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**BUREAU OF AGRICULTURE AND FISHERIES
PRODUCT STANDARDS (BAFPS)**

APEC Scientific Seminar-Workshop on Food Safety Risk-Benefit Analysis

**Manila, Philippines
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**Committee on Trade and Investment (CTI)/Sub-Committee on Standards and Conformance (SCSC)
APEC Food Safety Cooperation Forum (FSCF)
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ABBREVIATIONS

ACFS	National Bureau of Agricultural Commodity and Food Standards (ACFS)
ADI	Acceptable Daily Intake
ALOP	Appropriate Level of Protection
ARfD	Acute Reference Dose
APEC	Asia-Pacific Economic Cooperation
AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine of People's Republic of China
BAFPS	Bureau of Agriculture and Fisheries Product Standards
CAC	Codex Alimentarius Commission
CAIQ	Chinese Academy of Inspection and Quarantine
CCPR	Committee Meeting on Pesticide Residues
CDC	United States Center for Disease Control
COAG	Council of Australian Governments
COFEPRIS	Federal Commission for the Protection from Sanitary Risks of Mexico
COMPIAL	Multisector Commission of Food Safety (COMPIAL)
CSFII	Consumer Survey for Food Intakes for Individual
DBP	Di-n-butyl phthalate
DHA	Docosahexaenoic acid
DINP	Di-isononyl phthalate
DLCs	Dioxin and dioxin-like compounds
DMSc	Department of Medical Sciences of Thailand
DoA	Department of Agriculture
DOST	Philippines Department of Science and Technology
DIGESA	General Direction of Environmental Sanitation of Peru
EDI	Estimated Daily Intake
EFSA	European Food Safety Authority
EMRL	Extraneous Maximum Residue Limit
EPA	Eicosapentaenoic acid
FAFST	Foundation for the Advancement of Food Science & Technology, Inc.
FAO	Food and Agriculture Organization of the United Nations
FCSC	Food Consumed by School Children in Indonesia
FDA	Food and Drug Administration
FDC	Philippines' Food Development Center
FNRI	Food and Nutrition Research Institute of the Philippines
FPA	Philippines Fertilizer and Pesticide Authority
FSANZ	Food Standards Australia New Zealand
FSCF	APEC Food Safety Cooperation Forum
FSO	Food Safety Objectives
FSVPS	Federal Service for Veterinary and Phytosanitary Surveillance of Russia
GAP	Good Agricultural Practices
HACCP	Hazard Analysis Critical Control Point
IARC	International Agency for Research on Cancer
ICMS	International Commission on Microbiological Specification
IESTI	International Estimated Short-term Intakes
IFSS	Integrated Food Safety System

IPCS	WHO International Programme on Chemical Safety
JECFA	Joint Expert Committee on Food Additives
JEMRA	Joint Expert Meetings on Microbiological Risk Assessment
JMPR	Joint Meetings of Pesticide Residues
JMPS	Joint Expert Meeting on Pesticide Specifications
KFDA	Korean Food and Drug Administration
LCn-3PUFA	Long Chain Polyunsaturated Fatty Acids
ML	Maximum Levels
MoA	Ministry of Agriculture
MeHg	Methylmercury
MOAC	Ministry of Agriculture and Cooperatives of Thailand
MoH	Ministry of Health
MOPH	Ministry of Public Health (MOPH) of Thailand
MRA	Microbiological Risk Assessment
MRL	Maximum Residue Limit
NADFC	National Agency of Drug and Food Control of Indonesia
NAFIQAD	National Agro-Forestry and Fishery Quality Assurance Department
NAQIA	National Agriculture Quarantine Inspection Authority of PNG
NIFDS	National Institute of Food and Drug Safety Evaluation
NOAEL	No-Observed-Adverse-Effect Levels
OBPR	Office of Best Practice Regulation
OECD	Organisation for Economic Co-operation and Development
PAC	Peruvian Association of Consumers
PO	Performance Objectives
PPTAC	Philippine Advisory Committee
PTMI	Provisional Tolerable Monthly Intake
RBM	Risk-Benefit Managers
RIS	Regulation Impact Statement
SAIC	State Administration for Industry and Commerce of China
SCSC	APEC Sub Committee on Standards and Conformance
SENASA	Agrarian National Health Service of Peru
SFA	State Food and Drug Administration of People's Republic of China
SPRT	Supervised Residue Trial
SPS	Sanitary and Phytosanitary Measures
STMR	Supervised Trial Mean Residue
TBT	Technical Barriers to Trade
TDI	Tolerable Daily Intake
TMDI	Theoretical Maximum Daily Intake
USDA	United States Department of Agriculture
USFDA	United States Food and Drug Administration
VFA	Vietnam Food Administration
VGSKI	State Centre for Quality and Standardisation of Veterinary Drugs & Feed
WTO	World Trade Organization

APEC SCIENTIFIC SEMINAR-WORKSHOP ON FOOD SAFETY RISK-BENEFIT ANALYSIS

Project No. CTI 2011T
The Richmond Hotel, Ortigas Center, Manila, The Philippines
22-24 November 2011

The project on APEC Scientific Seminar-Workshop on Food Safety Risk-Benefit Analysis (CTI 22 2011T), hereinafter referred to as the Seminar, was implemented by the Bureau of Agriculture and Fisheries Product Standards (BAFPS), Department of Agriculture (DA) on 22-24 November 2011 at the Richmond Hotel, Ortigas Center, Manila. This undertaking was sponsored by the BAFPS and the Asia Pacific Economic Cooperation (APEC) as one of the capacity building activities of the APEC Food Safety Cooperation Forum (FSCF) under the Sub Committee on Standards and Conformance (SCSC).

The project generally aims to introduce the concept of Food Safety Risk-Benefit Analysis in the APEC region and explore its possibility in complementing the traditional Food Safety Risk Analysis tools. Specifically, the Seminar aims to: *(a) identify available scientific approaches and methods needed for conducting risk-benefit analysis of foods; (b) to explore opportunities and limitations to quantitatively/qualitatively compare risks and benefits; and (c) to define further research or capacity needs of each member economy in the region.*

There were 53 participants from 17 APEC member economies and one participant from non-APEC member organization. Representative member economies were from Australia; Brunei Darussalam; Chinese Taipei; Hong Kong, China; Indonesia; Japan; Malaysia; Mexico; Papua New Guinea; Peru; People's Republic of China; the The Philippines; Republic of Korea; Russian Federation; Thailand; Viet Nam; and the United States of America. Non-APEC member organization is the Food and Agriculture Organization of the United Nations.

Resource speakers came from various agencies namely, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), Food Standards Australia New Zealand (FSANZ), The Philippines Food Development Center (FDC), and the FAO.

The project overseer was Mr Israel Q. Dela Cruz, OIC Chief Science Research Specialist of the BAFPS and the project consultant was Dr Sonia de Leon, President of the Foundation for the Advancement of Food Science & Technology, Inc. (FAFST).

The list of the participants, resource speakers and project team can be found in **Appendix 1** of this document.

INTRODUCTION¹

Risk Analysis is an internationally recognized scientific process in the development of standards for food and food ingredients safety. It is a systematic, disciplined approach for making food safety decisions includes three major components: risk management, risk assessment, and risk communication. It is a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to food safety problems.

However, over the past years the Risk-Benefit Analysis in relation to foods has gained much attention. It envisages comparing both risks and benefits of foods and food ingredients in one currency. It is a new issue in the area of food and nutrition, though such analysis is already well established in pharmaceuticals, medicine, microbiology, societal, economic, and consumer perception. Currently there is no broad scientific consensus on the general principles or approaches for conducting risk-benefit analysis for food and food ingredients, hence the impasse focuses mainly on how and when to conduct such analysis, for instance, when a food or a food substance is recognized to have the potential to exert both health risks and health benefits, it is important for risk managers or the food control officers to be able to weigh the risk against the benefit. One of the profound advantages of risk-benefit analysis is it allows for more detailed scientific information and can therefore be reported into policy makers or risk managers to allow them to make more “balanced” management decisions and therefore it’s potential for complementing the work of the traditional risk analysis is worth studying.

This project generally aims to introduce the concept of Food Safety Risk-Benefit Analysis in the APEC region and explore its possibility in complementing the traditional Food Safety Risk Analysis tools. Specifically, the Seminar aims to: *(a) identify available scientific approaches and methods needed for conducting risk-benefit analysis of foods; (b) to explore opportunities and limitations to quantitatively/qualitatively compare risks and benefits; and (c) to define further research or capacity needs of each member economy in the region.*

To facilitate the delivery of the expected outputs, the project was executed through lectures from the resource persons and member economy presentations and workshop.

OPENING PROGRAM

The APEC Scientific Seminar-Workshop on Food Safety Risk-Benefit Analysis started with the opening remarks given by the project consultant, Mr Gilberto F. Layese. In his message, he extended his warmest welcome to the resource persons, guests, and participants of the seminar-workshop. He likewise stressed the diligence of the BAFPS in submitting proposals to APEC including this project that introduces new concept and novel idea in the region, leading to its prompt approval and support by the member economies. Mr Layese wished the participants to enjoy their brief stay in the Philippines and make this seminar the opportunity to network with other participants.

¹ **Best Practices for Risk-Benefit Analysis: Experience from out of food into food.** <http://www.matis.is/english/projects/nr/2904>. Accessed on 25 November 2011; **EFSA Scientific Colloquium Summary Report, Risk-Benefit Analysis of Foods, Methods and Approaches.** 2007. European Food Safety Authority: Parma, Italy; **Food Safety Risk Analysis, A Guide for National Food Safety Authorities.** 2006. Food and Agriculture Organization of the United Nations and World Health Organization.

PROJECT RATIONALE

The Project Overseer, Mr Israel Dela Cruz presented the rationale of the Seminar. He mentioned that the three (3) day seminar-workshop is one of the capacity building activities under the APEC FSCF, a forum for food safety regulators seeking to build robust food safety systems in the region that are consistent with Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) of the World Trade Organization (WTO). He further informed the delegates that the forum is currently co-chaired by Australia through the FSANZ and the People's Republic of China through General Administration of Quality Supervision, Inspection and Quarantine of People's Republic of China (AQSIQ). Mr Dela Cruz also cited the agreement of member economies in this forum to build robust food safety systems to accelerate progress on harmonising food standards with international standards to improve public health and facilitate trade. He presented the priority areas of the FSCF in capacity building where he stressed that the Seminar addresses the technical skills and human resource capacity needs identified in the forum.²

Similarly, Mr Dela Cruz explained the project background and mentioned that currently, there is an established risk-benefit analysis in some areas like pharmaceuticals and medicine, but risk-benefit analysis in food is new in the field of food safety. It envisages comparing both risks and benefits of foods where issue lies on the beneficial and adverse potential can be in the same food or even in the same ingredient. He also indicated that the discussion on the concept focuses on when to conduct such analysis especially that there is no current international agreement on the general principles or approaches for conducting a qualitative and quantitative risk-benefit analysis for food. He stated that the European Food Safety Authority (EFSA) has explored the idea of risk-benefit assessment wherein they had carried out a scientific colloquium³. Some European Member States like the Netherlands and Sweden had successfully institutionalized Risk-Benefit Analysis.

The project according to Mr Dela Cruz intends for the delegates to have a better understanding of the fundamental scientific issues related to risk-benefit assessment of food components and its feasibility as alternative or complement to traditional risk analysis framework. Consequently, during the workshop, participating economies were asked to suggest ideas and other possible projects that could be undertaken in the future based on the outcomes of this activity. His presentation is found in **Appendix 2**.

Codex Food Safety Risk Analysis Framework/FAO/WHO Development of Scientific Advice

Dr David James, FAO consultant, initially discussed the underlying principles of risk assessment and its development over the years and how this is view in an international perspective through his presentation on Codex Food Safety Risk Analysis Framework attached as **Appendix 3**.

² Further information on APEC Food Safety Cooperation Forum can be found on the following website: <http://www.foodstandards.gov.au/scienceandeducation/apec2011/>

³ Website of EFSA on Scientific Colloquium can be accessed on the following: <http://www.efsa.europa.eu/en/supporting/pub/116e.htm>

He elucidated the concept that supported the risk analysis framework is the 1995 WTO/SPS Agreement establishing that food can be freely imported if it does not endanger the member's Appropriate Level of Protection (ALOP). Further, he described risk assessment as the most important tool for assisting in the elaboration of food safety measures. ALOP according to him is the level of protection deemed appropriate by a member establishing a sanitary or phytosanitary measure to protect human, animal, plant life or health within its territory although he clarified that level of zero risk cannot be attained or expected. While in the context of food safety, he mentioned that ALOP is a statement of the degree of public health protection that is to be achieved by the food safety systems being implemented by a member economy.

From country level to operational level

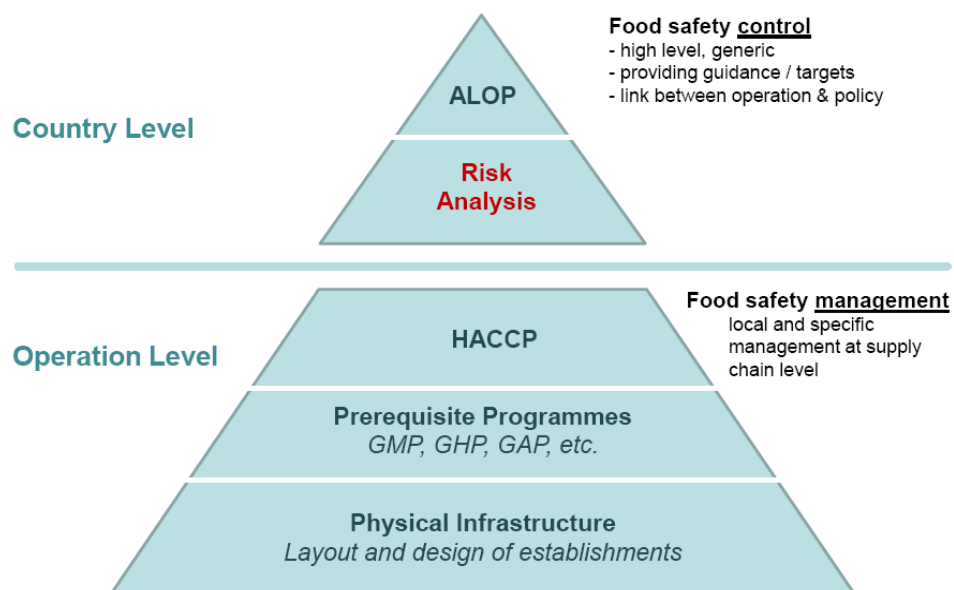


Figure 1. Food Safety Control and Management from Country Level to Operational Level

The figure above shows ALOP in the top most level explaining that this could be achieved through several prerequisite programs such as Good Agricultural Practices (GAP), Good Hygienic Practices (GHP), Good Manufacturing Practices (GMP), etc being traced back to the production part of the food safety systems.

After which, he defined risk in accordance to Codex, as a function of probability of an adverse effect and the magnitude of that effect, consequential to a hazard in food. He also cited the components of risk analysis such as risk assessment, risk management, and risk communication. He started the risk analysis with risk management in consideration of political process entailed in it. Risk assessment process should be done based on sound science separated from the opinions and political pressure. Most importantly, the outcome of the latter process should be communicated in a form that consumers will understand complex ideas and will not cause any adverse reaction from the hearing public.

Specifically, he mentioned that sound science applied should be consistent, open, transparent, and documented. At the same time, this should be evaluated and reviewed as appropriate in the light of newly generated scientific data. Upon the development of process and

implementation of risk management, he stated that this should be based on adequate food control systems harmonized with international food control systems of other member economies in the interest of trade under the WTO agreement wherein FAO/WHO Codex Alimentarius serves as a venue of forum discussion.

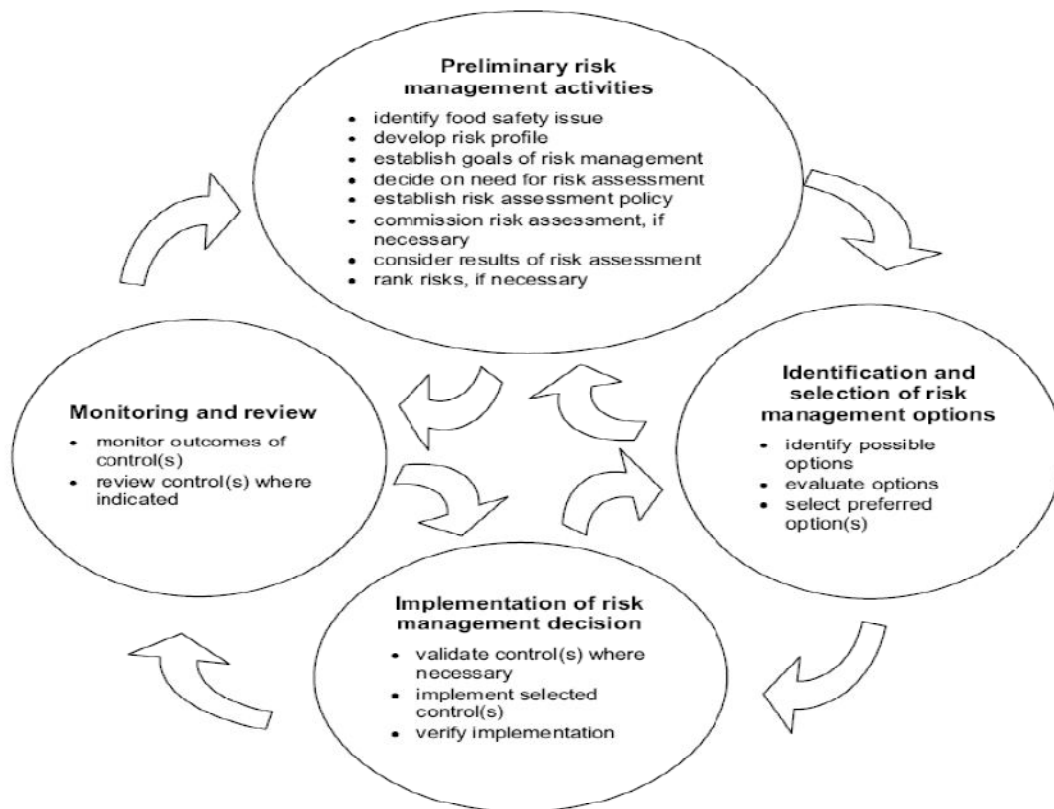


Figure 2. General Framework for Risk Management
<http://www.who.int/foodsafety/publications/micro/riskanalysis06.pdf>

He further explained several Codex principles of risk management starting with the structured approach that should be followed presented in a generic framework (see Figure 2). He also enumerated other principles such as (i) protection of human health should be the primary consideration in risk management decisions; (ii) risk management decisions and practices should be transparent; (iii) determination of risk assessment policy should be included as a specific component of risk management; (iv) risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment; (v) risk management decisions should take into account the uncertainty in the output of the risk assessment; (vi) risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process; and (vii) risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.

Dr James then described the execution of risk assessment through Codex Alimentarius Commission (CAC) where Joint Expert Meetings on Microbiological Risk Assessment (JEMRA) and Joint Expert Committee on Food Additives (JECFA) are the ones performing the scientific process. The output of risk assessments are then considered by related Codex Committees to be adopted later on by the CAC.

He then shared the overview process of microbial risk assessment starting from the request coming from Codex Committees to be forwarded to the FAO/WHO JEMRA to perform the

entire Microbiological Risk Assessment (MRA). The MRA process begins when a pathogen-commodity combination for which risk based scientific advice is required has been identified and ideally when the scope of the work had been outlined and the specific questions which the MRA needs to address identified. A “Call for experts” in the relevant scientific disciplines and a “Call for data” that will be needed to undertake will follow, where after which exposure assessment and hazard characterization are performed dependent on the scope of the work and are usually flexible. The work undertaken by the drafting group is reviewed by a group of independent experts through an expert consultation. The report produced from this meeting will be subjected for future development to be opened for public comment and review. A report of the progress made and if needed a request for further guidance is made to the relevant Codex Committee. The original request for the work came from this committee and ultimately they will be the users of the outcomes of the work.

The second year of the process focuses on completing the MRA by linking the exposure assessment and hazard characterization components in the risk characterization step and in this way trying to adequately answer the questions that were posed at the beginning of the work. Also at the beginning of the second year there may need to be some refinement of the work based on the review by the expert consultation, the public review in year one and any feedback received from the relevant Codex committee.

Again the work is carried out primarily by the MRA team who interact mainly via e-mail but also with one or two meetings of the group. A draft of the complete risk assessment is then reviewed by an expert consultation and the risk assessment revised as appropriate. Following that the MRA is subjected to a peer-review by about twenty experts in relevant disciplines, the purpose of the various review steps is to ensure that the work being developed is scientifically sound and forms a valid basis for the provision of scientific advice to Codex and to member economies.

The last year of the process is dedicated to finalising the MRA based on the comments received from the peer-review before publication in both hard and electronic format. As a summary of the risk assessment procedure, he made mentioned that this process is deemed necessary to communicate the risk of illness from food. Despite involving intensive data and resource, this was considered an important tool in assisting food safety managers at national level.

Furthermore, Dr James demonstrated how the public perceived risk showing that consumers give more importance to food irradiation which is actually having a low risk, against microbiological contamination determined to have high actual risk. He commenced his presentation on risk communication by enumerating responsible entity for this process including international organizations, national governments, industry, consumer and consumer organizations, academe and media. He also highlighted that nature of risk and benefits as well as uncertainties and risk management options should be part of risk communication. Risk communication has several principles in order to be effective where Dr James enumerated as the following: (i) knowing the targeted audience; (ii) involving experts both in scientific and communication aspects; (iii) source of information must be credible and transparent; and (iv) put the risk in perspective.

Additionally, he explained the development of scientific advice by the FAO/WHO stating that this offers a neutral, international forum for scientific discussions on food safety and nutrition and advices are being provided by established expert committees and ad hoc

consultations. The latter was being conducted for the purpose of generating scientific advice or to respond to requests for advice. Experts involved are selected on the basis of their expertise where selection procedures are closely monitored. Meanwhile, the aforementioned expert committees are joint expert bodies which are known as the following: Joint Expert Committee of Food Additives (JECFA, 1956), Joint Meetings of Pesticide Residues (JMPR, 1963), Joint Expert Meetings on Microbiological Assessment (JEMRA, 2000) and Joint Expert Meeting on Pesticide Specifications (JMPS, 2002). Likewise, he gave details on the coverage of issues handled by this forum specifically safety assessment of chemicals in food, safety assessment of biological agents in food, assessment of production technologies for foods and human nutrition.

Such advice gathered from scientific processes are provided to CAC and its subsidiary bodies, member economies and other interested parties which includes industry, consumer, groups, research institutes, etc. supported by legal framework laid down in basic texts of both FAO and WHO. Its core principles indicate soundness, responsibility, objectivity, fairness, transparency and inclusiveness.

He also provided definition of the scientific advice which is the conclusion of a skilled evaluation taking into account the scientific evidence, including uncertainties. Furthermore, he listed down several products of FAO/WHO scientific advices composed of chemical or microbiological risk assessments related to food, guidelines and resource documents related to food safety and nutrition and risk assessment methodology and its international harmonization. Finally, he mentioned that communication of scientific advice is documented through various forms depending on the target audience such as monographs, technical reports or publication series.

During the Open Forum, one delegate asked on how the risk communication done in the international level which was clarified by Dr James telling that most of the communication advice were made mainly through governments. He however justified that other interested parties, like consumers, may also receive the said message in consideration that the advice is made public like through the use of several media and conduct of conferences.

Traditional Risk Assessment Procedures: Microbiological

Dr Janell Kause, Director of the Risk Assessment Division of the FSIS-USDA shared an overview discussion of microbial risk assessment focusing on data and model quality issues demonstrated with some applications found in **Appendix 4**.

She started the discussion with the WHO reported cases of foodborne pathogens affecting people of the United States and other parts of the world where 250 plus types of existing and emerging food borne illnesses were identified such as *Listeria monocytogenes*, *Salmonella* and *Escherichia coli* O157 to name a few. Recently according to her, the United States had to address issues of *E. Coli* O157 and antimicrobial resistance. Foodborne illnesses are highly under reported around the globe, thus there have been better efforts from WHO to try get a better risk assessment on attribution. She enumerated several food control systems being applied traditionally by several economies to control food borne illnesses emphasizing that these management mechanisms shall be conformed to science.

Subsequently, Dr Kause mentioned that Microbiological Risk Assessment (MRA) is considered by majority of economies as the cornerstone of international and national policies. She added that this is a science based approach that integrates a wide variety of scientific data including epidemiology, microbiology, consumer behaviour, retail practices, industry practices and other information to guide decisions which is also recognized by the WTO SPS agreement for trade particularly on Article 5.1 where measures are based on assessment of the risk to human health. With MRA, information are systematic and data are integrated through a logical, science based, transparent and holistic approach providing public health information helping deal with a decision.

In particular, she defined MRA as a scientific process for estimating the probability of an adverse public health effect and the severity of the effect. She also outlined the four basic steps provided by the Codex for traditional microbial risk assessment consisting of hazard identification, hazard characterization, exposure assessment and risk characterization. She continued by explaining each steps in particular such as (i) hazard identification as identification of agents capable of causing adverse health effect; (ii) hazard characterization either qualitative or quantitative evaluation of the nature of the adverse health effects including the dose-response assessment; (iii) exposure assessment, either qualitative or quantitative, as the evaluation of the likely intake; and (iv) risk characterization, either qualitative or quantitative, as the estimation, including attendant uncertainties, of the probability of occurrence and severity of adverse health effects. She emphasized on the functional separation of risk assessors and risk managers being independent with each other but having an interdependent relationship meaning working together to come up with practical solution.

Furthermore, she elucidated that between the two types of microbial risk assessment – qualitative and quantitative, the best type will be the one that fits and most directly informs the risk management issues. However on her discussion, she focused on the latter type stating that this is a basic food chain systems model having a holistic approach covering a farm to table concern and is consisted of Codex risk assessment components.

In addition, quantitative risk assessments are known to be well established approach to food safety risk assessments for microbiological hazard where the conduct of such, either national or international, are made available on different internet sites. She also added that this method is resource intensive requiring significant amount of time, expertise and financial commitment. Traditionally, they are being conducted as product-pathogen pair like poultry and *Salmonella* or *Campylobacter*, *Listeria monocytogenes* and deli meat, *E. coli O157:H7* in beef or *Vibrio* and seafood looking at the likelihood of presence, survival, and growth of pathogens in foods as well as the qualitative portion of hazard identification.

At the moment, the USDA decision-making on product-pathogen pairing is guided by the crisis being encountered, although attempts in engaging with the attribution model in order to have a more systematic way of hazard-product combination. She revealed that recently there are attempts on engaging multiple hazards, multiple processes, and multiple products approach trying to equalize them in the sense of comparability with each other and in consideration of probing economics which is something to be regarded in risk-benefit analysis. This model is shown in the following figure:

Conceptual Exposure Model for QMRAs

- “Food Chain” System Models
- Provides the scientific evidence of the nature of the hazard and the risk it presents to consumers

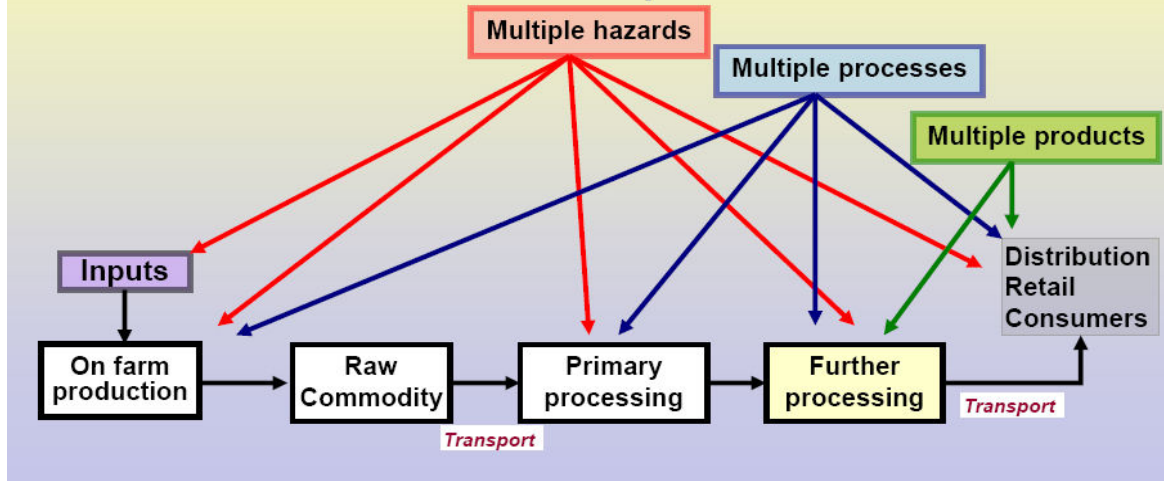


Figure 3. Conceptual Exposure Model for Quantitative Microbiological Risk Assessment

She also presented the conventional way of showing exposure assessment determining the concentration of pathogen as it moves from farm to plate. She clarified that most model parameters are characterized as distributions using a probabilistic simulation allowing simulation of variability and uncertainty in the values resulting to typical output of distributions. She cited as well the dose-response using stochastic models adding that this has been a great challenge to the USDA due to high number of uncertainties. She revealed that their data sources include epidemiological data, animal studies, and few from human feeding trials due to ethical reasons. Surrogate pathogens were also utilized in order to make a dose-response curve referring to *Shigella dysenteriae* as one specific example. She noted, in addition, that there are new streamlined approaches using attribution models instead of dose-response, requiring a robust epidemiological system. Currently, this new process is being worked on by Center for Disease Control (CDC), the United States Food and Drug Administration (USFDA) and the USDA.

Furthermore, Dr Kause disclosed that in risk characterization, USDA is using a scenario analysis or the “what if scenario analyses” where they are regarding the probability of having a change in the future predicted to be bringing public health impact. She likewise tackled that this method identifies key opportunities for risk mitigation and evaluates several matters like policy options, changes in behaviors, adoption of intervention, introduction of hazards and preventive measures. Additionally, she highlighted other important components of risk characterization like baseline risk, sensitivity analysis and uncertainty analysis.

As another component of risk characterization, she pointed out that in sensitivity analysis, the following are being taken into account: (i) systematic investigation of model parameters, model inputs, assumptions and model functional form; (ii) parametric variation of input variable values to examine effects of output; and (iii) evaluation of drivers of risk. On the

other hand, uncertainty analysis is believed to be an important part of risk assessment as when this is carried out together with sensitivity analysis, the identification of unknown from the quantitative MRA can be provided. Consequently, the outputs yielded from the quantitative MRA are integrated into cost-benefit analysis making a model that will have economic analysis serving as an extension of quantitative MRA, thereby weighing both the public health benefits and societal costs.

In order to be confident in coming up with an estimate, Dr Kause expounded that both data quality and model validation should be considered. According to her, data should be transparent and reproducible adding to the factor that they have to be prioritized based on the sensitivity and uncertainty analysis focusing on data gaps that are driving the public health risk as against the calibration of model where it takes into account the plausibility of model inputs and reasonability of assumptions.

Thus, in order to have a model quality assurance, calculations are ensured to be transparent together with a well explained choice of assumption and expression of uncertainties. Most importantly, Dr Kause stressed that they tend to make the quantitative MRA models, aside from the report, available to the public for the sense of transparency.

Furthermore, peer review process is also used to attain model quality assurance entailing iterative review processes and involving broad range of scientific expertise where reviewers considered could either be in the United States or an international representative. She also detailed as to how the stakeholder could be engaged in the risk assessment process through public meetings and “call for data” aside from ensuring them equal access to information. She pointed out that involving stakeholders in the deliberation of risk assessment is significant as they could provide clear perspective on the concerns of society balancing the technical aspect of this process.

Dr Kause moreover reminded the delegates that MRA is not a “one size fits all” process as the type of risk management concern determines the type of MRA to be developed. This was demonstrated through enumeration of several models developed in assessment of risk beyond traditional quantitative MRA such as attribution modeling (e.g Danish Model), risk profile (USDA non-0157 risk profile), rapid risk evaluations, risk-benefit analyses, decision analyses, risk-based sampling algorithms, risk-based inspection allocation algorithms, risk-ranking models and, data and regression analyses combined with attribution to illness, all of which are dependent on the planning and scoping phase of the MRA. She explained that it is during this phase that risk management objectives are defined where scenarios are being specified and availability and quality of data are being evaluated.

She also enumerated different applications of MRA and these are in the areas of policy development, assurance through inspection of establishments based on related public health risk, measurement of federal performance in achieving health goals, evaluation of past policies on public health and response to emergencies. As an example, she expressed how they have applied quantitative MRAs in the case of Listeriosis. Initially, they have identified management options for this particular case through series of applicable questions. After which, they engaged in risk-ranking foods possibly affected by *Listeria monocytogenes* classifying twenty-three ready to eat foods where they have identified deli meat as the primary contributor of the said microorganism affecting the risk group of elderly. They then perform process control through several available interventions like sanitizing, testing as part of monitoring technique. Through this MRA, the US made a regulation encouraging the

industry to adopt certain food safety control verified by the US government. This case was considered to have an economic impact as products held due to suspect of *Listeria monocytogenes* contamination may not go to market unless otherwise been cleared in the testing protocol leading the industry to adopt recommended food safety control systems. However, despite of the success undergone in the aforementioned case, Dr Kause revealed that upon adherence to recommended food safety systems, a plateau in listeriosis case was experienced. A comparative risk assessment was conducted between prepackaged and retail-sliced deli meat and found out that cross-contamination is happening in the latter causing the US to evaluate several factors that preventing and contributing to it through an inter-agency risk assessment model.

As a summary, she underlined that lessons learned from traditional MRA can be readily applied to risk-benefit analysis. In addition, she expounded that food safety risk assessment is an evolving field. Lastly, she emphasized that food safety risk-benefit analysis and quantitative MRA continues to evolve, inform each discipline, and moves towards decision support modeling.

During the open forum, several questions were asked by the delegates for clarification. One was regarding the effectivity of enforcing regulations that has been previously mentioned during the lecture particularly in retail establishments. Dr Kause replied that as of the moment, the USDA have no intention of regulating the retailers but rather focus on the massive information campaign where it is from there that they can recommend to adopt certain procedures. Another delegate inquired about the budget entailed in collecting the data and conducting the plan. As a response, she mentioned that a simple streamlining risk assessment does not involve much financial commitment. Building a model is not the expensive part of the process but the data collecting aspect. Another query was raised regarding the minimum data requirement for a probabilistic model, Dr Kause clarified that this depends on the risk management decision needed to be performed and how much uncertainty could be tolerated for a certain decision in consideration that probabilistic model provides high level of uncertainties.

Moreover, questions pertaining to risk profiling on emergency cases and data sharing by the industry were raised. She responded that risk profiling is not being performed frequently in the US and mostly done during the presence of emerging pathogen, while for emergencies; she declared that they are doing rapid risk assessments that are gathering point estimates. As for the data sharing by the industry, she explained that industry are not required by the law to share data and will often inform that their data are proprietary, where at present this concern is still debatable.

Another inquiry was asked pertaining to the provision of information to consumers regarding excellent performing establishments. Dr Kause particularly mentioned of their communications group conducting public meeting after the carrying out of scenarios. She also noted that risk communication gets the least of attention and needs development. Regarding the “Fight Bac” risk communication program of the US, she specifically noted on its efficiency and its consequent risk communication program. Unfortunately, she responded that data on how consumer responded to the ad is not yet established leaving uncertainty to the effectivity of the message. The program is still on-going with application of innovative measures to be more efficient.

The presence of epidemiological surveillance in the United States was also asked that she confirmed and described as a multi-million surveillance system. She further added the presence of their food consumption surveillance program, robust microbial testing program on meat and poultry products for *Salmonella*, *E.coli* and *Listeria* depending on the product.

Furthermore, Dr Kause was questioned on the availability of any models helping predict or prevent appearance of antimicrobial resistant microorganism strains. She concurred of the present model they have in the US particularly on fluoroquinolones in chickens, though she also shared of the other models found outside their economy which they are planning to review in the future. As a follow up, clarification was sought on the matter of veterinary drug residue risk analysis where she noted that there is a good residue program and risk assessment being carried out by the FDA in addition to the National Residue Program implemented by the USDA.

Lastly, frequency of performing food consumption data was asked by one delegate where Dr Kause explicitly explained that it is done every four (4) years by the Consumer Survey for Food Intakes for Individual (CSFII).

Risk Analysis: Dietary Risk Assessment of Pesticide Residues and Implementation for Philippine Food Safety

Dr Amelia Tejada, Director of the Food Development Center (FDC) and former Secretariat of the JMPR talked about Dietary Risk Assessment of Pesticide Residues and its implementation in the Philippines. Her full presentation is found in **Appendix 5**.

She commenced her presentation by introducing the Codex and SPS Agreement of the World Trade Organization. The CAC is the international body that develops food safety standards and is being recognized by the WTO in international trade. Its aim is to protect consumers health and ensure fair practice in food trade. The WTO on the other hand, which is the forum for trade negotiations and handles trade disputes, recognizes Codex as the key reference point in the WTO SPS Agreement, therefore any country that employs Codex standards are presumed to be consistent with the provisions of the SPS Agreement. She also added that Codex incorporate risk analysis principles into its elaboration of its standards. Risk analysis is a systematic, disciplined approach for making food safety decisions developed primarily in the last two decades, includes three major components: risk management, risk assessment, and risk communication. Risk Assessment is the scientific evaluation of known or potential adverse health effects from exposure to chemical/microbial hazards. She explained that it needs a reliable data, both toxicology and residue data. Example of the risk assessors are the JECFA and the JMPR. Such bodies provide the (scientific) recommendations to the Risk Managers usually the CAC and its member governments. As regard the risk assessment of JMPR, Dr Tejada enumerated some of the residue data and information required for its evaluation, namely: identity, metabolism and environmental fate, residue analysis and stability of pesticide residues in stored analytical samples, use pattern, residues resulting from supervised trials on crops, fate of residues in storage and processing, information and data from farm animal feeding and external animal treatment studies, residues in food in commerce and at consumption, national maximum residue limits, reconsideration of previous recommendation, data requirements for Extraneous Maximum Residue Limit (EMRL) estimation. She noted that these are the same residue data needed for evaluation of pesticides in the Philippines. As regard the Maximum Residue Limit (MRL) establishment, JMPR

requires the following data: Biological data (Biochemical aspects, absorption, distribution and excretion, biotransformation, effects on enzymes and other biochemical parameters) and Toxicological studies (acute toxicity, short-term toxicity, long-term toxicity/carcinogenicity, genotoxicity, reproductive toxicity & special studies like human exposure to pesticides).

Moreover, she detailed the steps in the conduct of risk assessment. (1) Hazard Identification, (2) Hazard Characterization, (3) Exposure assessment, and (4) Risk characterization.

According to her, the exposure assessment has been the central work of the JECFA and JMPR. Similarly, the JMPR merely assesses the pesticide based on the exposure or dietary risk assessment because all the toxicological data will produce the Acceptable Daily Intake (ADI) and the latter that will be compared to the theoretical maximum daily intake that can be computed through the acceptable MRL or the supervised maximum residue trial. Likewise, the Codex MRLs are convenient for making a first estimate of dietary intake which is referred to as the Theoretical Maximum Daily Intake (TMDI). She explained that in the absence of national data, the Codex may be used as the national MRL. Furthermore, the long-term dietary intakes are calculated by multiplying the residue concentrations (STMRS, STMR-Ps or MRLs) by the average daily per capita consumption estimated for each commodity on the basis of the GEMS/Food diets (cultural diets) and summing the intakes for each food. She explained that the per capita consumption may be calculated by the average production divided by the population.

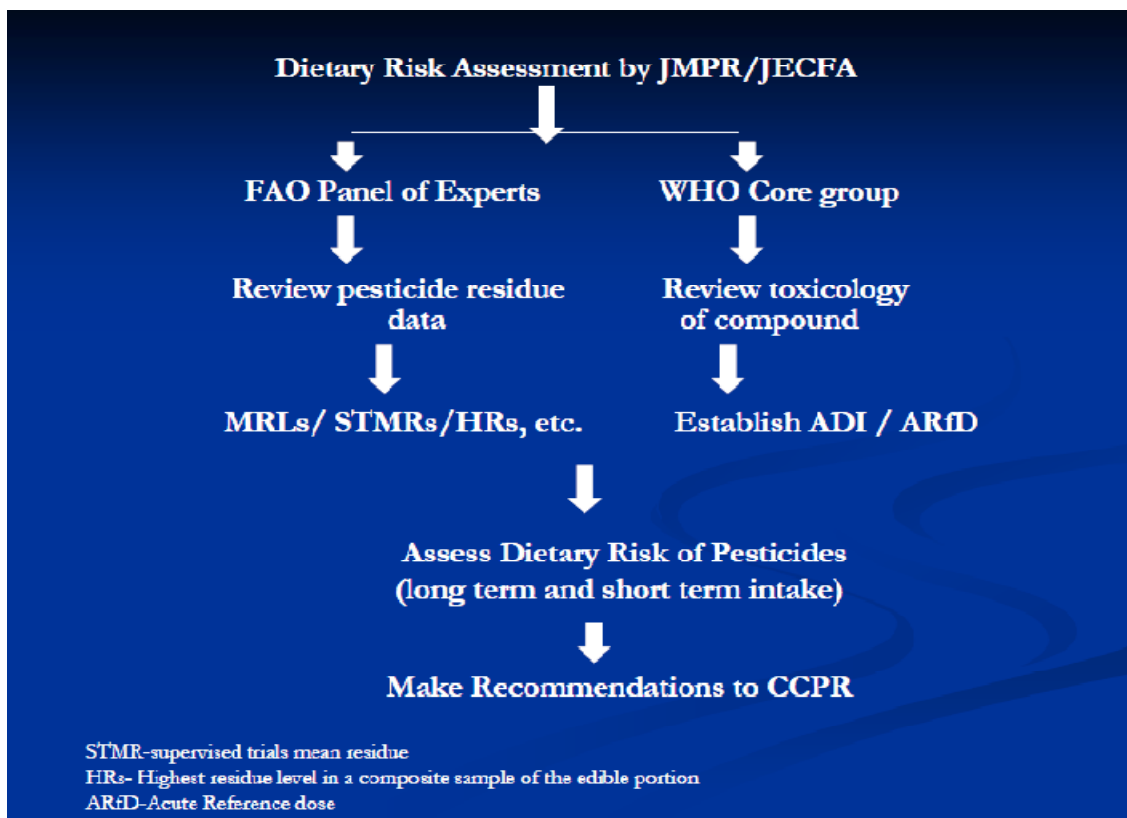


Figure 4. Dietary Assessment of JMPR and JECFA

In addition, she also explained the difference between the risk assessments being conducted by JMPR with JECFA. The former evaluates supervised residue trial data resulting from pesticide use according to GAP while the latter evaluates residue depletion studies using

radiolabelled parent compound for veterinary drugs to determine a marker residue based on the Good Practices on the Use of Veterinary Drugs. Now, she noted that when the estimated dietary exposure to a chemical is below the ADI, Maximum Levels (MLs) in food contributing to the exposure are unlikely to have any health effect. If there is exceedance, however, the Estimated Daily Intake (EDI) could be undertaken for refinement at national level, either changing the consumption data or the GAP. One time, Codex requested the JMPR to change the GAP or use the GAP that will not cause exceedance of the ADI. This is quite difficult according to her particularly to the industry because they have to revise the Supervised Residue Trial (SRT) to come up with a new GAP.

The **Figure 4** summarizes the Dietary Risk Assessment by JMPR and JECFA.

The endpoints that the JMPR uses are (1) Acute Reference Dose (ARfD) - derived from Toxicological evaluation of the No-Observed-Adverse-Effect Levels (NOAEL) with safety factor of 10. It is the single amount of food that can be eaten in one sitting. ARfD is the highest amount of food that can be eaten in single sitting; (2) ADI – derived from Toxicological evaluation of NOAEL with safety factor of 100; and (3) Maximum Residue Limit or the set for agricultural commodities based on GAP which are allowed to go in trade.

The FAO panel of experts reviews the pesticide residue data and come up with the MRL, Supervised Trial Mean Residue (STMR) and Highest Residues (HR). The JMPR uses the HR to the ARfD and the STMR to actual risk assessment. The MRL is not used to the actual risk assessment, but the edible portion which is the STMR. For the WHO side, they review the toxicology of the compound and establish the ADI or the ARfD. After which, both organizations will join in a single meeting to assess the dietary risk of pesticides, either short or long term. Finally, the final output of the Joint Expert meeting will be recommendations to the Codex Committee Meeting on Pesticide Residues (CCPR).

On the other hand, Risk Characterization is the integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties. She explained the process by which the risk characterization for pesticide are calculated at the national and international level (as shown in **Figure 5**). Given the ADI and propose MRLs, at the national level, you can calculate the National Theoretical Maximum Daily Intake (NTMDI) and compare it with the ADI then calculate the National Estimated Daily Intake (NEDI) and compare with the ADI.

Some general considerations in Risk Assessment, if international dietary exposure assessments exceed a health based guidance value (e.g. ADI), then national authorities should be asked to submit their national exposure estimates through CAC or its technical committees. Also when the acute RfD is exceeded, JMPR should consider alternative GAP with adequate field trials to identify the GAPs resulting in the highest residue value for which the International Estimated Short-term Intakes (IESTIs) would be below the ARfD. Similarly, the CODEX states that food containing residues at the level of the adopted Codex MRLs must be safe for the consumers. It retains the current policy that when there is exceedance of the acute RfD, the MRLs are not advanced to higher step of the Codex Procedure.

On the risk/benefits of pesticides, the most obvious benefits and easiest to calculate are economic benefits derived from the protection of commodity /crop yield and quality.

However, maintenance of aesthetic quality, and protection of human health from disease carrying organisms are difficult the difficult.

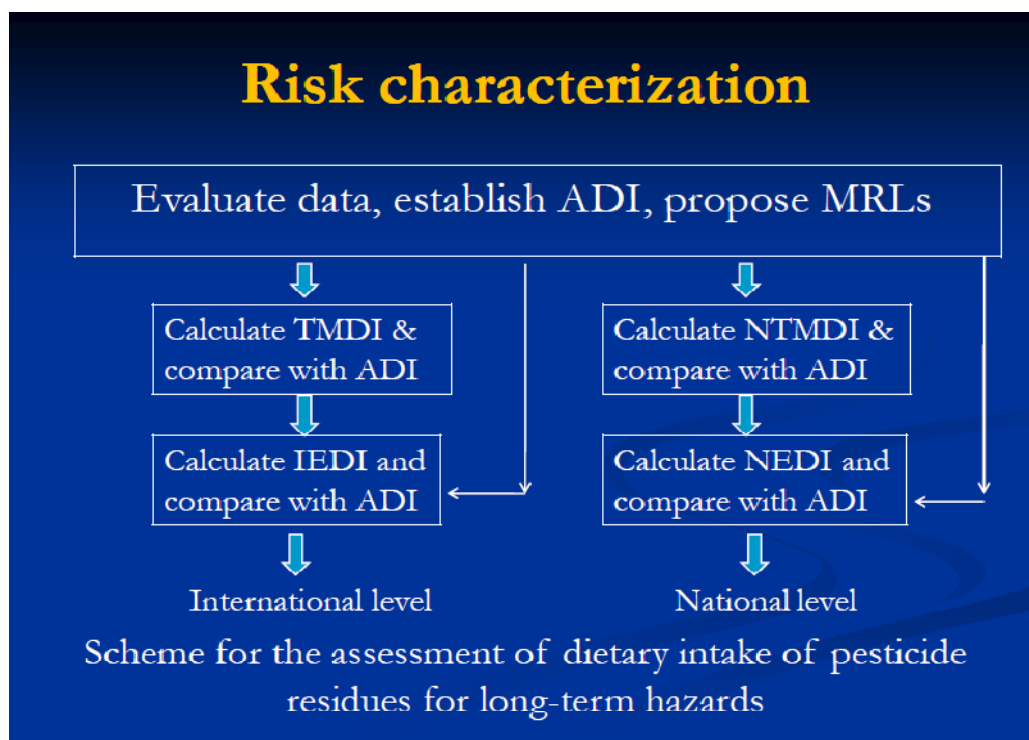


Figure 5: Scheme for the assessment of dietary intake of pesticide residues for long-term hazards

She also introduced the case of the Philippines in the risk of assessment for pesticides. The Fertilizer and Pesticide Authority (FPA) is the sole authority in approving the registration of pesticides and regulating their use after the evaluation of all the data requirements. It is also mandated to establish the MRLs based on GAP for use of pesticides in raw agricultural practices in the Philippines. In pesticide registration on food crops will not be allowed without a proposed MRL based on supervised trials conducted in accordance to GAP. These supervised trials are submitted by the industry. And the trials will be evaluated and validated by a pool of experts. The agency has established pool of expert scientists, medical doctors, and technical consultants. It has reactivated the Philippine Advisory Committee (PPTAC) who can be assigned to evaluate and study data submission related to pesticide regulation, residue monitoring including risk assessment among others.

Furthermore, she also introduced the Philippines National Codex Organization (NCO) and how it operates within the ambit of the Codex Alimentarius framework. The NCO is an advisory body chaired by the Secretary of Agriculture and co-chaired by the Secretary of Health on the implication of various food standards and food control issues arising from Codex to protect the health of the consumers and ensure fair trade practices.

In conclusion, assessments of dietary exposure are used for deciding on the acceptability of proposed draft Codex MRLs. If the ADI is exceeded by the estimate of exposure after all relevant factors are applied, dietary exposure concerns become a risk management issue. Because of different approaches in dietary exposure estimates, member economies of CCPR may arrive at different conclusions about the acceptability of certain MRLs.

During the open forum, one delegate asked whether in the establishment of MRL, the Philippines uses specific acute or chronic toxicological parameters abroad or the specifications of the JMPS. Dr Tejada replied that the Philippines uses the specifications from the JMPS, but it also conducts actual analysis of the active ingredient of the product for the establishment of the MRL. She also added that, all the data evaluated by the WHO are also considered, but at the same time, local data for exposure is also being utilized. As regard for the supervised trial, the Philippines accepts the data from other countries as long as conditions are the same, for instance that of Thailand or Indonesia. Another delegate observed that some of the fruits and vegetables from Southeast Asia have no MRL established by Codex, and therefore whether any economies from this region requested Codex for the establishment of MRL for such commodities. Dr Tejada recalled that Malaysia has been active in the effort of establishing MRL for fruits and vegetables from Southeast Asia that currently have no MRL values from Codex. She also noted that Codex is in fact extrapolating MRL values from major crops to the commodities considered to be “minor crops.”

PRESENTATION OF MEMBER ECONOMIES

Brunei Darussalam

Ms Siti Khadizah Hj Abd Latiff, public health officer from the Ministry of Health (MoH) delivered the presentation discussing about an overview of food safety national food control system and risk analysis in Brunei Darussalam.

She began her lecture by providing brief demographical information on Brunei Darussalam. This was followed by illustrating their food safety regulatory framework where she stipulated that MoH acts as the lead agency in enforcing food safety and quality standards as given in their Public Health Food Act. In addition, she noted that this regulation covers food officers and food analysts from the MoH and other relevant agencies including the Department of Agriculture (DoA), Department of Fisheries and Halal Import Permit Board, thereby tasking them with responsibilities over food within their jurisdiction. Several relevant regulations were also mentioned such as Infectious Disease Order 2003, Fisheries Act 2002, Poison Act, Municipal Board Act, Miscellaneous Licensing Act and Custom Act.

In details, she discussed the specific tasks of previously mentioned agencies involved in the implementation of the Public Health Act particularly their involvement with National Food Control System. She started with the MoH and declared that the Food Safety and Quality Control Division under this Ministry is the one engaged in the National Food Control System. Its main tasks are the following: (i) registration of food or food products which requires date marking; (ii) issuance of food export certificate; (iii) issuance of medical examination certificate for food handlers; (iv) control quality and safety standards for processed foods which are being imported; (v) random sampling of imported processed foods; (vi) carrying out of investigation on food poisoning cases for food premises only; and (vii) confiscation and witnessing of destruction of non-compliant food products with Public Health (Food) Regulations.

After which, she pointed out the main role of the DoA which is assisting the local farmers and food processors in complying with requirements via monitoring, sampling, and analysis particularly in microbial contamination, antibiotic residue, pesticide residue, food labelling,

expiry date, and other relevant laboratory analysis. In addition, DoA is tasked to control quality and safety standards of imported, exported and locally sold raw foods via monitoring, sampling and analysis. Likewise, tasks of Department of Fisheries are similar with the DoA, only the former focused mainly in fish and fishery products. She further pointed out that chemical, microbiological and water analyses are routinely performed especially during “red tide”.

Agencies in Brunei for Food Safety Control System are as follow:



Figure 6. Food Safety Control System in Brunei Darussalam

Aside from the three cited Ministries, other departments were also tapped for the same food control program due to their jurisdiction over food concerns. These are: Brunei Industrial Development Authority, responsible for providing local Small and Medium Enterprises (SMEs) with industrial sites for food processing and other manufacturing industries; National Standard Center, in charge of implementing standards and quality management procedures in their productions as well as guiding SMEs in achieving required standards for their products; Municipal Board/District Office accountable for enforcing and regulating issuance of miscellaneous license upon compliance with health requirements for hygiene and sanitation; and Halal Import Permit Board tasks to inspect and certify food and food establishments according to Islamic Laws.

Moreover, she outlined the differences between traditional and modern food safety systems in accordance to FAO Food Safety Risk Analysis (June 2005). The former was considered to be a reactive approach where main responsibility lies within the government. Also, this type of system does not provide structured risk analysis and mainly relies on end product inspection and testing. On the other hand, modern food safety system is deemed as a preventive approach addressing farm to table concerns. It is science based and uses a structured risk

analysis. She admitted that as to date, their economy is still engaged in traditional food safety systems.

In conclusion, as for the Acts being implemented in Brunei, she revealed that mostly are based on ASEAN economies due to similarity in food commodities being consumed. Finally, she disclosed that there is no risk analysis being conducted in their economy due to absence of expertise.

Her presentation is found in **Appendix 6**.

Chinese Taipei

Food Safety Risk Analysis in Chinese Taipei was presented by Ms Hui-Ying Wang from the Taiwan Food and Drug Administration (TFDA) where she began her presentation by demonstrating the organizational chart of TFDA outline composed of seven divisions and three regional administrations. Her full paper is found in **Appendix 7**.

In particular, she highlighted several sub-units from the organizational chart specifically responsible for food safety related tasks. These are three divisions are: Risk Management, Food Safety and Research and Analysis; three regional administrations such as: Northern Center, Central Center and Southern Center; and Center for Consumer Protection and Center for Science and Technology. All are working together ensuring the smooth implementation of the program.

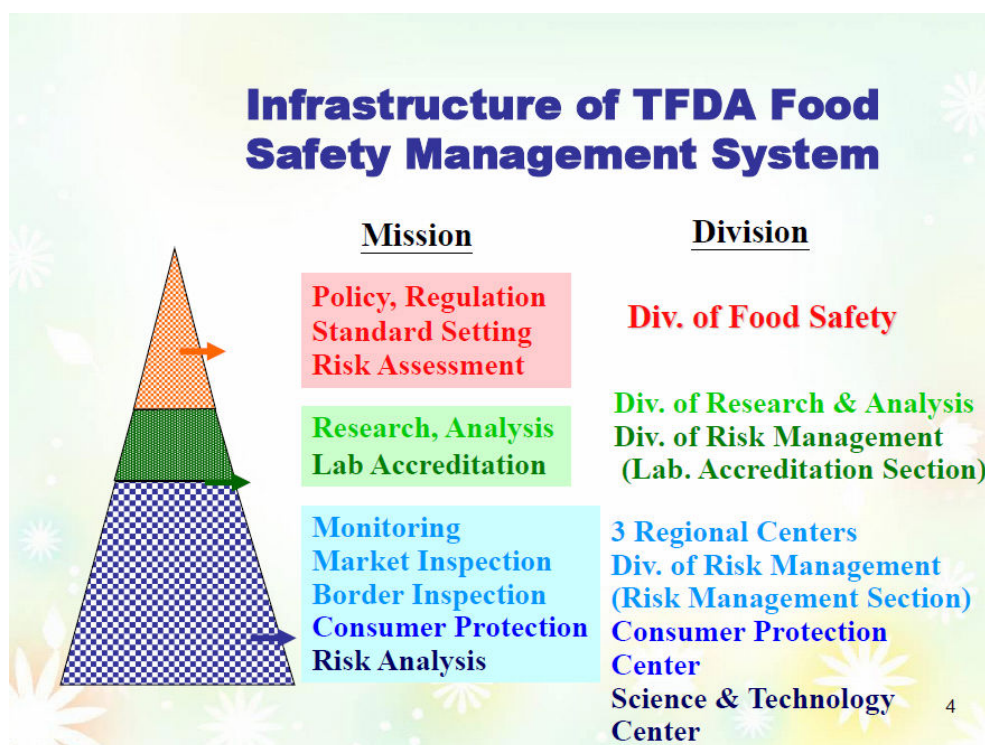


Figure 7. Infrastructure of TFDA Food Safety Management System

Subsequently, she stipulated the framework and functions of food safety management system of TFDA (see **Figure 7**) through a pyramid showing Division of Food Safety at the topmost

level whose main function includes policy making, regulation amendments in accordance to risk assessment; Divisions of Risk Management (Laboratory Accreditation) and Research and Analysis in the middle layer devoted to maintain and improve the examination and analysis capabilities of the system; and at the bottom layer, three aforementioned Regional Centers in charge of border and market inspection collaborating with Division of Risk Management on Food Safety Monitoring programs. Included as well in the last layer are the Consumer Protection Center who undertakes the collection of relevant data, communication and assistance for consumer protection and Science and Technology Center who performs the risk analysis and gives suggestions to risk reduction program of the economy.

Ms Hui-Ying provided also their Risk Assessment Task Force enumerating several priorities such as chemical contaminants, food additives, pesticides, heavy metals, toxin of aquatic products and biological toxins. In addition, to ensure efficient performance of TFDA applicable to food safety concerns, several technical committees are set up for a comprehensive food safety network involving non-profit supporting organization. These committees are the following: Food Safety and Nutrition Advisory, BSE Advisory, GMO Review, Health Food Review, Analytical Method Review, Laboratory Accreditation Review, Food Labeling and Advertisement Review, GMP-CAS Association and Food Industry Research Development Institute.

She also enumerated the risk assessment procedures namely hazard identification, hazard characterization, and exposure assessment which all are based on scientific evidences mainly toxicological evaluation, national food consumption data and residue information from monitoring program, taking in consideration of data from susceptible populations. She also noted the conduct of risk-benefit analysis in their economy specifically in fish where she cited this as an example explaining further that market potential of this commodity is being questioned due to being contaminated with mercury. But not disregarding the nutritional value of it being a good source of protein and long chain fatty acids, thereby, TFDA conducted risk-benefit analysis in order to come up with a good advice towards consumer particularly women during their pregnancy. Such scientific procedures discussed by Ms Hui-Ying are said to be based from TFDA database on Food Safety Risk Assessment, which provides collection of data both from domestic and international evaluation research serving as an official reference for risk assessment which unfortunately available only in Chinese language.

In addition, she also elucidated their process of establishing food safety measures, mainly based from scientific evidence and international standards and indicates the following procedural steps: drafting of measures by TFDA; review of this draft by experts; invitation of comments both local and international; consultative meeting with stakeholders if necessary; adoption and promulgation of said measure by TFDA; and promotion campaign if applicable. TFDA likewise gives importance to risk communication, especially after experiencing significant food safety crisis in their economy. Thus in order to enhance the awareness of the public, information are shared through numerous ways like web page, press release and consumer hotlines wherein all relevant issues being distributed are ensured transparent and comprehensive with proper way of handling media inquiries to avoid unnecessary panic from the public.

Following the presentation of Ms Hui-Ying, one delegate noted that most of the seminar participants came from either Ministry of Health or Ministry of Agriculture, and asked whether there is a collaborative effort in Chinese Taipei between these two Ministries in

developing unified system of risk assessment. Ms Hui-Ying did concur of the joined efforts from these two Ministries specifically on pesticide risk assessment and other chemical contamination issues.

Hong Kong, China

The Food Safety Risk Assessment in Hong Kong, China was expounded by Dr. Chow Chor-Yiu of the Center for Food Safety of Food and Environmental Hygiene Department. His presentation is attached as **Appendix 8** of this report.

He outlined his presentation into two, namely Food Safety Risk Assessment and Use of Risk Assessment Results. Discussing first the risk assessment, he defined this as the scientific basis for appropriate formulation of risk management actions and risk communication messages to protect public health enumerating as well its components such as hazard identification, hazard characterization, exposure assessment and risk characterization. Description of their risk assessment section structure were also provided naming several officers such as food safety officers and senior medical officers both having specific aspects to focus on, all to be supervised by a consultant as shown below:

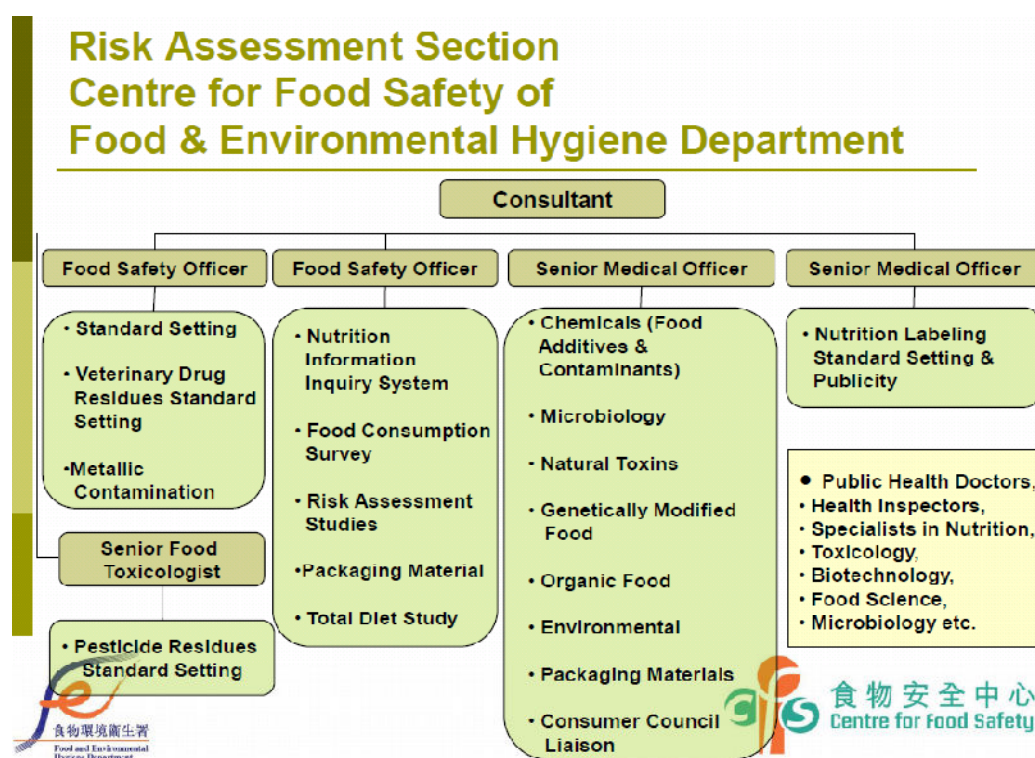


Figure 8. Officers under the Risk Assessment Section of the Center for Food Safety of Food & Environment Hygiene, Hong Kong, China

Dr Chow commenced with the food incident monitoring of Hong Kong, China by explaining that their economy is a free port relying chiefly in their 95% imported goods around the globe entailing them to establish a monitoring system that will enable them to develop a timely response to any food related incidents. He added that food incident monitoring aims to identify food incidents locally or overseas, assess the local impact of such incident if there is any and provide timely responses that will minimize adverse impact on public health. Such incidents are screened through defined list of websites from food safety authority (33

websites), local and overseas media agencies (5 websites) and other non-governmental organizations (2 websites).

As part of their preliminary risk assessment, they conduct hazard identification and characterization focusing on the health related effects of the risk such as acute and chronic toxicity, genotoxicity, carcinogenicity, and its safety reference values with consideration of international recommendations coming from JECFA, JMPR, International Agency for Research on Cancer (IARC), WHO International Programme on Chemical Safety (IPCS) and their national food safety authorities. Thereafter, food consumption data and the substance level in food should be available in order to perform exposure assessment. As regard, data gathering for food consumption, Dr Chow shared that they conducted surveys from year 2005-2007 covering 5008 people in their economy from ages 24-84 years old. Consequently, together with substance concentration level, estimation of dietary exposure and assessment of associated health risk form part of the exposure assessment process. After which, food incident reports will be disseminated to relevant officers of risk management and risk communication teams for follow-up of actions and formulation of risk management options.

Dr Chow carried on the second part of his presentation involving usage of risk assessment results where he made use of the plasticiser incident in Chine Taipei found out during the food incident monitoring last 24 May 2011. Through this monitoring, it was discovered that phthalates, which are known to be industrial chemicals used as plasticizer to improve flexibility and durability of plastic materials, were found to be intentionally added in the food. Since this case is not usually encountered in routine food surveillance programme of their economy, no specific rules were established governing the phthalates presence in the food. In order to estimate the exposure assessment of Phthalates, like Bis(2-ethylhexyl)phthalate, commonly abbreviated DEHP, their economy used an in-house developed web-based computer system called Exposure Assessment System (EASY). As per computation, a Tolerable Daily Intake (TDI) may be achieved when a 60 kg person will have an intake of 1.5mg DEHP a day. Similarly, in the absence of TDI levels from JECFA or WHO of other form of phthalates like Di-isononyl phthalate (DINP) and Di-n-butyl phthalate (DBP), levels established by EFSA were considered as reference.

Additionally, he explicated that risk assessment results are also used in standard setting upon the conduct of food standards review in order to keep them aligned with international development and advancement of food science and technology, in consideration of several factors such as public health concern, local food standards, international standards and stakeholder concern. This process scientifically assesses the dietary exposure to the hazard of concern and possible adverse health effects on their local food community, deeming the local food consumption as a significant matter. As examples, he cited several food standards applying regular review such as pesticide residues, veterinary drug residues, natural toxins, heavy metals in foods, and microbiological guidelines for ready to eat food.

To clearly illustrate the process of review being applied in the standards above, Dr Chow shortly described the procedure in setting standard and conducting review for pesticide residues in food. Primarily, standards of individual pesticides are proposed based on the Codex recommendation, supported by other relevant standards of major exporting countries. These draft standards are evaluated through risk assessment taking into account its capacity to protect the public health of their economy.

Also, risk assessment results are regarded as important when providing food safety information to the public. One specific sample he provided was the performing of risk assessment study of mercury in fish last 2008 where the level of Total Mercury (tHg) and Methylmercury (MeHg) in fish commonly consumed in Hong Kong was computed together with its corresponding dietary intake. On the other hand, benefits of consuming fish were also noted specifically recognizing this as a good source of long chain omega-3 fatty acids, especially Eicosapentaenoic acid (EPA) and Docosahexaenoic (DHA), something that cannot be obtained from edible plant oils by the consumer. Weighing the risks over benefits of such cases, selection of healthier fish should consider the amount of comparatively high level of long chain omega-3 fatty acids and relatively low levels of MeHg.

Lastly, he named other risk assessment studies carried out in their economy such as dietary iodine intake in adults, nitrate and nitrite in vegetables, dietary exposure to acrylamide in adult, hepatitis E virus in fresh pig livers, microbiological quality of non-prepackaged beverages mixed or topped with solid ingredients.

In conclusion, Dr Kause asked on what influenced Hong Kong, China to include phthalate in their routine food surveillance. Dr Chow responded that the initiative was a proactive move in order to be prepared for any unlikely event that this chemical may bring upon on consumers.

Indonesia

Ms Yustina Muliani Budijanto under the National Agency of Drug and Food Control (NADFC), Indonesia presented a case study Risk Analysis on Food Consumed by School Children. The full presentation is found in **Appendix 9**.

Initially, Ms Budijanto described Food Consumed by School Children (FCSC) as foods available at school, sold by street food vendors, school canteen or cafeteria and are commonly consumed by school children. Brief statistical overview of FCSC was also provided referring to the results of monitoring and verification of its safety profile conducted by the NADFC in 2008 showing distribution of elementary students consuming FCSF specifically: 48% have bough snacks more than four times a week; 51% have occasionally bought snacks in a week; and one percent have almost never bought snacks in a week.

Moreover in 2004, a survey was conducted in Bogor according to her and reported that FCSC has a major contribution in nutrient requirements for school children taking into account that 36% of their energy requirement were obtained from their snacks. On the other hand, she revealed that FCSC contains high risk due to the possibility of nutrient imbalance, the potential usage of illegal chemicals and excessive additive, the possibility of chemical and microbial contamination, as well as the possibility of non-hygienic practices in the foods/snacks processing.

Data of food poisoning outbreak in schools and campus/universities had been collected from 26 Regional Office of NADFC throughout Indonesia between the year of 2007 and 2010 which showed highest percentage of food poisoning outbreak coming from elementary schools (70-79%) compared to that in kindergartens, junior high schools, senior high schools, and universities. Following this, Ms Budijanto provided the risk analysis of FCSC initially by defining risk analysis in general as a systematic and transparent process by collecting,

analyzing and evaluating scientific and non scientific information relevant about the dangers of chemical, microbiological and physical that may be present in food as a cornerstone of decision making to choose the best option to handle those risks identified under the various alternatives. She further provided the components of risk analysis which are the risk assessment based on a scientific study; risk management based on policy decision; and risk communication based on the interactive information and opinions exchange continuously.

Essentially, strategies formulated to alleviate the problems of FCSC were based on the aforementioned risk analysis. Commencing from the risk assessment, she enumerated activities entailed in this phase such as sampling and laboratory analysis of FCSC at the same time, launching of laboratory mobile (laboratory car) that involves sampling and quick-testing of noodles, meatballs, colored drinks, ice, snacks, and crackers using rapid test kits looking for specific contaminants such as formalin, borax, Rhodamin B, and Methanyl yellow. In particular, the following are the detailed risk assessment performed by Indonesia according to her: *The Development of Exposure Assessment based on Maximum Level; Exposure Assessment of Food Additives on Schoolchildren Using TDS methods in Malang (2002-2003); Exposure Assessment of Cyclamates on Schoolchildren in Surabaya (2006); The National Monitoring and Verification of Food Commonly Purchased by School Children (2008); and Exposure Assessment of Cyclamates and Benzoate on Schoolchildren in Palembang, Yogyakarta, Banjarmasin, and Makassar (2009).*

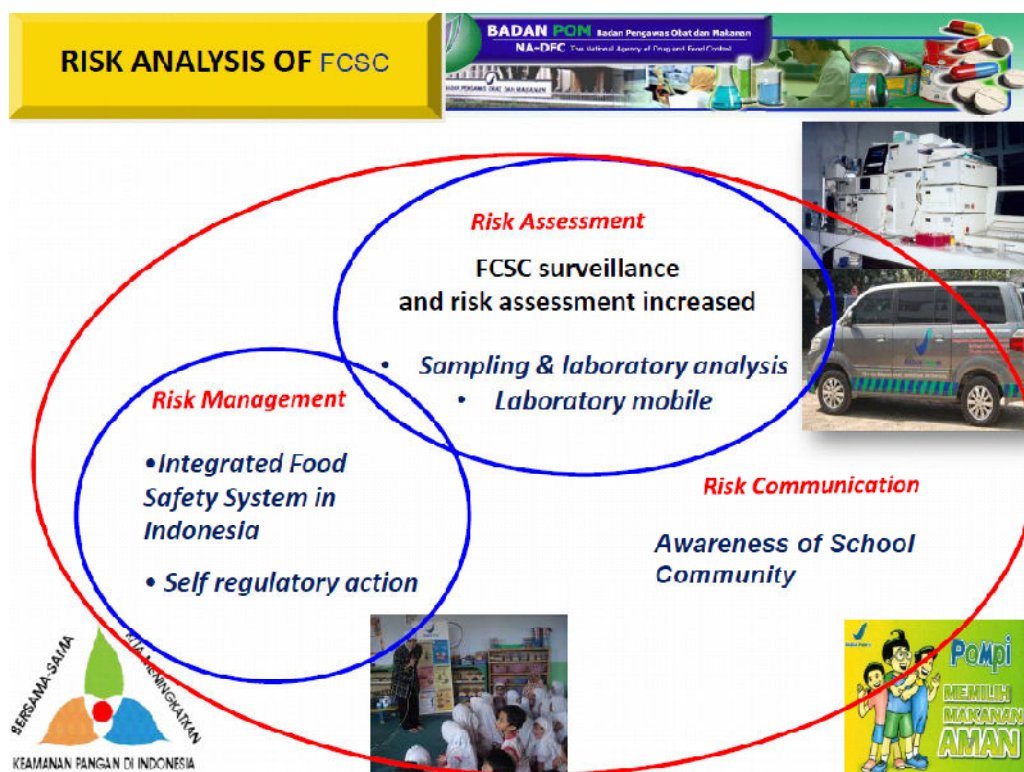


Figure 9. Risk Analysis Framework of Food Consumed by School Children in Indonesia

From the carried out assessment, it was found out that the safety level of FCSC is still low due to a serious problem associated with the development of human resources in Indonesia. Observing this reality, Movement Toward a Safe, Nutritious and Qualified, FCSC was launched by their economy's Vice President last January 31, 2011 as a measure that will help

address the problem. The NADFC through Integrated Food Safety System (IFSS), a communication system designed for food safety professionals to share knowledge and experience in this field, has conducted cross-sector meetings with ministries or agencies, and also developed advocacy partnerships with local governments in order to gain support from stakeholders for IFSS superior program, which is the National Action plan. As a result and as part of the risk management, an agreement of cooperation and commitment between several offices was published in support of the previously mentioned program.

To complete the whole process of risk analysis, activities for communication, information, and education were also developed in order to disseminate the program on National Action. These are in the form of food safety campaign, talk show, exhibition, mass media, training, participatory multilevel campaign food safety and food safety star award for school canteen. She also added that brochures, leaflets and posters, websites, articles, animation films, public service advertisement, and advertising spots were also used to effectively communicate with the consumers.

Figure 9 summarized the risk analysis conducted by National Agency of Drug and Food Control for FCSC.

Japan

Sharing information on Food Poisoning Measures for Raw Meat in Japan was given out by Ms Emi Saito from AUDIS Corporation. Her presentation is attached as **Appendix 10** of this report.

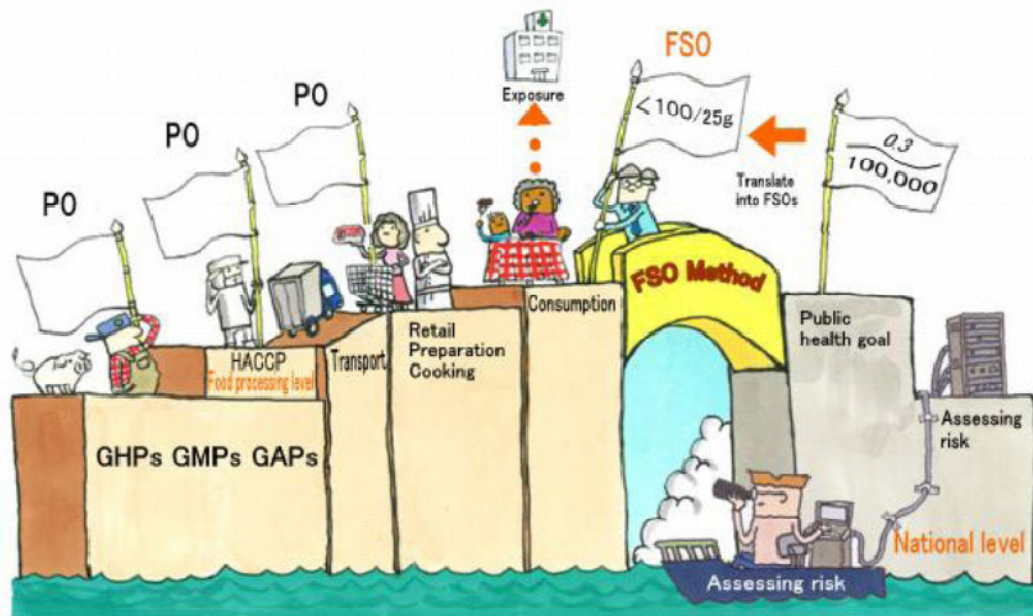
As an introduction, she characterized two existing food safety systems such as traditional and modern food safety systems in accordance to Codex Alimentarius. She expressed that despite the effective food hazards reduction of the former food safety systems as exhibited in the past experiences, it is still unable to detect and resolve current problems and evolving changes confronting different parts of the food chain. The latter on the other hand, with the new Risk Analysis approach, has the ability to diagnose the problems quickly leading to suggestions of more appropriate interventions.

She explained the application of the International Commission on Microbiological Specification's (ICMS) Simplified Guide to Understanding and Using Food Safety Objectives and Performance Objectives as shown in **Figure 10**.

“Food Safety Objectives” (FSOs) and “Performance Objectives” (PO) can be used by an authority to communicate food safety levels to industry and other governments. FSOs and POs are distinct levels of foodborne hazards that cannot be exceeded at the point of consumption and earlier in the food chain, respectively, and can be met using good practices like GAP and Good Hygienic Practices (GHPs) and Hazard Analysis Critical Control Point (HACCP) programs. FSOs and particularly POs, also allow for comparison of the degree of safety provided by different food processing techniques. The principles of using good practices and HACCP, in order to produce safe foods, will not change with the introduction of these concepts, i.e., the good practices and HACCP are the tools for achieving an FSO or PO. An FSO should only be developed if a need for this has been specifically identified, e.g., when it is anticipated that an FSO will improve food safety. FSOs and POs serve a purpose different from a microbiological criterion, which describes sampling and testing of foods for acceptance or rejection. Assessing processing and preservation parameters is the preferred

option to check that an FSO or a PO is met, but sometimes, sampling and testing against a microbiological criterion can be used for this purpose.⁴

FSO and PO is a means of communication to understand the values that meet public health goals of GMP and HACCP by food manufacturers, the industry is able to set the PO to meet the FSO



ICMSFならびに源竜弥氏

Figure 10. ICMSF Guide to Understanding and Using Food Safety Objectives and Performance Objectives

To be more specific, she mentioned of the main bacteria causing of food poisoning in raw meat and related encountered reports and cases which include: *Campylobacter*, observed since 2003 generally in raw meat of chicken and beef liver; Enterohemorrhagic *Escherichia coli* which is associated with all meat and causes concomitant haemolytic uremic syndrome with encephalopathy that may lead to death; and *Salmonella* distributed widely in meat and intestinal tract of some animals whose main symptoms upon infection involve acute gastroenteritis in human.

She relayed in details that from April to May of 2011, food poisoning related to Enterohemorrhagic *E. coli* was frequently observed and hence Food Safety Commission of the Ministry of Health set standards for hygienic consumption of raw meat supported by several health impact assessments carried out last 08 July 2011. It was also found out that contamination of such bacteria was mainly in seafood and raw beef liver. Further, she demonstrated the development process of *E. coli* and *Salmonella* infection and described that the probability of their occurrences are similar.

⁴ A Simplified Guide to Understanding and Using Food Safety Objectives and Performance Objectives. 2006. The International Commission on Microbiological Specifications for Foods (ICMSF). Accessed on November 26, 2011.

As a response to these cases, heating measures contained in the standards for consuming raw meat was recommended to be done during the processing and consuming stage of the food chain aiming to reduce the number of food poisoning to zero level. Explicitly, heating temperature should be 60°C for two minutes or more, one centimeter depth from the meat surface taking into account that microbial contamination primarily occurred in the latter. After which, heat treated meat will be subjected to cooling where upon doing the process, a certain part of the meat outer layer will be trimmed off. Unfortunately, reduction of pathogenic microorganisms obtained during heat treatment cannot provide direct estimates of reduced risk. As a support, in the primary production stage, good farming practices are recommended to be applied as well.

Malaysia

Mr En Azhar bin Ahmad from the State Health Department, Ministry of Health conveyed the presentation on Malaysia’s Experience on Food Safety Risk Analysis.

He outlined his presentation into two parts: Malaysia’s experience in Food Safety Risk Analysis including relevant training, project or case study and other related activities; and challenges of food safety risk analysis.

Initially, he showed the framework of risk analysis through an illustration, followed by their economy’s Food Safety Risk Analysis (**Figure 11**). He reported that Malaysia has been involved with activities entailing the latter since year 2000 as coordinated by their Food Safety and Quality Division. He also stated, that risk analysis is acknowledged by their economy as an important basis for all food safety management actions, development of food safety standards and managing risks associated with food hazards complementary to existing food safety initiatives currently implemented.

FOOD SAFETY RISK ANALYSIS IN MALAYSIA

- Malaysia involved in Food Safety Risk Analysis activities since year 2000.
- Food Safety Risk Analysis activities are coordinated by Food Safety and Quality Division.

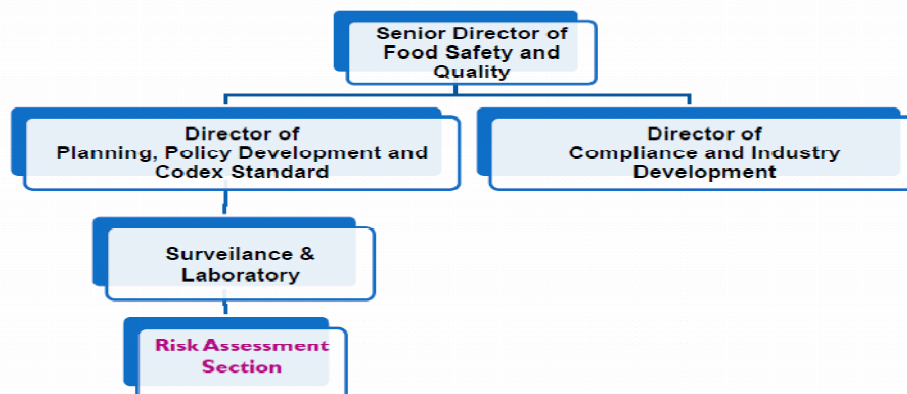


Figure 11. Food Safety Risk Analysis in Malaysia

Subsequently, he pointed out that some of their activities involved in the abovementioned scientific process are doing microbiological and chemical risk assessment and publishing of guideline on the *Application of Risk Management for Food Safety*. In order to be updated and for technical capability enhancement they have participated to several trainings and seminars. Currently Malaysia has conducted several chemical and microbiological risk assessment case studies at the national and regional level with the aim of enhancing the expertise of trained personnel and ensuring that the practice of conducting risk assessment is in the work culture. The case studies include: Risk Assessment of Formaldehyde in Marine Fish; Chemical Risk Assessment of Acrylamide in Malaysian Foods; Microbiological Risk Assessment of *Vibrio parahaemolyticus* in black tiger prawns; and Quantitative Microbiological Risk Assessment of *Bacillus cereus* in Fried Rice Prepared and Served in School Hostels.

On top of these, he also made mention of other related endeavors such as risk profiling which is description of the background of an identified food safety issue, current state and potential control options; conduct of exposure assessment where estimation of risk or hazard is being done; and development of ad-hoc risk assessment.

Finally, he revealed that they are facing several challenges in implementing food safety risk analysis such as in term of ensuring the quality of information like that of level of contaminants and food consumption data for risk assessment and maintenance of expertise. His presentation is found in **Appendix 11**.

Mexico

Imparting the relevant experience of Mexico to Risk-benefit Analysis was tasked to Dr Matiana Ramirez Aguilar of Federal Commission for the Protection from Sanitary Risks (COFEPRIS) under the Ministry of Health. Her full presentation is found in **Appendix 12**.

She started her discussion by introducing their office and its primary responsibility covering production, commercialization, imports and exports, and promotion of different products. Their mandate, as she elaborated deals with medicine and health technologies, consumer products, toxic and dangerous substances, occupational health, environmental risks and basic sanitation. See **Figure 12** for COFEPRIS Responsibility.

At the same time, she mentioned that COFEPRIS does coordination with other federal entities in the states particularly those performing inspection, control, and promotion of sanitation. As she progressed, she shared on the impact assessment performed by their economy specifically on the contamination of food and its related health impacts. Accordingly, Dr Aguilar identified foodborne diseases (FBD) as one of the growing problems worldwide deeming several critical points in the process of food surveillance like aspects related to processing and handling of food as well as the different characteristics of microorganisms and mechanism of spread. In addition, she mentioned that it is said to be a case of FBD when a similar illness occurring in two or more people has been brought about by intake of same food and water.

To be more specific, she differentiated two major types of food-intake diseases recognized worldwide as intestinal infections and intoxications. The former is known to be caused by microorganisms such as virus, bacteria and parasites while the latter is prompted by toxins produced by microorganisms like *Staphylococcus aureus* and *Bacillus cereus*.

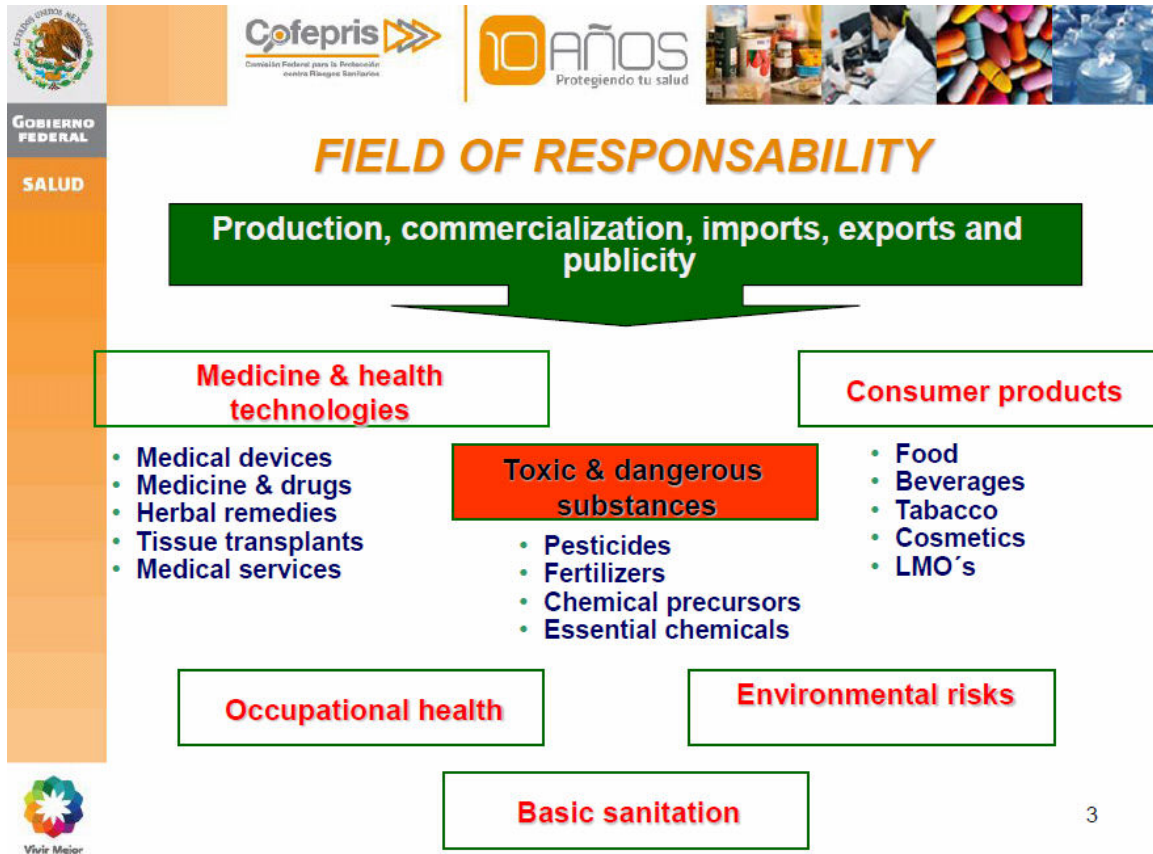


Figure12. Mandates of COFEPRIS, Mexico

World Health Organization report even indicated that 88% cases of diarrhea worldwide are attributed to water contamination and poor hygienic practices. Mexican Survey was conducted last 2006, wherein it was found out that there were diarrheal cases of children under five years of age and almost half percentage of those reports were consulted to medical doctors. Among the illnesses enumerated were typhoid and paratyphoid, shigellosis, food poisoning, brucellosis, amoebiasis, giardiasis and cholera mostly contracted through oral route of transmission (either by physical contact and/or ingestion of contaminated water and food). Relevant information about this concern is being disseminated through epidemiological surveillance of Mexico.

Additionally, with data gathered from several Gastrointestinal (GI) disease outbreaks experienced by their economy, she demonstrated that 72% of which was traced to be related with ingestion of food alone, 15% with food and water combined and 12% with water alone. Dr Aguilar added that meat has been named as a source of outbreak such as chicken, pork and lamb. Other source of GI disease outbreak involves human contact (like nails and hands), fruit water, fomites, milk formula and expired canned juice.

She further highlighted that regulations in Mexico aiming to provide order in their economy and protect their population may be updated from time to time based on the conduct of risk assessment and analytical methodologies. Epidemiological evidences previously cited are used in turn to support the health impact assessment their economy is carrying out. Results of such assessment are then taken into account in the formulation of risk management.

Lastly, as an example, she cited the 2011 Pesticide Surveillance Program of Mexico. Selection of pesticide and food to be tested in the laboratory was chosen based on the survey conducted last 2002-2003 and upon database validation, removal of non-pesticide relevant commodities was done leaving only 12 food such as rice, onion, chilli, bean, red and green tomato, corn, apple, orange, potato, banana and carrot. These were tested against toxicity level of pesticides listed from Mexican Pesticide Catalog.

Papua New Guinea

Mr Andy Yombo from the National Agriculture Quarantine Inspection Authority (NAQIA) imparted information on Food Safety and Legal Framework in PNG: Shortcomings and the Way Forward is attached as **Appendix 13**.

He initially stated that issues on food safety risk-benefit analysis can best be attended to when there are clear and coherent national food safety legislation to effect its implementation. Unfortunately, according to Mr Yombo, PNG lacks such a strategy or legal framework that protects food from hazards covering all stages of production to processing and distribution. Existing laws and subsequent issuances either come under different jurisdictions or cover only certain aspects of the food chain and or type of products. The whole sector of control is not clearly provided for in the current legal framework and is fragmented, not complete and not enforced as a result. Food laboratory testing facilities are not properly equipped and lack capacity to do the required tests.

Current National Food Law PNG has now includes The Food Sanitation Act of 1991 which gives authority to the Food Sanitation Council of the Department of Health, to oversee food processing, preparation, packing, distribution and sales component. This law is supported by Food Sanitation Regulation of 2007, lacking with binding instruments of standards, food safety codes or policy documents. The said legislation also has narrow scope and purpose that it does not cover the basic principles of food legislation such as risk analysis, integrated farm to table approach, transparency on decision making process, producer liability and protection of consumers.

As a realization, Mr Yombo stressed that this is a serious drawback for food safety in their economy as well as a barrier to trade leading them to take necessary steps to rectify the shortfalls. The trade facilitation team from the Department of Foreign Affairs have sought the services of the European Union (EU) where a food law expert was engaged through the EU funded Trade Related Assistance Project (TRAP) to examine the existing food laws at the same time define problems in the national food safety system. In addition, this food law expert is tasked to devise improvement mechanism and make applicable recommendations for the improvement of the food Sanitation Act. Accordingly, a report was made from the aforementioned project noting that the above shortfalls could be resolved either by amending the current Act - *Food Sanitation Act (1991)* or developing a completely new Food Safety Law. Recommendations made by the expert cover wider scope pertaining to different concerns such as improvement of scope of the Act; inclusion of integrated farm to fork approach; consideration of risk analysis as a significant pillar of food safety act; enhancement and specification of food safety requirements; mandatory implementation of Food Safety Code and Food Safety Management that entail HACCP principles; provision for traceability section should be included; definition of administrative structure and framework covering

inspections should be considered; and establishment of cooperation among agencies whose function intersects in food safety concerns.

Mr Yombo clarified that recommendations given were accepted by their government and an action plan is being prepared for the implementation of internationally accepted principles.

He continued by providing a brief overview of the NAQIA which is considered the Quarantine and Biosecurity organization in PNG. One of its functions includes the provision and regulation of the veterinary service in the economy. As the authority on animal health, NAQIA is better placed to play an essential role in animal origin food safety legislation and its implementation including the risk-benefit analysis.

NAQIA under its animal health and veterinary public health mandate carries out meat inspection at all major abattoirs and slaughterhouses in the economy as well as monitoring and regulation of annual licensing under the auspices of the Slaughtering (Amendment) Act (Chapter 238) of 1991. All major slaughterhouses and abattoirs are monitored by resident meat inspectors to ensure standards in animal welfare and hygiene and sanitation are adhered to from transportation of animals for slaughter to the holding yards at the slaughterhouse, to killing, skinning, evisceration and preparation of carcasses for chilling and further processing of carcass for meat. The Slaughtering Act covers functions relating to the processes as far as the preparation of the whole carcass at the end of the slaughter floor for chilling.

However, he emphasized that NAQIA or other regulators have no say on the control of meat safety hazards at the farm level. There is also no regulation to even ensure producers are aware of the type of feed they feed to their animals and the public health significance when slaughtered. This makes controlling hazards at the point of source difficult. Hazards can be biological, chemical or physical agents in meat which may have the potential to cause an adverse health effect in humans, whether or not it causes disease in animals.

In order to address the abovementioned concerns on food of animal origin, several interventions are to be accounted. These are (i) revising and developing a quality assurance HACCP based system for animal slaughter and meat inspection based on equivalence of current best practice; (ii) review and draft procedures and guidelines for meat safety at farm (production) level to control hazards at point of source; (iii) on-going training of staff on food safety standards; and (iv) opened dialogue and communication with other regulatory authorities on post slaughter meat handling, processing and packing standards.

In conclusion, Mr Yombo stated that the current legislation of food safety in PNG is still fragmented and ambiguous. Having made initial necessary actions to improve food safety in our country, he disclosed that more support would still be needed from colleagues who have well managed to develop food safety laws and systems in order to build their systems towards strong food risk analysis.

After his presentation, a clarification was made by one delegate particularly on the program of PNG as regards to the contaminants in the farm level such as veterinary drugs and microbiological hazards which are aggravated at the primary production of meat and meat products. He explained that their economy is still planning on establishing a section that will monitor the drug residues in meat and assistance is necessary in order to build their capacity on this aspect.

Peru

As an overview to the Food Safety Risk Analysis in Peru, Mr Roberto Acosta, Agrarian Health National Service of Ministry of Agriculture, delivered the presentation where his full paper is seen in **Appendix 14**.

Mr Acosta described Peru as an economy having a food safety system under the law approved in 2008. This aims to establish the legal regime that will ensure the safety of food intended for human consumption as well as to protect the lives and health of people, to recognize and secure the rights and interests of consumers, and to promote competition economic agents involved in the food chain, including feed, subject to constitutional and legal.

He further showed the three branches of their food safety system engaging three different ministries such as Agriculture (Agrarian National Health Service, SENASA), Health (General Direction of Environmental Sanitation, DIGESA) and Production (Fishery Technological Institute-Fish Health, ITP-SANIPES). SENASA of the Ministry of Agriculture is said to be in charge with primary food production and processing while DIGESA of the Ministry of Health leads the food industry commodities with the exception of fishery products which fall under the management of ITP-SANIPES of Ministry of Production. In addition, representatives of consumers, academe and laboratory network are also involved in their food safety system (see **Figure 13**).

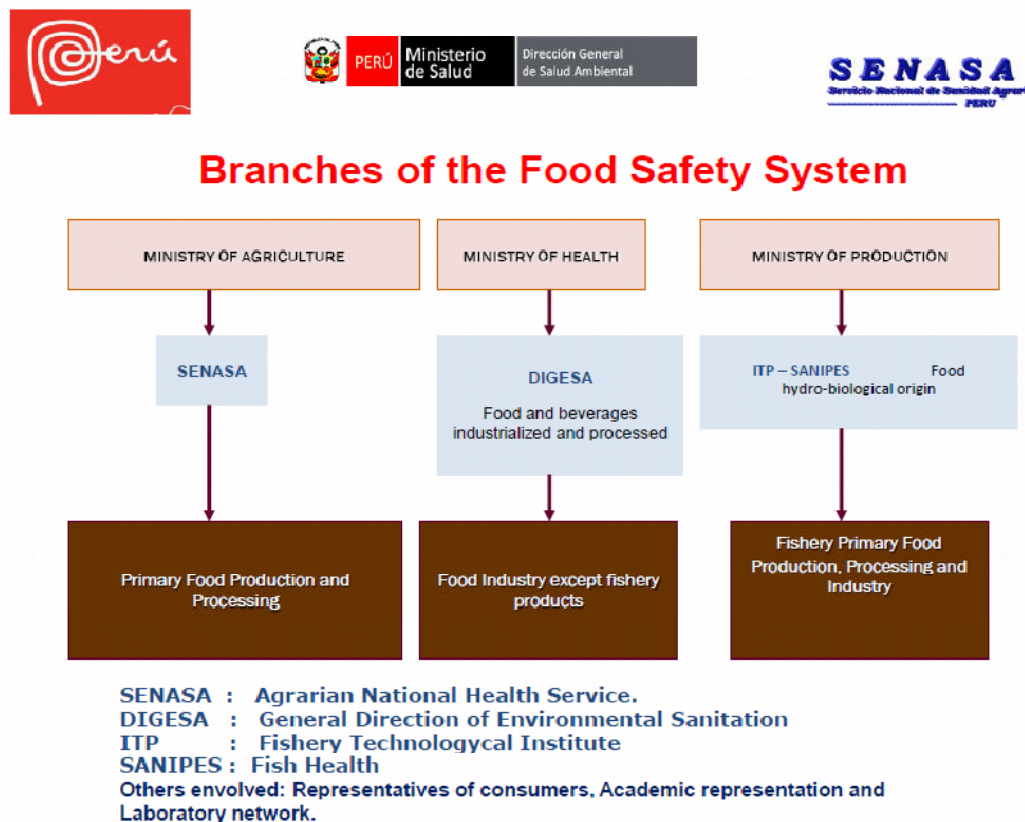


Figure 13. Food Safety System in Peru

As an explanation to the current situation of their food safety risk analysis situation, he identified four steps being undertaken by their economy starting with the overview of food

safety risk assessment. He disclosed that Peru is also working hard in overcoming major difficulties being encountered, through several strategies such as strengthening of the surveillance system for illness caused by foods; setting up of a system that will collect food safety information from food industry, academe and other related sources; establishment and strengthening of the Food Quality Control Laboratories Network for surveillance; and conduct of cost benefit studies to develop a more effective mitigation measures.

Consequently, several strategies were taken as well in order to enhance microbiological risk assessment. As part of the measures adopted for risk management also, taking in account the harmonization of food legislation, food standards and a re-evaluation of food-control procedures, regulations pertaining to food safety concerns have been developed where mostly are based from international standards particularly the agreements on SPS and TBT.

Mr Acosta also discussed the mechanisms involved between risk assessment and management as part of the third step being applied for in their risk analysis describing the newly established Multisector Commission of Food Safety (COMPIAL) which has been operating for approximately six months. The Commission is a tripartite body involving the three Ministries handling food safety aspects such as Agriculture, Health, and Production. The functions of these competent authorities, in addition to surveillance, are to perform the risk analysis of food that has been identified as hazardous to health, propose management activities and risk communication regarding these products in aspirant of establishing a preventative approach.

As an observation of the issues being encountered by the economy and also of the region, several proposals were identified by Mr Acosta putting emphasis on strengthening of surveillance methods, screening, and testing as well as appropriate prioritization of risks relevant to each participating economy.

As regard risk communication, he divulged that Peru does not have strong foundation for this aspect and only entails usage of this process during the time of an outbreak. Moreover, he mentioned that risk communication is carried out through COMPIAL as well, where civil society is represented by Peruvian Association of Consumers (PAC) having the main purpose of defending human rights on several matters including food safety and effective risk communication by addressing some barriers being experienced.

One delegate sought clarification on the presence of GM Food and risk assessment of such commodities Peru. He elucidated that GM Foods are not allowed in Peru and that risk assessment of such products has been put on hold for some time now.

People's Republic of China

Risk Analysis and Risk-Benefit Assessment Application in China was given out by Ms Yi Luo who serves as the Deputy Director of Food Safety Risk Analysis, Institute of Food Risk Management and Application, Chinese Academy of Inspection and Quarantine (CAIQ).

Ms Yi narrated how the risk analysis framework in China was established taken off from the enforcement of Food Safety Act on 1 June 2009 specifically providing guidelines on food safety risk analysis procedures as well as agencies tasked to carry out the said scientific process at the national level.

Food safety management model (**Figure 14**) in China was also presented by Ms Yi stating that under the State Council, a Food Safety Committee is present who will relay information to Ministry of Health (MoH). The latter will then perform collaborative efforts regarding food safety incidents with different agencies such as General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) tasks to oversee food manufacturers; State Administration for Industry and Commerce (SAIC), responsible for managing food distribution; State Food and Drug Administration (SFDA) in charge of overseeing food catering; and Ministry of Agriculture (MoA) accountable for supervising agricultural products.

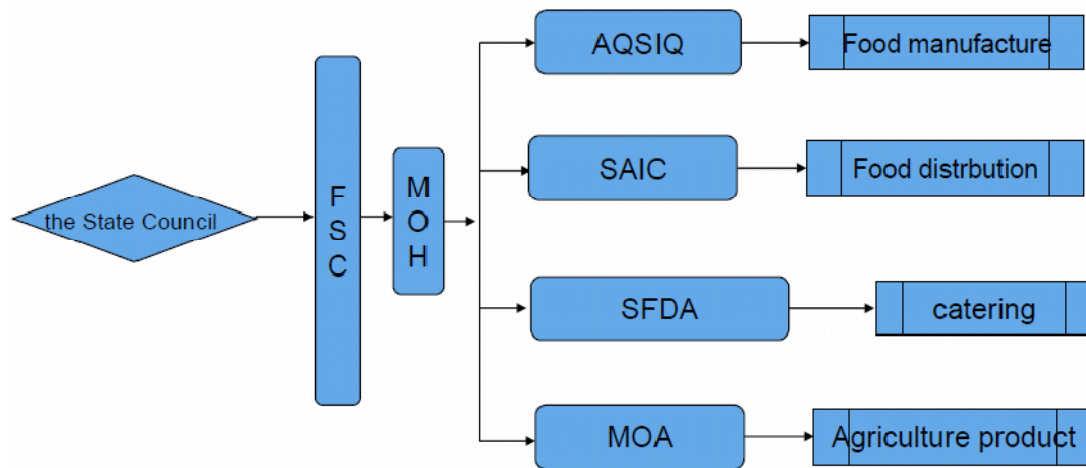


Figure 14. Food Safety Management in China

To show the delineation of function under the Food Safety Committee, risk management and risk assessment are explained to be handled by distinct offices. Certain agencies under MoH and MoA participate in conducting risk management in addition to AQSIQ, SFDA and SAIC. On the other hand, risk assessment is being performed by MoH and MoA.

Under the Food Safety Act, risk assessment department in China was detailed by showing the State Council having its own State Food Safety Risk Assessment Center where related tasks are being performed by MoH. Its works are said to be forwarded to the National Level Food Safety Risk Assessment where results gathered will be used for the establishment of national food safety standards like that of pesticide residues.

Ms Yi also presented several food risk management systems of China starting from AQSIQ where two related functions are being carried out such as the risk evaluation and risk management. The former covers import and export food safety issues, provision of advices to risk management, collection of food risk information and food manufacture risk assessment, functions which are being done by CAIQ. Meanwhile, risk management is jointly conducted by Bureau of Import and Export Food Safety, tasks to supervise food safety issues on import and export, and Department of Supervision on Food Production in charge of supervising process of food manufacturer.

On the other hand, risk management in MOH handles organizing of risk assessment, risk monitoring, drawing food security standard, risk prediction, and organizing risk

communication in comparison to MOA which mainly controls policies and advices on risk assessment for national agricultural products.

She then conveyed the risk management functions tasked for SFDA and SAIC respectively. SFDA according to her leads in directing relevant local work regarding food and drug administration, emergency response, inspection and information dissemination. At the same time, this agency is also responsible for carrying out international communication and cooperation related to food and drug regulation, whilst, SAIC takes charge of formulation of good practices, food hygiene licensing and food safety supervision at consumption stage.

She likewise, introduced the risk-benefit assessment of China by defining the following terms for better appreciation: *risk* as the probability of an adverse effect in an organism, system or (sub)population in reaction to exposure to an agent; *benefit* as the probability of a positive health effect or reduction of an adverse health effect in reaction to exposure to an agent; and *risk-benefit* when a food or food substance is recognized to have the potential to exert both health benefits and risks.

She proceeded by showing the proposed procedure for risk-benefit assessment and several cases this process had been used. The said procedure entailed similar steps as that of risk assessment like hazard characterization, hazard characterization, and risk characterization. Such steps will be compared against the additional processes that include positive health or reduced adverse health effect identification, positive health or reduced adverse health effect characterization and positive health or benefit identification. Such evaluation is named risk-benefit comparison.

She also made mentioned of the following practical application of risk-benefit assessment such as during observation of both positive and negative health effects on a single compound, observation of similar dietary exposures associated with both risk and benefit and when chemicals are used to reduce microbial contamination like disinfection process. Dwelling in this scientific protocol, she shared the proposed approach for this process involving three steps. Initially, the problem identified will be assessed and weighed for both the risk and benefit entailed. Either risk or benefit outweighs each other, the report will be sent back to the Risk-Benefit Managers (RBM) suggesting to stop the formulated problem. However, if upon assessment both the risks and benefits do not clearly outweigh each other, the report will be given back to RBM with recommendation of proposal refinement. Upon refinement, if the risk or the benefits had been found out be to outweighing each other, proposal will be halted and report will be given back to RBM. However if upon refinement of exposure, hazard or positive health effect and consideration of different populations, the risks and benefits do not still clearly show outweighing of each other, three choices will be given: (i) no conversion into composite metric possible leading to reporting back to RBM and holding of the proposal; (ii) conversion into composite metric possible but no data available advancing to reporting back to RBM and consequently identification of data needs; or (iii) conversion into composite metric possible with available data progressing to reporting back to RBM suggesting to refine proposal using composite metric. Consequently, upon comparison using composite metric, report will be given back to RBM with end of data need assessment identification. Currently, according to Ms Yi, this procedure is being applied for safety evaluation of drug quality in China having a description of high, medium or low as a means of further comparison of drug risk and benefit.

Her complete presentation is found in **Appendix 15**.

The Philippines

In behalf of the Philippines, Ms Catherine Cruz from the Food and Drug Administration (FDA) discussed the economy's experience in risk analysis (see **Appendix 16**).

She explained the regulatory function of the FDA, based on the Republic Act 9711 also known as the Food and Drug Act of 2009, such as establishment of standards and quality measures for food, adoption of measures that ensure pure and safe supply of food in the country at the same time prescription of general guidelines with respect to the veracity of nutritional claims and advertisements. She further elucidated that in terms of food safety aspects, two departments are leading its campaign, the Department of Agriculture (DA) and the Department of Health (DOH). The former covers the standards and practices that ensures safety of food products in the farm production while the latter, through the FDA is mandated to oversee and handle processed food safety. In addition, food safety program is as well participated and supported by Department of Science and Technology (DOST), academe, and consumer groups.

Ms Cruz then explicated that for the past several years, different foodborne challenges were experienced by the economy. She focused on water diarrhea cases which are considered among the top five morbidity cases reported nationally.

Moreover, she cited several factors that contribute to the development of food safety assessment in the Philippines such as series of food safety events, continuous emergence of risk, outbreak of an illness and standards development. As an address to the food safety issues presented, Ms Cruz highlighted that usage of risk assessment method by the FDA where she stated that in conducting hazard identification and hazard characterization, they use relevant literature and gather significant information about the contaminant present in food. Availability of relevant health standards is also taken into account. On the other hand, FDA is conducting exposure assessment noting the assumption, limitations and uncertainties of the study. Data being utilized in this process are those coming from the Food and Nutrition Research Institute (FNRI) of the DOST and the results gathered from the exposure assessment are then compared to established health standards. Inputs from stakeholders, relevant to gathered information from the assessment, are then considered gathered through consultative meetings

In the carrying out of risk analysis, risk communication is considered a challenge according to Ms Cruz. Although she relayed that an efficient risk communication plan is necessary and significant to the success of the whole process as this sets common understanding of food safety issues to both the regulators and stakeholders.

As part of their management to identified risks, advisories are issued by the FDA posted in their official website or announced in prime media like radio, newspaper or television. She also remarked that trained personnel are involved in communicating the risk or health implication observed in a food safety event. For clarity, Ms Cruz named some of the food safety issues faced by the Philippines for the past years such as aflatoxin in peanut butter, cyclamate in juices, melamine in milk and milk products, 3-MCPD in soy sauce, salmonella in noodles, and peanut butter.

Subsequently, she enumerated several challenges being faced as well by the economy regarding food safety system. Some included are food consumption data that are specifically

based on nutritional data available lacking information on food category, data gaps on food contamination and epidemiological data, insufficient number of experts capable to conduct risk assessment and emerging concerns such as emerging pathogens, nanotechnology, allergens, antimicrobial resistance, dioxin, mercury, melamine and other chemical contaminants. Such are already incorporated in strategies being developed for a more comprehensive risk analysis.

Republic of Korea

Dr. Hae Jung Yoon, Director, Risk Analysis Research Division talked about incorporating risk analysis in food safety control system in Korea. Her presentation is found in **Appendix 17**.

She mentioned that having a national food control system is essential to guarantee food safety and protect public health. To ensure that food is safe requires constant interference from government, including the industry and consumers. Based on risk analysis framework, food control in Korea has four key points, namely, laboratories, food legislation, food inspection and information exchanges among stakeholders.

She also stressed Article 15 of the Food Sanitation Act of Korea specifies the application of Risk-based regulatory framework. KFDA according to her adopts the Codex risk analysis framework. Risk Assessment is being conducted by National Institute of Food and Drug Safety Evaluation (NIFDS), while Risk Management is through the Food Safety Bureau. Both agencies are under the Korean Food and Drug Administration (KFDA). Similarly, NIFDS's Food Safety Evaluation Department provides core scientific infrastructure to KFDA and fostering scientific research. The department undertakes risk assessment in foodborne pathogens, pesticides residues, veterinary drugs, and contaminants through provision of peer-reviewed scientific research and related activities.



Figure 15: NIFDS Food Safety Evaluation Department Risk Assessment Activity

Likewise, prior to market release, food additive, GMOs and nutrient supplement, the department starts by method development for laboratory analysis and disseminate scientific information to stakeholders and regulatory partners. The work of the department is summarized by the **Figure 15**.

She also presented the some of the risk assessments conducted by KFDA in the past five years, mostly on assessment of pesticide residues. As regard on-going activities on chemical assessment of food, KFDA conducts survey on dietary intake of food additives by Korean population, e.g. tar colorant, preservatives and anti-oxidants. They carry out on the other hand Total Diet Study for pesticides and contaminants.

She also mentioned current and future activities of KFDA risk assessment. She pointed out that in addition to risk-benefit assessment, NIFDS is interested in carrying out aggregate risk assessment in the future particularly on the use of bio-monitoring (see **Figure 16**). They are also interested in relative ranking for chemicals to determine which chemicals need immediate research or monitoring, with heavy metals as first priority. The paradigm shift in the conduct of risk assessment in Korea is also noteworthy, i.e. shifting from sheer food monitoring/surveillance to integrated exposure survey to provide enforcement authorities more coherent inputs to the decision-making process (see **Figure17**). She also noted, that in 2010, KFDA launched a web-based tools, namely Monitoring Information Management System (MIMS) for collection of hazardous substances monitoring and Monitoring database and Assessment Program (MAP) as the dietary exposure assessment system of hazardous substances. She emphasized that Korea being one of the advanced countries in terms of technology likewise has developed some phone applications for risk profiles for their inspectors in the field.

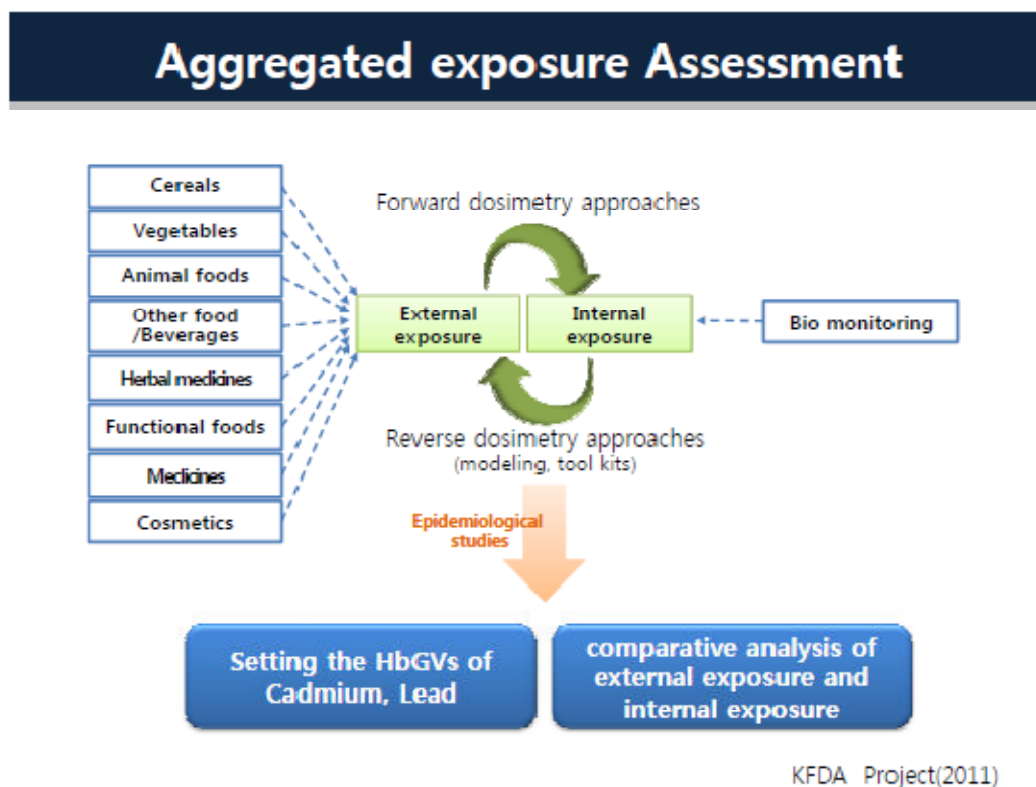


Figure 16: KFDA Aggregated Exposure Assessment

She concluded her presentation by introducing some of the international partners of KFDA in their work, e.g. USDA, FSANZ, APEC-FSCF, WHO, EFSA, CAC, and German Federal Institute for Risk Assessment by which they have signed a Memorandum of Understanding.

During the Open Forum a question was asked whether Korea or other economies which have conducted full risk assessment, has a program by which they are willing in assistance to review simple risk assessment or dietary exposure of developing economies. Korea doesn't have that system but however is willing to share their results of risk assessment to other economies.

Another delegate requested for clarification why KFDA has conducted more a hundred risk assessment of pesticides. She explained that pesticide has set MRL for each agricultural products and each product has standards that's why they have to conduct such many standards.

Another asked for the considerations of the KFDA in their in risk ranking of contaminants. She replied that as regard risk ranking for contaminants, they usually check hazard index, data reliability, and KFDA interests. Lastly, one delegate raised how KFDA evaluates functional and GM food. For functional food according to her, the company has to provide scientific data for food safety then KFDA reviews the documents prior to pre-market approval. Same is required for GM products evaluation.

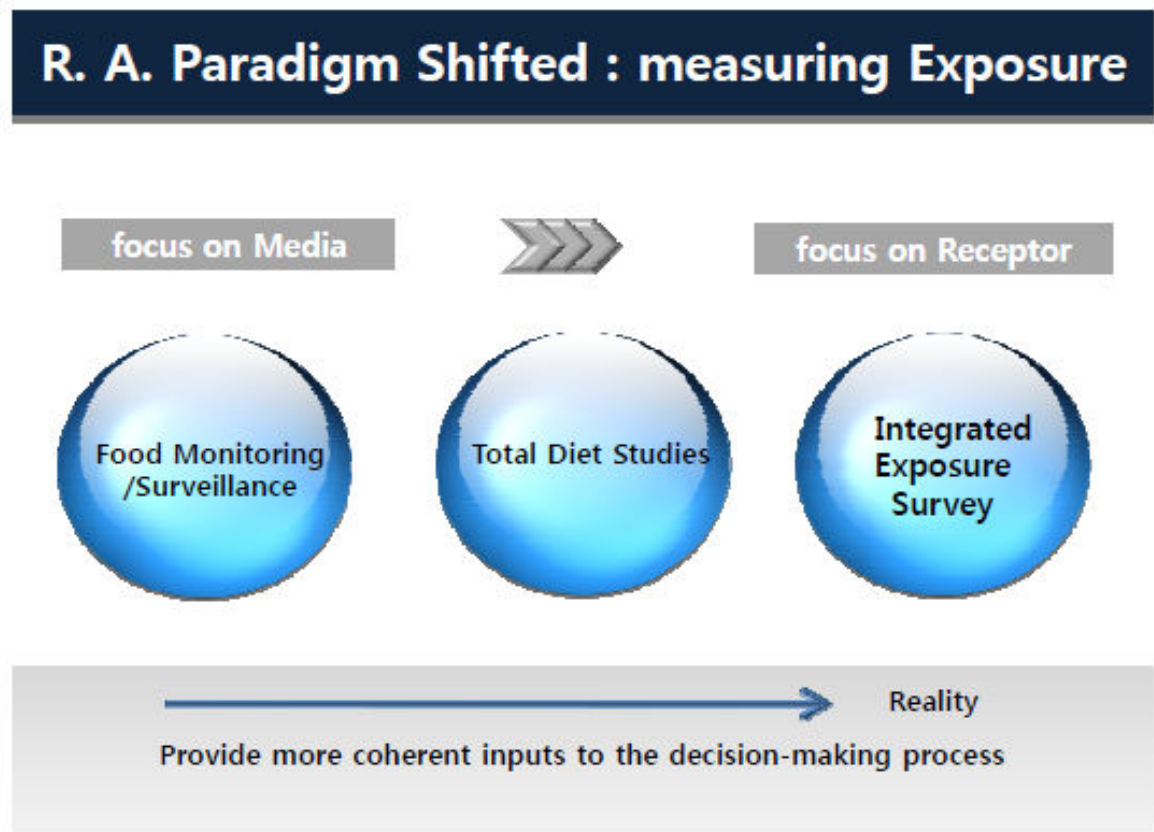


Figure 17: KFDA New Paradigm for the conduct of Risk Assessment

Russia

Mr Renat Selimov of Food Safety Department., Leningrad Interregional Veterinary Laboratory in Saint Petersburg presented the Developing State Monitoring Program as a tool for food safety risk assessment in Russia. His presentation is found in **Appendix 18**.

He commenced his presentation by noting the Food Safety Doctrine of the Russian Federation, to wit: “Food safety of the Russian Federation is one of the main trends to keep national safety of country, a key factor of maintaining its statehood and sovereignty, important component of demographic politic.”

The Federal Service for Veterinary and Phytosanitary Surveillance (FSVPS) also called Rosselkhoznadzor is responsible for surveillance in the area of veterinary and sanitary requirements for the safety of food of animal origin. FSVPS is the federal body of executive power, carrying out functions on control and supervision in the field of veterinary science. It is located in Moscow and carries out its administrative functions via Regional Offices and Border Control Posts. The laboratory network of the FSVPS includes Veterinary Laboratories and Reference Centers. The FSVPS also includes three Scientific Institutes.

He also enumerated some of the main functions of Rosselkhoznadzor, namely, veterinary and phytosanitary surveillance at the state border; state laboratory control; surveillance on the safety of drugs for animals, feeds and feed additives; state control of safety and quality of grains, combined feedstuff; advising for development of regulatory documents concerning diagnostic investigations and vaccination programmes; and cooperation with foreign authorities and risk analysis within imported animals, food and feedstuff.

The following shows the Veterinary authorities system in Russia:



Figure 18: Veterinary Authorities System in Russia

He further elucidated that among the number of sources of information for risk assessment as recommended by FAO Guide is the national food monitoring data. In the past the food safety control was mostly performed via analysis of processed products and inspection of processing plants. Such system is currently considered to be ineffective, because the prophylaxis aspect was not taken into account. At present time, attention should be paid to preventive measures for avoiding contamination of products with biological,

chemical, and physical agents at the stages of farming and all stages of food processing. He added another provision from the Russian doctrine of food safety, to wit: to maintain food safety it is necessary to control the compliance...of agricultural, fishery products at every stage of producing, storage, transporting, processing, and retail. Thus, special role should be carried out by monitoring – a system of planned observations in critical control points in order to identify problems timely and achieve necessary information to generate preventive measures covering all stage of food production.

Moreover, monitoring of imported food becomes a special part of the monitoring program because of the differences in criteria and estimating the food safety parameters in Russia with other economies, as well as in preparation in joining the WTO. He also enumerated some of the food items being tested as part of the monitoring program, e.g. cattle, sheep, pigs, poultry, horses, rabbits, wild animals, fish and aquatic animals, meat and meat products, dairy, eggs, honey and feedstuff.

He noted that sampling and moving samples to laboratories is the key element of any monitoring program, and is being performed by Regional Offices, covering all levels of production chain for domestic food, and separate part of sampling plan is dedicated to sampling from imported products. If necessary, laboratory results are confirmed in arbitrary laboratories for toxicology and GMO at State Centre for Quality and Standardisation of Veterinary Drugs and Feed (VGNKI) and virology at the Federal Center for Animal Health. The information on positive findings is collected at Central Scientific Veterinary Laboratory which is also the confirmatory laboratory for microbiology and then data is transferred to Central Office. He explained that in case of positive findings within domestic production the corrective actions are developed and implemented by FSVPS regional office in collaboration with local Veterinary Authority. However, in case of positive findings from imported production, it may lead to import restriction and/or introducing increased laboratory control for the production of the corresponding producer depending on the parameter failed. He showed that incompliance (or those tested positive) are usually found in meat and meat by-products both for domestic and imported foodstuffs.

The explicated that the general idea of future in increasing the Russian monitoring effectiveness is by the development of three-level monitoring program, which includes: 1) Federal level (target programs based on risk analysis and mostly covering imported and exported products); 2) Regional level (programs developed relying upon priorities in each separate region: regional veterinary authorities should maintain the control of domestic food producers); 3) Internal (self-) control by domestic producers. Similarly, he added the necessary conditions for effectiveness of monitoring program, i.e. traceability, urgent response to incompliance; development and update of documents regulating the monitoring process and decisions for violation cases; unification of methods, used within monitoring programs; and increasing the responsibility of producers

Lastly, a special concern is building and development of laboratory capacity which is a necessary requirement considering a great and permanently increasing number and variety of food safety parameters. In this regard establishment of Rosaccreditation in 01 November 2011, a newly-built accreditation body, whose main target is to achieve international recognition by joining the International Laboratory Accreditation Cooperation (ILAC) and accreditation to ISO 17025. This in turn will maintain international recognition of Rosselkhoz nadzor's laboratory results.

As clarification was asked on what is in-house developed method. He explained that in-house method designed in rule-type laboratory and checked in-house validation and inter-laboratory survey. Another question was asked whether Russia follows some WTO compliance rules given that they are still not a member of the WTO. He answered that Russia

checks the requirements and tries to comply with rules and regulations of its WTO-member trading partners.

Thailand

The Risk Analysis for Food Safety in Thailand was presented by Director Mongkol Chenchittikul, Bureau of Quality and Safety of Food, Department of Medical Sciences, Ministry of Public Health. His presentation will be found in **Appendix 19**.

In 2003, the Thailand food safety policy was declared with the aim to protect public health and to facilitate international trade. Food safety strategies and a road map on food safety covering the whole food chain were developed by the two main ministries, the Ministry of Agriculture and Cooperatives (MOAC) and the Ministry of Public Health (MOPH). Strategy of Food Safety System in Thailand is illustrated below:

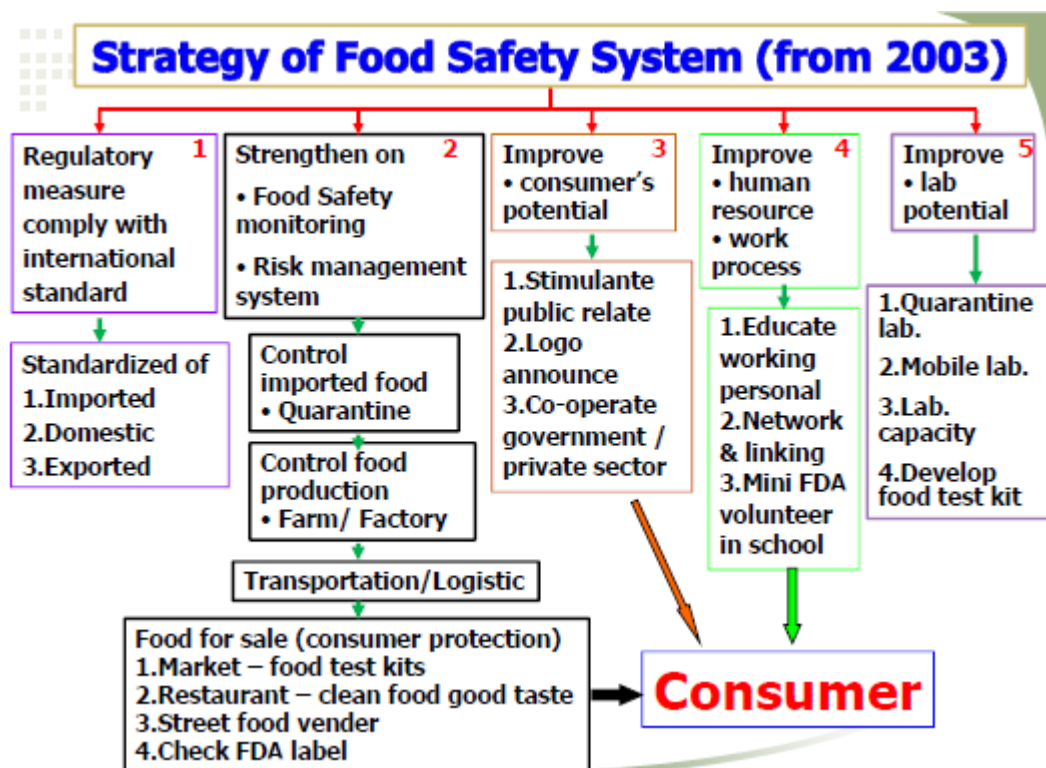


Figure 19: Thailand Food Safety System Strategy since 2003

In 2008, the National Committee on Food Act 2551 has been issued to establish National Committee on Food. This has resulted in an initiation of planning for a formulation of national policy direction and strategies to control, monitor and strengthen food quality control, food safety, food security, food education, and food alert system.

Responsibility for food safety is shared by everyone involved with food from production to consumption, including growers, processors, regulators, distributors, retailers, consumers, governments and scientific institutions. He also added that Thailand has a food control system in place that incorporates a number of essential elements: food laws, policies, regulations and standards; institutions with clearly defined responsibilities for food control management and public health; scientific capacity; integrated management approach; inspection and certification; diagnostic and analytical laboratories; standard-setting;

infrastructure and equipment; monitoring structures and capabilities; surveillance of human health problems related to food consumption; capacity for emergency response; training; and public information, education and communication.

The Thai food control system has been installed throughout the food chain. It consists of both mandatory and voluntary standards. At present, standards concerning food safety issued by most institutes are voluntary, only standards issued by Thai Food and Drug Administration are mandatory, by which legal action can be enforced to those who violate the standards.

Compliance to standards is verified by laboratory test result. Many government organizations, academic institutes and private companies provide testing services relating to food safety. Conformity assessment system to ensure reliability of test results has been installed through accreditation and proficiency testing schemes.

Moreover, surveillance and monitoring, inspection activities relating to food safety in Thailand are implemented by six departments of the Ministry of Public Health and the Ministry of Agriculture and Cooperatives. They are the Thai FDA, Department of Disease Control, Department of Health, Department of Agriculture, Department of Livestock Development, and Department of Fisheries.

As regard risk analysis activities, the Thai FDA and National Bureau of Agricultural Commodity and Food Standards (ACFS) play the role of “risk managers.” They have overall responsibility for ensuring that a risk analysis is carried out, as well as the ultimate responsibility for choosing and implementing food safety control measures. On the other hand, the Department of Medical Sciences (DMSc), some government organizations, and academic institutions act as “risk assessors.” They will use the best scientific knowledge available to support risk-based standards or other risk management options and described as characterizing the potential adverse effects to life and health resulting from exposure to hazards over a specified time period. Everyone though involved in a risk analysis is a “risk communicator” at some point in the process. Since 2003, Thailand has conducted several projects of chemical and microbiological risk assessment in food as shown in **Tables 1 & 2**. Safety assessment of genetically modified foods has been conducted for the past few years to ensure safety of the products allowed to be imported into the country.

Year	Host	Risk Assessment	Hazard	Commodity
2003	ACFS	Chemical risk Assessment	3- MCPD	Seasoning sauce
2003	ACFS	Chemical risk Assessment	Sulfure dioxide	Food
2003	ACFS	Chemical risk Assessment	Ochratoxin	Food
2003	ACFS	Chemical risk Assessment	Cadmium	Food
2007	Thai FDA	Chemical risk Assessment	Acrylamide	Food
2011	Thai FDA	Exposure Assessment	Sodium benzoate	Ready to eat food packed in plastic bag

Table 1. Food Chemical Risk Assessment in Thailand

Furthermore, in 2011, DMSc conducted a project of risk assessment plan and framework as part of the capacity building activities on risk assessment. Under this project, there are three meetings organized, established a risk assessment committee and three working groups of chemical, microbiological risk assessment and genetically modified organisms safety assessment. Everyone involved with food safety activities participated in the meetings to prepare risk assessment roadmap and framework include priority list of food-borne hazard, capacity building, and list of experts. One of the most profound examples under this project is the “Risk Assessment of 3-MCPD in Food to Thais.”

Year	Host	Risk	Hazard	Commodity
2002	ACFS	Exposure Assessment	<i>V. parahaemolyticus</i>	Shrimp
2003	ACFS	Microbiological Risk Assessment	Salmonella	Chicken
		Microbiological Risk Assessment	<i>C. jejuni</i>	Chicken
		Microbiological Risk Assessment	<i>V. parahaemolyticus</i>	Crab meat
2005	ACFS	Exposure Assessment	N/A	Consumption
2006	ACFS	Microbiological Risk Assessment	<i>L. monocytogenes</i>	Chicken
	BIOTEC	Microbiological Risk Assessment	<i>Staph. Aureus</i>	Nham Muu
2008	BIOTEC	Microbiological Risk Assessment	<i>V. parahaemolyticus</i>	Shrimp
	BIOTEC	Microbiological Risk Assessment	Salmonella	Vegetable
2009	BIOTEC	Hazard Characterization	Salmonella + <i>V. parahaemolyticus</i>	N/A
2010	Thai FDA	Microbiological Risk Assessment	<i>B. cereus</i>	Milk powder

Table 2. Food Microbiological Risk Assessment in Thailand

Viet Nam

Mr Trinh Minh Tung of Directorate for Standards, Metrology, and Quality (STAMEQ) presented the Food Safety Risk-Benefit Analysis in Viet Nam. His presentation is in **Appendix 20**.

He began his presentation by introducing relevant laws and directives related food safety in Viet Nam, namely: Law on Food Safety (No. 55/2010/QH12); Government Decree Guiding the Implementation of the Law on Food Safety; Circulars guiding the detailed implementation of Law on Food Safety; Mandatory-National Technical Regulations (QCVNs); and Voluntary National Standards (TCVNs).

Authorities responsible for food safety are the Ministry of Health – Viet Nam Food Administration (VFA) and Ministry of Agriculture and Rural Development – National Agro-Forestry and Fishery Quality Assurance Department (NAFIQAD). The former performs the function of state management of quality, hygiene and food safety for food products while the latter carries out specialized state management and executing management tasks in the field of quality and safety of agricultural, forestry, fishery and salt products.

He also mentioned some of the common food subject to risk analysis, namely foods of high poisoning rate; foods with samples taken for surveillance showing high rate of violating technical regulations on food safety; food production or trading environment or establishments which are suspected of causing pollution; foods or food production or trading establishments which are subjects to risk analysis to meet management requirements. Part of the assessment is the investigation and laboratory testing to identify microbiological, chemical and physical hazards including assessment of the extent of the hazards to the community's health.

Moreover, risk communication in Viet Nam involves providing information on preventive measures in cases of food poisoning or unsafe food-borne diseases to raise public awareness about and responsibility for food safety risks; notifying or forecasting food safety risks; building an information system for warning food safety risks, and food-borne diseases. He noted with the system in place, more than 300 enterprises qualified for export to the European Union market, more than 200 enterprises qualified for export to the Canada market and more than 400 enterprises qualified for export to the Korean market.

He also added that having a food safety system has profound effects to the market and economy by enhancing reputation and image of the business; raising customers' confidence; improving the export to international markets; reducing duplicate for testing, inspection, and control by importers and ensuring sustainable development; reducing costs associated with the risk of product recall and compensation to consumers; reducing costs of recycling and destruction of products through mechanisms of preventing, and detecting food safety risks at the early stage.

On the other hand, he also emphasized the difficulties faced by Viet Nam in establishing the food safety system, for instance, most of food production and trading establishments in Viet Nam are mainly small enterprises which have very limited resources for implementing various management systems and investing to new equipment and technology; awareness of food hygiene and safety is still very limited; and training for HACCP and other systems requires time and expenses.

In conclusion, he enumerated some of the future strategies of Viet Nam as regard food safety, for example, establishing a legal framework and implementation roadmap mandatory system: Good manufacturing practices (GMP), Good Agricultural Practice (GAP), Good Hygiene Practices (GHP), Hazard Analysis Critical Control Points (HACCP) and the management system of food safety and other advanced in the process manufacturing, the food business, providing information on measures to prevent the occurrence of food poisoning, food-borne diseases caused by unsafe foods; raising awareness about and responsibility of citizens for food safety risks, establishing an information system for warning food safety risks, and food-borne diseases, providing more training and consulting services on implementing food safety risks, developing a network of accredited food testing laboratories, developing and issuing

more TCVNs and QCVNs which are based on existing international standards and good practices.

A Quantitative Model for Risk-Benefit Assessment of Seafood Consumption

Dr David James, FAO Consultant presented the result of the FAO/WHO expert consultation in risk-benefit of seafood consumption (see **Appendix 21**)

The risk-benefit assessment of seafood consumption was carried in 2010 through FAO/WHO Expert Consultation to find scientific advice to member governments to the whole community regarding risk-benefit of fish consumption as there is growing concern regarding the presence of chemical contaminants in fish although at the same time, multiple nutritional benefits of fish consumption have become increasingly clearer with time. The risk is far more compelling than benefits making a headline and this type of reaction springing up in the press or televisions. Notable case was in the US where the conflict between advocate of eating fish and supporter of against it has been particularly strong – leading to an ill-informed community. As a result, public becomes confused. Mr James cited the infamous line from USA Today in 2007 on the outrageous claim: “600,000 children in the US annually are born with brain damage due to fish-eating mothers.” The statement was attributed to a US government employee and the USFDA was distraught from this claim. He explained that this statement has been made absolutely with no scientific evidence and although the evidence was already supplied to USA Today, they have not retracted the story as of yet, hence it is very difficult to get the “benefit” message across. Moreover, another interest group emerged pushing alternatives to fish without nutritional benefits of the other component of fish apart from the essential fatty acids. This led to request Codex Alimentarius Commission in 2008 to conduct risk-benefit assessment of fish consumption. The FAO/WHO accepted the challenge, held a small group meeting followed by an expert consultation composed of 17 members on January of 2010 in Rome. The consultation was tasked to review the data on nutrient and specific chemical [particularly MeHg and DLCs (dioxin and dioxin-like compounds)] as contaminant levels in a range of several fish species; review recent scientific literature covering the risks and benefits of fish consumption; and then consider the risk-benefit assessments for specific end-points of benefits and risks. The intention was to provide guidance to national food safety authorities and the Codex Alimentarius Commission specifically on managing risks related to eating fish, taking into account the growing accumulation of data on the benefits of eating fish. Similarly, expert consultation was mandated to provide (1) assessment of the health risks associated with the consumption of fish and other seafood; (2) assessment of the health benefits of fish and other seafood consumption; comparison of the health risks and health benefits of fish and other seafood consumption; (3) and to develop a methodology for carrying out quantitative assessment of the risks and benefits related to seafood consumption. The consultation was composed of seventeen experts in nutrition, toxicology, epidemiology, dietary exposure, and risk-benefit assessments, representing 11 economies and 5 continents.

He noted that qualitative assessment was relatively easy to carry out even quantification of risk, however quantitative assessment is much more difficult particularly for estimation of benefits.

The assessment commenced with the assumption that there is a convincing evidence that LCn-3PUFA (long chain polyunsaturated fatty acids) particularly DHA and the optimal brain

development during gestation and infancy and that maternal fish consumption during gestation and nursing lowers the risk of suboptimal brain development in their children. In addition to LCn-3PUFA, the consultation noted that fish is a good source of positive benefits of omega 3-fatty acids, multiple vitamins and minerals, low-calorie protein source, low-sodium heart healthy food, with hypothetical mercury risk. At the same time, the consultation also noted that maternal MeHg intake during gestation increases the risk of suboptimal brain development in their children.

Taking the above considerations, the consultation decided to conduct a comparison between the effects of prenatal exposure to LCn-3 PUFA and MeHg on child IQ to establish a dose-response relationship from multiple cohort studies available, leading to a quantitative risk-benefit analysis of fish consumption. Consequently, the meeting found that the neurodevelopmental risks of not eating fish exceed the risks of eating fish under most circumstances evaluated.

On MeHg risks, the three main meta-analyses studies that presented were the cases in Faeroe Islands, Seychelles, and New Zealand. The experts were looking for meta-analysis based on sufficient length of follow-up on IQ. He noted that data from Faeroe Islands has been questioned by the observation that people from Faeroe Island consumed large quantities of pilot whale (taken along their fish consumption) which has high level of Hg (mercury) and dioxin contamination. The following assumptions were made: serving size of 100g, body weight of 60 kg, ration of Hg in hair and daily MeHg intake ($\mu\text{g}/\text{kg}$ body weight/day) is 9.33.

Estimated changes in child IQ

2x 100g fish / week		EPA + DHA			
		$x \leq 3$ mg/g	$3 < x \leq 8$ mg/g	$8 < x \leq 15$ mg/g	$x > 15$ mg/g
Methyl mercury	$x \leq 0.1$ $\mu\text{g}/\text{g}$	-0.04, -0.2 +1.5	-0.04, -0.2 +4.2	-0.04, -0.2 +5.8	-0.04, -0.2 +5.8
	$0.1 < x \leq 0.5$ $\mu\text{g}/\text{g}$	-0.2, -0.9 +1.5	-0.2, -0.9 +4.2	-0.2, -0.9 +5.8	-0.2, -0.9 +5.8
	$0.5 < x \leq 1$ $\mu\text{g}/\text{g}$	-0.6, -2.3 +1.5	-0.6, -2.3 +4.2	-0.6, -2.3 +5.8	-0.6, -2.3 +5.8
	$x > 1$ $\mu\text{g}/\text{g}$	-1.2, -4.7 +1.5	-1.2, -4.7 +4.2	-1.2, -4.7 +5.8	-1.2, -4.7 +5.8

Table 3. Estimated Changes in Child IQ

As regard PUFA's benefits, Mr James enumerated the four analyses that were generally considered: Cohen et al 2005; FDA 2010; Oken et al. 2008; and Oken et al. 2008. They worked on the assumption that 28 g fish gives 100 mg (DHA average) and the DHA ratio of LC n-3 PUFA is 0.67. They observed from the studies on IQ increase/decrease, together with

additional experimental evidence reviewed separately, the Expert Consultation concluded that there was convincing evidence for benefits of maternal DHA consumption during gestation on neurodevelopment in their children. Here they observed that there is 4 IQ points gain per 100 mg/day DHA up to a maximum gain of 5.8 IQ points and the central estimate of IQ points decrease per $\mu\text{g/g}$ MeHg in maternal hair is 0.18 to an upper limit of 0.7.

On the estimated changes in child IQ, the experts took some time working out of way expressing the estimate succinctly. **Table 3** shows increasing PUFA levels and increasing Hg levels and the corresponding IQ point gain and IQ point loss for a child.

On the other hand, the **Table 4** shows several species of fish which are commonly consumed with corresponding PUFA levels vis-à-vis MeHg levels. Fishes like marlin, orange roughy, tuna and bigeye have considerable low levels of PUFA but at the same time high levels of Methyl mercury.

The Expert Consultation also considered dose–response data presented in several studies relating intake of EPA plus DHA to coronary heart disease mortality. Fish and EPA + DHA consumption lower the risk of Coronary Heart Disease (CHD) mortality whereas, high DLC exposure increases the risk of cancer. The result was established that CHD mortality benefits exceed theoretical upper estimate cancer risks for all frequencies and categories of fish consumption and DLC exposure evaluated.

While the experts consultation acknowledged the regional differences on fish consumption, nutrients including LCn-3PUFA and contaminants in fish including MeHg and especially DLCs, there is a need for more data. It is critical that national and regional authorities have specific information on nutrients and contaminants in fish consumed in their region.

Dr James also noted some of the recommendations of the expert consultation namely: member governments should minimize risks in target populations and acknowledge fish consumption as an important food source of energy, protein, and a range of essential nutrients and as part of the cultural traditions of many people; emphasize the CHD mortality benefits of fish consumption (and CHD risks of not eating fish) for the general adult population; emphasize the neurodevelopment benefits to offspring through women of childbearing age, pregnant women, and nursing others consuming fish and the associated neurodevelopment risks to offspring through such women not consuming fish; develop, maintain, and improve existing databases on specific nutrients and contaminants in fish consumed in their region; and to develop and evaluate risk management and communication strategies that both minimize risks and maximize benefits from eating fish.

Lastly, Dr James highlighted some of the conclusions of the FAO/WHO Expert Consultation which include: Consumption of fish provides energy, protein, and a range of essential nutrients, including the long-chain n-3 polyunsaturated fatty acids (LC n-3 PUFAs); eating fish is part of the cultural traditions of many people and in some populations is a major source of food and essential nutrients; among the general adult population, consumption of fish, particularly oily fish, lowers the risk of CHD mortality.

There is absence of probable or convincing evidence of CHD risks of MeHg. Potential cancer risks of DLCs are well below established CHD benefits; among women of childbearing age, considering benefits of LC n-3 PUFAs versus the risks of MeHg: fish consumption lowers the risks of suboptimal neurodevelopment in their offspring compared to not eating fish in most

circumstances evaluated. In order to lower suboptimal neurodevelopment: eat fish, but not eating fish is more damaging than eating fish.

EPA + DHA by total mercury

		EPA + DHA			
		$x \leq 3$ mg/g	$3 < x \leq 8$ mg/g	$8 < x \leq 15$ mg/g	$x > 15$ mg/g
Methyl mercury	$x \leq 0.1$ $\mu\text{g/g}$	Fish: butterfish; catfish; cod, Atlantic; cod, Pacific; croaker, Atlantic; haddock; pike; plaice, European, pollock, saithe, sole, tilapia Shellfish: clams; cockle; crawfish; cuttlefish; oysters; periwinkle; scallops; scampi; sea urchin; whelk	Fish: flatfish; John Dory; perch, ocean and mullet; sweetfish; wolf fish Shellfish: mussels; squid	Fish: redfish; salmon, (wild), salmon, Pacific (wild); smelt Shellfish: crab, spider; swimcrab	Fish: anchovy; herring; mackerel; rainbow trout; salmon, (farmed); sardines; sprat Fish liver: cod, (liver); saithe (liver) Shellfish: crab (brown meat)
	$0.1 < x \leq 0.5$ $\mu\text{g/g}$	Fish: anglerfish; catshark; dab; grenadier; grouper; gumard; hake; ling; lingcod and scorpionfish; Nile perch; pout; skate/ray; snapper, porgy and sheephead; tuna, yellowfin; tusk; whiting Shellfish: lobster; lobster, American	Fish: bass, freshwater; carp; perch, freshwater; scorpion fish; tuna; tuna, albacore Shellfish: crab; lobster; lobsters, spiny	Fish: bass, saltwater, bluefish; goatfish; halibut, Atlantic (farmed); halibut, Greenland; mackerel, horse; mackerel, Spanish; seabass; seabream; tilefish, Atlantic; tuna, skipjack	Fish: eel; mackerel, Pacific; sablefish
	$0.5 < x \leq 1$ $\mu\text{g/g}$	Fish: marlin; orange roughy; tuna, bigeye	Fish: mackerel, king; shark	Fish: alfonsino	Fish: tuna, Pacific bluefin
	$x > 1$ $\mu\text{g/g}$		Fish: swordfish		

Table 4. Species of fish with corresponding PUFA levels vis-à-vis MeHg levels

However, at levels of maternal DLC intake (from fish and other dietary sources) that do not exceed the provisional tolerable monthly intake (PTMI) of 70 picograms/kg bodyweight/month established by JECFA, the neurodevelopmental risk is negligible. At levels of maternal LC intake (from fish and other dietary sources) that exceed the PTMI, neurodevelopmental risk may no longer be negligible.

Only nine percent of DLC comes from fish, high proportions coming from dairy in the US whereas, in EU between 30 and 70% of DLC from fish (depending on the country and the dietary habits) but the important thing here is if you are above the PTMI of neurological risk it may no longer negligible. They didn't do anything about the population in general they were looking at CHD and neonates because the data among the infants, young children, and adolescents, the data available were insufficient to be able to derive a quantitative framework of health risks and benefits of eating fish. However, healthy dietary patterns that include fish established early in life influence dietary habits and health during adult life. Healthy eating pattern developed in early life will give you advantage in the future.

The complete FAO/WHO report can be downloaded on the following website: <http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf>

Several questions were raised during the Open Forum. One delegate asked whether a specific framework for the conduct of risk-benefit analysis was already available. Dr Janell Kause of

the US answered that the USFDA have already drafted a framework but is yet to be published, although preliminary results will be presented during her discussion of the US experience on Risk-Benefit analysis of fish consumption during pregnancy. Another delegate requested Dr James insights on the applicability of the FAO/WHO risk-benefit report to Asian/Southeast Asian people because the data on food consumption used in the FAO/WHO report was basically based on Western dietary pattern. Dr James replied that data considered cover a wide geographic regions, Faeroe in the Northern Hemisphere, Seychelles in the South Atlantic/Indian ocean and New Zealand in the Pacific. They also looked into some data from Japanese studies. Though according to Dr James it would be better to have data from Asia/Southeast Asian region. One delegate requested for additional information on traditional practices as presented. Dr James elucidated that it's important to consider traditional practices especially on data-gathering. One more delegate asked, considering the report of the FAO/WHO on fish consumption, if it's better to eat fish with contaminants than not fish at all. Dr James replied, depending on a circumstance, but as long as the level of contaminants is within the tolerable level, it is better to consume fish.

Risk-Benefit Assessment of Food: Fish Consumption During Pregnancy

Dr Janell Kause of the USDA commenced her presentation by emphasizing the points already raised by Mr James on FAO/WHO report on fish consumption. She also acknowledged her USDA colleagues and Mr Philip Spiller of USFDA, who is an expert on the topic.

She underlined that her presentation will highlight on the risk-benefit analysis itself, looking first and foremost at risk communication, subsequently at some of the miscommunications that occurred in the US and how science came in, some methodological issues and other broad issues that will come out.

According to Dr Kause, the risk-benefit analysis of fish consumption for pregnant women is a major undertaking in the US. It was designed to better understand the health consequences of developing nervous system of the fetus from a pregnant woman's consumption of fish. This initiative began out of concern that MeHg in fish eaten by pregnant women could adversely affect the neurological development of unborn children.

She highlighted few of the historical events that caused or lead to a risk management concern in the US, namely: poisoning events in Japan and Iraq in the last century demonstrated that at extreme levels of exposure, methylmercury can be highly neurotoxic and can easily pass on from pregnant woman to fetus and that fetus could be more sensitive than mother; and children exposed during pregnancy were often severely harmed, while mothers were only mildly affected. Consequently, in 1994, the US government put out a risk communication in great concern for the developing fetus to pregnant women: women who might become pregnant, nursing mothers, and young children on what and how much fish to eat to limit their exposures to MeHg: avoid four commercial species (shark, swordfish, King mackerel, and tile fish) with the most MeHg in US marketplace; not to eat more than 12 ounces/week (340g) of all other commercial species; do not eat over six (6) oz/wk (170 g) of albacore regardless how low of the MeHg does it might be.

There are two important points that Dr Kause highlighted surrounding the advice, that it was initially given in 1994, and still the advice that being given at present but they haven't updated as of yet. First the advice was not based on any quantitative risk assessment but

based on concern of past historical event that occurred. Admittedly, the US didn't know at that time why and how to conduct risk-benefit analysis hence they didn't have an idea of the extent or likelihood and severity of harm to unborn child when fish is consumed higher than or lower than the recommended amount during pregnancy. Second, researches (six of six studies) published after the advice was updated in 2004 gave the US contradictory information, that is eating fish during pregnancy would improve neurodevelopment in offspring. For instance, eating more than 12 oz (340g) fish/wk during pregnancy would become associated with more benefits than with risks compared to eating less than 12 oz.

On the other hand, three studies produced evidence of a "plateau" which demonstrate that beneficial effect apparently does not increase indefinitely in proportion to consumption. This prompted FDA to see new way to measure risk-benefit of a single food (e.g. fish) with countervailing beneficial and adverse effects on exactly the same health endpoint of fetal neurodevelopment. The new way is to measure the net effects of eating fish.

Moreover, Dr Kause explained that the Risk-Benefit Analysis Approach modeling used by the USFDA is based on generally accepted QRA techniques (RBA techniques), but with multiple dose-response functions, that is, there is an adverse dose-response function for MeHg, there is a beneficial dose-response function for "fish", and a dose-response function for the net effects that is a combination of the first two functions put together. The net effects in a dose-response curve could be adverse, neutral or beneficial, depending on the amounts and types of fish consumed. The FDA published the draft net effects in 2009 and is hoping to publish risk-benefit assessment in the near term.

In addition, Dr Kause enumerated some of the issues that they need to address with in order to conduct of Risk-Benefit Analysis are: (1) Dose Response Relationship – (where would the data for the adverse and beneficial dose-response functions come from?); (2) Measuring Endpoints (would it be possible to measure the net effect of fish consumption on neurodevelopment as a whole, or only on aspects of neurodevelopment; (3) Control Confounding; (4) Combining Countervailing "Effects"; (5) Common Denominator (how to develop a common denominator in order to combine and compare non-identical effects; (6) Combining Dose-Response Relationship (how to combine an adverse dose-response relationship with a beneficial dose-response function (given a common denominator) for the "net effects"; and (7) What is causing the beneficial effect? How to model it if the cause is unknown?

As for the Dose Response Relationship, the data involving humans comes from observational-type research published in peer-reviewed journals where studies measure either prenatal exposure to MeHg, or maternal fish consumption of fish or both. Dr Kause noted that one of the problems encountered with the data was that only summary data in journal articles was available; hence there was a need raw data to develop dose-response relationship. To solve the problem, the USFDA obtained the raw data directly from researchers. They negotiated with the researchers with adequate summaries e.g. at least six data points. However in the absence of raw data or the summaries of data, the US used the dose-response relationships developed by others.

As regard the measuring the endpoints, the USFDA encountered that it was not possible to model results from every possible test at every possible age in a single assessment, therefore, they only model the results on a few tests that could be regarded as representative of the net effects of fish consumption on neurodevelopment as a whole. In 2009 draft, FDA modeled

the net effects on early age verbal development and in the soon to be published report, they modeled some of the net effects on IQ.

The third challenge as specified by Dr Kause dealt with confounding issue, which is whether the data for the MeHg dose-response function was not being confounded by the beneficial effect from fish or vice versa. To solve the problem, FDA used the data from situations where the possibility of confounding was limited like extreme poisoning. Such a case was observed in Iraq, where exposure was 100x the average US exposure (due to bread made from seeds tainted with MeHg in a fungicide) though according to Dr Kause, the results cannot be confounded in fish. Studies in the Seychelles Islands, the Faroe Islands, and New Zealand, (where exposures were around 10x the average US exposure) showed the effects at high consumption levels beyond the plateau of the benefits of consuming fish can only be attributed to MeHg. She expounded that there is strong evidence that the dose-response function for the beneficial effect from fish is not linear, that it eventually flattens out to a plateau beyond that amount there are only effects that could occur from MeHg. She also added that for the beneficial effect of fish nutrient, FDA used data from studies of the benefits of fish and correct for potentially small effect of undetected MeHg.

Moreover, according to Dr Kause, the USFDA tried to combine effects from the same domain of neurodevelopment such as language skills among children of the same age and data on IQ for both adverse MeHg and beneficial effect (i.e. child by child results) in order to address the concern on how to match adverse effects data from one or more studies with beneficial effects data in order to combine them into a dose-response function for “net effects”.

Regarding the issue in coming up with a common denominator in order to combine and compare non-identical effects specifically dose-response function from adverse MeHg effect on age of first talking and beneficial fish nutrients effect on scores on tests of early age verbal development, the USFDA came up with was the use of z-scores by comparing different endpoints. Dr Kause explained that FDA converted results from both age of first talking and the early age verbal test scores in Z-scores. The Z-scores were then converted into IQ points multiplied by 15 (IQ size equivalents). If sum of the scores was positive then net effect was beneficial, however if the net effect was negative then it was taken as an adverse outcome.

Regarding the sixth issue on how to combine an adverse dose-response relationship with a beneficial dose-response function (given a common denominator) for the net effects, the USFDA adds dose-response relationships together based on the assumption that the adverse and beneficial effects on fetal neurodevelopment are independent of one another. She denoted that there was no data in human that provides evidence that the two effects interact, so where the sum of the two dose-response relationships was positive, the net effect was taken to be beneficial and where the sum is negative, the net effect was adverse.

The seventh and final challenge for the US in conducting the risk-benefit analysis was identifying the cause of the beneficial effect and how to model such effect if the cause was unknown. The Omega 3-fatty acids are generally considered as the primary candidate nutrient causing the beneficial effect but it was unknown whether other nutrients play a vital effect and to what extent. The USFDA approach was to treat all fish as identical packages of nutrients, identical benefits, and identical effects. They also assumed that all fishes only differ from one another in terms of the amounts of MeHg they contain. Dr Kause noted however that the assumption was unlikely to be correct, so as an option, the USFDA considered

performing sensitivity analysis in which it treated omega 3-fatty acids as the sole source of beneficial effect. In order to conduct the said analysis, the USFDA will do a dose-response function for fish benefits but the dose in any given situation will taken into account how much omega 3-fatty acids are in particular species of fish in addition to how much of that fish was eaten by pregnant woman.

Lastly, she pointed out that the recent FAO/WHO risk benefit analysis on fish consumption, like the US was also an assessment of the ‘net effects’, although not identical in some extent, the results were fairly consistent, take for instance the outcome of the draft 2009 assessment where only an estimated 1/10 of one percent of US children experience net effects that were adverse due to their mother’s consumption of fish during pregnancy. Also, in most cases, all other children whose mothers ate fish during pregnancy would experience a net benefit. These findings somewhat reflect or were fairly consistent with the FAO/WHO report. However, she also added that the final US risk-benefit report is yet to be published.

Taking into account that more benefits can be attributed to the consumption of fish [as long as there are low levels of MeHg], Dr Kause concluded the US wants to revisit advice to pregnant women on fish consumption. They will re-focus the 2004 guidance on how pregnant woman can maximize the benefit from fish consumption while minimizing the risk from MeHg.

One delegate inquired why the US had to do the more quantitative approach given the lack of data. Dr Kause replied that in risk assessment, risk analysis, or risk-benefit analysis, it’s ideal to be as quantitative as possible. She also explained that indeed much of the data utilized were from literatures, however, they have systematically reviewed all details and they have acquired enough information for the risk managers. What’s important was it the analysis achieved its goal. They are correcting their risk communication and they are making changes to the advice that brought forth confusion in the past.

Dr Kause’s presentation can be found in **Appendix 22**.

Cost-Benefit Analysis (CBA) in Food Regulation

The Cost-Benefit Analysis in Food Regulation was presented by Mr Jason March, Principal Economist of Food Standards Australia New Zealand. Copy of his lecture can be found in **Appendix 23**.

He commenced his presentation with a quote from Ronald Reagan on what accounts an economist, to wit: “an economist is someone who sees something that works in practice and wonders if it would work in theory.”

Mr March explained that economics is not actually a financial thing; it is more of a tool that used to maximize utility providing and making choices within various options.

According to Mr March explained the relationship between cost-benefit analysis (CBA) and risk-benefit analysis (RBA). He elucidated that CBA is more of policy purpose and has wider frame of references than RBA. The actual output of the RBA analysis will be striking to CBA. He added that CBA is a method of organizing information to aid decision makers about the allocation of resources. Some of the main features of CBA are: (1) CBA is

expressed in a common metric. This allows comparison. Common metric is not about producing things with money value but rather a practical step to achieve comparison of different options; (2) Concerned about the whole community. When they CBA, they make a reference point/frame as wide as possible. They typically do CBA to community, CBA to government, CBA to industry; (3) allows comparison of costs and benefits over time through discounting. RBA seems to be often in one time frame, while CBA typically done over a 10-year period. If the government is implementing a new set of policy, all the costs are always upfront say when educating the industry, upgrading their facilities, training their staff - all costs are upfront. However as regard benefits, it is typically extreme extending through time. He explained that it's not possible to add up benefits over the year so typically, they use the concept of discounting or sort of negative interest in a sense; (4) CBA attempts to value externalities and non-market goods. When building a factory for example, the cost of constructing the factory, employing people and the value goods to be produced are known, potential externality is when the factory is causing pollution. What CBA does is a holistic view. Aside from doing the financial analysis (e.g. how much profit to be gained in building the factory), it also does putting value in negative externality or the negative effects of building a factory like the cost of pollution, health effects to people etc. An externality occurs when one party imposes on others benefits that are not paid for or costs that are not compensated through market prices; (5) another benefit of CBA, it can be used to justify use of resources for a new project or as a part of an evaluation process after something has been implemented; (6) CBA does not attempt to diminish the role of the decision maker but rather acts as an advice to decision maker.

On why does Australia need to do CBA, Mr March explained that is a pretty much an Australian New Zealand context and may even find in other economies like the US, Canada, UK, the Netherlands and some OECD member governments. CBA is part of the Best Practice Regulation guidelines (Regulatory Impact Analysis) as administered by the Council of Australian Governments (COAG). The role of COAG is to initiate, develop and monitor the implementation of policy reforms that are of national significance and which require cooperative action by Australian governments. The FSANZ Act also requires doing CBA. Similarly, stakeholders become receptive to new policies when CBA is available, hence, it becomes customary to perform CBA to address their expectations.

Moreover, Australia has the Office of Best Practice Regulation (OBPR). The OBPR promotes the Government's objective of improving the effectiveness and efficiency of regulation. It plays a central role in assisting Australian Government departments and agencies to meet the Australian Government's requirements for best practice regulatory impact analysis and in monitoring and reporting on their performance. It is required to assess whether a Regulation Impact Statement (RIS) is required. Therefore, a policy officer should contact the OBPR early in the policy development process to ensure that they meet the Australian Government's or COAG's requirements for best practice regulation. And within FSANZ, it is the Regulatory Analysis Unit (RAU) in the Economic Section has the role of contacting OBPR as regard compliance to regulatory practices. The role of the RAU is to lead FSANZ in delivering robust regulatory impact analyses.

Mr March also introduced the concept of developing the Regulatory Impact Statement (RIS). It is the framework by which CBA is incorporated. Preparing RIS includes identifying the (1) problem; (2) objective; (3) options to compare non-regulatory options, justify self-regulation, options on increasing severity; (4) impacts; (5) consultation which composed of stages; (6) recommendation, and (7) implementation and review. As regard consultation, in general, any

policy development process, including proposed new regulation or changes to regulation, will involve consultation with relevant stakeholders, including the main parties affected by the proposal: business, the not-for-profit sector, the community, regulators and other government agencies. Consultation starts with Preliminary Assessment Report. For example when a company applies for new sweetener and FSANZ identifies it to be safe for use, then, it is no longer necessary to do RIS. However for instance when a traceability policy will be put in say eggs and certain cost will be transfer to the community then OBPR will ask FSANZ to do a RIS. There are two RIS reports, first is the Consultation RIS and the more detailed Decision Making RIS which is published after the decision making process has been made and is publicly available on websites.

He also enumerated some of the major work they carry out: (1) in addressing information gaps, they conduct internal research through published reports, studies, and papers. They also do consultation with industry lobby groups. Although often you don't get the true story because they have a position that they want to get across, but he finds extremely helpful to talk to people in the field because you get to know valuable information first hand. For instance, when you are trying to enforce a food safety system, more often than not, the industry has already put 95% of that system and you will have an idea for how much still the cost to implement the remaining balance. Likewise, they also communicate with state government agencies to know the cost of enforcement or what is called activity-based costing. Although according to Mr March, sometimes this activity can also be difficult. Additionally on the occasion that something is highly contestable involving doubts in the science, they commission consultants, usually top scientists to do research and analysis to validate a work; Moreover, they (2) continuously in consultation with OBPR for direction & guidance. He noted that the more that a policy will have an effect to the economy, the more analyses that OBPR requires; in doing a project, from the very start, they (3) work closely with scientists and multidisciplinary teams involving risk assessors, risk managers, economists, lawyers, and risk communicators to be holistic in their approach; and (4) meet with key stakeholders. He noted that this is a policy process that needs to be open and transparent to meet the requirements of the OBP; lastly, they make sure that the (5) RIS must have sound analysis, allow informed decision-making and as much as possible transparent.

On the reason why they want to do CBA, one, because it is necessary to make right decisions more often. Although CBA is a rigorous process, he emphasized that when an opportunity arises to make a change to address the problem, it is important to hit the target when you get the opportunity to do so. Another, CBA forces them to challenge conventional wisdom and establish causation and assists decision making by making it more open, rigorous and much less likely to be captured by sectional interests.

In addition, Mr March also relayed the concept of "Real World Outcomes" as put forward by Dr Bridget Hutter of the London School of Economics and Political Science. One of the topics she relayed was the regulatory capacity of a business. In Australia, standards are outcomes based rather than prescriptive. What Dr Hutter found out in UK between big and small business, the latter does not have the capacity to comply with outcomes based standards compared to big business, hence regulatory design should see beyond the scientific component but the actual effect to the real economy, what's the "real world" effect or what are the outcomes going to be. The second point Dr Hutter made was in understanding the relationship between the regulation and the main actors is to understand who will be implementing and enforcing. Mr March noted that in Australia, a lot of the implementation and enforcement are done at the local government area, for example the Environmental

Health Offices. But they can't know everything, so according to March, they need to tap the expertise of the people on the ground who actually implement, enforce regulations, and educate the industry because small businesses can't afford to have consultants. Mr March elucidated that regulatory offices tend to do more and more regulation without asking if the current regulation is in fact being implemented at all. As regard understanding how the consumers likely to respond to regulations, he pointed that this is all about causation. Assumptions cannot be made on how humans will respond, what is needed are scientific evidences.

He also enumerated some of the challenges in doing CBA. According to him, regulation as a tool has an innate qualities. The problem with regulation is it keeps on pushing a lot of costs to the consumers and could even push more costs back to the industry. What CBA is telling regulators is when to stop. Mr March explained that at least in Australia, they are getting in the point where often they make the decision when to stop particularly when something is not sensible to do because of the "low hanging fruit" have already been sold out. Another challenge is the production and distribution of food is getting more complicated. The problem is where in the production chain that needs more intervention to get a reasonable reduction of risk at a reasonable cost.

As regard the tools and methodologies, Mr March pointed out that CBA provides better understanding of the intangibles, and this is what he and his team is currently doing an analysis. At present, they are doing a mapping on it, trying to figure out what they are not measuring, where they have methodologies and where they haven't. The second area where they put a lot of methodology is health economics. This is where the concept of quality adjusted life years comes in. So they start measuring a small effect in health across the population. Other tools are behavioral economics and reconsideration of the valuation techniques that underpin CBA. He also mentioned some of the strong relationships and partnership that FSANZ sustained particularly with economies with similar regulations as Australia like the Quad – US, Canada, UK and New Zealand.

In conclusion, Mr March explained how their work on CBA relates to science. Indeed the scientists still provide information on the number of illnesses, severity of illness and effective interventions. Some groups even question the CBA process as not so scientific but just merely guest estimates. He however emphasized that CBA provides the best guesses, because in situation where no information exists it's still better to work with something than not at all. He summarized his presentation by citing Dr Bridget Hutter of LSE that CBA can be considered an extension of risk management, in that technical intervention and real world outcomes are just as important to ensure the intended effect where the benefits outweigh the costs.

During the question and answer, one delegate asked for further clarification on the methodological problems that exist in measuring certain costs and benefits and some examples of CBA. Mr March cited that one of the problems is expressing CBA quantitatively in one common metric, which is not always possible. There is a range of tangibles that cannot be captured in the analysis which is always the source of contention. So sometimes in exploring methodologies to be used, they still borrow some in other fields of economics particularly for food safety which is very complex. Some of the examples of CBA are available in the website of OBPR. One example of CBA that he had been involved was on the establishment of traceability system for eggs in Australia.

Low Incidence High Impact Events-Seed Sprouts-Cost Benefit Analysis

Mr Jason March of FSANZ talked about the case study in Australia in the conduct of CBA in food regulation (see **Appendix 24** for his presentation).

He commenced his presentation by providing a distinction between the Risk and Uncertainty. Risk is the actual outcome is not known but the probability of various possible outcomes can be estimated; whereas, uncertainty it is not possible to estimate a probability distribution of outcomes.

In CBA, there are four types of decision making: with certainty, with risk, with uncertainty, and in ignorance. On the other hand there are three approaches to uncertainty: (1) does a compelling justification exist mentioning precautionary principle (not popular to Australia nor the European); (2) sensitivity analysis; (3) game problems in an economic sense.

As regard the Precautionary Principle, in the Australian context issues is there a compelling reason to act despite uncertainty. Example as applied in articulating security context in when talking about terms of security spending models, when the government will cost benefit analysis will now have idea on how much to spend. As this precautionary principle, this notion of precaution is based upon the assumption that in certain cases scientific certainty, to the extent that it is obtainable may be achieved too late to provide effective responses (OECD Joint Working Party on Trade and Environment 2002).

Sensitivity Analysis is a method being used in risk analysis in the same way as in economics. Values included in a cost benefit analysis are typically “most likely” or “best estimates” in the model -- these can be varied across a range you are reasonably confident contains the true value. Therefore, according to him, you can run the figures and provide the different estimates. If the sum is strongly positive you will have fair ideas; while if the sum is all negatives then there is a great concern. The second sensitivity analysis is switching values of key variables can be estimated so this is the break-even analysis. For instance, if you are unsure about the level of effectiveness of intervention you could find a model and say at what point and what level of effectiveness you need to perfectly offset the risk with the benefits. On Game Problems, therefore have series of outcomes and assumed probabilities, and scenarios. If you got no knowledge on the options, you can make choices on different levels of risks vis-à-vis options.

On Case Study of Seed Sprouts: Mr March said that they have severe data limitations; consumption of seed sprouts was associated with two foodborne illness outbreaks in 2005-06 in Australia. The first outbreak resulted in 125 reported illness cases whereas the second outbreak involved 7 reported cases - assumed to be around 987 cases due to their knowledge of under reporting. The cost per case was estimated to be \$2,165 AU on average. Therefore the overall cost was around 2.1 million AU (See **Table 5**).

What they know about seed sprouts: that outbreaks can and do happen and they are clearly detrimental to human health (clear rational basis for concern); that outbreaks have occurred in Australia and in numerous overseas locations; the size and timing of outbreaks have been highly variable. What they don't know: the likely size and timing of future outbreaks; the actual effectiveness of our proposed regulatory intervention. And the challenges: not widely eaten compared to other types of foods is the attribution (micro industry); and voluntary changes had been made by the industry, information is hard to obtain. Some of the options

considered are status quo; industry self-regulation; measures for seed processors, seed processors and sprout producers; and, measures for sprout producers only.

Cost	Amount (2011\$ AU)
Productivity Loss	\$ 638,016
Gastroenteritis individual welfare cost	\$290,803
Sequelae individual welfare costs	\$372,090
Less allowance for double counting	\$-95,702
Total business and individual costs from illness	\$1,205,208
Cost to industry	\$675,339
Costs incurred by government/states	\$256,789
Total cost	\$2,137,335
Cost per illness	\$2,165

Table 5. Cost Estimates of Seed-Sprouts Outbreak in Australia

A compelling story, two outbreaks have occurred and there maybe have been more; microbiological testing has since detected a range of pathogen on sprouts; whilst action has been taken by some we did not assume risk was evenly distributed, industry wants regulation. They had Japanese radish sprouts outbreak in 1996 there were 12,680 illnesses and three deaths due to *E. coli*; in the USA between 1995-2010 there were 2,046 reported cases and three deaths due to *Salmonella*; and German outbreak in 2011, there were 3,910 illnesses and 46 deaths as at July 2011 due to *E. coli*.

Likely effectiveness of the intervention again is highly problematic as the likely effectiveness was assumed to be in a range between 23% (state level) and 65% (HACCP system implemented) reduction in disease in Australia. A mean rate of effectiveness was estimated at 44%.

The numbers of actual illness from game modeling on a micro-industry (40 businesses) in the context of burden of illnesses/creating potential disasters; they vary them for the value of effectiveness and also vary the discount rates. The discount rates can be contentious when compared to seven percent because obviously the higher the discount rates the larger the value of future benefits, it does have effect on the outcomes. They predict the cost at different discount rates.

On Break Even Analysis, a simple model was shown, and a simple algebraic expression has been used and using an excel program set dummy variables and use excel function.

On Game Problems, they approached Professor Jim Butler from Australian National University because what they are doing at first regarding outbreaks in Australia, they will make some assumptions, say this such outbreaks occur every two or five years, hence their assumptions are unnecessarily limited to the past disease in Australia. Their analysis did not take into account the endemic as opposed to the epidemic component of the total number of cases caused by sprouts in Australia. So it reached a situation that they didn't know, so they need to used some expert opinion to put together to have probabilistic model of what they

thought. They used expert opinion by using past outbreak data to estimate size and relative chance of occurrence and converted an unknown into a subjective probability.

In conclusion, the CBA process is a policy one not a scientific one and a decision needs to be made and insufficient scientific information exists; what limits of information made clear to decision makers; and they used multiple techniques like sensitivity and break even analyses were used to provide the best guidance possible.

During the Open Forum, one delegate asked how Australia estimates the value of human life during the conduct of CBA. Mr March replied that they based it from a across all policy areas. There is a paper from the OBPR and the value is around 3.5million dollars. Though he emphasized that such approach is still really problematic. It depends upon what context are you talking about, say industry safety, food safety and you get a huge range of values from 3-11million dollars. He added that there's a plan to explore the valuation in the future. Some believe that the value should be higher than the OBPR's. But basically there is a correlation between the lack of control of the situation and the amount that they are willing to pay to avoid the risk.

Another asked for the sources of FSANZ in getting the costs for the industry in the prevention and for the government in regulation. In the sprout case, he said that New South Wales got the actual costs for regulating and they upscale such costs for the whole economy. For industry, they asked them through a questionnaire, though he said that sometimes this is problematic, so they request industry experts to do the costing. There are also some tools available like the business tool calculator. It breaks intervention into different elements which in turn gives you costing for each and often the result is used in their questionnaire as well.

A further clarification was requested on why it necessary to conduct CBA when the presumption is that the benefits will always outweigh the costs. Mr March explained that in the sprout case, they did it for all options. There was a paper from industry and government that the cost will be quite high if they applied the approach. However, CBA will provide scenarios whether such regulation will be helpful to the economy of the place. It gives decision makers some guidance to proceed or not to proceed with the regulation.

WORKSHOP

Participants were grouped into four and were asked to respond on the following questions:

- What is the strongest point of doing risk-benefit analysis that may be incorporated in the traditional risk analysis?
- What is the possibility of adopting risk-benefit analysis in your food safety system in the future?
- If it is possible to have a follow up seminar workshop, what would you recommend to APEC Food Safety Cooperation Forum (FSCF) as a follow up activity?

Workshop output is found in **Appendix 25**.

CLOSING CEREMONIES

Ms Angelina A. Bondad, OIC Director of BAFPS conveyed her closing message. She noted that in response to the rising international issues concerning food safety and public health, APEC member economies are continuously formulating regulations and guidelines that would address the need of the public demand particularly on the provision of assurance that food being offered are safe to eat and of best possible quality. She also added that risk-benefit analysis may be a new and a work in progress, but it may possibly provide a more comprehensive and balanced scientific advice both to the regulators and consumers, and therefore is worth exploring. She wished that this project will be the beginning of many more partnership to attain shared goals and interests in the region.

Mr Israel Dela Cruz, Project Overseer, officially closed the seminar-workshop, extending his gratitude to all the people who made the project possible, particularly the Project Team, composed of the staff of the Bureau of Agriculture & Fisheries Product Standards and his friends from WFP, FAO, FSANZ, Russia, and the USDA. Aside from meeting the goals of the Seminar, he hoped that it was also utilized by the participants to network and make friends with other delegates.

Appendix 26 for the Program of Activities.

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