priorities on common needs, especially in the area of trade facilitation.

2. BACKGROUND

1. The participating Latin American countries are primarily food exporters and rely on the use of modern agrochemicals to control pests and plant diseases, while protecting human and environmental health. IICA has been very active in SPS-related activities in Latin America and the Caribbean, focusing on a wide range of activities such as policy and regulations development, modernization of animal and plant health and food safety national services, capacity building, and lending technical support to national and regional agricultural health and food safety (AHFS) organizations. Furthermore, IICA has conducted medium-term (4-6 years) programs to promote the participation of its member countries in international SPS fora, particularly the SPS Committee of the World Trade Organization, the Codex Alimentarius, and the International Plant Protection Convention (IPPC). The contributions of IICA to the standard-setting procedures of the "Three Sisters" (OIE, IPPC, and Codex Alimentarius) have been widely recognized.

2. Since the entering into force of the SPS agreement in 1995, it has been noted that many developing countries have not been actively participating in the development of international SPS standards. Developing countries have also had difficulties aligning their regulations with international standards. Indeed, in 2009, the WTO-SPS Committee meeting in Geneva Switzerland observed that:

- There is need to enhance the participation of developing countries in development of international standards and other relevant areas;
- There is need to avoid unnecessary duplication of efforts and to identify future collaboration in light of limited financial and human resources in the "three sisters" i.e. IPPC, OIE and Codex; also to promote deeper understanding and increased usefulness for developing countries; and
- There is need to ensure that the standard-setting process is in line with the implementation of the SPS Agreement and facilitates trade on agriculture and food products, especially for developing countries.

3. Regional support for this project arose from weaknesses identified by the WTO-SPS Committee and the desire by the Latin American countries involved to strengthen their participation in international sanitary and phytosanitary standard-setting processes. The present initiative would also help achieve wider harmonization of SPS norms within the Latin American region.

4. The idea to have cooperation on pesticides residues was discussed during regional planning workshops organised by the USDA and IDB in 2012. The participants agreed to develop a project proposal for pesticides residue data generation. The project proposal on "Latin American Pesticide Residue Data Generation: Strengthening regional capacity to meet pesticides export requirements based on international standards" was developed for possible funding by the STDF.

5. Following to the approval by the Latin American participating countries, the Project Proposal was submitted to the STDF and approved in March 2013 by the Working Group for funding support. The Financing Agreement (FA) of the Project was signed by IICA and the WTO on behalf of the STDF, to begin on October 1, 2013.

6. Due to the delays in obtaining final commitments from the pesticide manufactures to agree upon crop/pesticide assignments and their marketing interests, field trials could not be initiated on time. Upon the request by IICA, the STDF Working Group approved a no-cost one-year extension. The project officially ended on 30 September 2016.

3. PROJECT GOAL

7. The project goal was to enhance the capacity of Latin American countries to meet pesticide-related export requirements based on international (Codex) standards in order to enhance global market access of agricultural commodities.

9. This goal was achieved through a collaborative data generation project based on international guidelines by incorporating technical capacity building as the primary means of delivery. With the establishment of Codex MRLs, it is expected that the access to international markets for Latin American agricultural commodities will be enhanced.

4. PROJECT IMPLEMENTATION AND MANAGEMENT

Implementation

10. The Project was implemented through a series of trainings and consultations, sharing theory and knowledge, and then applying this knowledge to practical experience by conducting actual field trials, performing sample residue analysis, packaging data, and ended with data submissions to the FAO/WHO JMPR for establishment of Codex MRLs. The project activities covered the identification of pesticide/crop priorities, nominations of pesticides to the FAO/WHO JMPR, conducting residue field trials, generating residue results from field samples, and packaging the data for submission.

11. The assignment of crop-pesticide-country combinations for the project was carried out in consultation with JMPR Secretariat, the U.S. Environmental Protection Agency (EPA), USDA, IR-4, and the involved pesticide manufacturers (Dow and Sumitomo), taking into consideration the national needs of participating countries, specific pests to be controlled, registration issues, and market conditions. The following pesticides were agreed upon by all stakeholders of the project: *Pyriproxyfen (Sumitomo) and Spinetoram (Dow).* The rationale for their selection included:

- These pesticides are very low-risk and would more likely receive approvals for experimental trial permits in the participating countries,
- Very little residue data exists for these pesticides on tropical crops,
- No Codex MRLs exist for these pesticides for many specialty crops (particularly, tropical fruits) grown in the region,
- Support was offered from the pesticide manufacturers to seek registrations for these chemicals in participating countries,
- The FAO WHO/JMPR, EPA etc. and other governments have promoted the use of reduced risk chemistries. Support from these organizations would provide successful implementation of the Project.

12. Finally, the following four studies were agreed to be carried out under the Project:

1. Pyriproxyfen/Pineapple: Panama
2. Pyriproxyfen/Banana: Costa Rica and Guatemala
3. Spinetoram/Avocado: Colombia
4. Spinetoram/Banana: Bolivia

*Note: Peru originally agreed to participate in the project, carrying out a study on pyriproxyfen on avocado. However, administrative moves of staff disrupted the make-up of the Study Team and the project failed to move forward. Peru terminated its involvement in the project in 2015.

Management

13. The project was managed by a Project Steering Committee (PSC) that met twice to plan and direct the work. The PSC consisted of the point contact members from each of

the project countries. As part of the global initiative, the Project was coordinated among the stakeholders at the national, regional and international levels, including sister STDF-funded projects being implemented in the ASEAN and African regions.

14. IICA was the lead organization in implementing the Project. The USDA Foreign Agricultural Service (USDA-FAS) played the role as the Technical Coordinator to coordinate technical aspects of the project. IICA and the Technical Coordinator reported the progress of the Project to the PSC. The JMPR Secretariat of the FAO provided technical advisory support on the implementation of the Project. IR-4, based at Cornell University, was the primary technical implementing organization, providing training, guidance, and coordination of field and laboratory work. The Project Study Teams were established, in consultation with participating countries, to carry out the work of the studies. The Study Teams consisted of the following roles: Testing Facility Management (primary contact point), Study Director (lead national coordinator), Quality Assurance Officer, Field Investigator, and Laboratory Investigator.

15. The pesticides manufacturers (Dow and Sumitomo) supported the Project by providing technical support such as: product samples, analytical standards, analytical methods, regulatory input, registration and labelling, etc. These manufacturers had shown their commitments to seek registrations of the proposed pesticides in the respective participating countries, and support the data at the Codex level. This commitment also included in-kind contributions for conducting required efficacy trials and determining the most appropriate good agricultural practices (GAPs).

16. The Project was implemented with the engagement of Cornell University (IR-4, with headquarter office at Rutgers University) as the primary consultant Project Study Director. An agreement between IICA and Cornell University was signed in March 2015. Additional personal services contracts were established with field trial consultants based in Costa Rica and a laboratory analytical consultant based in Mexico.

5. PROJECT OBJECTIVE, OUTPUTS & ACTIVITIES

5.1. Project Objective:

17. The goal/objective of the project was to enhance the capacity of Latin American countries to meet pesticide-related export requirements based on international (Codex) standards in order to enhance market access of agricultural commodities.

5.1.1. Output Tier 1: Capacity building

Output: Acquired knowledge and skills for scientists and regulators to organize and implement field trials and to collect, prepare and analyse high-quality data for submission to JMPR.

Activity: A series of trainings, workshops, consultations on the conduct of field trials, sample preparation and analysis, SOP reviews and identification of core management team, facility inspections, SOP refinement, and protocol development.

18. The Study Director and technical experts provided multiple on-site trial training and support to Study Team members at the onset of each study and for data report preparations.

5.1.2. Output Tier 2: MRL Establishment/ Registration

Output: The availability on the market of new, approved chemicals for minor use crops.

Activity: Implement the result of trainings in practice that include: field trial applications and harvest, analytical validation and analysis, data packaging and submission, analytical summary report preparation, and final report development

19. The protocols for the studies had been developed by the Testing Facility Management of the respective participating countries and the Project Study Director. Following the signing of its protocols, the four studies were carried out. In the implementation of the studies, consultation among participating county Study Team members, Project Study Director, Project Technical Coordinator and IICA were closely established. Country visits were also carried out by Project Study Director and experts to the participating countries to provide lectures and guidance in order to ensure that trials and analytical work followed international best practices.

20. All submission of data packages and label under the four studies of the project to FAO/WHO JMPR for establishment of Codex MRLs was originally scheduled at the end 2016 for JMPR review in 2017. However, considering that the FAO/WHO JMPR had overbooked on its work schedule for 2017, the schedule for submission of data packages were adjusted as follow:

- Data packages and label for spinetoram were submitted in November 2016 for JPMR review in 2017.
- Data packages and label for pyriproxifen will be made in 2017, as the JMPR review for Pyriproxifen was postponed from 2017 to 2018.

i) Spinetoram – avocado (Colombia)

The study on spinoteram on avocado was conducted by Colombia. Colombia carried out 6 field trials, led by Study Team members from the Instituto Colombiano Agropecuario (ICA) and National Food and Drug Surveillance Institute (INVIMA). The test product used was Exalt 60SC (Spinetoram 60 g/L emulsifiable concentrate).

The final Report was completed in September 2016, and was submitted to JMPR in coordination with Dow in November 2017.

ii) Spinetoram – banana (Bolivia)

The study on spinetoram on banana was carried out by Bolivia. The Bolivian Study Team carried out 3 field trials, led by the Departamento de Certificaciones de Inocuidad Alimentaria. Laboratory analysis was not carried out on the samples since the Bolivian team did not have the necessary analytical instrument and the data would not be submitted to JMPR.

The Bolivian team completed the field portion of the trials, but did not obtain residue data from samples.

iii) Pyriproxyfen – pineapple (Panama)

The study of pyriproxyfen on pineapple was conducted in Panama. The Panamanian Study Team carried out 6 trials, led by the Ministerio de Desarrolo Agropecuario (MIDA).

The final Report was completed in September 2016, and will be submitted to JMPR in coordination with Sumitomo in September 2017.

iv) Pyriproxyfen - banana (Costa Rica and Guatemala)

The study of pyriproxyfen on banana was jointly carried out by Costa Rica and Guatemala. Eight field trials were carried out total, with Costa Rica conducting 7 trials and Guatemala 1 trials. Guatemalan samples were shipped to Costa Rica for laboratory analysis, since the Guatemalan laboratory did not have the necessary equipment to conduct the analysis. Costa Rica lead the preparation of the Final Report and data packages for submission for FAO/WHO JMPR review.

The final Report was completed in January 2017, and will be submitted to JMPR in coordination with Sumitomo in September 2017.

Initially, six distinct residue studies were planned for the Latin American countries, which would have resulted in the establishment of at least six new Codex MRLs. However, with Peru cancelling their participation, Bolivia not having a partner country to complete the necessary number of trials, and Costa Rica and Guatemala deciding to partner on a larger banana project (eight total trials needed), only three new Codex MRLs will be established from this project. If, however, crop grouping will be allowed during the JMPR reviews of both pyriproxyfen and spinetoram, the 006B crop sub-group could acquire a total of 84 new Codex MRLs.

In the four countries completing the residue studies, registrations of these reduced-risk pesticides were successfully completed. Growers now have access to use these new pest control tools, which will be complimented with having international trade standards established in 2018-19. During 2017-18, USDA and IR-4, as part of continuation of this work, will provide follow-up to expanding registrations of these project pesticides to other Latin American countries.

6. MONITORING AND EVALUATION OF THE PROJECT

21. During the Project life, mid- and end-Project surveys were conducted. The pre-Project survey was not able to be completed. Instead of pre-Project survey, the baseline data/information was collected by the Project Study Director in the form of facility inspections. The Project Study Director conducted an assessment for each participating country prior to the conduct of individual training and field work. This assessment included: establishment of Study Teams, facilities (field and labs), equipment, and standard operating. This baseline information provided a description on the situation of each participating country in regard to technical capacity at the beginning of the project.

22. The mid-project survey was conducted in August 2014, while the end-Project survey was conducted in January 2016. The end-Project survey summary is provided in Appendix B, and full responses of the survey can be provided upon request. In short, the end-Project survey showed an exceptional positive response to the project. Highlights of the survey are provided below.

Here is a brief on the survey responses:

1. Has the research and training program improved your ability to conduct field residue studies/laboratory analysis of pesticide residue samples? If so, how?

Overall response to this question was that this project has greatly improved the participant's ability to conduct supervised residue field trials. Examples ranged from sprayer calibration and

delivery application techniques, to laboratory sampling and analyses, SOP development, Data reporting, and GLP experience.

2. Do you believe this project will result in a greater probability of future data being accepted internationally? Why or why not?

Overall response to this question indicates that project teams have gained significant confidence in conducting the residue trials and that experience gained will provide greater assurances that future data generation can be used to establish MRLs. The reason for this confidence was that this project didn't only provide general training, but it provided hands-on experience in carrying out real work, collaborating with many technical and regulatory partners, and other national project teams.

3. How will this project improve the trade opportunities for your country?

Overall, responses indicated that work through this project will improve trade opportunities for the Latin American countries, as a result of better abilities to understand residue data research in support of pesticide registration, improved ability by governments to support local farmers and exports by providing new pesticide products, and improved reporting of data analyses.

4. Were project funds distributed in a fair manner? Why or why not?

Most of the responses expressed satisfaction with the distribution of the project funds, which was a complicated process since each country required different levels of funds, depending on the type of crop researched, if laboratory analysis was conducted in the country, shipping and travel costs, and needed supplies and equipment. One response indicated that the funds were not allocated equally, as originally outlined in the project proposal.

5. Could the process of assigning trails be improved? If so, how?

Most responses were satisfied with the trial assignment process (which countries worked on which crop/pesticide combination). One suggestion was that the capabilities of each country should be better assessed prior to commitments from countries to ensure that they are actually capable of doing the work.

6. How could the information covered in the trainings be clearer and more easily understood?

Responses to this question varied, including suggestions to provide more information in video format; more training and guidance on report preparation and writing; and suggestions on how to provide field/lab notebooks; better templates for reports; and better order of trainings should be in a more logical order.

7. What were your expectations of this program before it started? To what degree has the project met these expectations?

Responses indicated an original expectation to participate in, and gain experience in, conduction field residue trials – which was the intended objective of this project. The survey participants expressed that the project mostly met their expectations. The reason for not fully meeting the expectations included that updates and more information on the larger program should be better shared with the members.

8. What were some of the areas that could be improved?

Areas that could be improved in the project included better training, coordination and communication between the parties involved, the allocation and management of funds, personnel and equipment for laboratory and field.

9. What are some topics on which you would like to receive additional training in the future?

Requested future training topics included the following: field sampling processes; trials on other types of cultivars; method validation; report writing; risk assessment; data management.

10. Have you experienced any setbacks in the process of completing your study? If so, please explain what happened in detail and what is being done to correct the problem.

Some identified setbacks by the study team members included the following: inability to analyse samples because lack of lab equipment and partner country not able to conduct planned work; staff turnover; confusion with quality assurance officer requiring replication of unnecessary work; field sites cancelled due to other disease outbreaks in the area.

11. Is the model of your current Study Team (make-up of Ministries, Agencies, Personnel, etc.) a sustainable model? Will this current Study Team be appropriate to perform future work? Do you recommend a different make-up of the members? Please advise how we can best help strengthen your Study Team ensure that it is more sustainable.

This was an important question to determine the sustainability of countries to carry out future work. Most responders indicated that their core teams are appropriate, but did make some suggestions for improvements. These included: gain higher level Ministry commitment prior to starting new projects; need to establish dedicated staff to the program; different team members to prevent cross-agency conflicts.

12. Is your Study Team interested in continuing future residue projects with IR-4 and/or other countries within your region? If yes, please advise how we can better ensure that your Study Team receives the necessary support from your management and leadership?

All Study Teams expressed interest in future collaboration with IR-4 and other countries in carrying out new residue research projects. USDA and IR-4 will work directly with these countries to identify and implement new projects under the newly formed Global Minor Use Fund (managed by IR-4 and supported by USDA). New projects are being discussed at this time, and expected to begin during 2017-2018.

13. Any other comments: Do you have any other suggestions, recommendations, comments, requests?

A suggestion was made to include more funds for equipment in the future.

Section 2: Special Technical Knowledge/Skills/Ability

The question asked the respondents to rate their teams' skills in nine technical abilities on a scale of 1-5. In the mid-project survey, the average response was 3.6 (some knowledge/skill). The final survey showed significant improvement in responses to an average of 4.6 (increasing toward full knowledge/skill).

Section 3: Understanding of Codex MRL establishment process

The question asked the respondents to rate their teams' skills in five areas of Codex MRL understanding on a scale of 1-5. In the mid-project survey, the average response was 3.7. (some knowledge/skill). The final survey showed a significant drop in responses to an average of 2.7 (below some knowledge/skill). This indicates that participants may have thought they understood the Codex process much better than they actually did, and through this process realized that requirements are much more complicated than anticipated. More emphasis on the Codex process needs to be incorporated better into future projects.

7. FINANCIAL OVERVIEW

23. The total estimated value of the project, at the time of contracting, was USD 1,195,416. This included an STDF contribution to the project of up to USD 374,116.

IICA provided an in-kind contribution in the form of human resources, working time, use of office/lab premises etc. Other donors, USDA, CropLife and pesticides manufacturers (Dow and Sumitomo), also supported the Project in the form of in-kind and cash contributions. The participating countries also contributed some of their own resources to the project. In particular, Costa Rica made a substantial contribution to conducting their work, financing nearly 100% of their study.

Contribution estimates are provided below:

USDA/FAS	$374,000 (consultants, workshops, travel, staff salary)
IICA	$40,000 (staff time)
IDB	$90,000 (meetings and trainings)
CropLife	$6,000 (meetings and regulatory support)
Dow and Sumitomo	$60,000 (test chemicals, shipping, registrations)
Participating countries	$30,000 (staff time and supplies)
Costa Rica	$30,000 (staff time and supplies)

*Costa Rica supported entire field trial project cost with own funds

24. The projected STDF contribution to this project was up to $374,166, of which expenditures under this project totalled $314,602.87. Beyond cost savings realized through the efficient execution of resources, two issues explain this underspending. First, as mentioned above, Costa Rica assumed the majority of the costs associated with their participation. This contribution was not foreseen when the budget was developed, although it was obviously viewed positively and demonstrates the importance of this work for that country. Second, Peru withdrew from the project approximately mid-way through the execution period. Their withdrawal resulted in the reduction of project outputs by one data package and, accordingly, resources budgeted to support various interventions in that country were not expended.

The financial report is *attached.*

8. OVERALL PROJECT RESULTS AND LESSONS LEARNED

8.1. Results

25. The Project provided practical experiences for participating countries in generating quality data to support the establishment of MRLs based on international guidelines/procedures. From this project, at least one new Codex MRL will be established each for avocado, banana, and pineapple. If crop grouping can be applied to this data, in combination with data generated under the ASEAN project, up to 84 new Codex MRLs could be established that would include additional crops within the 006B tropical fruit sub-group (as this project targeted the representative crops of the crop grouping classification in order to increase potential impact). This focused capacity has been enhanced in the areas that include:

i. Sampling and data collection for field residue studies.
ii. Sample preparation and method validation for the laboratory analysis.
iii. Sample analysis for pesticide residues.
iv. Preparation and recording information in field notebooks (application, location, direction, sampling and weather).
v. Traceability.

vi. Study management.
vii. GLP knowledge and experience.

The participants from Latin America shared experiences on how to coordinate a work-sharing effort amongst many countries, between government regulatory officials, and laboratory and field technicians, as well as pesticide manufacturers and FAO/WHO. Coordination among these stakeholders presented considerable challenges and required close communication to ensure the process went on track to achieve successful results. The success of each study relied on the close coordination and partnerships between all of these stakeholders involved.

26. More broadly, this project has provided the governments in Latin America an opportunity to collaborate with each other on agricultural research to address very real needs in pest control solutions and development of international standards, where none had existed before. This also provided an opportunity for government agencies within each country to collaborate, communicate, and build relationships which did not exist previously. Finally, this project initiated dialog between government researchers, the pesticide industry, and grower/exporter stakeholders to identify and prioritize crop protection needs. With this expanded communication and skills developed among stakeholders in the region, the goal is to systematically work towards replacing "high risk" pesticides with lower-risk alternatives, providing increased safety to consumers, field workers, and the environment, while enabling governments to respond quickly to new outbreaks of pests and diseases.

27. In addition to the objective of building capacity for conducting field residue studies, another substantial result of this project has been the enhanced participation of the country teams at the Codex level. The national study teams needed to coordinate the project work with their Codex Contact Points and their lead delegates to the Codex Committee on Pesticide Residues (CCPR) in order to have their project pesticides placed on the CCPR review schedule. Prior to the 2014 CCPR meeting, USDA and IR-4 facilitated communication between the study teams, their Codex representatives, FAO, and the pesticide manufacturers (Codex data sponsors) to firm up plans for the CCPR review nominations. On the margins of the CCPR, all the countries participating in the STDF-supported projects (including Asia, Africa, and Latin America), along with the pesticide manufactures and IR-4, met to further coordinate the nomination process – which was successful in getting all the project pesticides placed upon the review schedule. This provided an opportunity for the CCPR delegates to directly engage on the floor of the CCPR, and the delegates were able to participate in discussing other related agenda items at the CCPR, including discussions on crop grouping, methods of analysis, and dietary risk. With this enhanced level of engagement at Codex, many of the survey respondents commented that additional training or opportunities to better understand and engage in Codex are priorities for future capacity building.

This project has also helped the JMPR work through some new issues during their evaluation and MRL recommendation process. This project has brought forth discussions on incorporating data into the new crop grouping system using representative crops; combining data sets from multiple countries in a joint submission; creating guidance on procedures for sampling large fruits when storage space is limited or shipping samples can be very far (for developing country situations); and the level of GLP compliance required to accept data (for developing country situations). The guidance provided by FAO on these issues will be extremely valuable for conducting future work.

28. This STDF-funded project has laid the technical foundation and logistical mechanisms for a sustainable, cost-sharing, international residue program. A major spin-off result of this project was the establishment of the Global Minor Use Foundation (GMUF). In September 2015, with a clear demonstration that the data generated by the study teams was of high quality, and the expressed high interest of the study teams to

continue collaborations once this STDF project was completed, USDA/FAS contributed $500,000 to IR-4 to establish an international branch of its program, called the GMUF. Shortly after, Syngenta contributed another $40,000 towards this new program and IR-4 has leads to receive additional funds from other pesticide manufactures. The objective of the GMUF is to provide a coordination mechanism to receive and prioritize pest control needs at a global level, and to coordinate data generation projects amongst multiple countries to establish national and Codex MRLs. FAS and IR-4 have begun discussions with Colombia, Costa Rica, and Panama (and Malaysia, Thailand, and Vietnam) for a next round of joint residue projects to begin in 2017-18. To date, IR-4 via the GMUF, has established either formal Memorandums of Understanding, or informal cooperative agreements, with the involved ministries of these six countries to partner on future joint projects. The GMUF will provide coordination, training, and guidance for the joint work, with the pesticide manufactures providing registration support and materials/methods for field and lab studies, and the country teams providing support of their staff, equipment, and facilities to conduct the work. The GMUF is also looking to develop partnerships with grower/exporter associations to provide the fields/trees for the research.

29. The efforts under this project have been communicated at multiple fora as a model example for collaboration to increase local technical capacity, but also for establishing standards to support international trade. This project has been a topic of discussion at the CCPR meetings (2012-2016) for enhancing developing country participation in data generation efforts. Presentations describing the project work were delivered at the second Global Minor Use Summit (2012, and third Summit planned for 2017); the Latin America Pesticide Residues Workshop (LAPRW) conference (2014 and a planned symposium in May 2017); American Chemical Society conferences (2012 and 2014); the IR-4 Global Minor Use Workshop (2015); a special session on pesticides at a pre-WTO/SPS Committee meeting (2016); and planned regional Codex coordination meetings Asia and Latin America (2017).

8.2. Lessons Learned

30. The most significant lesson learned under this project was the importance of the study team make up. It became very clear that the composition of each national Study Team needed to be very different for each country – what worked in one country didn't necessarily work in another country. It is important to select members from research institutions with the ability to dedicate staff time, replace members if needed, and coordinate among other institutions involved in the work. One-on-one meetings with the Directors (or equivalent) of participating institutions is critical for ensuring buy-in and commitment to the work, and explaining the importance and long-term goals of the work. A critical element of each Study Team is to have a strong in-country Study Director or contact person who can communicate with all other members of the team, IR-4, and other stakeholders.

31. Identifying project pesticide/crop combinations is an extremely difficult challenge, as there are many interests at play. Foremost, there must be a real agronomical need for the pest control solution to be addressed. However, there is also a marketing interest by the pesticide industry to support a registration and stewardship of the project. Because of the lack of harmonized registration procedures and recognition of efficacy data amongst countries within a region, many pesticide manufacturers are unwilling to seek new registrations. Finally, it is meaningless to generate residue data for Codex MRLs if there is no opportunity for the pesticide to be placed upon the JMPR review schedule. So, there is a complex dialog that needs to take place to balance these three key considerations. The project technical coordinators managed to strike this balance eventually, but the lesson learned is that the process can be quite slow. Future projects should allow more options, allow more time for consensus, and include more fall back options in case primary options fail.

32. The most significant lesson learned from a budgetary perspective was the high cost of travel to conduct the research. Initial budget development was based on the IR-4 experiences of conducting work in the United States, where experimental farms are located very near to research institutions, requiring little long-distance travel. Under this project, most study sites were quite far from the researchers, and in some cases required air travel and lodging for field investigators. As there is no solution to this distance problem, future work needs to build larger budgets for site travel. It is also critical to identify multiple alternative sites in case that a problem develops at the initially planned site. For example, a disease outbreak in Guatemala led the participating grower to cancel trials because of concern that disease would enter the farm. The project team scrambled to find an alternative site at the last minute, and fortunately a Dole farm volunteered to support the continuation of the project.

9. RECOMMENDATIONS

9.1. Specific recommendations to the project

33. The result of surveys showed that the outcomes of the project met the participating country expectation in regard to the: i) conduct of field trials according to GLP, ii) generation of valid data for determining MRLs, iii) application of OECD-GLP and residue field trials, iv) challenge of doing GLP work following the established SOPs, and v) estimation of the safety level of hazardous substances in agricultural products. Additional recommendations by the laboratory expert trainer are provided in their final report.

34. Experiences in project implementation identified some areas which would benefit from additional attention in the future, including:

i. documentation and final data report preparation.
ii. exposure on instrument analysis such as system suitability test, peak integration, etc.
iii. conformity with food safety standards.
iv. understanding about which is more important for field residue trials, national GAPs in the use of pesticides or the critical GAP in the meaning of JMPR.
v. how JMPR, EU, Japan, USA, etc. consider data sets from field trials.
vi. understanding which data needs to be included in the Field Data Notebook.
vii. better understanding of working plans and timelines to work in the field.
viii. harmonization of analytical methods among AMSs.
ix. competency and skills to improve analysis of pesticide residue samples.
x. understanding on risk evaluation processes.
xi. development of a GLP study protocol and SOP for a GLP study.

35. Experiences in implementation also identified a number of areas where additional support and capacity building would be valuable to complement the project's achievements. It is recommended that in the future, capacity building in the following topics should be organised to complement the outcomes of this project. For future work under the IR-4 GMUF, this information will be valuable for better targeting capacity needs for conducting better work.

i. training on pesticide residue analysis by GC-MS-MS and LC-MS-MS.
ii. calibration of different types of sprayers such as boom sprayer, etc.
iii. sample preparation such as handling, extraction and clean up procedures as this is the main challenge for the analytical chemist in the instrumental analysis.

iv. how to get OECD-GLP accreditation, how to construct a team for conducting OECD-GLP work, facility management for OECD-GLP accreditation.
v. understanding of MRL establishment process of Codex and comparing it with EU, USA, Japan, Australia, etc.
vi. extrapolation of MRLs for crops grouping.
vii. data calculation for MRLs on percentile basis.
viii. risk of dietary intake assessment.
ix. laboratory competency.
x. spraying competency (calibration, spraying, equipment maintenance, etc.).
xi. mixture toxicity.
xii. details on data evaluation, crops grouping, MRL determination, work sharing and joint review concepts, and Codex process for establishing MRLs.

9.2. Broader recommendation

36. Learning from the success of this project, it is hoped that STDF would continue its support to Latin American countries in the area of pesticide residue standards, and that other partners and donors could be identified to support this effort. Future support could include the following:

i. establishment of a regional Technical Working Group to discuss common registration and data sharing issues, in order to improve dialogue, coordinate work, use available financial resources more efficiently, and determine regional MRL priorities.
ii. efforts toward regional mutual acceptance of efficacy and residue data amongst Latin American regional economic blocks
iii. efforts toward harmonization of registration processes, working toward single submission of registration submissions to establish registrations in multiple countries simultaneously
iv. efforts toward coordination with other regions (Asia and Africa) on related above topics

10. ANNEXES

10.1. Logical Framework

10.2. Financial Report

10.3. Contact List

STDF Standards and Trade Development Facility

ANNEX 10.1: LOGICAL FRAMEWORK: STATUS OF THE OUTPUTS AND ACTIVITIES

Output / Activity	Indicator / Target:	Actual performance: (% complete)	Comments (results and challenges faced)
Tier 1: Capacity building Scientists and regulators have acquired knowledge and skills to organize and implement field trials and to collect, prepare and analyse high-quality data for submission to JMPR.	Indicator i. At least 95% of the total invited scientists from participating Latin American countries trained during the project period (2012-2016) ii. A number of additional scientists trained in future years (during & beyond the Project period) via the "train of trainer" model. iii. Five (5) residue studies completed during the project period and submitted to JMPR for review.		
Activity: • A series of trainings, workshops, consultations on the conduct of field trials, sample preparation and analysis, SOP reviews and identification of core management team, facility inspections, SOP refinement, and protocol development.	Target i. Project team established. ii. Trainings under the Project organised. iii. Consultation between the participating countries and Study Director/Technical Coordinator/IICA established. iv. Protocol for each Study developed. v. Field trials/ Studies conducted. vi. Data generated from field trials submitted to JMPR	i) The Project teams had been established at national and regional levels. ii) Group field and laboratories were carried out, and multiple one-on-one trainings and consultations were carried out with participating countreis. iii) Close consultation among participating countries, the Study Director, Technical Coordinator and IICA established. iv) Country visit have been carried out by experts to participating countries to provide lectures and guidance on the conduct of the trial and lab analysis. v) Protocols for four studies	Overall, the Project was highly successful and positioned participating countries to continue and expand efforts in generating pesticide residue data in order to contribute to the process of establishing Codex MRLs, based on local needs and agricultural practices. However, it is recognized that the make up of national Study Teams should be re-examined to better ensure that the most appropriate institutions are included and assigned to their most fitting roles. Also, in order to ensure sustainability of this work, additional national staff need to be included in training to fill in and provide support to Study Team members.

		developed and signed. 1. Spinetoram – avocado (Colombia) 2. Spinetoram – banana (Bolivia) 3. Pyriproxyfen – pineapple (Panama) 4. Pyriproxyfen – banana (Costa Rica and Guatemala) vi) Field trials and analysis works had been completed for all studies. vii) Spinetoram and pyriproxyfen data packages and label submitted to FAO/WHO JMPR in 2016 and 2017, respectively.	Finally, national resources (staffing, travel, supplies, etc) need to be committed to support future work, as donor support will not always be available. This may require high-level meetings with collaborating partners.
<u>Output Tier 2: MRL Establishment/ Registration</u> The availability on the market of new, approved chemicals for minor use crops	<u>Indicator</u>: i. New residue data is generated for low toxicity chemicals on at least three tropical fruit varieties during the project period. ii. New chemicals are registered for use in three countries by the end of the project.		
<u>Activity</u> Practical implementation of training to include: field trial applications and harvest, analytical validation and analysis, data packaging and submission, analytical summary report preparation, and final report development	<u>Target</u> Key events of the field trials (application, harvest, sample preparation and sample analysis), and packaging of data for submission) carried out.	i) All field trials and data analysis had been completed for all five studies: ii) The following pesticides were studied at the respective countries 1. spinetoram in Colombia 2. spinetoram in Bolivia 3. pyriproxyfen in Panama 4. pyriproxyfen in Costa Rica and Guatemala	It was clearly recognized at the onset of the Project that national priorities may not align easily with JMPR/CCPR work schedules, marketing strategies of pesticide manufacturers, actual trade impediments, and priorities of partner countries and collaborators. Because of this need for higher-level global coordination and strategy development, a Global Minor Use Foundation was established by IR4 and supported by USDA.

ANNEX 10.2: FINANCIAL OVERVIEW

Output #1 - Capacity building

Output: Acquired knowledge and skills for scientists and regulators to organize and implement field trials and to collect, prepare and analyse high-quality data for submission to JMPR.

Activity: A series of trainings, workshops, consultations on the conduct of field trials, sample preparation and analysis, SOP reviews and identification of core management team, facility inspections, SOP refinement, and protocol development.

Financial Report	Description	Subtotal	Total
First	Steering Committee Meeting	2.459,23	2.655,97
First	Purchase of equipment and supplies	2.583,91	2.790,62
First	Training in Costa Rica (Aseguramiento de la calidad)	4.871,53	5.261,25
First	Training in Costa Rica (Técnicas de aplicación bajo estándares de Buenas Prácticas de Lab)	249,34	269,29
First	Consultancy Contracts (partial payments) - Amy Wang, Marvin Ramírez, Milena Ramírez y Eduardo Cartín	16.500,00	17.820,00
Second	Training in Costa Rica (Técnicas de aplicación bajo estándares de Buenas Prácticas de Lab)	29,00	31,32
Second	Steering Committee Meeting	4.438,20	4.793,26
Second	Transfer of funds to FAO	30.000,00	32.400,00
Second	Purchase of equipment and supplies Colombia, Panama, Guatemala	14.778,29	15.960,55
Second	Consultancy Contracts (partial payments) - Amy Wang, Marvin Ramírez, Milena Ramírez	14.500,00	15.660,00
Third	Purchase of equipment and supplies Colombia	645,47	697,11
Third	Purchase of equipment and supplies Guatemala and Costa Rica	1.502,63	1.622,84
Third	Purchase of equipment and supplies Panama	2.851,30	3.079,40
Third	Transfer of funds to UCR	35.000,00	37.800,00
Third	Purchase of equipment and supplies Bolivia	12.930,00	13.964,40
Third	Consultancy Contracts (partial payments) - Amy Wang and Marvin Ramírez	7.500,00	8.100,00
Third	Adjustment	-583,10	-629,75
Fourth	Purchase of equipment and supplies Costa Rica	3.022,73	3.264,55
Fourth	Purchase of equipment and supplies Bolivia	12.262,04	13.243,00
Fourth	Purchase of equipment and supplies Panama	9.145,50	9.877,14
Fourth	Consultancy Contracts (partial payments) - Amy Wang and Marvin Ramírez	10.000,00	10.800,00
Fourth	Adjustment	-37,92	-40,95
Fifth	Training in San José	4.685,94	5.060,82
Fifth	Purchase of equipment and supplies Colombia	2.810,00	3.034,80

Fifth	Bank commission	20,00	21,60
Fifth	Adjustment	-14.971,10	-16.168,79
Sixth	Purchase of equipment and supplies Colombia	3.617,00	3.906,36
Sixth	Purchase of equipment and supplies Guatemala	1.338,73	1.445,83
Sixth	Bank commission	20,00	21,60
Sixth	Purchase of equipment and supplies Guatemala - Adjustment	-20,49	-22,13
Sixth	Purchase of equipment and supplies Colombia - Adjustment	-243,05	-262,49
Sixth	Purchase of equipment and supplies Colombia - Adjustment	-844,10	-911,63
	Subtotal	**181.061,08**	**195.545,97**

Output #2 - MRL Establishment/Registration

Output: The availability on the market of new, approved chemicals for minor use crops.

Activity: Implement the result of trainings in practice that include: field trial applications and harvest, analytical validation and analysis, data packaging and submission, analytical summary report preparation, and final report development

Financial Report	Description	Subtotal	Total
Second	Technical Mission - Peru	14.309,80	15.454,58
Second	Technical Mission - Panama x 2	8.443,75	9.119,25
Second	Trials and samples - Panama	3.040,00	3.283,20
Second	Technical Mission - Colombia	11.762,70	12.703,72
Second	Technical Mission - Guatemala	5.314,80	5.739,98
Second	Technical Mission - Costa Rica	780,80	843,26
Second	Technical Mission - Colombia	6.612,11	7.141,08
Third	Technical Mission - Colombia	7.063,52	7.628,60
Third	Technical Mission - Guatemala x 2	13.633,00	14.723,64
Third	Technical Mission - Panama	2.736,00	2.954,88
Fourth	Technical Mission - Bolivia	9.557,91	10.322,54
Fourth	Technical Mission - Costa Rica	1.126,58	1.216,71
Fourth	Four trials - Guatemala	5.344,00	5.771,52
Fourth	Technical Mission - Colombia	2.112,00	2.280,96
Fourth	Technical Mission - Panama	456,00	492,48
Fifth	Trials - Guatemala	1.357,00	1.465,56
Sixth	Technical Mission - Costa Rica	5.483,60	5.922,29
Sixth	Technical Mission - Panama	5.020,00	5.421,60
Sixth	Technical Mission - Colombia	3.546,15	3.829,84
Sixth	Technical Mission - Guatemala	2.538,15	2.741,20
	Subtotal	**110.237,87**	**119.056,90**

SUMMARY OF EXPENSES	AMOUNT
Output #1 - Capacity building	181.061,08
Output #2 - MRL Establishment/Registration	110.237,87
Subtotal	291.298,95
Overhead 8%	23.303,92
TOTAL EXPENSES ON THE AGREEMENT	**314.602,87**

PROJECT'S SUMMARY	
First disbursement	$93.561,50
Second disbursement	$74.813,20
Third disbursement	$74.813,20
Fourth disbursement	$37.416,60
Fifth disbursement	$37.396,60
Sixth disbursement	$37.416,60
Funding received from STDF	$355.417,70
First Financial Report	$28.797,13
Second Financial Report	$123.130,21
Third Financial Report	$90.570,87
Fourth Financial Report	$57.268,90
Fifth Financial Report	$9.582,78
Sixth Financial Report	$23.288,71
Adjustments to expenses previously reported	-$16.699,76
Adjustment to overhead	-$1.335,97
Total spent	$314.602,87
Balance	**$40.814,83**

Contact Information Sheets

GLP Pesticide MRL Project
STDF PG
Latin America Region

Contents

Technical Consultants:

Amy Wang
GLP Field Trial Trainer
Awangw57@gmail.com
Cell: 8886-6993
Home 2283-0914

Marvin Ramirez
GLP Field Trial Trainer
mmramirea@gmail.com
Cell: 8885-1546
Home: 2283-0914
Land line: 2283-5427

Milena Ramirez
Laboratory Trainer

Eduardo Cartin
Quality Assurance Trainer

GUATEMALA

Luis Armando Menendez
Sponsor
Ministerio de Agricultura Ganaderia y Alimentacion
Viceministerio de Sanidad Agropecuaria y Regulacions
7 Avenida 12-90 Zona 13 VISAR-MAGA
Ciudad de Guatemala
Telf: 53446963, 24137000 Ext. 7431 y 7427
Email: luismenendez.maga@gmail.com

Carlos Enrique Acevedo
Study Director
Ministerio de Agricultura Ganaderia y Alimentacion
Viceministerio de Sanidad Agropecuaria y Regulacions
7 Avenida 12-90 Zona 13 VISAR-MAGA
Ciudad de Guatemala
Telf:
Email: acevedo.carlosenrique@gmail.com

Edgar Hernandez
Field Director
Ministerio de Agricultura Ganaderia y Alimentacion
Viceministerio de Sanidad Agropecuaria y Regulacions
7 Avenida 12-90 Zona 13 VISAR-MAGA
Ciudad de Guatemala
Telf: 24137000 Ext. 7431 y 7427, personal 53446963
Email: edher_9@yahoo.com

Karin Calderon Muller
Field Director
Ministerio de Agricultura Ganaderia y Alimentacion
Viceministerio de Sanidad Agropecuaria y Regulacions
7 Avenida 12-90 Zona 13 VISAR-MAGA
Ciudad de Guatemala
Telf:
Email: kcalderonmuller@gmail.com

María Del Carmen Castillo Perez
Laboratory Director
Área de Contaminantes de Ambiente y Salud
Laboratorio Nacional de Salud
Km. 22 Carretera Al Pacífico

Bárcena Villa Nueva. Código Postal 01064
Guatemala, C.A.
Telf: 050266440577 Y 050252019866
Email: madelccastillo@hotmail.com

Analysts:
Mónica Patricia Méndez de Maldonado <monica_mendez74@yahoo.com>
Gabriela Álvarez <gabriela.alvarez0110@gmail.com>

Danilo Guzman
Quality Assurance Director
Ministerio de Agricultura Ganadería y Alimentación
Viceministerio de Sanidad Agropecuaria y Regulaciones
7 Avenida 12-90 Zona 13 VISAR-MAGA
Ciudad de Guatemala
Telf: 53446963, 24137000 Ext. 7431 y 7427
Email: danguzsan@yahoo.es

COSTA RICA

Magda González Arroyo
Executive Director
Servicio Fitosanitario del Estado
Ministerio de Agricultura y Ganadería
200 m Sur Canal 7, antiguo Colegio La Salle,
Sabana Sur, San José, Costa Rica
San José, Costa Rica
Telf: (506)2549-3565 Fax: (506)2549-3599
Email: mgonzalez@sfe.go.cr

Roger Ruiz Zapata
Sponsor
Servicio Fitosanitario del Estado
Ministerio de Agricultura y Ganadería
200 m Sur Canal 7, antiguo Colegio La Salle,
Sabana Sur, San José, Costa Rica
San José, Costa Rica
Fax: (506) 2549-3685
Cel.: (506) 8371-8740 T
Telf: (506) 2549-3538
Email: rruiz@sfe.go.cr

Olger Borbón Martínez
Study Director and Field Director
Servicio Fitosanitario del Estado
Ministerio de Agricultura y Ganadería
200 m Sur Canal 7, antiguo Colegio La Salle,
Sabana Sur, San José, Costa Rica
San José, Costa Rica
Fax: (506) 2549-3685
Cel.: (5068375-8052
Telf: (506) 2549-3400
Email: oborbon@sfe.go.cr

Jorge Mora Bolaños
Field Director (1 trial, canceled)
Ministerio de Agricultura y Ganadería
Departamento de Investigación e Innovación, INTA
800 m Oeste POPS, Sabana Sur
Fax: (506) 2231-5004
Cel. (506) 8393-1249
Telf: (506) 2296-2495
Email: jormora@inta.go.cr

José Arturo Solórzano Arroyo
Field Director (1 trial, canceled)
Ministerio de Agricultura y Ganadería
Departamento de Investigación e Innovación, INTA
800 m Oeste POPS, Sabana Sur
Fax: (506) 2231-5004
Cel. (506) 8721-0693
Telf: (506) 2231-5055
Email: asolorzano@inta.go.cr

Verónica Picado Pomar
Servicio Fitosanitario del Estado
Ministerio de Agricultura y Ganadería
200 m Sur Canal 7, antiguo Colegio La Salle,
Sabana Sur, San José, Costa Rica
San José, Costa Rica
Fax: (506) 2549-3431
Cel.: (506) 8848-0234
Telf: (506) 2549-3604
Email: vpicado@sfe.go.cr

Karla Arrieta Viquez
Laboratory Director
Servicio Fitosanitario del Estado
Ministerio de Agricultura y Ganadería
200 m Sur Canal 7, antiguo Colegio La Salle,
Sabana Sur, San José, Costa Rica
San José, Costa Rica
Fax: (506) 2549-3431
Cel.: (506) 8848-0234
Telf: (506) 2549-3604
Email: karrieta@sfe.go.cr

Analyst
Adriana Mora Berrocal
Servicio Fitosanitario del Estado
Ministerio de Agricultura y Ganadería
200 m Sur Canal 7, antiguo Colegio La Salle,
Sabana Sur, San José, Costa Rica
San José, Costa Rica
E-mail: gmorales@sfe.go.cr
TEL.: (506) 2549-3529
Fax: (506) 2549-3431
Cel.: (506) 8845-9231

Erick Cedeño Navarro
Quality Assurance – Field
Servicio Fitosanitario del Estado
Ministerio de Agricultura y Ganadería
200 m Sur Canal 7, antiguo Colegio La Salle,
Sabana Sur, San José, Costa Rica
San José, Costa Rica
Fax: (506) 2549-3513
Cel.: (506) 8312-6175
Telf: (506) 2549-3468
Email: ecedeno@sfe.go.cr

Kattia Murillo Alfaro
Quality Assurance – Lab
Servicio Fitosanitario del Estado
Ministerio de Agricultura y Ganadería
200 m Sur Canal 7, antiguo Colegio La Salle,
Sabana Sur, San José, Costa Rica
San José, Costa Rica
Fax.: (506) 2549-3598

Cel.: (506) 8811-3313
Telf: (506) 2549-3613
Email: kmurillo@sfe.go.cr

PANAMA

Federico Ábrego Ruiz,
Sponsor

Analista de Control de Agroquímicos
Departamento de Agroquìmicos
Dirección Nacional de Sanidad Vegetal
Ministerio de Desarrollo Agropecuario (MIDA)
Telf: (507) 220-0733; (507) 6682-7861
Email: fabrego@mida.gob.pa
Email: fedabreg@yahoo.com

Eric M. Candanedo Lay
Study Director

Instituto de Investigación Agropecuaria de Panamá (IDIAP)
Edificios Nos. 161 y 162,
Ciudad del Saber Panamá, República de Panamá
Telf: (507) 5000519, (507) 5000520, (507) 5000521.
Email: emcandanedo@gmail.com

José Luis Causadías Samaniego
Field Director

Instituto de Investigación Agropecuaria de Panamá
Subcentro de Investigación e Innovación Agropecuaria y Forestal de la Cuenca Hidrográfica del Canal de Panamá Las Zanguengas
Telf: 66768970
Email: jlcausadias04@gmail.com

Brenda Itzel Checa Orrego
Laboratory Director

Coordinadora de Servicios Técnicos de Análisis Químico
Dirección Nacional de Sanidad Vegetal
Ministerio de Desarrollo Agropecuario (MIDA)
Río Tapia, Corregimiento de Tocumen, (Entrando por Harinas del Istmo a 1.5 km)
Ciudad de Panamá, República de Panamá
Telf: 6780-4199.
Email: brendacheca@yahoo.es

José Ortega
Quality Assurance - Field
Dirección Nacional de Sanidad Vegetal
Ministerio de Desarrollo Agropecuario (MIDA)
Río Tapia, Corregimiento de Tocumen, (Entrando por Harinas del Istmo a 1.5 km)
Ciudad de Panamá, República de Panamá
Telf:
Email: josetox820@yahoo.es

Maddala Serrano
Quality Assurance - Laboratory
Dirección Nacional de Sanidad Vegetal
Ministerio de Desarrollo Agropecuario (MIDA)
Río Tapia, Corregimiento de Tocumen, (Entrando por Harinas del Istmo a 1.5 km)
Ciudad de Panamá, República de Panamá
Email: maryonelly01@yahoo.com

COLOMBIA

Adriana Castañeda Cardena
Coordinator/Facilitator
Directora Técnica de Análisis y Diagnóstico Agrícola
Instituto Colombiano Agropecuario ICA
Av. El Dorado No. 42-42 Bloque IV
BOGOTÁ D.C.
Telf: 2692644 o 3686827/29 ext. 2183
Email: luz.castaneda@ica.gov.co

Rosana Matilde Brochado Matute
Sponsor
Subgerente de Análisis y Diagnostico
Instituto Colombiano Agropecuario-ICA
Carrera 41 N° 17-81 Zona Industrial de Puente Aranda
Telf: 57+1+3323700 extensión 1401
E-mail: rosana.brochado@ica.gov.co

Edwin Samir Barbosa Ángel, Químico Msc.
Study Director
Laboratorio Nacional de Insumos Agrícolas- LANIA.
Área de Residuos de Plaguicidas
Km 14 via Bogotá - Mosquera LANIA, cundinamarca Colombia
Bogotá, Colombia
Telf : 4 22 73 63

Email: edwin.barbosa@ica.gov.co

Javier Sorlano Leal
Field Director
ICA
Email: javier.soriano@ica.gov.co

Hugo Rodrigues
Laboratory Director
Laboratorio Nacional de Insumos Agrícolas- LANIA.
Área de Residuos de Plaguicidas
Km 14 via Bogotá - Mosquera LANIA, cundinamarca Colombia
Telf: 4 22 73 63
Email: hugo.rodriguez@ica.gov.co

René Alejandro Castro Jiménez
Quality Assurance – Field and Laboratory
Químico M.Sc
Profesional Especializado
Subgerencia de Análisis y Diagnostico
Grupo Gestión Analítica, BPL y Registro de Lab.
Instituto Colombiano Agropecuario – ICA
Avenida el Dorado No. 42-42. Bloque 4.
Teléfono 2692644. Ext. 2189

PERU

Ing. Josué A. Carrasco Valiente
Sponsor
Director General
Dirección de Insumos Agropecuarios e Inocuidad Agroalimentaria
Servicio Nacional de Sanidad Agraria- SENASA
Av La Molina 1915 La Molina - Lima
Telf: (051) 313 3300 anexo 2121
Email: jcarrasco@senasa.gob.pe

Ing. Agr. José Ortiz Rojas
Study Director
Especialista en plaguicidas agrícolas
Subdirección de Insumos Agrícolas
Dirección de Insumos Agropecuarios e Inocuidad Agroalimentaria

Servicio Nacional de Sanidad Agraria - SENASA
Av La Molina 1915 La Molina - Lima
Telf: 511-3133300 – anexo 2148
Email: JORTIZ@senasa.gob.pe

Ing. Agr. Henry Sosa Talledo
Field Director

Jefe del Área de Insumos Agropecuarios e Inocuidad Agroalimentaria
Dirección Ejecutiva Piura
Servicio Nacional de Sanidad Agraria - SENASA
Jr. Monitor Huascar S/N, Urb. Alborada, Piura
Tf. 5173-354917
hsosa@senasa.gob.pe

M.V. Moisés Crispin Marín
Field Director

Jefe del Área de Insumos Agropecuarios e Inocuidad Agroalimentaria
Dirección Ejecutiva Lima - Callao
Servicio Nacional de Sanidad Agraria - SENASA
Av La Molina 1915 La Molina - Lima
Tf. 511-3133306
mcrispin@senasa.gob.pe

Technician
Telf: 969676636
Email: ltimana@senasa.gob.pe,

Roxana Nohelia Ventocilla Reaño
Laboratory Director

Centro de Control de Insumos y Residuos Toxicos
Servicio Nacional de Sanidad Agraria- SENASA
Av La Molina 1915 La Molina - Lima
Telf: 511-3133300
Email: rventocilla@senasa.gob.pe

Ing. Agr. Pedro Molina Salcedo
Quality Assurance – Field and Laboratory

Director
Subdirección de Inocuidad Agroalimentaria
Dirección de Insumos Agropecuarios e Inocuidad Agroalimentaria
Servicio Nacional de Sanidad Agraria - SENASA
Av La Molina 1915 La Molina - Lima
Telf: 511-3133300 – anexo 1405

Email: pmolina@senasa.gob.pe

Mirtha Karon Zapata Gallo
Quality Assurance - Field
Telf: 976888984
Email: mzapatag@senasa.gob.pe

Ana Ramos
Quality Assurance - Laboratory
Email: aramosm@enasa.gob.pe

Ing. Agr. Gerard D. Blair Arze
Field Director
Director (e) Subdirección de Insumos Agrícolas
Dirección de Insumos Agropecuarios e Inocuidad Agroalimentaria
Servicio Nacional de Sanidad Agraria - SENASA
Av La Molina 1915 La Molina - Lima
Telf: 511-3133300 – anexo 2132
Email: gblair@senasa.gob.pe

ORLANDO LUCAS AGUIRRE, Q.F.,
Mag, Director, Centro de Control de Insumos y Residuos Toxicos
Servicio Nacional de Sanidad Agraria- SENASA
Av La Molina 1915 La Molina - Lima
Tf. 511-3133300 – anexo 1621
<olucas@senasa.gob.pe>

BOLIVA

Ing. Cristhian Fernández Andrade
Sponsor
DIRECTOR GENERAL EJECUTIVO SENASAG
Telf.: 72848469
Email**:** ing-chrisfer@hotmail.com

David Ramos
Study Director
Unidad De Inocuidad Alimentaria
SENASAG CBBA
Telf.: (591 - 4) 4263910; 72750299
Email: d_ramos67@hotmail.com

Ing. Luis Milan Arias
Field Director
COOORDINADOR DEL PROCEF SENASAG
Telf.:73764638
Email: mamamiko@hotmail.com

Raiza Castrillo Mariaca
Quality Assurance - Field
Responsable de Calidad de Laboratorio LIDIVECO
Telf: 71704787
Email: *calidad.lidiveco@gmail.com*

Marisol Uriona
Lab Director
Email: marisoluriona@yahoo.com