

APEC Sub-Committee on Standards and Conformance
Food Safety Cooperation Forum
Partnership Training Institute Network
Examination of Hot Issues in Risk Analysis
1-2 August 2009

Report to the Sub-Committee on Standards and Conformance

Introduction:

In 2007 the APEC Leaders' 2007 called on the Sub-Committee on Standards and Conformance (SCSC) to take credible steps to address challenges associated with food safety in the APEC region. In response to the Leader's request, the SCSC established the APEC Food Safety Cooperation Forum (FSCF) to improve food safety and facilitate trade in safe foods. The FSCF works to achieve these goals by improving and strengthening information sharing and capacity building activities, as well as enhancing cooperation between member economies and through regional activities.

Robust trade in safe foods is essential to the health and prosperity of the Asia-Pacific region. Recent incidents involving food safety, however, highlight the challenges we collectively face in building regulator and manufacturer technical competence and understanding of food safety management in APEC economies. In establishing the FSCF, APEC acknowledged the importance of food safety and the value of internationally developed and recognized food standards as key factors for improving public health and safety and facilitating trade in food among the APEC economies. As additional training is necessary to accelerate progress towards these outcomes, the FSCF has identified, prioritized and coordinated capacity building activities through its Implementation Plan for 2008-2011. In doing so, the FSCF designed an initiative to leverage and consolidate food safety expertise from around the region – the FSCF Partnership Training Institute Network (PTIN).

On behalf of the APEC Community and the FSCF, the United States invited representatives of industry, academia and APEC economy regulatory agencies to attend the *Examination of Hot Issues in Risk Analysis* workshop, 1-2 August in Singapore. The *Hot Issues Workshop* followed the one-day APEC Food Safety Cooperation Forum meeting and brought together leading food safety regulators, representatives from international and research organizations and key private sector food safety officials from the 21 APEC economies to discuss food safety challenges as well as the opportunities to collaborate to meet those challenges.

The workshop was opened by Mr Augusto Mello, the Co-Chair of the SCSC, who welcomed the more than 100 attendees to the inaugural event under the PTIN and stressed the importance of their work for entire APEC region. He was followed by Mr Dan Berman, US Department of Agriculture (United States), who encouraged active participation in the inaugural event presented by the Partnership Training Institute Network. Informative presentations – twenty-two in all – were made by representatives of industry, academia and government. Australia (Dr Steve McCutcheon, Food

Standards Australia New Zealand) and China (Dr Lin Wei, Deputy Director General, Import and Export Food Safety Bureau, General Administration of Quality Supervision, Inspection and Quarantine, People's Republic of China), co-chairs of the FSCF, moderated workshop sessions on Day 1 and Day 2, respectively.

Agenda

1. Overview of Risk Analysis

Dr Juliana M Ruzante, Risk Analysis Program Manager, JIFSAN

This presentation introduced the basic concepts and terms of risk analysis in the area of food safety. Risk analysis encompasses risk assessment, risk management and risk communication. The presentation used the proposed framework and language used by the *Codex Alimentarius*. In addition, the presentation discussed the use of risk analysis as a science-based tool to strengthen national food safety systems, improve public policy and support international trade under the Agreement on Sanitary and Phytosanitary measures of the World Trade Organization.

2. Scientific Food Safety Risk Management

Dr. Stephen Sundlof, Director, Center for Food Safety & Applied Nutrition, US Food and Drug Administration (FDA)

Dr Sundlof gave a brief overview FDA's history and role in ensuring the safety of foods consumed in the United States. He noted some of the challenges FDA faces, including increasing and changing consumer demands, the growth in global food trade, emergence of new foodborne pathogens and the need to address vulnerable populations with respect to food safety risks. Dr Sundlof outlined FDA's risk management approach, which places a heavy emphasis on risk assessment and also stresses transparency in decision making. He then discussed some new tools that FDA is employing, including Geographic Information Systems to provide visual information for risk analysis and i-Risk, a web-based tool for assessing risks to specific commodities. He closed by stating that greater international collaboration is essential, given the global nature of trade in foods, to setting and achieving appropriate food safety objectives.

3. Best Practices of Risk Assessment as the Scientific Basis for Food Safety Risk Management Decision Making

Dr David Goldman, Associate Administrator, Office of Public Health Science, Food Safety & Inspection Service (FSIS), US Department of Agriculture

Dr Goldman discussed how FSIS uses risk analysis for allocating resources and policy making, including setting performance standards and stressed the role risk assessment in establishing food safety policies, allocating inspection resources and evaluating FSIS food safety programs. He cited FSIS' risk assessments for *Listeria monocytogenes*, including a joint risk assessment with FDA on cross contamination and discussed the most effective methods for reducing the incidence of this foodborne pathogen. Dr Goldman then elaborated on future plans for FSIS to use a cumulative risk assessment process for chemicals in meat and poultry.

4. Risk Analysis in the International Setting

Dr Angelika Tritscher, Joint Secretary to the Joint Expert Committee on Food Additives and the Joint Meeting on Pesticide Residues

Department of Food Safety and Zoonoses, World Health Organization (WHO)

In her presentation, Dr Tritscher discussed how risk assessment, as a scientific basis for international food standards setting, is performed by independent scientific expert bodies established jointly by WHO and the Food and Agriculture Organization (FAO). The FAO/WHO Joint Expert Committee on Food Additives (JECFA) held its first meeting in 1956, with regular meetings since. JECFA performs safety evaluations/risk assessments for food additives, including processing aids and flavors, contaminants and natural toxins in food, and veterinary drug residues. The safety of pesticide residues is evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), which has met annually since 1963.

Dr Tritscher then explained that this international independent risk assessment work feeds directly into the Codex standard setting process, but the scientific advice is also taken up directly into the national standard setting processes in many countries. At the international level food standards are developed by the Codex Alimentarius Commission and its subsidiary bodies, with the aim of protecting consumers' health and ensuring fair practices in food trade. Codex standards are the benchmark within the WTO/SPS Agreement, and as such form an integral legal component of international food trade.

5. The Role of the Specialist Regional Bodies in the FSCF PTIN

Dr Laurence M Besley, Chief Executive and Chief Metrologist, National Measurement Institute, Department of Innovation, Industry, Science and Research

Dr Besley, of the Australian National Measurement Institute, gave a presentation outlining the importance and functions of numerous APEC Specialist Regional Bodies (SRBs). He explained the activities of these SRBs and what they hope to accomplish. He concluded his presentation with a call to PTIN to include and incorporate the SRBs in its development of objectives and future activities – the SRBs are eager to assist the PTIN in addressing food safety challenges.

6. Management of recent emerged chemical incidents in Australia

Dr Paul Brent, Chief Scientist, Food Standards Australia New Zealand

Dr Brent began with a brief overview of the structure and role of Food Safety Australia New Zealand (FSANZ) in ensuring food safety, including a description of its Food Incident response Protocol. Using a recent food incident involving cassava, Dr Brent described the response actions FSANZ took, including the use of safety assessment and dietary risk modeling. Dr Brent joined other presenters in stressing the value of international collaboration – FSANZ relies on international organizations and food safety experts from around the world in developing solutions to food safety incidents.

7. *Vibrio* in Tiger Shrimp and White Shrimp

Dr Nanthiya Unprasert, Director of Fish Inspection and Quality Control Division, Department of Fisheries, Thailand and Mrs Kanokphan Srimanobhas, Head of Microbiology Section, Fish Inspection and Quality Control Division, Department of Fisheries, Thailand

Dr Unprasert and Mrs Srimanobhas detailed the Thai approach to reducing the incidence of *Vibrio* in Seafood through a case study in white shrimp and tiger shrimp. They provided details on the structure and function of the Thai regulatory framework to ensure Thai seafood processors meet food safety requirements, as well as the measures in place to address violations of these requirements. The Department's approach includes a comprehensive set of monitoring, surveillance, control and traceability programs. Applied to Thailand's shrimp production, Dr Unprasert and Mrs Srimanobhas demonstrated the value of this approach in reducing microbiological contamination.

8. The Future for Global Pesticide Reviews and the Vision for Toxicity Testing in 21st Century

Dr Mary Manibusan, Chief, Toxicology and Epidemiology Branch, Health Effects Division US Environmental Protection Agency

Dr Manibusan described the EPA's Office of Pesticide Programs (OPP) mission of protecting human health and the environment, as well as ensuring access to safe pesticides and their accompanying benefits. The mission of OPP pertains to populations in the United States and those across the globe. To that end, OPP is actively engaged in global joint pesticide reviews geared to developing globally harmonized pesticide maximum residue levels (MRLs).

Dr Manibusan shared information on global harmonization efforts with respect to health endpoints selected and MRL expression, noting that additional challenges remain. To date, global joint pesticide reviews are becoming a standard way of doing business, as the number of participating countries increases.

9. Workshop Day 1 Summary

Dr Isabel Walls, Senior Technical Advisor, Office of Scientific and Technical Affairs, Foreign Agricultural Service, US Department of Agriculture

Dr Walls opened Day 2 by providing a comprehensive recap of the Day 1 presentations and observations. Besides detailing the highlights of the presentations, she noted the key themes underlying all of them – the value of good scientific information for decision making, the importance of communicating with stakeholders and educating consumers, and the ultimate goal of harmonizing food safety standards to protect public health and simplify trade.

APEC Member Economy Recent or Ongoing Food Safety Risk Assessment Activities

10. Recent or on-going food safety risk assessment activities

Canada – Dr Samuel Godefroy, Director General, Food Directorate - Health Canada

Dr Godefroy provided the workshop delegates with an overview of the Health Canada's approach to prioritization of food risk analysis issues. He described the agency's efforts to synthesize information from all Canadian stakeholders in order to develop action plans for food safety and chemicals management. He also highlighted lessons learned from recent food safety incidents and noted the need for international collaboration to address food safety challenges, given the global nature of trade in foods.

11. Chinese Taipei – Dr Kuen-Yuh Wu, Associate Professor, Institute of Occupational Medicine and Industrial Hygiene, College of Public Health, National Taiwan University, Chinese Taipei

Dr Wu examined the value of human data in conducting risk assessment, using melamine as an example. He noted the WHO's conclusion that epidemiological data were insufficient to establish a dose-response relationship. Dr Wu proposed that certain statistical simulations can be used to fit epidemiological data for dose-response assessment with limited and uncertain exposure information, which could in turn reduce uncertainty regarding melamine exposure among vulnerable populations, including children and infants.

12. Chile – Mr Rodrigo Sotomayor, Chilean Agency for Food Safety

Mr Sotomayor provided an overview of the challenges Chile has identified with respect to improving food safety, noting the prominent role that food exports play for the Chile. He outlined the process for developing Chile's Agency for Food Safety, the result of an effort to develop a national food safety policy, as well as the Agency's priorities: to improve the regulatory framework for food safety; to improve systems for monitoring and surveillance; to Promote the strengthening of scientific and technological capabilities; and to develop an institutional framework to facilitate and promote the coordination of public entities, including consumers and food producers.

13. Japan – Dr Fumiko Kasuga, Section Chief National Institute of Health Sciences, Ministry of Health, Labor and Welfare, Japan

Dr Kasuga provided an overview of the Japanese approach to risk management, risk assessment and risk communication, citing the roles of different government entities in the effort to address food safety challenges. She described how Japan's Food Safety Commission efforts to improve risk assessment, emergency response and risk communication related to food safety. She concluded by noting the need for greater information sharing among stakeholders, including the sharing of data and greater cooperation at the international level.

14. Mexico – Mr. Ruben Gonzalez Freaner, Director for Negotiations of Sanitary and Phytosanitary Measures - Ministry of Economy; and MVZ Octavio Carranza de Mendoza, Director General of Food Safety, Aquaculture and Fisheries - National Service of Agroalimentary Health, Safety and Quality

Mr Freaner and Dr Carranza gave the PTIN workshop delegates an overview of the food safety system in Mexico, including the challenges it faces in the national and global food market. They noted key components of the Mexican effort to improve food safety including a national certification system to minimize risk in food production and an effort to use information technology systems to share this risk reduction strategy and encourage its implementation.

15. Peoples Republic of China – Dr Xiumei Liu, Vice President, Chinese Institute of Food Science and Technology; Chair, Health Laboratory Technology Section,

Chinese Preventive Medicine Association; and Chair, Committee on Microbial Toxins, Chinese Society of Microbiology

Dr Liu described China's participation in international food safety efforts, as well as its domestic foodborne disease and food contaminants surveillance network. She cited China's efforts to collect data and develop risk mitigation strategies for several pathogens, including *Salmonella* (poultry), *Campylobacter* (poultry) and *V parahaemolyticus* (raw oysters). She also highlighted China's new Food Safety Law, with its focus on science, risk management and stakeholder accountability.

16. Philippines – Mr. Gilberto F. Layese, Director - Bureau of Agriculture and Fisheries Product Standards, Department of Agriculture; and Ms. Karen Kristine A. Roscom, Chief Science Research Specialist - Bureau of Agriculture and Fisheries Product Standards, Department of Agriculture

Mr Layese provided information on the Philippines' training program to manage microbiological food safety risks. This program was sponsored by Food Standards Australia New Zealand and also included China, Indonesia, Papua New Guinea and Vietnam. Philippine participation in the program included an evaluation of *Salmonella* in pork, *Bacillus cereus* in cooked rice and *V parahaemolyticus* in fresh/frozen uncooked shrimp. Mr Layese also noted ongoing work in ASEAN and the need in the Philippines to improve data gathering as well as risk assessment capabilities.

17. Food Safety Risk Analysis Programs at JIFSAN

Dr Jianhong Meng, Director, and Dr Juliana M Ruzante, Risk analysis Program Manager, Joint Institute for Food Safety and Applied Nutrition

Dr Meng and Dr Ruzante gave a presentation explaining their work at the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). They described the research, education and outreach programs JIFSAN offers, including extensive foreign and domestic training programs geared for food production facilities, designed to develop and improve food safety risk analysis. They also provided overviews of JIFSAN's online food safety information management resources. JIFSAN indicated its interest in working APEC economies to advance its food safety efforts.

Private Sector Perspective on Food Safety – Panel Discussion

Moderated by Dr Robert Brackett, Senior Vice President and Chief Science and Regulatory Affairs Officer, Grocery Manufacturers Association

18. Dan Schmitz, Group Manager, Global Research Services, R & D Operations, Abbott Nutrition

Mr. Schmitz of Abbott Nutrition, explained in his presentation Abbott Nutrition's approach to food safety for its infant formulas (IF) and medical foods (MF), which are often the sole source of nutrition for the vulnerable populations they serve. Ensuring they meet their compositional requirements is a fundamental safety issue. IF and MF are among the most stringently regulated categories of foods. The *Codex Alimentarius* standard for infant formula stipulates at least 57 separate nutrient requirements.

This category of foods is also one of the most challenging for which to verify compliance because of the complexity of the matrices and because many of the micronutrients occupy ranges in the low ppm to ppb. Increasingly, disputes are arising in international trade that hinge on the methodology applied in verifying nutrient levels against national standards. Codex has assembled a list of “referee” methods specifically for infant formula, but member governments acknowledge that they are not sufficiently robust to resolve most disputes.

19. James S. How, PhD, Asia Regional Director, Corporate Food Safety & Regulatory Affairs, Cargill, Inc.

Mr How’s presentation outlined the idea that suppliers are vital links in the food supply chain from farm to table. He explained that the food company’s role in the food supply chain is finding and working with the right suppliers and understanding how the customers are using the products. Cargill uses a systematic and risk based approach to select, train and develop its suppliers. Cargill’s food safety approach is based on *Codex Alimentarius* guidelines, Good Hygienic Principles (GHP) and Hazards Analysis Critical Control Points (HACCP). Its supplier qualification program covers a comprehensive assessment and audit of food safety management systems, raw materials, production process, equipments, packaging and critical service providers. Identification of the supply chain for each product type enables a risk assessment for each of the components or inputs.

20. Ana Hooper, Vice President, Total Quality, Darden Restaurants, Inc

Ms Hooper gave an overview of how Darden Restaurants, the world’s largest full service restaurant company, utilizes a risk based, Total Quality, HACCP-based approach to ensure the safety of more than 3,000 products sourced from 1500 suppliers in 35 countries around the world. Total Quality practices are fully integrated at every level of the Darden Supply Chain, beginning as early in the process as possible, from the hatcheries and growing areas, to the ponds/packing sheds, processing facilities and distribution channels.

21. Dr Sarah Geisert, Senior Director, Product Safety & Regulatory Affairs, General Mills, Inc

Dr Geisert explored the value of practical risk analysis to improving food safety programs. Practical risk analysis for a food processor means it is achievable, with standards that are certain and finite (not based on zero risk). Practical risk analysis also means focusing on prevention rather than detection of risks. Finally, it means it is useful...partnering with regulatory and academic communities to provide risk analysis guidance that is actionable at the production level. This perspective from a global food processor allows the consideration of not only food safety, but also regulatory and financial risks.

Dr Brackett noted the theme throughout the private sector presentations that food safety is everyone’s responsibility – from government regulators to academia to industry – and that food safety is good business. Each private sector presenter’s company places the highest priority on maintaining the highest food safety standards,

which means working with suppliers from around the world to ensure delivery of high quality ingredients.

22. Ms Boon Yee Yeong, Executive Director, Southeast Asia Region, International Life Sciences Institute

Ms Yeong provided an overview of the capacity building and information sharing activities of the International Life Sciences Institute (ILSI) has conducted many activities throughout Southeast Asia designed to improve familiarity with and adherence to international food safety standards and guidelines. She indicated ILSI's willingness to work with the FSCF and the PTIN to achieve its food safety objectives.

Dr Paul Brent closed the first PTIN workshop by summarizing the themes covered during the two-day event. He noted the value of having all those responsible for food safety present in one venue – food safety regulators from throughout the APEC region; officials from international standard setting bodies and academic institute; and representatives from private sector food producers. He stressed that this workshop was a beginning, not an end to the work that must be done by all present to improve trade in safe foods throughout APEC.

Dr Brent then solicited questions and comments from the workshop participants. Dr Stephen Sundlof/United States noted the value of this workshop for the United States, given the US President's and Congress' calls for improved food safety. Dr Brent/Australia and Dr Godefroy/Canada stressed the immediate need going forward to focus on outcomes, not activities. This was reiterated by the suggestion for development of a strategic plan. At the same time, some member economies, including China and the Philippines, called for the PTIN to provide specific capacity building and training, such as training on risk-based inspection for aquaculture (with industry providing such training). This call for industry-provided training was echoed by other developing economies, who noted the unique position of the private sector to identify food safety issues that impact trade. It was clear from this discussion that the PTIN Steering Group will have to balance an interest in specific, targeted capacity building and training activities with a competing interest for development of a more strategic approach to improving food safety in the region.

Several areas for cooperation and further work emerged from the workshop's concluding session. One proposed topic raised during this concluding session was that of zero tolerance and its impact on trade in safe foods. As technology enables increasing levels of detection, attention must be paid to balancing these technological capabilities with actual food safety needs. Another was the dire need, expressed by Dr Angelika Tritscher/WHO and affirmed by others, that there must be a mechanism for sharing food safety information that is presented at workshops and activities. This effort will reduce redundancy and enable the wider application of principles and lessons learned at gatherings such as this workshop. Finally, the concept of risk communication was identified throughout the workshop and during this concluding session as a critical factor in addressing food safety challenges – more stakeholders, including consumers, should

have a clearer understanding of the roles everyone can and must play in order to improve food safety.