



APEC FSCF PTIN Laboratory Capacity Building

Pilot projects and Regional Workshop 2013
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2013 Objectives

- Develop a tool to help economies or regions prioritize laboratory capacity building activities for food safety
- Hold a stakeholders meeting to refine and use the tool to define current priorities in the APEC region

Background

The Asia-Pacific Economic Cooperation, or APEC, is a forum for facilitating economic growth, cooperation, trade and investment in the Asia-Pacific region. APEC also works to create an environment for the safe and efficient movement of goods, services and people across borders in the region through policy alignment, and economic and technical cooperation.

APEC and Food Safety

APEC has been a vehicle for cooperation on food and agricultural issues. APEC activities promote productivity and growth in the agricultural sector, encourage the development and adoption of new agricultural technologies and facilitate food trade. The Committee on Trade and Investment's Subcommittee on Standards and Conformance (SCSC) is the focal point for efforts to harmonize regional standards regarding the safety of food and consumer products. The SCSC oversees the Food Safety Cooperation Forum (FSCF), which manages food safety work among various APEC groups. The FSCF is a forum of food safety regulators, which operates as an advisory body to APEC via the SCSC on food safety related project proposals.

The FSCF Partnership Training Institute Network (PTIN) was created to address the need to engage the food industry with academics and regulators, to strengthen capacity for food safety across the APEC region. APEC leaders endorsed the FSCF PTIN

initiative in 2008. An APEC/PTIN Expert Working Group held a meeting in May 2010 in Washington, DC, where policy officials met to discuss gaps in knowledge across the APEC communities and prioritized areas for possible collaboration. During the discussion, the group emphasized the need to focus on laboratory capacity building efforts. Specifically, the following eleven priority areas were identified as critical laboratory capacity priorities:

- Critical Role of Laboratories in National Food Safety Progress
- Assessing needs of laboratories
- Safety (personnel and laboratory)
- Quality Assurance/Validation
- Metrology
- Sampling
- Laboratory Management
- Lab Accreditation
- Analytical Methods
- Data Analysis and Interpretation
- Maintenance and Troubleshooting

Since the Expert Working Group convened in May 2010, stakeholders have worked to carry out the Working Group's recommendations, develop and disseminate a survey tool, and organize a lab competency workshop which brought together technical experts from 17 APEC economies in Bangkok in August 2011. Post-workshop follow-up activities led to the conclusion that a collaborative approach was the optimal way to advance the competency building activities.

The laboratory collaboration program consists of five critical components:

1. Establishing or leveraging existing Lab Accreditation/Quality Assurance measures. This includes sharing SOPs, best practices, identifying scope of accreditation and recommending sources for gap analysis. Laboratories can range from no quality assurance system to highly rigorous systems (for example, ISO 10725 accredited). Current laboratory status will dictate needs assessment.
2. Proficiency Testing (PT). This includes the identification of programs and leveraging of available resources and reference materials. While usually included under laboratory accreditation/quality assurance, it is separated to emphasize the importance of participation in a PT program. PT samples are a direct measure for demonstrating laboratory testing competency.
3. Training. Utilizing current programs, including government sponsored training courses, and international training laboratories, among others. Training will cover screening and confirmatory testing. Prerequisites can be satisfied by developing web-based modules or through existing training material available from government agencies and other organizations.
4. Laboratory Infrastructure. This includes recommendations for current and new technologies and equipment utilized by regulatory laboratories. Based on current testing methodologies, guidance can be provided as to what equipment, standards and reagents are most suitable for test methods. Although flexibility in method selection exists, eventually, equipment platforms for testing will harmonize.
5. Methods. This includes sharing current food testing methods (microbiological and chemical) and method validation protocols, as well as participation in collaborative studies. Method validation criteria can also be captured under laboratory accreditation/quality assurance but is included here to highlight the importance of methods, their intended use and performance.

In 2012, a series of three hands-on laboratory workshops was deployed in the region:

- Lima - June 18-21, 2012: Peru, Chile, and Mexico
- Kuala Lumpur - July 9-12, 2012: Malaysia, The Philippines, Indonesia, Thailand, and Singapore
- Hanoi - July 16-19, 2012: Vietnam, China, Russia, and Papua New Guinea

The workshops received excellent evaluations and participants indicated the following in a survey:

100% of training attendees agreed or strongly agreed that they have a better understanding of the technical information presented as a result of their participation.

100% of training attendees agreed or strongly agreed that having participated in the training will improve their ability to perform in their role/job.

76% of training attendees agreed or strongly agreed that they experienced increased opportunity for international laboratory collaboration as well as significant growth of their lab network as a result of their participation.

100% of training attendees said they plan to share the expertise acquired/strengthened with their home laboratories, and as of 11/9/12, 96% have related that they have already done so.

52% of training attendees related that their laboratory has already experienced decreased erroneous results, delays, and/or rejected shipments as a result of their participation.

64% of attendees related that their lab/economy has already been able to produce more reliable, internationally compatible data as a result of their participation.

Difficulties encountered in 2012 workshops:

- Short period of performance
- Laboratory supplies held up at customs
- Trainer cancellation
- Smaller training rooms; lack of a/c
- Need for some basic lab skill review identified

Infinite Needs, Finite Budgets

Facing the challenge of investing in a single activity again in 2013, it was obvious that the task of selecting such activity demanded an evaluation of many factors that were not seen as equally important by different stakeholders and across the region. To this effect, a Scientific and Technical Advisory Group (STAG) was gathered in the Spring 2013 to develop a tool for the prioritization of laboratory capacity building activities that could be used independently by national or regional governments or stakeholders groups to decide their own priorities for investments.

A “mini-STAG” was composed of experts from USDA (Dr. Charles Pixley and Dr. Emilio Esteban, Mrs. Cathy McKinnel, Ms. Kelly McCormick and Mrs. Fania Yangarber), U.S. FDA (Dr. Elizabeth Calvey, Dr. Palmer Orlandi, Mr. Carl Sciacchitano), academia (Dr. Janie Dubois, University of Maryland JIFSAN), and industry (Dr. DeAnn Benesh of 3M, Dr. Wayne Wargo of Abbott Nutrition).

The team developed a capacity assessment tool to enable a better understanding current and desired capacity. The draft tool was presented and discussed at a STAG meeting in November 2012 in Washington DC. It was agreed that economies would volunteer to conduct a pilot application of the prioritization tool to support further development. Chile and China were announced as the pilot economies at the APEC SOM II meeting in Indonesia in April 2013.

There were strong imperatives to avoid duplicating existing resources in this project, so assessment and prioritization tools used by international organization were investigated by JIFSAN (University of Maryland’s Joint Institute for Food Safety and Applied Nutrition), the program implementation organization.

The World Organization for Animal Health Tool for the Evaluation of Performance of Veterinary Services (OIE PVS) tool was selected as a good model for assessment, and the Multi Criteria Decision Analysis developed to prioritize Sanitary and PhytoSanitary capacity building needs at the Standards and Trade Development Facility (STDF) could be tailored to fit the purpose of prioritization for laboratory capacity United Nations Industrial Development Organization. More information may be found using these links: [OIE PVS](#) and [STDF MCDA](#)



2013: Stakeholders meetings were held in Chile with industry, academia, government and government-certified laboratory managers.

2013 Pilot Projects

The first pilot project was undertaken in collaboration with the Food Safety and Quality Agency (ACHIPIA) in Chile. The project consisted in stakeholder meetings held in Chile in June 2013 with a small team of laboratory experts consisting in Drs. Emilio Esteban, USDA FSIS, Palmer Orlandi, U.S. FDA Office of Food and Veterinary Medicine, Melinda Hayman, Grocery Manufacturers Association and Janie Dubois, University of Maryland.

Dr. Nuri Gras, Executive Secretary of ACHIPIA, presented the activities and outcomes of this pilot project at the Regional Workshop. The slides of her presentation are available in Appendix 1.

This project can be summarized as a government-driven needs assessment and prioritization.

The consultation yielded a long list of needs in most of the prioritization tool categories. Further discussions concluded with a short list of four priorities and activities to address them. The priorities were:

- 1- Bridge the gap of Information imbalance regarding rapid techniques in microbiology;
- 2- Expert advice on the measurement of veterinary drug residues in fish, seafood, meat and poultry;
- 3- Expert advice on the USDA and FDA-recommended methods for the detection of *Salmonella* and viruses in fish, seafood and poultry;
- 4- Guidance on the requirements for verification and validation of laboratory methods.

The complete workplan of activities to address these priorities is available in Appendix 2.

A different approach was sought for the second pilot project to complement the information and points of view obtained in Chile. The collaboration with China was started later in the fall with the Qindao Agricultural University (QAU), located in the Shandon Province. The team from the University is by nature academic, but the team also manages a spin-off contract laboratory offering analytical services to the food industry, importers, exporters and the government in China.

The second pilot project was initiated via telephone conversations, and activities started in November 2013. Dr. David Ji of QAU presented a summary of the outcome of activities that took place in the fall at the PTIN Regional Workshop; his slides are available in Appendix 3. The draft workplan (as of December 13, 2013) for this pilot is available in Appendix 4.

A draft prioritization process was assembled by JIFSAN following the pilot project activities of the fall 2013 and was shared at the Regional Workshop in a presentation discussing the objectives and processes used during the summer and fall activities to define the preliminary decision making process.

PTIN Regional Workshop on Strengthening Laboratory Capacity in Food Safety

The Regional Workshop was held at the University of Maryland and hosted by JIFSAN, with financial support from the USDA Emerging Markets Program, the University of Maryland's Division of Research and Division of University Relations, and 3M.



Train-the-trainer program on veterinary drug residue analysis provided opportunities to learn and network to build collaborative teams.

Representatives from governments, academia and industry participated in a program of presentations, round-table discussions and technical assistance as per the agenda available in Appendix 5. The list of attendees is available in Appendix 6. There was a satisfactory mix of experienced laboratory program managers and newer analysts and manager who provided different points of view on needs and availability of resources. Some of the participants had also participated in the Regional Workshop of 2011, which ensured continuity in the discussions.

All documents presented in the Workshop as well as additional information gathered as a result of the Workshop are shared in a “Dropbox” with all participants; the majority of participants had signed in less than 1 week after the Workshop.

Outcomes

1. Presentations on Pilot Projects

Presentations are available in Appendices 1 and 3, and will be made available on the APEC FSCF PTIN webpage.

There was particular interest in the model of coordination for all food safety agencies in Chile presented by Dr. Gras. It was indicated that the central agency for food safety felt better equipped to understand the “big picture” and address capacity building in a coordinated manner that included consultation of all stakeholders and prioritization of activities based on the overall need.

Dr. Janie Dubois of JIFSAN presented the method development process undergone by the travel team during the Chile pilot project and the decision tree summarizing the process. (Appendix 7)

2. Round-table Discussion on Capacity Building Needs and Process of Prioritization

Each economy was asked to contribute an opinion on capacity building needs, and discussions about why and how these needs may be addressed led to a prioritization for one particular need to be drafted by each team.

At the end of the meeting, the questions discussed paths proposed from various teams enabled the additions to be made to the basic decision tree presented by Janie Dubois for one particular aspect of capacity building needs (personnel training) (Figure 1).

One of the important aspects brought into the decision tree was the confidence in the ability to count on collaborations with other APEC economies to address needs, often at no cost to the requesting economy. This is well-aligned with the purpose of the FSCF as stated in its Operating Principles: “To accelerate progress towards these outcomes, APEC will improve and strengthen information sharing and capacity building activities in food safety by enhancing cooperation between member economies and in regional activities.”

(<http://www.apec.org/~media/Files/Groups/AFS/Revised%20FSCF%20Operating%20Principles.docx>)

After Reg. Workshop

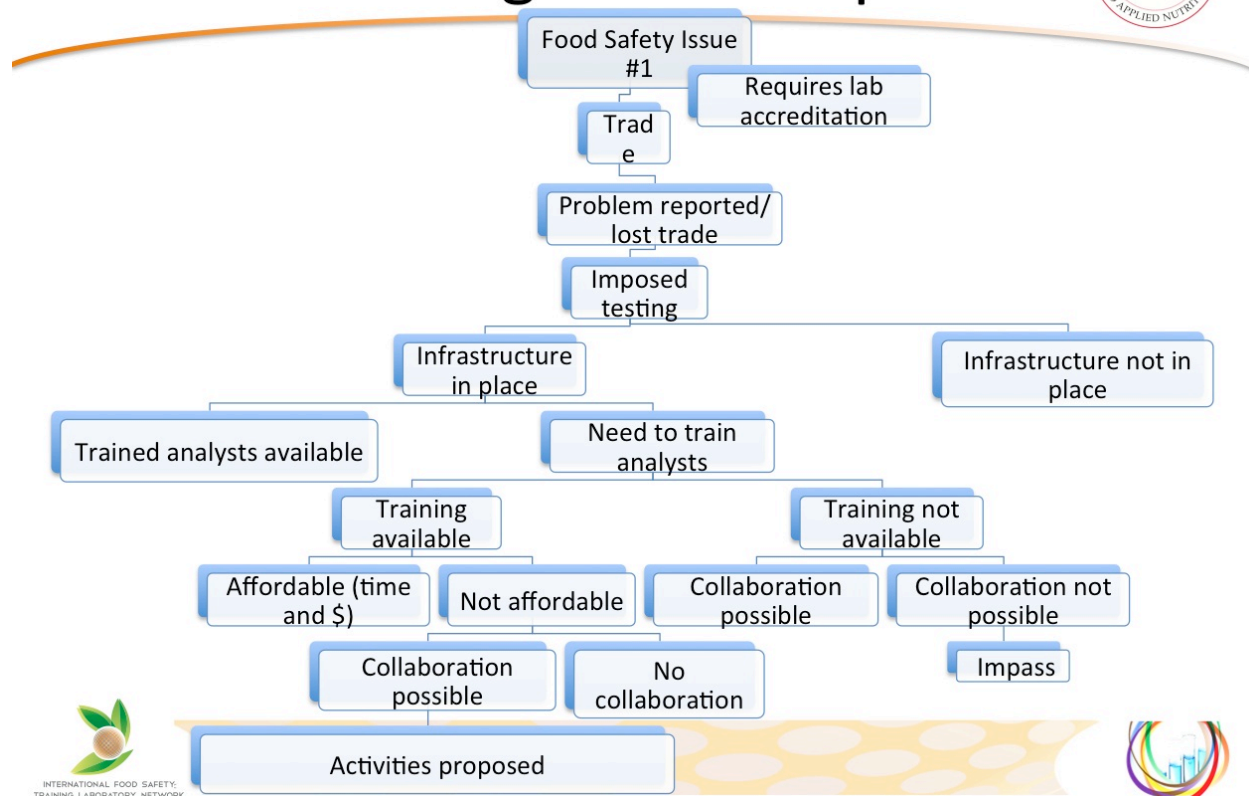


Figure 1: Decision tree for capacity building activities related to the implementation of new testing methods and the needs for personnel training.

These activities were a little more difficult than expected to start, but clear understand and benefits were observed on the second day of the Workshop during the planning sessions for capacity building in chemistry.

All the data collected during the round-table discussions will be used in the development of a Multi-Criteria Decision Analysis (MCDA) to be developed in the winter 2014 by JIFSAN.

3. Technical Assistance Addressing Information Imbalance

Many regulatory laboratories from developed countries publish reports of using new rapid methods in microbiology to address the need for faster answers on a growing number of samples. The techniques are typically available in direct sales channels in these countries and information is readily available at trade shows and through sales specialists visits to government laboratories. The situation is quite different in developing countries where the techniques may be available only through distributor-based sales channels, and these distributors have little or insufficient technical understanding to fulfill the needs of the regulatory laboratory analysts. Consequently, this information imbalance prevents laboratories in certain countries from investigating the applicability of new techniques in their environment. Information on rapid microbiological techniques for food safety was identified as a priority in the Chile pilot project and addresses through a series of five webinars presented in Spanish.

Seven private sector stakeholders agreed to perform hands-on demonstrations of laboratory instrumentation and tools used for rapid methods. The presenters were from 3M, Dupont, Life Technologies, BioMerieux, BioControl, Invisible Sentinel and Microbiologics. Participants were able to ask questions during the demonstrations, or individually towards the end of the event. Besides getting physical access to the instrumentation, this activity enabled the creating of many relationships between instrument manufacturers and laboratory analysts, which will be useful when participants have questions in the future.

This activity was a clear benefit and result of the creating on the PTIN, as stated in paragraph 5.3 of the FSCF Operating Principles: “The FSCF Partnership Training Institute Network (PTIN) established in 2008, will further support capacity building activities by enlisting leadership from the private sector and academia to bring additional expertise, resources, and commitment towards addressing the capacity building priorities and goals identified by members of the FSCF.”

A second area of information imbalance identified during the pilot work concerned the use of the words validation and verification as applied to laboratory methods in regulatory texts. Dr. DeAnn Benesh of 3M prepared a presentation on this topic and compared the definitions utilized by different official organizations in the field. The presentation is available in Appendix 9. It was originally presented during a webinar with the Chile pilot work group.

Finally, the third area of information imbalance that could be addressed during the project was a need for a better understanding of the latest technologies used for chemical analysis for food safety. One of the reasons this topic rose to the top of the priority list was a move by some organizations to use what was deemed overly expensive and cumbersome instrumentation to address questions that could largely be addressed with more standard, yet still advanced, technologies. Diana Luque of Waters Corporation discussed the technologies available and their fit for purpose. Her presentation is available in Appendix 10.

4. Planning of Investments to Address Priority Needs in Chemistry

The table entitled “Compiling Choice Set” in Janie Dubois’ presentation was used during the round-table discussion to guide the prioritization and the selection of proposed activities.

Two round-table discussions were held.

Table 1: Challenges identified by team 1, needs defined and activities proposed to address these needs.

Food Safety Challenge	Needs	Proposed Activities
Organic contaminants in seafood, from effluents, persistent	<ul style="list-style-type: none"> - Training in analytical chemistry - Infrastructure - Training on how to approach the problems - Communications about non-fit-for-purpose methods being applied 	<p>1- Webinar series on screening non-targeted components, to cover pesticides, persistent contaminants, allergens, mycotoxins, etc. A series by manufacturers of instruments (like done in micro in the Chile pilot) was proposed.</p> <p>2- Webinar or written document on “how to approach the problem of non-targeted ID”, to include discussions of what technologies are used, the level of expertise required, flags for what “looks right” or “looks wrong”. It was suggested that webinar should be presented by government expert, and should include the concept of “broadly targeted methods” to ensure the understanding that we are still targeting some chemical groups.</p>

Unavailability of reference/standard materials and reference methods, proficiency testing	-Local control matrix -Food safety control materials (incurred materials are not addressed by metrology institutes)	1- Mexico is already involved in a project for the productions of local control materials and has proposed to make them available to APEC economies. 2- Training on how to prepare food safety control materials (Mexico to see if they can do this following the first phase of their project).
Non-targeted identification	Same as first row.	Addressed in activities in first row.
Allergens determination	Same as first row.	Addressed in activities in first row.
Validated methods of nutritional value/label claims	Could not define specific needs	Nothing proposed
Disconnected authority within governments	Implement collaborative approaches among government organizations	1- Webinar by Chile to present how ACHIPIA reached their objective of coordinating food safety efforts across multiple government organizations (to be organized as part of China pilot and recorded for posting on APEC FSCF PTIN website)

Table 2: Challenges identified by team 2, needs defined and activities proposed to address these needs.

Food Safety Challenge	Needs	Proposed Activities
Lack of understanding of PAH testing	Training on PAH testing	1- Hands-on train-the-trainer workshop with experts on preparing samples and analyzing for PAH. (JIFSAN proposed to lead) 2- Trainees selected for ability to reproduce in their sub-region 3- Redelivery in sub-regions with a team of 3 instructors: 1- leader from the host country, 2- expert from activity 1, and 3- young analyst in the field to ensure continuity.
Inadequate infrastructure	Understand how to develop infrastructure efficiently	Find a way to share experience in infrastructure development. No specific activity could be defined
Unavailability of PT Material	Training on how to prepare PT samples	No activity was identified as a priority since this service exists from the private sector.
Lack of understanding of each other's system and other info available	Ahead of APEC meetings, someone should gather information about the food safety regulatory systems of all participants, include	1-Each economy to prepare a 5-10 minute web-delivered recording explaining their food safety regulatory system ahead of the APEC meeting (hosted on APEC FSCF PTIN website)

	international organizations such of OIE, WHO, SPS, IPPC, Codex (in particular risk assessments)	2- Develop a resource (web-based) on where to find various info from international organizations. It was proposed that this could be part of the GFSP information platform.
Uncertainty of measurement (in micro and chemistry)	<ul style="list-style-type: none"> - Training on the measurement of uncertainty and its interpretation - Better visibility of guidelines on sampling 	<p>1- Webinars on the measurement of uncertainty, separate for micro and chem including a review of guidelines offered by different organizations, data distributed ahead of the webinar and the webinar should show the steps of the calculation (using data distributed).</p> <p>2- Web-based training on designing a sampling plan (in China, contract labs design the sampling plan).</p>

5. Optional technical assistance in the measurement of mycotoxins

The IFSTL at JIFSAN offered a discounted rate for participants of the Workshop to attend a 9-day hands-on laboratory workshop on methods of determination of mycotoxins. The workshop agenda is available in Appendix 8.

The workshop covered topics of regulations regarding mycotoxin limits in food, the means used in the United States to address these regulations,

Vietnam and Papua New Guinea representatives participated in the hands-on training.

Metrics of impact

An evaluation survey has been sent out to all participants, but results will only be available at a later time.

Difficulties Encountered

The short timeframe for the performance of the activities was a challenge, but it was met through collaboration and a tight planning by the implementing organization, JIFSAN.

Financial constraints associated with the source of funding for these activities could have prevented the realization of some of the activities, but financial (3M and University of Maryland) and in-kind contributions from the private sector bridged the gap.

Summary of Workshop Activities

Sponsors: 3M, BioControl, BioMerieux, Dupont, Invisible Sentinel, Life Technologies, Microbiologics, Vicam, Waters Corporation, University of Maryland and USDA Emerging Markets Program



Presentations of status of the pilot projects by Chile and China:

Nuri Gras of ACHIPIA and David Ji of the Qindao Agricultural University discussed the activities that had taken place so far and the context of the prioritization discussion.



Round-table discussions on laboratory capacity building needs and prioritization processes:

Each table created a short list of priority needs and also discussed the factors considered in the determination of which needs and which activities get allocated resources



Technical assistance to bridge information imbalance:

Seven private sector partners joined forces with JIFSAN to offer 3 hours of demonstrations and exchange of information on rapid methods for microbiological analysis in food safety. The event was hosted in the International Food Safety Training Laboratory of JIFSAN.



Planning of investments to address priority needs in chemistry:

Participants agreed on priority needs in chemical analysis for food safety and used the prioritization process developed earlier in the Workshop to compile a short list of desired activities that would address the priorities.



Optional technical assistance in the measurement of mycotoxins:

Two economies (Vietnam and Papua New Guinea) took advantage of the offer to increase the impact of their travel to the Regional Workshop by also attending hands-on training on methods for the measurement of mycotoxins in food offered at the IFSTL of JIFSAN.