Standards and Trade Development Facility

PROJECT: STDF/PG/ 337 ASEAN PESTICIDE RESIDUE DATA GENERATION PROJECT

ASEAN PESTICIDE RESIDUE DATA GENERATION PROJECT: STRENGTHENING REGIONAL CAPACITY TO MEET PESTICIDES EXPORT REQUIREMENTS BASED ON INTERNATIONAL STANDARDS

FINAL REPORT

February 2017

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PROJECT SUMMARY

Title

ASEAN Pesticide Residue Data Generation Project: Strengthening regional capacity to meet pesticides export requirements based on international standards

Implementing Agency: ASEAN Secretariat

Partners : National pesticide regulatory authorities of ASEAN Member States (AMSs), FAO/JMPR, USDA, Rutgers University/ IR-4, pesticide manufacturers (Syngenta, Dow, and Valent/Sumitomo)

Start Date : 1 December 2012

End Date 30 November 2016.

Beneficiary

National pesticide regulatory authorities of AMSs, farmers, agri-food industries, and consumers.

Budget

Project value:	US$ 1,242,000
Approved STDF contribution:	US$ 637,000

LIST OF ABBREVIATIONS

AEC	:	ASEAN Economic Community /
AMAF	:	ASEAN Ministers on Agriculture and Forestry
AMSs	:	ASEAN Member States
ASEAN	:	Association of South East Asian Nations
CCPR	:	Codex Committee for Pesticides Residue
DOA	:	Department of Agriculture
EPA	:	Environmental Protection Agency
EU	:	European Union
EWG-MRLs	:	Expert Working Group on Harmonization of MRLs of Pesticides among ASEAN Countries
FA	:	Financing Agreement
FAO	:	Food and Agriculture Organization
FAS	:	Foreign Agricultural Service
GAP	:	Good agricultural practices
GC-MS-MS	:	Gas Chromatography/Tandem Mass Spectroscopy
GLP	:	Good Laboratory Practice
JMPR	:	Joint Meeting on Pesticide Residues
LC-MS-MS	:	Liquid chromatography/Tandem Mass spectrometry
MRLs	:	Maximum Residue Limits
OECD	:	Organisation for Economic Co-operation and Development
PSC	:	Project Steering Committee
QA	:	Quality Assurance
SOM-AMAF	:	Senior Officials Meeting for the ASEAN Ministers on Agriculture and Forestry (SOM-AMAF)
SOP	:	Standards Operating Procedures
SP-FAF	:	Strategic Plan of Action for Cooperation on Food, Agriculture and Forestry (SP-FAF)
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

1. The Project was initiated by the United States Department of Agriculture (USDA) in collaboration with the ASEAN Secretariat in 2010 with the aim to assist ASEAN Member States (AMSs) to enhance their capacity to meet pesticide-related export requirements based on international (Codex) standards in order to enhance market access of ASEAN agricultural commodities. The Project was in-line with the ASEAN Economic Community Blueprint (AEC-BP) to increase agricultural production and its competitiveness to enhance ASEAN trade.

2. With the support from the Standards and Trade Development Facility (STDF), the project was implemented from 1 December 2012 and ended on 30 November 2016. Six pesticide residue studies were carried out :

i. Pyriproxyfen/ mango – Malaysia & Singapore
ii. Pyriproxyfen / papaya- Philippines, Malaysia & Brunei Darussalam
iii. Spinetoram/ mango – Thailand
iv. Spinetoram / lychee - Thailand
v. Azoxystrobin and Difenoconazole/ dragon fruit (*) – Indonesia & Viet Nam

(*) Azoxystrobin and Difenoconazole is considered as two studies as these compounds generated two separate MRLs from the mixture.

3. Field trials and laboratory analysis work was completed for all six studies under the project. Indonesia, with Vietnamese data included, submitted the data package and label documentation for Azoxystrobin/Difenoconazole on dragon fruit to FAO/WHO JMPR on 31 May 2016 (two studies). Thailand submitted data packages and label for Spinetoram on lychee and Spinetoram on mango to Dow AgroScience (two studies); which joined the larger package on Spinetoram after the start of the project) through IR-4 on 12 December 2016. The data packages and label for Spinetoram were submitted to FAO/WHO JMPR by December 2016.

4. Considering the overbooked FAO/WHO JMPR's work schedule in 2017, the review for Pyriproxifen is rescheduled to 2018. Data packages and labels for Pyriproxifen will be completed in coordination with Sumitomo (partnering pesticide manufacturer) for submission to FAO/WHO JMPR in 2017. This includes studies on Pyriproxyfen on papaya from Malaysia, Philippines, and Brunei Darussalam (one study), and Pyriproxyfen on mango from Malaysia and Singapore (one study).

5. The project helped AMSs by providing 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 AMSs to generate quality data for establishing an MRL based on international guidelines (e.g., OECD-GLP, EPA-GLP, FAO Manual (2009)). ASEAN also learned and shared experience on the coordination of work sharing and capacity building efforts among AMSs, between government regulatory officials, laboratory and field technicians, as well as pesticides industries.

6. The success of the project was due to the good collaboration and partnership among the AMSs, USDA, Rutgers University/IR-4, pesticides manufacturers and the ASEAN Secretariat which led implementation of the Project.

7. Learning from the success of the Project, it is expected that ASEAN-STDF partnership will continue and be further enhanced in the future, for instance to support ASEAN priorities on common needs, especially in the area of trade facilitation.

2. BACKGROUND

8. The AMSs are primarily food exporters and rely on the use of modern agrochemicals to control pests and plant diseases, while protecting human and environmental health. The ASEAN Economic Community (AEC) Blueprint 2015, adopted by the ASEAN Leaders, provided guidance to enhance agricultural production and increase its competitiveness to enhance ASEAN trade.

9. The Project supported the realisation of AEC measures through the harmonization of MRLs for commonly used pesticides for widely traded horticultural products in accordance with international standards/guidelines. The project also addressed the issue of market access due to a lack of acceptable pest control products and corresponding MRL trade standards for crops of importance to the AMSs and its trading partners.

10. AMSs are major producers of tropical fruits and vegetables. Many pesticides are critical to the production and export of tropical fruits and vegetables in ASEAN region, however Codex MRLs for these "minor use" crops do not exist. As a result, importing countries often set acceptable residue levels at "limits of determination", which sometime create a problems when newer, safer (less toxic) pesticides become available on the market but cannot be used because Codex MRLs have not been established.

11. The idea to have cooperation on pesticides residue was discussed during the Roundtable on Maximum Residue Limits (MRLs) for Pesticides Collaboration, organised by the United States Department of Agriculture (USDA) on 16-17 September 2010 in Jakarta. The Roundtable agreed to develop a project proposal for pesticides residue data generation. The project proposal on "ASEAN Pesticide Residue Data Generation: Strengthening regional capacity to meet pesticides export requirements based on international standards" was developed for possible funding by STDF.

12. Following the approval of the SOM-AMAF, the Project Proposal was submitted to the STDF and approved by the Working Group on 2 November 2011 for funding support. The Financing Agreement (FA) of the Project was signed by the ASEAN Secretariat on behalf of ASEAN, and the WTO on behalf of the STDF, on 15 and 24 October 2012, respectively.

13. The Project was officially commenced on 1 December 2012 and was supposed to end on 30 November 2015. However, following delays in the commencement of some trials, which needed to follow harvesting seasons of the commodity, as well as the effect of natural calamities on some sites, upon the request by ASEAN, the STDF Working Group at its Meeting in March 2015 approved a no-cost 12-month extension. The project officially ended on 30 November 2016.

3. PROJECT GOAL

14. The project goal was to enhance the capacity of AMSs to meet pesticide-related export requirements based on international (Codex) standards in order to enhance market access of ASEAN agricultural commodities.

15. This goal was achieved through a collaborative data generation project based on international guidelines. The project was implemented based on a strong public-private partnership approach, within countries and across the ASEAN region, and used technical capacity building as the primary means of delivery. With the establishment of new Codex MRLs, it is expected that the project will increase access to international markets for ASEAN agricultural commodities.

4. PROJECT IMPLEMENTATION AND MANAGEMENT

Implementation

16. The Project was implemented through the conduct of trainings and consultations to share the theory, and culminated with the conduct of actual field trials, data generation, sample analysis, data packaging, 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 trial, generating data from field trials, and systematically package the joint data for submission to FAO/WHO JMPR.

17. The identification of crops-pesticides-countries combinations for the project was carried out in consultation with JMPR Secretariat, the U.S. Environmental Protection Agency (EPA), USDA, IR-4, and the pesticide manufacturers (Syngenta, Dow, and Valent/Sumitomo), taking into consideration the

national needs of AMSs, specific pests to be controlled, registration issues, and market considerations.

The project partners initially agreed to focus on the following reduced-risk pesticides:

- *Azoxystrobin (Syngenta)*
- *Pyriproxyfen (Sumitomo)*
- *Chlorantraniliprole (Dupont)*
- *and Spinetoram (Dow)*

The rationale of the selection of these pesticides was based on the following factors:

- These pesticides are extremely low toxicity and would easier to seek approval for experimental trial permits in the participating countries,
- Very little residue data exists for these pesticides on certain groups of specialty crops,
- Currently, there was no Codex MRLs for these pesticides for many specialty crops (particularly, tropical fruits) grown in the ASEAN region,
- Support of the pesticide manufacturers to work with the participation countries in seeking registrations for these chemicals,
- The FAO WHO/JMPR, EPA etc. and other governments have promoted the use of reduced risk chemistries

18. Following further discussions, Syngenta agreed to use AMISTAR TOP for *Azoxystrobin*, which is a mixture of two active constituents (200 g/L Azoxystrobin and 125 g/L Difenoconazole). In addition, Chlorantraniliprole was removed as it was considered not a good fit for any pests on proposed project crops within the region.

19. Finally, the following six studies were agreed to be carried out under the Project:

1. Pyriproxyfen on mango – Malaysia & Singapore
2. Pyriproxyfen on papaya – Philippines, Malaysia & Brunei Darussalam
3. Spinetoram on mango – Thailand
4. Spinetoram on lychee - Thailand
5. Azoxystrobin and Difenoconazole on dragon fruit (*) – Indonesia & Viet Nam

(*) Azoxystrobin and Difenoconazole is considered as two studies as these compounds generated two separate MRLs from the mixture.

Management

20. The project was implemented under the purview of the Expert Working Group on Harmonization of MRLs of Pesticides among ASEAN Countries (EWG-MRLs), a subsidiary body of the Senior Officials Meeting for the ASEAN Ministers on Agriculture and Forestry (SOM-AMAF). The EWG-MRLs acted as the Steering Committee for the Project, which met annually as part of its regular meetings.

21. Implementation of the Project relied on effective coordination and collaboration among diverse stakeholders at the national, regional and international levels

- National: researchers and pesticide control authorities of AMSs.
- Regional: ASEAN Secretariat, EWG-MRLs.
- International: FAO, USDA, IR-4
- Pesticide manufacturers and industry associations (Dow, Syngenta, Valent/Sumitomo, CropLife Asia).

22. The ASEAN Secretariat was the lead agency in implementing the Project. The USDA Foreign Agricultural Service (USDA-FAS) played the role of Technical Coordinator, ensuring linkages and synergies with the other two STDF-supported regional MRL projects to coordinate technical aspect of the project. The ASEAN Secretariat 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. The Project Teams were established at the ASEAN Participating Countries to carry out the studies under their purview, consisting of: Testing Facility Management,

Study Director, Quality Assurance, Field Research Director, and Laboratory Research Director. The Project Team and the EWG-MRLs Focal Points appears as ***Annexes 1 and 2***.

23. The pesticides manufacturers (Dow, Syngenta, Valent/Sumitomo) supported the Project by providing technical support such as: product samples, analytical standards, analytical methods, regulatory input, registration and labelling, etc. These manufacturers showed their commitment to seek registrations of the proposed pesticides in the respective ASEAN Participating Country, and support at the Codex level as well as provided in-kind contributions for conducting required efficacy trials and determining the most appropriate use rates, timing, application method, etc. (aka Good Agricultural Practices: GAPs).

24. The Project was implemented with the engagement of IR-4 as the consultant Project Study Director. The Special Services Agreement (SSA) between the ASEAN Secretariat and Rutgers University was signed on 10 March 2013. The revised SSA was made and signed by ASEAN Secretariat and Rutgers University on 2 December 2015 to cover additional services and travel of experts for implementation of new work under the Project, namely: i) the involvement of Brunei Darussalam in the study for Pyriproxyfen on papaya, and Viet Nam in the study for Azoxystrobin and Difenoconazole on dragon fruit, and ii) a new study on Spinetoram for lychee (Thailand).

5. PROJECT OBJECTIVE, OUTPUTS & ACTIVITIES

5.1. Project Objective:

25. The objective of the project was to enhance the capacity of AMSs to meet pesticide-related export requirements based on international (Codex) standards in order to enhance market access of ASEAN 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.

26. The following trainings were organised and delivered by the Study Director and experts from the IR-4 network, and the International Atomic Energy Agency (IAEA).

i. Training on Field Trials, 29-31 January 2013, Bangkok. The training was attended by 21 experts from AMSs.
ii. 1st Training on Supervised Good Laboratory Practice (GLP), 18 – 22 March 2013, Bangkok. The training was conducted at the Central Laboratory in Bangkok and attended by 24 experts from AMSs.
iii. 2nd Training on Good Laboratory Practice (GLP), 18-20 November 2014, Bali, Indonesia. The Training was attended by 24 experts from AMSs.
iv. Training on Quality Assurance (QA), 20 – 22 January 2016, Bangkok. The training was attended by 18 experts from AMSs.
v. On-site trial training and support for Study Team members at the onset of the first trial of each study in both the field and the laboratory.

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

27. The protocols for the studies had been developed by the Testing Facility Management of the respective ASEAN Participating Country and the Project Study Director. Following the signing of its protocols, the five studies were carried out by the participating countries. In the implementation of the studies, consultation among ASEAN Participating Countries, Project Study Director, Project Technical Coordinator and the ASEAN Secretariat were closely established. Country visits were also carried out by Project Study Director and experts to the ASEAN Participating Countries to provide lectures and guidance in order to ensure that trials and analytical works followed international best practices.

28. All submission of data packages and label under the five 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:

- The submission of data packages and label for Azoxystrobin/Difenoconazole and Spinetoram was made in 2016 for JPMR review in 2017.
- The submission of data packages and label for Pyriproxifen will be made in 2017, as the JMPR review for Pyriproxifen was postponed from 2017 to 2018.

i) **Pyriproxyfen – mango (Malaysia & Singapore)**

The study on pyriproxyfen on mango was conducted in Malaysia for 6 trials in 5 locations: i) Pendang, Kedah; ii) Bikam, Perak, iii) Bumbung Lima, Pulau Pinang, iv) Serdang, Selangor, and v) Kandang, Selangor. The lab analysis work for the trials was shared between Malaysia and Singapore.

The Field Data Notebooks and Field Data Summaries, Analytical Summary Reports, and the Final Report were completed in November 2016. In coordination with Sumitomo, the Final Report will be submitted to JMPR in 2017.

ii) **Pyriproxyfen - papaya (Philippines, Malaysia, Brunei Darussalam)**

The Study on pyriproxyfen – papaya was jointly carried out by Philippines, Malaysia and Brunei Darussalam. Seven field trials were carried out with the following details: 3 trials in Philippines (in Balingasag, Alubijid (Misamis Oriental)), 3 trials in Malaysia (in Perlis and Selangor), and 1 trial in Brunei Darussalam. Analytical works were carried out by Philippines, and Malaysia that covered the analysis of the trial from Brunei Darussalam. Malaysia led the preparation of the draft Analytical Summary Report for FAO/WHO JMPR review.

The Field Data Notebooks and Field Data Summaries, Analytical Summary Reports, and the Final Report were completed in November 2016. In coordination with Sumitomo, the Final Report will be submitted to JMPR in 2017.

iii) **Spinetoram – mango (Thailand)**

The study for Spinoteram on mango was conducted by Thailand. Thailand carried out 6 field trials, shared between the Department of Agriculture (DOA) (3 trials: Chachoengsao, Nakorn Ratchaseema, Supanburi) and the Central Laboratory (CLA), Bangkok (3 trials: Kanchanaburi, Petchaburi, Saraburi).

The Field Data Notebooks and Field Data Summaries, Analytical Summary Reports, and the Final Report were completed in November 2016. In coordination with Dow, the Final Report was submitted to FAO/WHO JMPR in December 2016.

iv) **Spinetoram – lychee (Thailand)**

The study for Spinetoram on lychee was carried out by Thailand, and shared between the Department of Agriculture (DOA) and the Central Lab (CLA). The DOA had completed 3 field trials in Chantaburi, Chiang Mai and Chiang Rai, while the CLA completed another 3 field trials in i) Mai Ai, Chiang Mai; ii) Fang, Chiang Mai; and iii) Mae Chai, Phayao.

The Field Data Notebooks and Field Data Summaries, Analytical Summary Reports, and the Final Report were completed in November 2016. In coordination with Dow, the Final Report was submitted to FAO/WHO JMPR in December 2016.

v) **Azoxystrobin and Difenoconazole - dragon fruit (Indonesia, Viet Nam)**

The study for Azoxystrobin and Difenoconazole on dragon fruit was conducted by Indonesia. Indonesia carried our 6 trials. Indonesia field trials were carried out in the following sites: Kulon Progo (Yogyakarta), Bogor (West Java), Lampung (South Sumatra), Sragen (Central Java), Mojokerto (East Java), and Malang (East Java).

Viet Nam conducted 1 trial and sent the samples to Indonesia for lab analysis.

The Field Data Notebooks and Field Data Summaries, Analytical Summary Reports, and the Final Report were completed in November 2016. The Final Report was submitted by Indonesia to FAO/WHO JMPR in December 2016.

29. At the initiation of the project, residue studies were planned for five of the ASEAN member countries (Indonesia, Malaysia-Singapore, Philippines, Thailand), with five "observer" countries (Brunei Darussalam, Cambodia, Lao PDR, Myanmar, Viet Nam), which would result in the establishment of five new Codex MRLs. However, with encouragement under the capacity training, Brunei Darussalam and Viet Nam requested to also join as participating countries, bring the total countries participating in residue studies to seven. And, since the project's budget was doing well, Thailand volunteered to undertake an additional study, bringing the total number of studies to six, which will result in six new Codex MRLs. 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 80-100 new Codex MRLs.

30. In the seven 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 2018-2019. During 2017-2018, USDA and IR-4, as part of continuation of this work, will provide follow-up to expanding registrations of these project pesticides to other ASEAN Member States.

Monitoring and evaluation of the project

31. During the Project life, mid- and end-Project surveys were conducted. The pre-Project survey was not able to be completed due to some difficulties, including the requirement to have specific type of questions for each study team member due to their different skills and responsibilities. The pre-Project survey only received low responses from the AMSs. Instead of pre-Project survey, the baseline data/ information had been collected by the Project Study Director in the form of facility inspections. The Project Study Director conducted assessment for each ASEAN Participating Country prior to the conduct of individual training and field work. This assessment includes: establishment of study team, facilities (field and labs), equipment, standard operating procedures of the ASEAN Participating Countries. This baseline information provided description on the situation of each participating country in regard to technical capacity at the beginning of the project.

32. The mid-project survey was conducted in August 2014, while the End-Project survey was conducted in early November 2016. The End-Project survey summary is provided in ***Annex 3*** 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. One response quoted "…*this is one of the best organized and delivered international projects we have ever participated*."

33. Summary of the survey responses as follow:

i. 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. And, examples ranged from sprayer calibration and delivery application techniques, to laboratory sampling and analyses, SOP development, Data reporting, and GLP experience.

ii. 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 conducted 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.

iii. 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 ASEAN members, 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.

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

- There were no responses that expressed dissatisfaction 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 sufficient to cover all costs.

v. 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). Some suggestions, however, were provided to improve the process in the future, including this quote: "*From the experiences gain and lessons learnt, we could improve in several aspects when it comes to assign field trial projects"*. Firstly, before nominating the pesticide-crop combinations for conducting the field trials, there should be closer collaboration and firmer commitment among all stakeholders, including the agrochemical company, the pesticide registration authority and the participants of field trial studies. This is to ensure that a GAP label will be made available timely. Secondly, some assessment, including the competency of personnel, level of commitment and availability of the required equipment and resources, should be conducted prior to assigning a residues field trial project. This is to ensure the assigned residues field trial project can be moved forwarded and delivered soundly and on schedule."

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

- Responses to this question varied, including suggestions to conduct the group trainings in more different countries; more training and guidance on report preparation and writing; and suggestions on how to provide field/lab notebooks.

vii. *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 the need to have more staff included in the training and not fully understanding the GLP process by all staff.

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

- Areas that could be improved in the project included better adherence to SOPs and auditing; more training on laboratory analyse; regulatory requirements; better communication from the technical trainers when questions arose.

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

- Requested future training topics included the following: sampling processes; crop grouping; trials on other types of cultivars; Codex MRL setting process; method validation; managing and handling archive systems; risk assessment; and how GAP labels are established by pesticide registrants.

x. *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: completing the GLP requirements quickly; shipping samples in a timely manner; increased work-load in laboratories which led to delays; delays in providing reports due to level of detail required; analytical equipment breakdowns; and auditing of the reports. However, the project teams did overcome these challenges and successfully completed their work on time.

xi. *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 if this project is to be sustainable and countries plan to carry our future work. Most responders indicated that their core teams are appropriate, but did make some suggestions for improvements. These included: include more junior staff members who can take on some of the work or fill in for senior staff, when needed; appointing two QA staff – one for field and one for lab in order to spread out workload and expertise; and inclusion of other institutions and agencies to broaden available experts.

xii. *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.

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

- Responses included suggestions for additional training topics for laboratories, more collaboration on future residue projects, harmonization of registration systems within ASEAN, and more GLP training but with OECD or Japanese requirements (not just the U.S. angle).

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 2.8 (some knowledge/skill). The final survey showed improvement in responses to an average of 4.0 (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 2.2 (between little or no knowledge/skill and some knowledge/skill). The final survey showed improvement in responses to an average of 3.3 (increasing a little over some knowledge/skill).

6. FINANCIAL OVERVIEW

34. The total estimated value of the project, at the time of contracting, was USD 1,242,000. This included an STDF contribution to the project of up to USD 637,000. Over the course of the project, a total amount of USD 605,148 was transferred by the STDF to the ASEAN Secretariat. Following cost savings realized through the efficient execution of resources, the final STDF contribution to this project amounted to USD 603,518, leaving an unspent balance of USD 1,630, as shown in the Financial Report (***Appendix 4***).
ASEAN provided in-kind contribution in the form of human resources, working time, use of office/lab premises etc. Other donors, USDA, Croplife, pesticides manufacturers also supported the Project in the form of budgeted in-kind contributions, as reflected in the Financial Report (***Appendix 4***).

7. OVERALL PROJECT RESULTS AND LESSONS LEARNED

7.1 RESULTS

36. 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 six new Codex MRLs will be established (one for lychee, one for papaya, two for dragon fruit, and two for mango. If crop grouping can be applied to this data, in combination with data generated under the Latin America project, up to 80-100 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 following 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.

37. The participants from ASEAN member countries 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.

38. The willingness of Brunei Darussalam and Viet Nam to take part in the studies in a later stage of the Project had showed positive development in the learning process for establishment of MRLs

39. More broadly, this project has provided the governments in ASEAN Member States 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.

40. The Project will deliver its full benefit to beneficiaries once the Codex MRLs for these newer low toxicity pesticides are established. The benefits that would be gained are expected to include the following:

- farmers will have better protection for their crops, mitigate pest resistance and produce crops that safe for consumption.
- consumers will benefit with safer food.
- crops production of the AMSs will increase and food security in the region would be ensured, while environment is maintained.
- Agri-food industries/traders will be benefitted with the competitiveness of crops commodities to access international market.

41. 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.

42. 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.

43. 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.

44. 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 Malaysia, Thailand, and Vietnam (and Colombia, Costa Rica, and Panama) 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 create partnerships with grower/exporter associations to provide the fields/trees for the research.

45. 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 real trade 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 for Asia and Latin America (2017).

46. The Logical Framework: Status of the Outputs and Activities appears as ***Annex 5***.

8.2. Lessons Learned

47. 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.

48. 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.

49. 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.

8. RECOMMENDATIONS

8.1. Specific recommendations to the project

50. The result of surveys showed that the outcomes of the project met the AMSs' 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 was provided in their final report which appears as ***Appendix 6***.

51. Experiences in project implementation identified some areas which would benefit from additional attention and support 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.

52. 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 sprayer 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.

8.2. Broader recommendation

53. In the area of food, agriculture and forestry (FAF), ASEAN has set a new Vision and Strategic Plan of Action for Cooperation on Food, Agriculture and Forestry (SP-FAF) 2016-2026. The Key Performance Indicators (KPIs) was also approved by AMAF in October 2016 to monitor the implementation of SP-FAF 2016-2025. The FAF Cooperation is also guided by the ASEAN Economic

Community Blueprint (AEC BP) 2025, which is part of *ASEAN 2025: Forging Ahead Together,* adopted by Leaders at the 27th ASEAN Summit 22 Nov 2015

54. The outcomes of the project contributed to the realisation of the SP-FAF 2016-2025, the AEC-BP 2025, especially on measures relate to trade facilitation, removal of trade barriers and market access. The enhanced capacity of AMSs to meet pesticide-related export requirements based on international (Codex) standards will provide greater opportunity to enhance market access of ASEAN agricultural commodities. At the end, this will lead to reducing trade barriers, increasing trade flows and supporting sustainable economic development of the Member States.

55. ASEAN welcomed the support from dialogues and development partners and to support realisation of the set goal, objectives and programme.

56. Learning from the success of this project, it is hoped that STDF would continue its support to ASEAN member states 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 ASEAN member states
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 (Latin America and Africa) on related above topics

9. ANNEXES

1. The Project Team
2. the EWG-MRLs Focal Points
3. The End-Project survey summary
4. The financial report
5. The Logical Framework: Status of the Outputs and Activities
6. Recommendations by the laboratory expert trainer

Annex 1: Project Team

ASEAN WTO-STDF Project on Pesticide Residue Data Generation
(PROJECT TEAM)

As of end 2016

I. ASEAN Participating Countries (capacity building & trial study)

Country - Residue trial	EWG Focal Point/ National Focal Point	Designation/ role in the Study	Personnel
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		Field Research Director	Mrs. Liliek Sri Utami Liliek_utami@yahoo.co.id
		Laboratory Research Director	Ms Syanti Asviatuti MSc sasviatuti@yahoo.com
2. Malaysia *pyriproxyfen in mango*	Mr. MOHAMMAD NAZRUL FAHMI BIN ABDUL RAHIM Principal Assistant Director Pesticide Control Division, Department of Agriculture Malaysia Tel: (+603) 203 014 99 Fax:(+603) 269 175 51 Email: nazrulfahmi@doa.gov.my; nazsmie@yahoo.com	Testing Facility Management	Dr. Mohammad Zabawi Bin Abdul Ghani* Miss Khairatul Azmah Binti Mohamed** atul@mardi.gov.my
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		Field Research Director	Mr. Mohammad Shahid Bin Shahrun shahid@mardi.gov.my
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3. Singapore *pyriproxyfen in mango* *(Lab only)*	Dr. Wu Yuan Sheng Assistant Director, Pesticide Residue Section Veterinary Public Health Laboratory Singapore 718837 T: (65) 6795-2807	Testing Facility Management	Dr. Wu Yuan Sheng WU_Yuan_Sheng@ava.gov.sg

Country - Residue trial	EWG Focal Point/ National Focal Point	Designation/ role in the Study	Personnel
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		Laboratory Research Director	-
4. Philippines *chlorantraniliprole in pineapple*	Mr. Wilfredo C. Roldan Executive Director Fertilizer and Pesticide Authority FPA Building, BAI Compound, Visayas Avenue Diliman, Quezon City Tel. No: +632-9208173;639178470297 Fax No: +632-9208173 Telefax: +632-4261572 Email: fpa.oed@gmail.com; fpacentral77@gmail.com;	Testing Facility Management	FPA Analytical Services Laboratory
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		Laboratory Research Director	Dr Amelia Tejada
5.1 Thailand (Central Laboratory) *spinetoram in mango*	Mr. Pisan Pongsapitch Deputy Director General, Office of Commodity and System Standard Bangkok 10900, T: 66 2 561 2277 ext 1401 F: 66 2 561 3373 E: pisan@acfs.go.th; Codex@acfs.go.th	Testing Facility Management	Dr. Nuansri Tayaputch nuantaya@hotmail.com
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Country - Residue trial	EWG Focal Point/ National Focal Point	Designation/ role in the Study	Personnel
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Annex 2

EWG-MRLs FOCAL POINTS

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Annex 3: Final Survey Summary

ASEAN WTO Pesticide Residue Data Generation Project:
Strengthening Regional capacity to meet pesticides export requirements based on international standard

Final Project Survey Summary

The text below each question is a summary of responses gathered from the returned surveys. In some cases when similar responses were provided, the responses were combined into a single response or a merged response. In most cases, the person/country that provided the response is not included to help ensure that future responses remain candid and honest.

Section 1: Overall Assessment of the Project and Management

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

- The research and training program has definitely helped improve our team's ability through providing detailed training material as well as practices from the lab to the field.
- Sprayer calibration, mixing and application of pesticide in the field and method validation for residue analysis.
- Implementation of research step by step accordingly to the field data notebook, beginning from site selection, experimental layout modifications, experimental setups, sprayer and speed calibration.
- The local pesticide laboratory has gained valuable exposure through several training attended throughout the project and the collaborative work.
- Sending our field residue sample in dry ice using air freight services and understanding the importance of monitoring storage temperature on the studied samples.
- Ability to directly interact with industry's representative particularly pesticide manufacturer and have them supply their analytical standards.
- The training program covered all elements of GLP which starting from Laboratory facility, Field facility and Quality Assurance Unit development, all concerned SOPs, Lab and Field practices, QA protocol and practices, Analytical Summary Report demonstration as well as Final Report, post report reviewed and very importantly for the Q&A to all the entire of the study.
- Industries now have a choice to propose that a new study is either based on DOA's Notification or a GLP study that is more worldwide accepted. So, the quality obtained from GLP can be traceable to all steps of studies. Even though we have in place a pesticide residue laboratory based on ISO/IEC 17025, we now have a laboratory (residue analysis) based on GLP. Now, we can conduct both systems depended on client requests.

- The team members have more confidence to conduct residue study that is in accordance to GLP.
- This program helps the staffs improved the knowledge of the GLP system include both field trial and laboratory activities. This knowledge were implemented to the other field trials ever since.
- Yes, Definitely. Singapore has benefited greatly from the ASEAN STDF Pilot Project on the Pesticide Residues Data Generation, especially on how to run a proper pesticide residues field trial studies with GLP (or 'GLP-like') compliance.

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

- Yes, because our records and procedures will be according to field data books, and application of GLP and SOP for laboratory operations.
- We strongly believe the project will help our future residue data generation conducted in our country as we have been directly involved in the project with close technical support from IR-4 experts (from protocol development to field trial conduct) and got a successful outcome for the first time. We now feel confident to go further in the future.
- Yes, but we would still need further capacity building in order to be able to generate future data for the development of Codex MRLs.
- Yes, because this project will be part of pesticide registration harmonization among the ASEAN Member States so that all can implement and accept standardized quality data in the future, particular, and establishing ASEAN MRLs as well as CODEX MRLs. Some countries can apply GLP practices to other sectors, such as drug development, cosmetics and food additives and etc. by means of this training.
- Yes, the project helps to enhance capability to generate quality residue data, thus leading to acceptance internationally.
- Yes, Definitely. Through the in-class training sessions and in-field practice, we now understand a lot of details on how to design, plan and execute the pesticide residues field trial studies with GLP compliance, e.g., how the study team and audit team should be organized and partitioned, how the study protocols and SOPs should be drawn out, what type of data should be collected in the field and during the lab testing, how to draft the analytical summary report and the final study report as well as how to conduct proper audits to check for any deviation from the study protocol and SOPs.

  While we are now quite comfortable with running the GLP-like residues field trial independently, the Pesticide Lab of AVA will enter into the actual residues field trial studies only when the critical needs arise. This is because the core function of our Lab is to run pesticide residues testing on fresh fruits and vegetables and many other food products for supporting Singapore's food safety regulatory programmes, under which we have around 10,000 samples to be analyzed each year, making us very busy all year round.

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

- Our trade opportunities will be improved through this project as pesticide residue is one of the big challenges of our products for export. The project has directly targeted this issue to find the solutions.
- In theory, it is yes if GLP is established. However the three pillars of the fundamental GLP (Regulator/CMA/Facility) have not been setup and certified in some AMS and then they cannot fulfill the GLP concept and be certified. It may take some time to set up and implement for the three pillars in all AMS and then it may impact to the trade requirements and opportunity to trade.
- Yes. Residue data from Thailand and National MRL are more reliable which are good for trade.
- Not relevant at the moment since no residue data is generated locally and there is no export of any agricultural commodities.
- Yes, acceptance of residue data for import tolerance or MRL setting by authorities of developed countries indirectly help to expand market access and increase income to the exporting countries.
- Singapore believes so. The knowledge we gained from the Project not only allows us to collaborate with ASEAN Member States for carrying out joint residues field trial studies to produce residues data packages for setting Codex MRLs and/or harmonized ASEAN MRLs for facilitate intra-regional and international agri-food trade, but also boost our confidence in reviewing pesticide dossier and residues data packages from other countries for the purposes of product registration approval, MRL (or import tolerance) setting, etc.

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

- Yes. The project have provided opportunities for all member countries to learn, work and share experiences in dealing with the common issues for the common benefits.
- Yes, because it depended on the existing facilities (pesticide residue decline study in Lab and field) in each AMS. For instance, the practical training actually took place in those facilities in order to fulfill the requirements of the study, as well as increase the competency of relevant personnel staffs.
- Yes it was distributed fairly, considering some countries only actively involved in the field trial aspects, whereas the sample analysis may have been carried out in another country laboratory.
- This project funds were not enough, especially for tropical fruits which requires a high budget.
- Yes. The fund was fairly distributed in term of number of trials.
- Yes, Singapore thinks the distribution of project funds is generally fair and transparent. The allocation of field trial projects and funding was openly discussed at the annual

EWG-MRLs meetings as well as at the training sessions when all the participating countries were present.

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

- The assigning of trails was both adequate and covered both field and laboratory activities, so there are no need for adjustment at this moment.
- Yes, establish automated recording/tracking system that help reduce continuous recording by study personnel.
- Yes. From the experiences gain and lessons learnt, we could improve in several aspects when it comes to assign field trial projects. Firstly, before nominating the pesticide-crop combinations for conducting the field trials, there should be closer collaboration and firmer commitment among all stakeholders, including the agrochemical company, the pesticide registration authority and the participants of field trial studies. This is to ensure that a GAP label will be made available timely. Secondly, some assessment, including the competency of personnel, level of commitment and availability of the required equipment and resources, should be conducted prior to assigning a residues field trial project. This is to ensure the assigned residues field trial project can be moved forwarded and delivered soundly and on schedule.

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

- Training in the lab and field should be conducted in different countries so more staff of the host countries are able to participate.
- Formulation and reference of field data book, protocol, check list and auditing procedure
- More practices should be covered.
- The training information on the field part of the study was clear enough, it just has to be practically tested to know what the problematic outcomes that challenges the training's implementation. One good example is the Mock Field Test carried out in Thailand where participants have the opportunity to learn the GLP processes of field residue trial without having to deal with the actual pesticide and without having to be at an actual farm.
- Yes, it is clear and covers in some extent, however GLP system and writing a report is taken time and also it can applicable to several activities, so more experiences are needed such as in different plant commodities.
- The information covered in the training are clear except archive activity was not in practice.
- Perhaps more practical trainings for the participants.
- Singapore thinks that the trainers from IR4 did an excellent job to conduct the training courses. One suggestion is, it would be more helpful if the latest soft copy of the

training materials, study protocol, SOPs, forms, etc, can be stored in a thumb drive and given to every trainee.

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

- Information and knowledge will be learnt from this program to generate quality data for residue decline study.
- We have started the training as observer, then become a reach remember of the project by jointly conducting the field trial with another member country. With the initial positive outcome we have got, the project has highly met our expectations.
- We expect to be able to replicate this process for other commodities in the future.
- From the field part of the study, it was a totally new experience when actually doing the training and implementation of the study compared to when attending as an observer but it totally went over my expectations in terms of the effort that was required to be put into the training to complete the implementation especially in terms of field selection and improvising the field plots to comply to the GLP requirement.
- On the scope of laboratory analysis, despite already being an ISO 17025 accredited laboratory, it seems that carrying out laboratory work under GLP felt more labor intensive where high emphasis is placed on proper documentation and recording to ensure the success of the entire project. With the participation in this project, laboratory personnel were able to collaborate with the Malaysian team in the analytical work i.e. in the sample processing, clean-up and further qualitative and quantitative analysis was done on the samples using sophisticated analytical instrument i.e. the LC-MS/MS.
- The Central Laboratory (Thailand) Co., Ltd had already planned to develop a GLP laboratory for toxicology and residue decline study, and this program was able to support our certain target to meet our expectation.
- After this project, the team improved ability to better understand the GLP system, and all of the staff could follow it. 85% met these expectations.
- The expectation was how to conduct a GLP residue study. The project has almost fully met our expectation. There is another aspect of GLP such as validation of computerized system in the analytical laboratory setting that may have to be improved in terms of training.
- Singapore's expectation in the Project is to gain the related knowledge and skills for running proper residues field trial studies with GLP compliance, so that we can run residues field trial studies independently when the need arises. We think the above expectation has been mostly met as we are now quite confident with running the GLP-like residues field trial by ourselves.

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

- Adherement to Standard Operating Procedure (SOP), access and archiving and auditing laboratory compliance.
- We really hope to receive more training on lab analysis under international standards in the near future.
- In Thailand, there are at least two areas improved from the regulatory requirement, such as the pesticide residue decline study for DOA registration and secondly BA/BE for drug registration.
- The trainer might take some time to reply to our questions/request or need to be reminded (e-mail communication) due to busy working schedule. The trainer should focus more answering trainee questions and needs.

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

- Sampling method, sample processing and preparation.
- Crop grouping.
- Residue field trials on different crops with different forms of cultivation.
- Detailed process in MRL establishment by Codex and others.
- Task of method validation process under GLP.
- I think GLP in different commodities (pesticide residue) and also pesticide product quality (formulation quality) and registration harmonization among the AMS.
- Some more topics which are needed for the further training include management and handling in the archiving system.
- Validation of computerized system in GLP study, crop grouping classification and risk assessment.
- We would like to receive some training to understand more on how GAP label is developed by the pesticide registrant, especially how to translate the LC50 values obtained from R&D lab to the initial application dose to be tested and fine-tuned via efficacy field trial studies.

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.

- The process for conducting the residue field trials under GLP is completely new for us, so it took so much time for us to complete and fulfill the requirements. We finally overcome the difficulties then we were very pleased with our outcome due to our hard working and the strong, close technical support by IR-4 expert (Dr. Michael Braverman).
- Our planned laboratory training in Malaysia was supposed to be carried out following the sample arrival in the Malaysia Laboratory. Unfortunately it was not possible and samples were being sent off first in September and stored frozen until the Brunei participants came for the training in March 2016, this year. The delay in sending off the samples to Malaysia laboratory was initially requested by the Malaysian team, due to

the workload in the laboratory and also technical problems encountered i.e. accessories/spare parts for the analytical instruments were not available yet. However, laboratory personnel from Brunei Darussalam were not able to undergo laboratory attachment and to analyze the samples together with the Malaysian team on the agreed planned i.e. scheduled date, due to the unavoidable circumstances and prolonged administrative approval.

- I have less experience in term of GLP document summary such as ASR, Summary Report and also report submitted to the agencies for proposing MRL. There are many details and much complicate from persons, places and time that must be initialized and synchronized in all steps. To correct the problem, relevant staffs must learn more experiences in practices of records, documented in term of reports and hand-on practices.
- In Thailand or most of the AMS need only two different trials (for residue study) where it is too small and not possible to establish MRL, it is only to verify the value proposed by the pesticide companies. However, this learning can enhance the normal practice of efficacy/residue trials to have more quality data/records and archive.
- There were some setback during the process due to understanding on the standard operating procedure (SOP) and the implementation of the SOP in the activities of each study. These problem were overcome by adjust the SOP suitable, the current activities and staff.
- Analytical instrument (LCMSMS) breakdown (due to wear and tear; > 10 years in service) has slowed the progress of the project significantly. Fund from other source was used to repair the instrument (spare part was very costly and the project fund was not adequate to cover the repair).
- Initially there were some difficulties to stay on schedule for the internal auditing of our residues field trial studies, because both our lab staff and audit team have their own busy daily agenda. Through good coordination, understanding and strong commitment to ensure the success of our project, we managed to overcome the difficulties.

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.

- The current Study Team is appropriate.
- Members of Study Team should be constituted with junior scientists who can substitute for senior technician's termination.
- The current Study Team is appropriate except on the appointment of the same Quality Assurance Unit for both field and laboratory work. We plan for any future project to improve by assigning different QA Unit/Officer for field and laboratory work ensuring that the task fits their day-to-day work scope or expertise.
- In term of sustainable model, our future is depended on the DOA's policy to require GLP's results/records and also develop the CMA pillar for regulators. I have also

recommended that the Thai-DOA should setup himself to comply with the national CMA (as regulator) so that all related worked can be international standardization and sustainability.

- The current study is very sustainable in the pesticide residue laboratory of the department of agriculture. These activities were implemented in this laboratory since 2013 and were carry-on until present. This program will help DOA improve the quality of the work to meet the requirements of international standards. Moreover, DOA can expand this knowledge and pass through the branch laboratory throughout the country and can help neighboring countries in the future.
- To a certain extent in term of analytical instrument (LCMSMS) good working condition is essential for smooth project implementation. LCMSMS from other agencies may have to be used if the current LCMSMS could not perform as expected in the future project. Alternative laboratory with LCMSMS has been identified.
- Change of team member (e.g. Field Research Director, Quality Assurance, etc.) may be unavoidable due to evolving work needs for the existing team members. Nevertheless, identification of suitable candidates for possible replacement has been made. Current working model between Department of Agriculture and Malaysian Agricultural Research and Development Institute is still feasible. Other government agencies (with LCMSMS) may be invited to join the project in the future.
- We are comfortable with the setup of our current Study Team. We can also tap into the knowledge and experience of staff in the other parts of our organization when the need arises.

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?

- Yes, it is.
- Yes, our Study Team is highly interested in continuing future residue projects with IR-4 and/or other countries within the region. We need more in-county training (field trial and lab analysis). As pesticide residue research is one of the priority issues in our agricultural sector, the international project leaders should directly contact with our headquarter (Plant Protection Department/ Ministry of Agriculture and Rural Development) as a focal point.
- The Study Team would be interested to be involved in any future capacity building. The only limitation is that the crop under study is usually not a major crop in Brunei Darussalam and the field size for the study is also not within the requirement criteria for the field trial.
- Yes, we are interested to join the IR4 project or other projects. Based on this we have developed the agreement to cooperate with the international agencies such as Eurofins Agrosceince Services Co., to perform GLP study of pesticide residues for registration in and outside the country. And because, this activity will be depended on the regulator's

policy to how strictly require to the registration processes. Most of the management team understand and support all necessary resources.

- Yes. Thailand is the country to submit the data to establish ASEAN MRL and to submit the pesticide residue data for tropical fruit to JMPR. The quality of data should be complied with GLP. This project helps improve the competency of the staff, change the knowledge among the ASEAN countries, and should continue. DOA is responsible to conduct the residue field trials in exporting crops to establish MRLs, such as ASEAN MRLs, Codex MRLs.
- Yes. Continuous engagement with the IR-4/USDA expert should be continued for future projects. Trainings related to residue study are also welcome.
- Our involvement in the future residues project with IR-4 will be based on the assessment of our upper management on the relevance of the project to Singapore as a food importing country.

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

- It should have more time of agenda for chromatographic or Mass Spectrum data evaluation, calibration and calculation of interest compound in the sample
- More collaboration in residue data generation should be done among countries with the common products to save costs and time.
- I would like to thank the IR4 project, the ASEAN STDF project and all experts especially, Dr. Michael Braverman who has entirely helped us in all steps of the GLP studying. The experiences in this project is uncountable benefit to our staff in developing GLP study as well as chances to participate with the international experts in the AMS as well. However, due to the different registration processes in each AMS, so harmonization is needed. I do hope that ASEAN will continue to develop the ASEAN criteria/directives so that only one standard would be applied.
- The other comment is, even though we have been trained in GLP/US-GLP, sometimes we cannot assure that it complies with the OECD-GLP that is implemented among OECD members. I had an opportunity to discuss with the Japanese's expert from FAMIC/MAFF which may different in some categories.
- This project helps improve in the making of good experiments and good reporting to meet the international standards which were accepted to the international panel. So it will be good to expand this knowledge to the other ASEAN countries and raise the scope of GLP to meet the same level which increases the power of food safety among ASEAN community.
- The current working model of the project should be continued so that network of resources, locational test sites can be leveraged to generate maximum impact (representative trials throughout the world) with minimal resources (cost sharing).
- Near the end of the ASEAN STDF Pilot Project on Pesticide Residues Data Generation, Singapore would like to thank specially Mr. Jason Sandahl of USDA, Dr. Michael

Braverman of IR4 for the professionalism and resourcefulness demonstrated as well as your dedication and strong commitment to the success of the Project. Our Singapore team believes that this is one of the best organized and delivered international projects we have even participated.

Section 2: Special technical knowledge/skills/ability

*In Sections 2 and 3, please rank your answers with the following numbers (circle the number):

1 = little or no knowledge/skill
2 = *between 1 and 3*
3 = some knowledge/skill
4 = *between 3 and 5*
5 = full knowledge/skill

What is your current….

1. Understanding of the core concepts of GLP supervised field trials?	**Avg: 4.1**
2. Ability to develop and follow a GLP study protocol?	**Avg: 3.7**
3. Ability to develop and follow SOP for a GLP study?	**Avg: 3.9**
*For Study Directors and Field Research Investigators only:	
4. Ability to follow and complete a field notebook for a GLP study?	**Avg: 3.9**
5. Ability to calibrate a sprayer for a GLP study?	**Avg: 4.4**
6. Ability to set up a field plot for a GLP study?	**Avg: 4.3**
*For Study Directors and Laboratory Research Investigators only:	
7. Ability to validate an analytical method for a GLP study?	**Avg: 4.3**
8. Understanding of the role of the Quality Assurance auditor	**Avg: 4.0**
*For Study Directors and Quality Assurance only:	
9. Ability to audit a GLP study?	**Avg: 3.4**

Section 3: Understanding of Codex MRL establishment process

1. Understanding the Codex process for establishing MRLs	**Avg: 3.8**
2. Understanding the concepts behind crop grouping and the use of representative crops for MRLs	**Avg: 3.4**
3. Understanding the requirements for combining data sets from multiple countries into a single data package	**Avg: 2.9**
4. Understanding of how the minimum number of trials needed for a data submission is derived	**Avg: 3.1**
5. Understanding the nomination process of crops and pesticides for JMPR review	**Avg: 2.9**

6. Understanding how MRLs are determined **Avg: 3.8**

Section 4: Outputs

*To be answered by Study Directors only

1. Has a study protocol been successfully completed for your study? **Yes=7**
   No=0

2. Have field and laboratory SOPs been successfully developed and put into practice for your study? **Yes=7**
   No=0

3. How many field trials have been successfully completed for your study?
   Thailand= 6*2
   Malaysia /Singapore= 6
   Malaysia = 3
   Brunei= 1
   Philippines= 3
   Indonesia= 6
   Vietnam= 1

4. How many field trials have not been successful? Malaysia=1

5. Has the analytical method been successfully validated? **Yes=4**
   No=0

6. How many trials have been successfully analyzed?
   Thailand=6*2
   Malaysia/Singapore=6
   Malaysia/Phil/Bru = 7
   Indonesia = 7

7. How many trials have not been successfully analyzed? None

9. Has you project crop/pesticide been successfully nominated for JMPR review? **Yes=7**
   No=0

8. Has the study report been completed and submitted to the JMPR? **Yes=3**
   No=4

FINANCIAL REPORT

	RECEIPTS/ EXPENDITURES	AMOUNT (USD)			IN-KIND (USD)
A.	**RECEIPTS: DISBURSEMENT FROM WTO**			**605,148.76**	
	1-Jan-13	127,398.76			
	13-Mar-13	95,550.00			
	13-Nov-13	95,550.00			
	30-May-14	95,550.00			
	27-Mar-15	95,550.00			
	8-Jun-15	95,550.00			
B.	**EXPENDITURES**				
1	**PROFESSIONAL FEE - RUTGERS UNIVERSITY**		**195,000.00**		
2	**CAPACITY BUILDING**		**118,803.91**		
2.1	Training				
	a) Field Training (29-31 Jan'13, Bkk)	14,286.41			
	b) Lab Training (17-22 Mar'13, Bkk)	24,353.72			
	c) Training on GLP (18-20 November 2014, Bali) -	39,442.32			
	d) Training on QA (20-22 Jan 2016, Bangkok)	16,721.46			
2.2	Travel Consultants from IR-4 (Rurgers Univ)	24,000.00			
2.3	USDA : training supplement				30,000.00
3	**RESIDUE DATA GENERATION**		**259,106.53**		
3.1	Residue trials:				
	a) Pyriproxyfen/mango - Malaysia & Singapore	53,200.00			
	b) Spinetoram in mango - DOA Thailand & CLA Thailand	40,000.00			
	c) Azoxystrobin and difenoconazole on Dragon fruit - Indonesia & Viet Nam	55,605.88			
	d) pyriproxyfen – papaya (Philippines, Malaysia, Brunei Darussalam)	49,684.65			
	e) Spinetoram - lychee - DOA Thailand & CLA Thailand	50,000.00			
3.2	Private sector contribution (efficacy trials, test substances, analytical standards, analytical training, registration fees)				200,000.00
3.3	Participating AMSs's contribution (human resources/government officials)				60,000.00
3.4	Laboratory equipments	10,616.00			
4	**TECHNICAL ADVICE AND TRAVEL BY JMPR SECRETARIAT**		**30,000.00**		
5	**OTHER MEETINGS/ WORKSHOPS** (travel support to CCPR, global coordination with other regions at GMUS-II, project steering committee meetings				
	a) Croplife Asia				100,000.00
	b) USDA				25,000.00
	c) AMSs attend CCPR Meetings				10,000.00
6	**PROJECT MANAGEMENT AND COORDINATION**				
	a) ASEAN Secretariat: overall management of project, attending EWG MRLs & PSC, communication etc.				60,000.00
	b) USDA : Overall coordination				120,000.00
7	**BANK CHARGES**		**607.63**		
	TOTAL EXPENDITURES			**603,518.07**	605,000.00
	BALANCE			**1,630.69**	

18-Jul-17

Prepared by:

SO Sri Dyah Kusumawardhani

Approved by:

ADR Pham Quang Minh
Head, Food Agriculture and Forestry Division

Certified by:

ADR Heny Suwandi
Head, Finance and Budget Division

RECEIVED
18 JUL 2017
THE ASEAN SECRETARIAT
Finance and Budget Division
Trust and Project Funds

ASEAN-WTO PESTICIDE RESIDUE DATA GENERATION PROJECT

STATEMENT OF ACCOUNT

AS OF 30 JUNE 2017

	Amount in US$	
BALANCE AS OF 1 JANUARY 2017	1,308.04	
RECEIPTS:		
- Refund of Field trial on Pyriproxifen in Papaya, Brunei Darussalam (19 May 2017)	325.35	
	1,633.39	(+)
EXPENDITURES:		
- Bank Charges	2.70	
	2.70	(+)
BALANCE AS OF 30 JUNE 2017 *	**1,630.69**	

Prepared By

Ingrid Maya Sophy
TECHNICAL OFFICER

Approved By

Heny Suwardi
HEAD OF FINANCE & BUDGET DIVISION

(*) Receipts - Expenditures

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STDF Standards and Trade Development Facility

ANNEX 5: 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 ASEAN Member States trained during the project period (2012-2015) 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/ASEC 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) 4 group trainings were organised: 1. Training on Field Trials, 29-31 January 2013, Bangkok. (21 experts from AMSs were participated). 2. 1st Training on Supervised Good Laboratory Practice (GLP), 18 – 22 March 2013, Bangkok. (24 experts from AMSs were participated) 3. 2nd Training on Good Laboratory Practice (GLP), 18-20 November 2014, Bali, Indonesia. (24 experts from AMSs were participated)	Overall, the Project was highly successful and positioned AMSs 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.

		4. Training on Quality Assurance (QA), 20 – 22 January 2016, Bangkok. (18 experts from AMSs were participated). iii) Close consultation among ASEAN Participating Countries, the Study Director, Technical Coordinator and ASEC established. iv) Country visit have been carried out by experts to ASEAN Participating Countries to provide lectures and guidance on the conduct of the trial and lab analysis. v) Protocols for five studies developed and signed. 1. Pyriproxyfen– mango (Malaysia & Singapore) 2. Spinetoram – mango (Thailand) 3. Azoxystrobin and difenoconazole - dragon fruits (Indonesia, Viet Nam) 4. Pyriproxyfen on papaya (Philippines, Malaysia, Brunei Darussalam) 5. Spinetoram – lychee (Thailand) vi) Field trials and analysis works had been completed for all Studies.	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.

		vii) Indonesia and Thailand had submitted data packages and label to FAO/WHO JMPR in 2016 for review: - azoxystrobin/ difenoconazole on dragon fruit. - Spinetoram on lychee and Spinetoram on mango	
Output Tier 2: MRL Establishment/ Registration The availability on the market of new, approved chemicals for minor use crops	Indicator : 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.		
Activity 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	Target 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 at the respective AMSs: 1. Pyriproxyfen in Malaysia. 2. Spinetoram in Thailand 3. Azoxystrobin and Difenoconazole in Indonesia, 4. Pyriproxyfen in Philippines 5. Spinetoram in Thailand	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 6: Recommendations by the laboratory expert trainer

Southeast Asian GLP Training

Final Report

Wayne Jiang

Michigan State University
November 30, 2016

This report summarizes the laboratory GLP training in Southeast Asia (ASEAN). The report is consisted of three sections, i.e., 1. Summary of Trips, 2. Observations and Challenges, and 3. Conclusions and Suggestions.

1. Summary of Trips

I started the GLP training for Southeast Asia residue studies in 2012, together with Dr. Michael Braverman, Study Director at IR-4 Headquarters located in Princeton, New Jersey. Prior to the travel, I started to work with Michael and other experts from USDA on the training in Malaysia and Singapore. My first trip was to Bangkok, Thailand in March 2013. The last trip to Asia for the GLP training was to Bali/Jakarta, Indonesia in November 2014. Some of the activities of field residue studies are being carried out and the Analytical Summary Reports are being in preparation at the time of generating this report.

This Section is a summary of all the visits to the Association of Southeast Asian Nations (ASEAN) (see Table 1). This section includes the date and number of days for each visit (excluding travel days) as well as the preparation of the activities (Pre-trip) and on-site activities (During trip) for each of the visits. There are some Post-trip activities are expected in the near future. Table 1 shows that a total of 3 visits that I had made are for the GLP training visits and two regional workshops. These trips were relatively long, for example, two trips were of 2-week trips, including the travel time. Some of these training activities are combined as one long trip. All of the trips were directly linked to the proposed GLP residue studies, such as Spinetoram / Mango (Thailand), Pyriproxyfen/Papaya (Philippines), and Azoxystrobin + Difenoconazole / Dragonfruit (Indonesia). In the two regional workshop, all ten ASEAN member countries attended, plus two visiting countries (two people from Korea and two people from China). There were two separate analytical labs in Thailand, and one lab in Philippines and Indonesia, each.

As can be seen in Table 1, the participating analytical laboratories significantly improved the work quality and greatly enhanced their GLP capacity after the GLP training sessions.

2. Observations and Challenges

Summary: As can be seen in Table 1, all of the labs were ISO 17025 certified prior to the GLP trainings. However, none of these labs were ready for a GLP residue study before the GLP training. Although ISO 17025 requires a robust system and a good amount of documentation, GLP appears to require more documentation in details. There are some big differences between these labs due to the nature of their daily work and government system. Since ISO 17025 helped to establish a relatively efficient system for the labs, the trainings went on for these labs quite smoothly.

Conclusion: We are confident that all the participating laboratories, are currently capable of conducting GLP residue analysis.

Challenges: In the meantime, there are still a lot of challenges. Some of them had been solved through the training process but the other would take a long time to improve.

The knowledge of science and technology is the most important question and could be a largest problem in the lab affecting the laboratory progress. For example, the Thai central lab encountered low responses from the mass spec (Waters Acuity TQD LC/MS/MS) for one of the spinetoram's metabolites. The Pilipino lab could not figure out the source of cross-contamination significantly affecting the spike recoveries. The labs could not do a good GLP job without proper science. Here is one example was that I had to show one lab how to perform basic Excel calculations of residues, recoveries and LOD/LOQ.

There are big difference in their infrastructure. The Thai central lab has used LC/MS/MS routinely for 10+ years where the laboratory in the Philippines just had one in the lab shortly before the GLP residue study. Some of them were starting to use dry ice in sample processing, although in these countries, the source of dry ice was not a problem. In general, the freezer storage capacities were relatively small and often were considered as non-GLP if being shared with non-GLP samples. The freezer temperature monitoring system needed to be upgrade to more reliable systems. Some labs had no calibration for balances, mechanical pipets, or volumetric measurement apparatuses.

I really liked the person acting as the "local SD" (or principal investigator, PI), such as Prof. Sri (Indonesia). They communicated in a timely manner and did help a lot in project progress.

The Quality Assurance (QA) remains the weakest area among all of these labs, as I observed. So, QA needs to be improved and be stronger when the labs are doing residue studies for regulatory purposes.

In these labs, most chemists worked very harder during my training. For example, during the GLP training in Thailand, the lab people often worked 8+ hours per day and were working in labs at 6 pm on the days when I gave hands-on GLP training. It is obvious that all labs were eager to learn GLP. The score of Willingness to learn was high. However, sometimes, the response was slow (including email responses).

Section 3. Conclusions and Suggestions

It can be concluded that overall, after the GLP training sessions, the participating analytical laboratories are capable of performing the GLP residue analysis. Some additional training and follow-up is highly preferred to improve the weakness.

Discussions/suggestions are listed below in two separate sections, i.e., '3.1. What has been accomplished' and '3.2. What more can be improved in future'.

3.1. What has been accomplished?

1. Each pesticide laboratory has successfully received at least one on-site, one-week's Good Laboratory Practices (GLP) training and participated in two regional GLP workshops;
2. Each lab has established a complete set of lab SOPs, created necessary lab forms and logs in order to conduct the residue studies under EPA GLP standards.
3. Each participating lab has completed method validation and to carry out partial sample analysis meeting the GLP requirements, together with the trainer being on-site and with the guidance of the study director, for the proposed pesticide residue studies.
4. Each participating lab has learned the details on samples reception, storage, chain-of-custody, grinding and processing, extraction, cleanup, analysis, deviations, reporting and archives, using the IR-4 model, while conducting the proposed residue study.
5. All participating labs had the experience of writing analytical summary reports (ASR) using IR-4 reporting templates. The trainer is being helping the labs in data reviewing and ASR preparation.
6. The two Thai labs have completed their draft ASRs (studies of Spinetoram/Mango).

3.2. What more can be improved in future?

1. Each lab is expected to establish a solid system to ensure its GLP system is sustainable. This includes the support from sponsors and the management, laboratory personnel's continuous efforts for working under the GLP, QA's continuous auditing, etc..
2. While the analytical laboratories are being improving their routine practices, Quality Assurance (QA) audit is apparently needed to be improved in the participating laboratories.
3. The labs should make serious commitment to reviewing SOPs, performing studies per protocols and SOPs, taking time to create documentation of all records/logs, effectively and promptly communicating lab directors and study directors, while they are continuing 'physically' working in the analytical laboratories on the method and analysis.
4. The lab chemists should obtain better knowledge on new sciences and technologies, such as how to operate a new LC/MS/MS instrument, how to use new software, how to improve the efficiency of solid phase extraction (SPE) for problem solving and troubleshooting, etc.
5. All lab personnel should renew/refresh the GLP knowledge periodically and have better understanding on the requirements and regulations by US EPA, other government agencies, and international organizations.

Table 1. Summary of Trips

For an overall assessment of the labs, they were ranked on efficiency, systems, forms, willingness to learn and personnel using a 5 point scale were 5 is excellent, 4 is good, 3 is average, 2 is below average, and 1 is poor. The scores are based on the labs' GLP system and practices. Table 1 also includes the scores before and after the GLP training.

		Thailand		Philippines	Indonesia	Malaysia*	Singapore*
Laboratories		Thai Central Lab	Thailand (DOA Lab)				
ISO 17025 Certified		Yes	Yes	Yes	Yes	Yes	Yes
Efficiency		4[*1] -> 4[*2]	3 -> 4	3 -> 3	3 -> 4	3 -> 3	3 -> 4
System		3 -> 4	4 -> 4	3 -> 4	4 -> 4	3 -> 4	4 -> 4
Forms		2 -> 4	2 -> 4	2 -> 4	2 -> 4	2 -> 4	2 -> 4
Willingness to learn		4 -> 5	4 -> 5	4 -> 5	4 -> 5	4 -> 5	4 -> 5
Personnel	Local SD / PI	3 -> 4	3 -> 4	2 -> 4	3 -> 4	3 -> 5	3 -> 4
	Lab director	3 -> 4	3 -> 4	3 -> 4	3 -> 4	3 -> 4	3 -> 4
	Lab chemists	3 -> 4	4 -> 4	3 -> 4	4 -> 4	4 -> 4	4 -> 4
	QA	2 -> 3	2 -> 3	2 -> 3	2 -> 3	2 -> 4	2 -> 3
Total		21 -> 28	22 -> 28	20 -> 27	22 -> 28	22 -> 28	22 -> 28

Notes: [*] Local SD (or principal investigator, PI), scored by Michael Braverman for oversight. They did help a lot in project progress. The laboratory scores were based on work with Elizabeth Culbert and Michael Braverman

[*1] The score estimated before GLP training.

[*2] The score is after GLP training.

Table 2. Summary of Training Visits and Activities

Trip			Country	Study, *or* *Workshop*	Activities		
No.	**Date**	**Days**			**Prep-Trip**	**During-Trip**	**Post-Trip**
1	March, 2013	5	Thailand	Spinetoram /Mango	• Review SOPs • Review Forms	• Initial GLP training - presentations • Hands-on GLP practices • Method development, solving the problem of low responses of the metabolites • Sample preparation (including mango seed removal, fraction weighing, grinding, subsampling, storage, etc.) • Standard preparation and method validation (fortification, calibration, analysis) • Sample numbering, standard numbering • Record keeping • Data checking (QC)	• Follow up • Reviewed data for both Thai Central and DOA labs • Reviewed ASR
		5	Thailand	Workshop	ASEAN Regional Workshop	• Field GLP training – presentations • Lab GLP training - presentations • Laboratory Report preparation - presentations	• Some email communications as following up
2	June, 2014	5	Philippines	Pyriproxyfen /Papaya	• Review SOPs • Review Forms	• Initial GLP training - presentations • Facility inspection • Hands-on GLP practices • Problem solving – cross-contamination • Sample processing (including grinding, subsampling, storage, SS prep, calibration, etc) • Method development • Standard preparation & Method validation	• Follow up • Reviewed method validation data

						• Calculation in Excel • QC checking	
3	November, 2014	4	Indonesia	Workshop	---	• Field GLP training – presentations • Lab GLP training - presentations • Quality Assurance - presentations • Laboratory Report preparation - presentations • JMPR submission – presentations	• Some email communications as following up
		5	Indonesia	Azoxystron + Difenoconazole / Dragonfruit	• Review SOPs • Review Forms	• Initial GLP training - presentations • Facility inspection • Hands-on GLP practices • SOP modification • Problem solving – used organic dragon fruit to eliminate cross-contamination • Sample processing (Balance calibration, sample grinding, fractioning, subsampling, storage, SS prep, calibration, etc) • Standard preparation & Method validation, and Calculations	• Reviewed method validation data