



**Asia-Pacific
Economic Cooperation**

APEC Laboratory Capacity Building Workshop

Purpose: Information
Submitted by: United States

**APEC Subcommittee on Standards and Conformance
Food Safety Cooperation Forum
Partnership Training Institute Network
Thailand Regional Laboratory Capacity Workshop
August 2011**

**APEC Subcommittee on Standards and Conformance (SCSC)
APEC Laboratory Capacity Building Workshop
Report to the SCSC**

BACKGROUND

In May 2010, under the APEC Food Safety Cooperation Forum (FSCF), through the Partnership Training Institute Network (PTIN), an Experts Working Group (EWG) meeting was held in Washington D.C. on food safety training needs in the APEC region. Eleven food safety capacity building priority areas were identified as areas for the FSCF PTIN to focus efforts toward improving public health and facilitating trade in the APEC region, one of which was building laboratory capacity. Subsequently, the United States self-funded a project entitled “APEC Laboratory Capacity Building – Working toward Ensuring Laboratory Proficiency.” This project was implemented in four phases:

- Phase 1: Development of Evaluative Tools – Working Group Meeting
- Phase 2: Data Collection and Administration of Needs Assessment Survey
- Phase 3: Survey Assessment Review and Workshop Agenda Development and Implementation
- Phase 4: Implementation of APEC Regional Laboratory Capacity Building Workshop “Improving APEC Laboratory Capacity: The Global Context of Food Safety”

OVERVIEW

The APEC FSCF PTIN Regional Laboratory Capacity Building Workshop was held August 25-26 in Bangkok, Thailand, and brought together individuals from 18 different APEC economies¹. Participants from multiple sectors representing academia, industry, international organizations, and government were in attendance. Chulalongkorn University and Thailand’s Ministry of Public Health partnered with the U.S. Department of Agriculture to execute the workshop. The two-day workshop featured speakers from industry, academia, APEC Specialist Regional Bodies (SRBs), international organizations, and government representatives from 15 APEC economies².

The workshop was presented in five parts: an introductory section, three training modules, and a section highlighting the laboratory capacity assessment results and ways to address the findings.

¹ Participants represented the following economies: Australia, Brunei Darussalam, Chile, China, Hong Kong, Indonesia, Japan, Malaysia, Mexico, Papua New Guinea, Peru, Philippines, Russia, Singapore, South Korea, Thailand, United States, and Vietnam.

² Australia, Brunei Darussalam, Chile, China, Chinese Taipei, Hong Kong, Malaysia, Mexico, Papua New Guinea, Philippines, Peru, Russia, Thailand, United States, Vietnam.

Introductory sessions included “The Global Context of Food Safety” and highlighted the importance of food safety laboratory capacity to trade and industry, public health implications, the SRB perspective, and the importance of economic support to the sustainability of laboratories. The second section included three training modules and focused on a number of technical areas from the list of food safety laboratory capacity building priority needs identified at the May 2010 FSCF PTIN expert working group including:

- Quality Assurance and Validation
- Sampling
- Laboratory Management
- Laboratory Accreditation
- Analytical Methods
- Data Analysis and Interpretation

At the end of Day 2, the Food Safety Laboratory Capacity Assessment preliminary results were presented by a contracted administering institution, Texas Tech University. The Food Safety Laboratory Capacity Assessment was administered to different types of testing laboratories including those testing for microbiological, chemical molecular analysis, and genetic analysis, alone or in combination. The assessment results were preliminary as the sample size of respondents was insufficient to draw statistically significant conclusions. As of August 14th 2011 there were 62 responses representing 15 APEC economies. Nine of the responding economies provided only one or two responses while one country submitted 17 responses. There were no responses received from the Republic of Korea, Russia, Indonesia, Philippines, Chinese Taipei, or Brunei Darussalam. Although further sampling will be necessary to determine a quantifiable baseline, there were some reoccurring themes presented. Over half of those surveyed expressed deficiencies in human resources, equipment maintenance and troubleshooting, sampling procedures, and access to certified reference materials. The majority of respondents reported no connection to a metrology network and more than half of the respondents indicated that their laboratories were not accredited for one or more types of the testing that they performed. Texas Tech University continued administration of the survey through September 30th 2011, and additional information from this extension is forthcoming.

The 2-day workshop concluded with a roundtable to discuss the assessment results and ways forward. Eight roundtable groups of 10-12 participants were asked to provide concrete recommendations to the PTIN on where the PTIN could add value in the future, prioritize those recommendations, and suggest appropriate performance measures to use. In addition, the groups were asked to offer suggestions for how the PTIN might better engage with Specialist Regional Bodies and academic partners, and how to enhance the PTIN website.

PROJECT OBJECTIVES

As noted at the May 2010 Experts Working Group, it is important that laboratory personnel and policymakers understand the critical role of laboratories in the food safety system, how the activities carried out by laboratories fit into the overall picture of risk management, regulatory frameworks, public health, and global food trade. Raising awareness of the importance of strong laboratory systems for improving both local and global food safety, and the importance of data sharing between laboratories, is essential to building widespread support for food safety testing laboratories in the APEC region. This workshop was designed to provide training, facilitate information sharing, and provide a forum to:

- Assess the current level of need in the eleven priority areas noted in the May 2010 EWG
- Prioritize capacity building areas based on needs assessment and feedback
- Determine optimal training methods and approaches to which the PTIN can add value
- Determine ways in which the PTIN can work effectively with the SRBs in addressing accreditation, proficiency testing, and certified reference materials
- Suggest ways that the PTIN can more fully utilize academic partnerships
- Suggest ways in which the PTIN website can better function as a central point for training, information sharing, and forming laboratory networks

SUMMARY OF THE PRESENTATIONS

Day 1:

Global Context of Food Safety: Dr. Hans-Joachim Huebschmann, Thermo Fisher, discussed the critical elements for enhanced laboratory capacity including appropriately trained personnel, access to fit-for-purpose methods, suitable analytical technology, laboratory management tools, and quality assurance procedures. Highlighted was the role of international authorities and government entities in maintaining trustworthy trade-enhancing food safety systems, and the intricacies involved in establishing and maintaining food safety laboratory capacity for multiple laboratory types in accordance with multiple national regulations and Codex guidelines.

Importance of Laboratory Capacity to Trade/Industry: Shannon Cole, Grocery Manufacturers Association (GMA), discussed the economic costs to trade (e.g. repeat testing, demurrage, spoilage, loss of confidence) if proper laboratory procedures are not followed. Highlighted was the importance of improving transparency in sampling and testing protocols and the advantages of developing more similar testing methodologies within the APEC region.

Importance of Laboratory Capacity, the Public Health Implications: Dr. Lalith Goonatilake, United Nations Industrial Development Organization (UNIDO), stressed the importance of metrology and accreditation and illustrated how growth in service demand can

offset associated costs. Dr. Goonatilake highlighted the costliness of “food scares” to the agricultural sector, and shared several resource links, including the Lab Network web portal.

Importance of Laboratory Capacity, the Specialist Regional Bodies’ (SRB) Perspective: Dr. SK Wong, from the Government Laboratory Hong Kong and Asia Pacific Metrology Programme (APMP), gave a presentation on providing economies with information on where and how they can improve their laboratory capacity. Dr. Wong discussed the need for ISO/IEC 17025:2005 standard accreditation and highlighted how this standard has both management and technical requirements. Dr. Wong pointed out that through customer focus the management requirements will drive the technical requirements when using ‘fit for purpose’ methodology.

Economic Support and Sustainability of Labs: Dr. Laurie Besley, National Measurement Institute (NMI), Australia stressed the need to support labs during critical stages of development in order to ensure their sustainability. He highlighted the need for a long-term strategy for labs and emphasized the need for follow-up training. Dr. Besley further stressed the importance of knowing customers and their requirements in order to ensure customer-driven income and acquisition of appropriate equipment as key elements for continuing operational sustainability.

APEC Laboratory Capacity Assessment Results: Dr. Alejandro Echeverry, Texas Tech University, provided a broad overview of the food safety laboratory capacity assessment findings.

Training Module I: Management System: Darryl Sullivan, Covance, AOAC International, and Thamolwan Laovittayanurak, 3M Thailand, discussed the critical role of quality assurance in ensuring that laboratories accurately detect and quantify food safety risks. They underscored importance of validating methods according to internationally accepted standards such as ISO/IEC 17025:2005 for ensuring food safety and facilitating confidence in food trade. Of particular emphasis was the importance of method validation, measurement uncertainty, internal quality control, traceability, and accreditation.

Importance of Reference Materials and Where to Get Them: W.W. Wong, Hong Kong Accreditation Service (HKAS) discussed the importance of using internationally competent, regional/certified food reference materials and appropriate sources for obtaining secondary reference materials.

Quality Assurance: Case Study—Thailand: Boonmee Kanjanopas Betagro Group, Thailand, discussed the lessons learned from validating temperature controlled equipment including incubators, water baths, ovens and refrigerators in microbiological testing labs.

Risk Surveillance Case Study--Thailand Mode: Dr. Panadda Silva, Ministry of Public Health, Thailand, discussed how Thailand is using test kits as a front line scanning tool for food safety risk surveillance in the community by local authorities.

Day 2:

Training Module II: Fit-for-Purpose Analytical Methods: Dr. Panadda Silva, Ministry of Public Health, Thailand, provided an overview on how fit-for-purpose analytical methods can be an effective food Safety control mechanism and how to avoid methodology-driven administrative impediments to trade.

A Comprehensive Approach to Fit-for-Purpose Analytical Methods: Dan Schmitz, Abbott Nutrition discussed the AOAC Stakeholder Panel process followed by a description of the key process elements: 1) Development of Standard Method Performance Requirements (SMPRs), 2) Down-selection of methods, 3) Method validation, and 4) Performance verification (i.e. leveraging a collaborative study). A case study on the AOAC SPIFAN (Stakeholder Panel on Infant Formula and Adult Nutritionals) initiative was provided.

Fit-for-Purpose Analytical Methods: Case Study: Dr. Henry Chin, Senior Director for Food Safety at The Coca Cola Company, examined current issues in determining appropriate analytical methods to educate government laboratory managers on the link between fit-for-purpose methods and effective food safety management. Dr. Chin presented a case study on DEHP (plasticizer) contamination.

Training Module III: Sampling, Data Analysis and Data Interpretation: Maria Estela Ayala, Peruvian Institute of Fish Technology (ITP) tied the prior fit-for-purpose section to the food safety/public health topic introduced in Module III. She stressed the use of a process approach as an integral part of the implementation of a laboratory management system.

Importance of Structured Sampling Plans and Accurate Product Sampling: Dr. Emilio Esteban of the USDA Food Safety Inspection Service gave an overview of good sampling techniques and practices and important statistical aspects of sampling (i.e. determining how many samples to take and from where), as a precursor to meaningful data analysis. Dr. Esteban highlighted the distinction between statistical sampling and physical sampling and stressed the need for proper techniques regarding both, providing examples. Dr. Esteban stressed Codex recommended methods for validation of qualitative and quantitative food safety sampling and sampling plans.

Importance of International Standards and MRLs and MLs for Accurate Data Analysis: Pisan Pongsapitch, National Bureau of Agricultural Commodity and Food Standards (ACSF) Thailand, discussed how international standards in safety control limits (MRLs, MLs) are essential for facilitating safe food trade. Mr. Pongsapitch discussed several articles within the the WTO Agreement on Sanitary and Phytosanitary Measures (SPS) and the role of the SPS Agreement in resolving trade disputes. The talk also focused on risk assessment and the development of Codex and national food safety standards.

Data for Public Health Decision Making: Maria Estela Ayala, Peruvian Institute of Fish Technology (ITP) discussed data interpretation and how data is used to make real life decisions in determining public health and safety issues and avoiding false alarms. Ms. Ayala highlighted the importance of understanding decision criteria and how to deal with uncertainty including the

concept of Limit of Detection (LOD) vs. Limit of Quantification (LOQ) for data analysis and method validation. She also stressed the critical role of uncertainty in risk assessment.

Sampling, Data Analysis and Scientific Evaluation: Case Study: The 2008 Pepper Outbreak in the U.S: Dr. Sufian Al Khaldi, United States Food and Drug Administration shared lessons learned from the U.S. food outbreak of Salmonella saintpaul isolated from peppers. Dr. Al Khaldi discussed the sample collection procedures used in the field and sample analysis in the lab, as well as the development of standard operating procedures.

Food Safety Laboratory Capacity Assessment Results: Dr. Alejandro Echeverry, Texas Tech University provided details on each of the nine areas the assessment probed. This presentation preceded roundtables on what was learned and where the FSCF/PTIN could add value in the future.

Roundtable on FSCF/PTIN Way Forward in Lab Capacity Building: Dr. Laurie Besley, National Measurement Institute (NMI) Australia moderated the roundtable session. Participants formed groups of 8 individuals each. Based on the discussion of assessment results participants provided concrete recommendations to the PTIN on which priority areas to focus on to add value, and what order would prove most beneficial. Participants also provided feedback on ways that the FSCF PTIN could add value to laboratory capacity building efforts in the future. Recommendations are highlighted in the following section.

OUTCOMES

The workshop focused on the technical elements of food safety laboratory capacity that are the foundation for establishing consistent and transparent food safety systems in the APEC region, and how approaching food safety testing standards from a global perspective fosters confidence in trade. These topics generated significant discussion among participants about developing closer alignment of, and transparency of, testing methods and standards between APEC economies. Also discussed was the role of international metrology and accreditation bodies, access to certified reference materials, and the importance of proper sampling, collection, and handling techniques, to ensure sample integrity and increase confidence in test results.

Participants were advised of the importance of the ISO/IEC 17025:2005 standard for microbiological and chemical compliance, the use of certified reference materials, fit-for-purpose analytical methods, and proper sampling. Each training module emphasized the use of international standards to improve the flow of food trade among the APEC economies. Participants laid out a vision for future laboratory connectivity, data sharing, and networking across emerging market economies that is expected to ultimately result in improved standardization of testing protocols and techniques across the APEC region resulting in fewer incidents of erroneous determinations of safety violations and safety-related trade delays and disputes. Additional trade-enhancing outcomes from the Bangkok regional workshop will likely continue to unfold as the APEC Food Safety Cooperation Forum PTIN begins to explore the

feasibility of creating an interactive food safety forum accessible through the current PTIN website. The idea of an interactive web-based forum came out of the workshop's roundtable discussions, and conceivably has the potential to crystallize a network of laboratory technicians, managers, and international food safety experts, further solidifying the use of international standards in common practice. Consistent employment of international standards and practices will improve the fidelity of food safety testing and increase transparency among APEC trading partners.

During the roundtable, participants identified quality assurance/validation/proficiency testing as their top training priorities. Other top priorities were sampling and analytical methods, laboratory accreditation, and laboratory management systems. The majority of the workshop participants suggested some form of proficiency testing (PT), including round-robin proficiency testing, as a performance measure for quality assurance. Several training-based performance measures were suggested for improving sampling such as the development and administration of written examinations following training on topics such as developing sampling techniques and performing sampling-based statistics, to test knowledge acquired. Also suggested was training followed by auditing to capture accreditation metrics, and documenting data analysis techniques by linking them to actions taken.

Concerning future training opportunities, participants indicated that they would like to attend a hands-on workshop focused on proficiency testing, certified reference materials, and ways to improve accessibility to both, particularly for meat, honey, shrimp, fruit, vegetables, and fish. Participants also suggested organizing a mentoring program as a follow-up to training that focuses on linking laboratories and public private partnerships in the same economy to minimize language barriers.

Participants expressed a desire for ongoing collaborative efforts between the PTIN and SRBs to result in greater engagement between SRBs and laboratories with previously weak or absent connections to these bodies. A majority of the roundtable groups (6/8) expressed a desire to address proficiency testing and certified reference material availability and accessibility issues using the SRB/PTIN connection to leverage resources.

Several roundtable discussion groups recommended utilizing PTIN academic partners to provide hands-on training within a physical laboratory setting. This was highlighted as particularly useful for sample preparation training. Participants also expressed a desire for strong university connections that would allow them ready access to individuals with scientific backgrounds and expertise specific to the more technical aspects of this and future workshops. This includes the opportunity to work with experts in methods development, application of new technologies, and policy recommendations for food safety regulations. It was recommended that a list of willing academic experts from each country be made publicly available on the PTIN website.

Participants also suggested the implementation of academic/public laboratory internship programs.

Participants provided a number of creative suggestions for potential new uses for the PTIN website. Participants requested the addition of links to other websites that share relevant information and resources, including best practices and success stories, “standard protocols for reference methods,” databases on MLs and MRLs; links that provide access to contact lists within the PTIN network; a list of institutions responsible for food safety by economy; training modules including a repository for others to share their own modules such as laboratory safety training. Additionally, participants indicated that they would like to see future workshops recorded and made widely available through a familiar vehicle such as “You Tube.” Finally, participants indicated that they would like to see a link to a closed interactive group site and to participate in a discussion or blog format that would support information sharing (e.g. lessons learned during accreditation or proficiency testing, accessing specific regulations, in-group questions and answers), provide assistance with translations, and increase networking between regional laboratories.

NEXT STEPS

As outlined in the Outcomes section above, this regional laboratory capacity building workshop generated a great deal of discussion and recommendations for moving forward in the APEC region. In the area of future training five priority areas were identified in the roundtable session, with greater emphasis on the top three priorities: 1) quality assurance/validation/proficiency testing; 2) sampling; and 3) analytical methods. One way that this can be accomplished is by APEC economies continuing to move forward on the development and production of priority area specific training; it is advised that the training be formatted in a manner that will allow it to be reproducible and customized to future audiences, and made freely available on the FSCF PTIN website. Some elements of these topics may best be addressed by hands-on training by bringing trainers to in-country laboratories or sending students to regional laboratory training facilities. To begin follow-on activities the United States has initiated a self-funded project for 2012 to provide training focused on one of the top priority training needs identified by both the laboratory capacity assessment survey and this APEC Laboratory Capacity Building Workshop and roundtable. The United States is also proposing a self-funded project focusing on methods of pesticide residue testing. This project would be carried out in collaboration with the Joint Institute for Food Safety and Applied Nutrition’s International Food Safety Training Laboratory (IFSTL) a partnership between the United States Food and Drug Administration and the University of Maryland in the United States.

In addition, it was recommended that relevant presentations from this training workshop be posted on the FSCF PTIN website (<http://fscf-ptin.apec.org/events/workshop-on-laboratory-capacity-building/>) for future reference and to further facilitate the production of virtual workshop

sessions through the synching of visual presentations with captured audio for select presentations.

Building on the performance measures discussed in the Outcomes section above, the FSCF PTIN should continue working to develop and refine more sophisticated methods for assessing performance measures. This is a complex task, as is widely recognized by other entities.

The PTIN website offers an excellent platform to address many of the suggestions offered by participants. Exploring the possibility of developing interactivity on the PTIN website, as explained in the roundtable outcomes, can be accomplished through the creation of an interactive forum made accessible through a registration system³. A forum of this type would allow individuals to access documents or announcements prior to an APEC event, fostering group engagement and interaction early in the process. The FSCF PTIN is currently exploring the plausibility and potential structure of such a forum, usage rules, methods for identifying and establishing a rotation of qualified primary topic monitors, and funding for its administration. In addition, several recommendations were made to increase the use of links on the FSCF PTIN website to provide easy access to useful or critical information. The participants felt that this would increase FSCF PTIN website traffic which could be leveraged as a positive feedback loop to increase the value-added potential of all website postings.

³ The PTIN website is currently maintained by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) which is a partnership between the University of Maryland in the United States, and the U.S. Food and Drug Administration (FDA). A forum could be established on this site that accommodates all of the major topics within the FSCF PTIN.