



**Asia-Pacific  
Economic Cooperation**



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

# SEMINAR-WORKSHOP ON THE DEVELOPMENT AND STRENGTHENING OF FOOD RECALL SYSTEM FOR APEC MEMBER ECONOMIES

Manila, Philippines  
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**Committee on Trade and Investment (CTI)/Sub-Committee on Standards and Conformance (SCSC)  
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Prepared by:

**BUREAU OF AGRICULTURE AND FISHERIES PRODUCT STANDARDS**

BPI Compound, Visayas Avenue, Diliman

Quezon City Philippines 1101

Tel: (632) 920 6131; (632) 455 2858; (632) 467 9039

Fax: (632) 920 6131; (632) 455 2858

E-mail address: [bafpsda@yahoo.com.ph](mailto:bafpsda@yahoo.com.ph)

Website: [www.bafps.da.gov.ph](http://www.bafps.da.gov.ph)

For:

**THE ASIA-PACIFIC ECONOMIC COOPERATION SECRETARIAT**

35 Heng Mui Keng Terrace Singapore 119616

Tel: (65) 68 919 600 Fax: (65) 68 919 690

E-mail: [info@apec.org](mailto:info@apec.org)

Website: [www.apec.org](http://www.apec.org)

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## ABBREVIATIONS

AFSN	ASEAN Food Safety Network
AO	Administrative Order
APEC	Asia Pacific Economic Cooperation
ARASFF	ASEAN Rapid Alert System for Food and Feed
ASEAN	Association of Southeast Asian Nations
AVA	Agri-Food and Veterinary Authority of Singapore
AI	Avian Influenza
BAFPS	Bureau of Agriculture and Fisheries Product Standards
BAP	Best Aquaculture Practices
CFSAN	Center for Food Safety and Applied Nutrition
EMA	Mexican Accreditation Entity
FAFST	Foundation for the Advancement of Food Science & Technology Inc.
FAST	Food Alert System of Thailand
FPA	Fertilizer Pesticide Authority
FSANZ	Food Standards Australia New Zealand
GAHP	Good Animal Husbandry Practices
GAIN	Government, Academe, Industry and NGO
GAP	Good Agricultural Practices
GLP	Good Laboratory Practices
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practices
HHS	US Department of Health and Human Service
IAMS	Information Agenda Management System
IEC	Information, Education Communication
INFOSAN	International Food Safety Authorities Network
KFDA	Korea Food and Drug Administration
MOA	Ministry of Agriculture
MOH	Ministry of Health
MRL	Maximum Residue Levels
NADFC	National Agency for Drug and Food Control (NADFC)
NGO	Non Government Organization
NSWFA	New South Wales Food Authority of Australia
NSRI	Natural Sciences Research Institute
PFSE	Partnership for Food Safety Education
PPP	Primary Production and Processing
UM	University of Maryland
UP	University of the Philippines
USFDA	United States Food and Drug Administration
WHO	World Health Organization

# SEMINAR-WORKSHOP ON THE DEVELOPMENT AND STRENGTHENING OF FOOD RECALL SYSTEM FOR APEC MEMBER ECONOMIES

Project No. CTI 55/2009T  
The Richmond Hotel, Ortigas Center, Manila, Philippines  
4-6 May 2010

The project on Seminar-Workshop on the Development and Strengthening of Food Recall System for APEC Member Economies, hereinafter referred to as the Seminar, was implemented by the Bureau of Agriculture and Fisheries Product Standards (BAFPS), Department of Agriculture (DA) on 4-6 May 2010 at the Richmond Hotel, Ortigas Center, Manila. This undertaking was sponsored by the BAFPS and the Asia Pacific Economic Cooperation (APEC) Organization as one of the capacity building activities of the APEC Food Safety Cooperation Forum (FSCF) under the Sub Committee on Standards and Conformance (SCSC).

There were 42 participants from 15 APEC member economies and four participants from non-APEC member organizations. Representative member economies were from Australia; Brunei Darussalam; Chile; Chinese Taipei; Indonesia; Malaysia; Mexico; Papua New Guinea; Peru; the Philippines; Republic of Korea; Russian Federation; Thailand; Viet Nam; and the United States of America. Non-APEC member organizations were the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO).

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), University of Hawaii (UH) at Manoa, the FAO and WHO.

The project overseer was Director Gilberto F. Layese 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.

## INTRODUCTION

Food recall is the action taken to remove from sale, distribution and consumption foods which may pose an unacceptable risk to public health and safety. Food recall must be taken seriously as it greatly affects trade among economies, causing large economic losses both to exporting economy and that of the company. At present, there are widespread programs in strengthening different national food safety systems, but little has given importance to strengthening and development of effective food recall system particularly among APEC member economies. Every year many food manufacturers, distributors, retailers and importers within the region are faced with the prospect of conducting a recall. This Seminar intends to explore the current situation on food recall systems in place among APEC member economies and identify possible actions (or projects) that are needed to strengthen food recall in the region. It also aims to update recall standards among participating economies and focuses mainly on enhancing capabilities of key government officials among APEC member economies in developing recall protocols. This Seminar also complements the works of Codex Alimentarius Commission<sup>1</sup> especially on implementation of Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC GL 19-1995) and Codex Code of Ethics for International Trade in Food (CAC RCP 20-1979, revised 1985).

The Seminar was comprised of four main components namely lectures, case study presentations, member economy experiences and workshop. The major topics during the three-day seminar workshop were UN Programs on Food Recall, Food Incident Management in Australia, Meat and Poultry Recalls in the United States, USFDA Food Recall Protocols and Overview of Risk Communication in Australia. The program of activities is in **Appendix 2**.

## OPENING CEREMONIES

In behalf of the DA Secretary, Hon. Bernie G. Fondevilla, Assistant Secretary Preceles H. Manzo of the Office of Policy and Planning formally welcomed the delegates and opened the ceremony.

Asec. Manzo cited that despite the increasing popularity of food safety issues, majority of the world's population are still unaware, if not, are still on the stage of being nonchalant on the issues, not grasping the importance and gravity of its effect on one's life. The recent food incidents like the melamine-tainted milk and peanut butter contaminated by *Salmonella*, raised the concerns about effectiveness of current food control systems in protecting consumers and sparked increasing attention to the regulatory frameworks that govern food safety and food trade. These heightened consumer interest in diet-related health issues. At the same time these also challenged the government agencies around the region to come up with a competent strategy for an effective food control system especially on food recall policy. The full text of the Welcome Speech of Asec. Manzo is shown in **Appendix 3**.

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<sup>1</sup> Joint FAO-WHO Food Standards Programme



Dr Soe Nyunt-U, WHO Representative to the Philippines gave a message on behalf of the World Health Organization. In his message, with the advent of globalization and hence the greater accessibility and diversity of food available to consumers, there is also a high possibility of cross-border distribution of food that is not safe. Hence, food outbreaks which were once limited to local communities, can now affect several economies. He also stressed the importance of partnerships among WHO, its member states, other United Nations (UN), and fora like APEC and Association of Southeast Asian Nations (ASEAN) in developing effective national food control programs with the overall goal of improving public health through the reduction in foodborne disease. Sharing information, experiences and expertise are essential for achieving success in this goal. He also acknowledged the importance of preventive action as part of an effective food control system to avert foodborne disease caused by unsafe food.

Dr Soe's speech is attached as **Appendix 4**.

Ms Emiko Purdy, Agricultural Counselor of the USDA, on the other hand, also affirmed the importance and usefulness of sharing experiences by the more advanced economies with established and effective recall systems in streamlining existing and established food recall processes in the region.

Ms Purdy also cited the commitment of APEC Economic Leaders held also in Peru in 2008, where they "reaffirmed our commitment to improve food and product safety standards and practices to facilitate trade and ensure the health and safety of our populations." This Seminar is another step forward to strengthen national food safety systems among APEC member economies.

Her speech is shown in **Appendix 5**.

The Seminar proper was set off by the presentation of seminar-workshop details and mechanics by Mr Israel dela Cruz, the project manager and over-all coordinator.

Mr dela Cruz described the overall objectives of the Seminar and the expected deliverables of the project, i.e. information detailing current recall practices, recall programs/regulation, experiences from the member APEC economies, Strengths Weaknesses Opportunities Threats (SWOT) analysis of recall system in APEC and possible future APEC activities sustaining the initiatives of this project. He expected that the participants will use the knowledge acquired in this Seminar as tools to improve their respective government or organizations' competency in the area of food recall.

Mr dela Cruz further encouraged the participants to use the Seminar to expand their network of regional colleagues whose expertise rest on food recall. The full seminar mechanics presentation is found in **Appendix 6**.

## PRESENTATION AND PLENARY

### Food Recall Overview

Dr Sonia de Leon, the Project Consultant gave an overview of food recall. Her presentation is attached as **Appendix 7**.

Food safety nowadays is becoming a growing concern for everyone. With the increasing globalization occurring around the world particularly in the system of food and trade, new risks are being presented to the public. The increased in the amount and variety of food trade rendered safeguarding of food safety difficult demonstrated by augmented spread of foodborne diseases making the linkage between public health and international trade be recognized as an area of great significance for health particularly on food safety related issues.

Maintaining the safety of food requires constant attention from government, industry and consumers as the food supply changes resulting from new technologies, expanding trade opportunities, ethnic diversity in the population and changing individual diets. Thus, several programs pertaining to strengthening of different national food safety systems are established. However, not much significance is being given to the development of effective food recall system considering the potential of food manufacturers, distributors, retailers and importers within APEC region to conduct a recall every year.

A food recall is an action by a manufacturer, importer, distributor or retailer to remove unsafe food products from the market to help protect the public by removing unsafe or violative products from the market discontinuing further spread of contaminated product. As simple as it may seem, this action still requires careful and cautious planning so as not to create extensive damage on the trade system.

Problems reflected on the inspection performed by either regulatory authorities (including overseas) or a company on a product may prompt a food recall in addition to consumer complaints. Upon detection of pathogens, chemical contaminants, undeclared allergens, extraneous matter or non-permitted food ingredients from a food product, confiscation such food from the market should be conducted.

Depending on the severity or seriousness of health consequences upon exposure to or use of contaminated products, a country may classify food recall into 1) Class I as a situation that may cause serious adverse health consequences or death; 2) Class II as a situation that may cause temporary adverse health consequences or remote serious health consequences and; 3) Class III as a situation that is not likely to result to any adverse health consequences.

### Food Recalls in Australia

The participants were given an overview of food recall in Australia by Dr. Barbara Butow, A/G Section Manager of Food Safety Section from FSANZ. The presentation can be found in **Appendix 8**.

She began the lecture by giving an overview of Australia system and Food Regulatory Framework. Australia has a federal system consisting of Commonwealth government with six states and two territories. On the other hand, she illustrated the food regulatory framework of Australia as comprised by three sectors including (1) policy setting managed by ministerial council consisting of health and agriculture ministers from Australian States and Territories and New Zealand, (2) standards development set by FSANZ and (3) enforcement of standards at the state/territory and New Zealand. The figure below demonstrates how these functions come together.

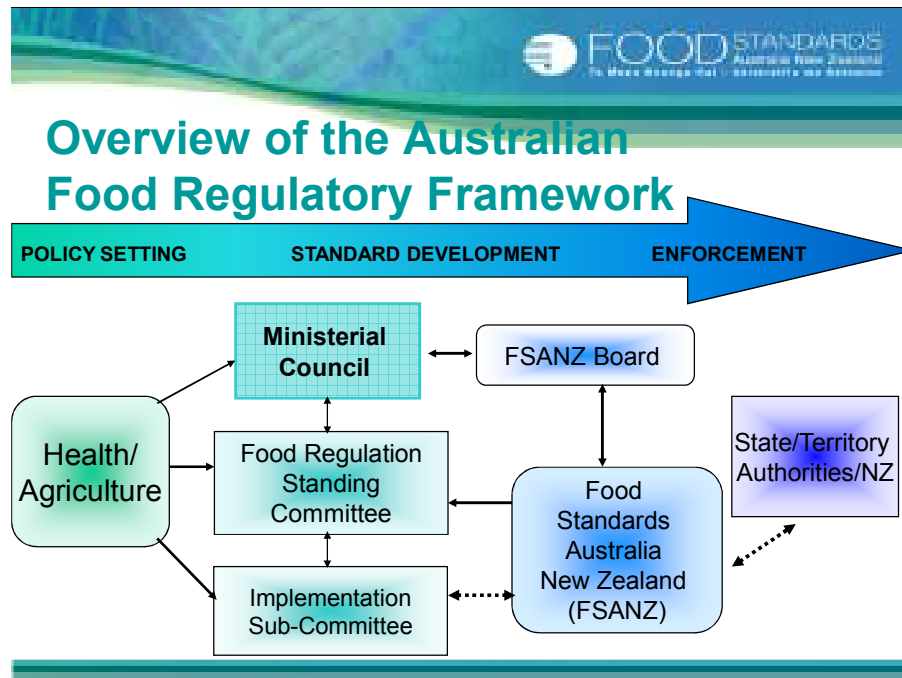


Figure 1. Overview of the Australian Food Regulatory Framework

She continued by discussing the responsibility of FSANZ being a bi-national, independent, expertise-based statutory agency that develops food standards in Australia and New Zealand. She elaborated that aside from standards of food composition and labeling, FSANZ also formulates food safety and primary production standards. These are included in the Australia and New Zealand Food Standards Code together with the standards of General Food and Food Products. These primarily aim to protect public health and safety by maintaining a safe food supply through provision of relevant information to consumers about food giving enough options and preventing them from being misled and deceived.

Other function of FSANZ includes managing the national food surveillance in Australia by coordinating the incidents and food recalls in collaboration with the Australian Quarantine and Inspection Service (AQIS) and other government food regulatory bodies ensuring imported food is safe and standard setting process is consistent. Afterwards, she briefly described the standard setting process of the agency being based on evidence and risk analysis model undergoing consultative meeting, economic and social analysis aligned with international standards. Formulated standards are then enforced by health authorities of Australian States

and Territories, New Zealand Food Safety Authority and Australian Quarantine and Inspection Service for imported foods.

Dr. Butow started the second part of her lecture by defining product withdrawal and recall. Withdrawal is the action taken to the products that are defective in quality and is being done to those products with pending further investigation prior to the official recall conduct. In contrast, recall is an action taken to remove foods from sale, distribution and consumption which may pose an unacceptable risk to public health and safety. The latter is being executed with the purpose of informing the relevant authorities and public of the problem and removal of potentially unsafe product from the marketplace effectively and efficiently.

As part of legal requirements stated in clause 12 of Standard 3.2.2 Food Safety Practices and General Requirements of the Australia New Zealand Food Standards Code, a food business engaged in the wholesale supply, manufacture or importation of food must have a system in place to ensure recall of unsafe food. This should contain procedures and arrangements that will enable the food business recover food products from the supply chain should a problem arises detailed in written recall plan made available to an authorized officer upon request.

She went on the discussion by identifying the level of recall as trade and consumer. Trade recall involves retrieval of food product that has not been available for direct purchase of general public like food from wholesalers, distribution centers, supermarkets, hospitals and restaurants. This is classified as such if a food product has a potential public health and safety risk while in the distribution centre or wholesaler. On the other hand, it is classified as consumer recall when food products are claimed from all points in the distribution networks/chains including those affected food products in the consumer. This level is more extensive than trade recall and public must be informed usually through the form of media. Furthermore, she elucidated the difference between the voluntary and mandatory recall. It was explained that when the food business entity having primary responsibility for the supply of a food production or simply referred to as the sponsor is the one initiating the recall, voluntarily removing the food from the market place it is called a voluntary recall. On the contrary, a mandatory recall is implemented when the Commonwealth, State or Territory Government order a food to be recalled when the sponsor does not willingly remove the product from the market.

Dr. Butow also enumerated key elements of a food recall. Initially, she cited that there should be a full documentation of a plan entailing important information such as contact phone number for relevant authority, customer contact details, recall management and recall advice. Following this, the trigger of the recall should be identified frequently observed in routine testing within a food company or by the regulatory authority, complaints from consumer due to several possible reasons involving illness and detection of problem with imported products. In relation, she pointed out common causes of food recalls like microbiological results beyond the acceptable limits, foreign matter presence, chemical contamination, biotoxin, processing, labeling errors and tampering of products. After which, the recall should be initiated and undertaken by relevant parties. From here will be decided if food products are to be retrieved and disposed once approved by the government authority. Lastly, evaluation of the recall progress and measures to prevent

recurrences of the problem should be established. She stressed out that an effective food recall system should be reviewed and consulted regularly with government and industry stakeholders for continuous improvement.

### **United Nations Programs on Food Recall**

#### **Food and Agriculture Organization of the United Nations**

Ms Shashi Sareen, FAO Senior Food and Nutrition Officer briefed the participants on the work done by FAO on food recall. Her presentation can be found in **Appendix 9**.

She initially enumerated some recent food recall incidents, namely among others the *E. coli* contaminated spinach and lettuce, melamine-tainted milk products from China, Sudan 1 contaminated chili powder exported to European Union (EU). She highlighted the report from FAO investigation, that lack of knowledge among the manufacturers about the risk of melamine and Sudan 1 was the main cause of the outbreak. In the report, communication gap between government agencies and industry on what prohibited ingredients is very evident. Citing the Sudan 1 contaminated chili powder exported to EU from India in 2002, when communication gap persists, product recall may take years before it can take place (the chili powder was recalled only in 2005).

She also noted the increasing food product recall in the United States over the years. Categorically, to the 565 recalled products in 2008, 117 or 21% came from fruits and vegetable sectors. While the incidents of *E. coli* contamination decreased as compared to 2007, *Salmonella* and *Listeria* contamination increased by 800% and 20% respectively.

In FAO, food recall is defined as an action taken to remove a marketed food product that may pose a health & safety hazards/ risk to consumers, from distribution, sale and consumption. Moreover, she then enumerated some of the importance of food recall namely, to minimize risk of injury to consumers (food safety), to ensure compliance with legal requirements and other quality related issues such as labeling and to protect company assets including brand reputation.

Another pre-requisite program related to food recall is the concept of traceability. According to Ms Sareen, having accurate information on where the product has come and where has it gone may well be a cost-effective approach, since the entire batch or lot may not necessarily be recalled when only one small batch is affected. Hence, proper documentation should be practiced. So when everyone does the “one step forward, one step backward” concept, it is possible to have the information of the product flow in the whole food chain and thus helpful in tracing back the product to be recalled.

She further explained the work done and currently being finalized by Codex and FAO on the area of food recall. These are the (1) *Recommended International Code of Practice – General Principles of Food Hygiene*. Here, she emphasized that under this principle, not only products that are withdrawn but also other products that produced under similar conditions should also be evaluated and may need to

recalled as well; (2) *Principles & Guidelines for Exchange of Information in Food Safety Emergency Situations*. This document chiefly helps the member states, in case of food emergency, decide on risk management options and communication strategy; (3) *Principles for traceability/ product tracing as a tool within a food inspection & certification system*. She explained that recall cannot be possible without the traceability system in place. Traceability is a risk management tool needed to ensure that targeted and accurate recall are undertaken, only appropriate information is disseminated and wider disruption of trade is avoided; (4) *Assuring food safety & quality: guidelines for strengthening national food control systems (FAO Food & Nutrition Paper 76)*; (5) *FAO Technical Guidelines for responsible fisheries*. The latter according to her has some clear provisions on food recall. Although this document focuses on feeds, it also states similar actions needed by government to recall unsafe foods; (6) *FAO/WHO Framework for developing national food safety emergency response plans*. Currently, this document is still being finalized, but for advance information of the group, food recall protocols can be found under the Incident Management and Communication Strategy of the document and; (7) *Food Recall Guidelines*. This document is a joint project by FAO-WHO and still on its developmental stage. However she underlined some important points under this new document e.g. (1) legislation should cover the entire food chain where responsibilities of each authorities in case of emergency need to be defined, (2) recall plan should be planned and shared with all stakeholders, (3) food recall is not just a onetime problem, the root cause should be rectified and corrected; (4) communication is critical to prevent inaccurate information leaking out that may exacerbate the emergency situation and (5) yearly review of recall and procedures should be implemented.

### **World Health Organization**

Ms Jenny Bishop of World Health Organization acknowledged the importance of partnership in developing a good food recall system. She commenced her presentation by citing a case study on countries with no food recall system in place. In Angola, bromide with similar physical characteristic as sodium chloride is being sold as table salt. During the outbreak, 467 were intoxicated. The absence of recall system, made the situation difficult to manage. Actions by authorities have been delayed; hence, further cases were expected. Every household was even needed to be visited to control the problem.

She then detailed the tasks being undertaken by WHO in relation to food recall system and strengthening of national food control systems. WHO works in collaboration with national counterparts, works in partnership with FAO, in-country missions providing technical assistance, provides assistance from afar, conducts regional/sub-regional training courses/workshops (though no specific workshop was conducted as of yet specifically for food recall) and guidelines development.

Figure 2 demonstrates the FAO/WHO key components of national food control systems. Ms Bishop emphasized the central part, food control management, as this is where coordination between agencies, policies and strategies on food safety including emergency response policy and food recall system are developed. Essentially, all five components can be applied to food recall system, for instance, in

Inspection Services, where food inspectors initially identify the problem. They oversee the food recall in the field, making sure it's done correctly. In addition, Ms Bishop enumerated some key principles in recall development: (1) *Prevention* is better than cure (food recall). It is easier to conduct recall when it's already in place and included in food safety systems like GMP and HACCP; (2) *Risk Analysis* should be part of recall protocols. She noted that not all incidences or outbreaks should result in recall. All aspects of the risk, including its consequences should be properly assessed; (3) *Farm to fork*. It must be feasible to do a recall at all stages of the food chain. Likewise, recall plan should also be designed to include ingredients from the food system; (4) *Food recall system must reflect the local situation*. Each state has unique situation and should therefore visualize what was going to work with their country before relying on traditional approaches; (5) Food recall system must meet the international obligations.

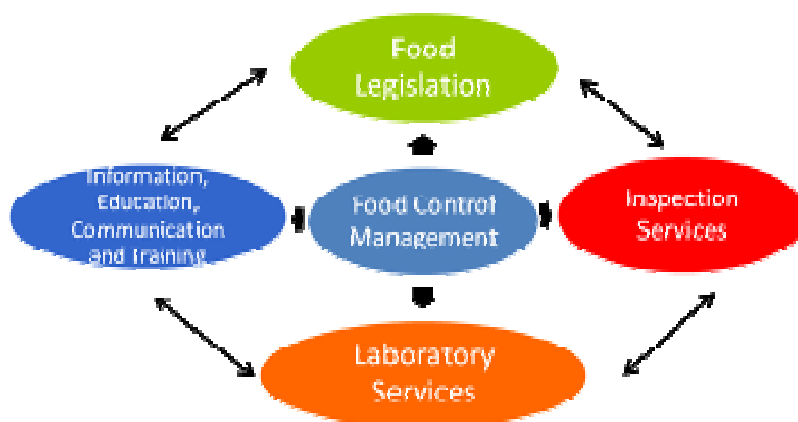


Figure 2. FAO/WHO Key Components of National Food Control Systems

Globalization or the widening trade of food may implicate rapid spread of foodborne illness across borders; hence recall also means involving several economies. But what makes this scenario even more difficult is that today's food product is composed of several ingredients that may come as well from different sources from different countries. The real challenge according to her is involving recall of food ingredients. Up to the challenge, WHO created the INFOSAN - International Food safety authorities network.<sup>2</sup>

<sup>2</sup> The International Food Safety Authorities Network (INFOSAN) is a joint initiative between WHO and the FAO. This a global network includes of 177 member states. Each has a designated INFOSAN emergency contact point for communication between national food safety authorities and the INFOSAN secretariat regarding urgent events. Recognizing that food safety is often a shared responsibility, countries are also asked to identify focal points in other ministries or relevant agencies to receive INFOSAN communications. The network aims to: promote the rapid exchange of information during food safety related events, share information on important food safety related issues of global interest, promote partnership and collaboration between countries, and help countries strengthen their capacity to manage food safety risks

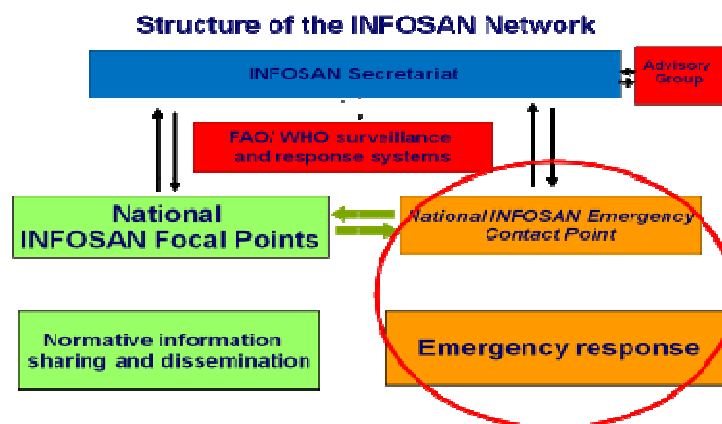


Figure 3. Structure of INFOSAN Network<sup>3</sup>

The INFOSAN Secretariat as shown above (Figure 3) is based in Geneva. It is composed of advisory group around the world in partnership with FAO. The Secretariat communicates through email with National INFOSAN Focal Points and with National INFOSAN Emergency Contact Point in times of food incidence. This network provides a means of identifying food products that have been exported, where it has been exported and where it come from. It also allows horizontal record exchange of information between WHO member states.

Ms Bishop explained that in 1969, the Member States of WHO adopted International Health Regulations (IHR) in agreement with the international community. These regulations represent the only regulatory framework for global public health. The IHR help prevent the international spread of infectious diseases by requiring national public health measures that are applicable to travellers and products at the point of entry. However, the revised IHR (2005), which went into effect in June 2007, requires that all member states notify the WHO of any public health threat constituting a significant risk to other states through the global spread of disease. In the event of such threat, the IHR enables a coordinated international response as well as specific assistance to the affected countries. In analyzing the potential risk of an event, WHO follows a structured procedure (Figure 4) to help them in their decision making process. To date, under this IHR procedure, no food safety issue has been assessed as under the Public Health Emergency of International Concern (PHEIC). Full copy of her presentation is attached as **Appendix 10**.

After her presentation, Ms Bishop clarified a comment regarding difficulties in information exchange between countries in times of an incident particularly getting information from foreign companies. She explained sharing confidential information among member states is indeed a challenge. Incomplete data cannot easily be disseminated. But INFOSAN is constantly on the process of improving the system. No matter how perfect the system may be, there are still so many things to do. There are areas that needed to be strengthened, particularly on balancing confidentiality issues. Ms Bishop further explained that there are still many ways to get informed, by emails, i-chats, or by phone calls.

<sup>3</sup> INFOSAN. [http://www.who.int/foodsafety/fs\\_management/infosan/en/](http://www.who.int/foodsafety/fs_management/infosan/en/)



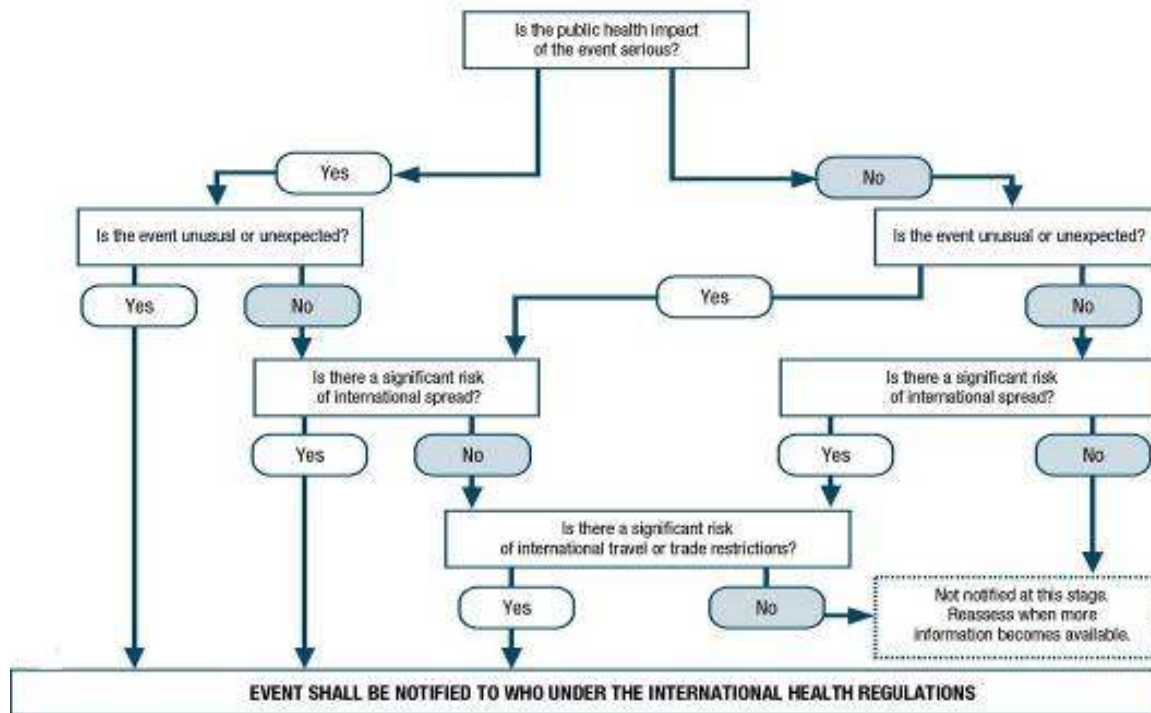


Figure 4. Decision Instrument for the Assessment and Notification of Events<sup>4</sup>

## Food Safety Incident Management

How Australia manages food safety incidences was presented by Dr Barbara Butow. She first noted that food safety incidents are really more intense, immediate and more problematic and complex type of recalls. They usually involve a number of government agencies, can occur at any time and can range from fairly simple, localised problems to complex, multi-jurisdictional (national and international). They are managed under an agreed set of structures, processes and protocols.

There is no single definition for food incident, but it may mean any situation within the food supply chain where there is a risk, potential risk or perceived risk of illness or confirmed illness associated with the consumption of a food. The foodborne hazard causing such illness may be microbiological, chemical, radiological, physical or unknown. The food incident can occur at any stage of the food supply chain, including activities at the primary production sector that have the potential to, or are perceived to impact on the safety of the end food product. The food incident may or may not have attracted media or political interest.

Some common features of food incident are: (1) *public health and safety risks*; (2) *consumer concerns* which a lot may come informally from chatrooms; (3) *usually do not have all of the information at the start*. Dr Butow citing the bonsoy (soy milk) incident as an example, where only later on that doctors found a linkage with patient with thyroid dysfunction and high consumption of bonsoy which apparently has high content of iodine. Here she emphasized the importance of networking between doctors, epidemiologist, food technologists and food safety regulators; (4) *scientific*

<sup>4</sup> International Health Regulations. <http://www.who.int/ihr/9789241596664/en/index.html>

*uncertainties* where there is lack of data, unresolved scientific debates on certain issues; (5) *involve more than one agency/organization*. Most of the time, these several agencies have different opinions and more often have (6) *inconsistent responses* primarily because each state and territories in Australia has different food laws and jurisdictions; (7) food incidents also impact a number of government levels; (8) food incidents lead to disruption to domestic and international trade and this may last for weeks or even months.

Dr Butow elucidated how Australia responds to food incidents. She stressed that response should be scientifically justified, efficient and consistent. It should have a legal basis and be balanced, taking into account public health, social impact and cost benefits. Response should also be well communicated. The public often exaggerates and perceives things riskier than they actually are, hence, effective risk communication is very important. Therefore, in managing the incident, it is essential that our measure should be comprehensive, by which it can address all hazards; integrated at all levels of government and with industry; and should contain prevention, preparation, response and recovery elements.

The second part of her report is an overview of Australia's National Food Incidence Response Protocol. Over the past 3 or 4 years, Australia had developed a protocol together with its States and Territories to encourage consistent and collaborative responses across jurisdictions. National food incidents are those that involve a potential or actual problem with a food sold within two or more Australian States or Territories. Hence, Australia qualifies the definition of an incident by saying that it *could, or is expected to, impact on multiple government jurisdictions.*" This protocol will ensure that the response and communication are timely, consistent and appropriate. It coordinates and formalises current arrangements and link Commonwealth and State/Territory protocols and to manage incidents for widely distributed foods. The protocol outlines that there is a single coordination point. According to Dr Butow this is very crucial in managing an incident. Overall, the response actions are designed to minimise disruption to industry/consumers while protecting public health and safety. The protocol is also structured so that there's an integration of food incident and public health incident response processes.

There are main phases in responding to a national food incident as shown in Figure 5. These are the (1) Alert Phase, (2) Action Phase and (3) Stand-down Phase. During the alert phase, an identified national food incident is notified to the Central Notification Point (CNP) by the government agency or the notifying agency. CNP then circulates a Food Incident Notification. This may be a one-pager document containing all basic information of what the problem is and what state or territory is affected etc. The primary focus during the 'Alert phase' is involving all agencies so that all jurisdictions are fully informed and aware of the food incident.

The second phase determines the level of the response activities depends on the extent of the national food incident. FSANZ informs through teleconference jurisdictions that will be affected by the required intervention. This intervention can either be a significant action, just some action is needed or no action is required at national level. In the latter, the notifying agency or affected jurisdiction may undertake all the response activities themselves. A notification form of the incident is

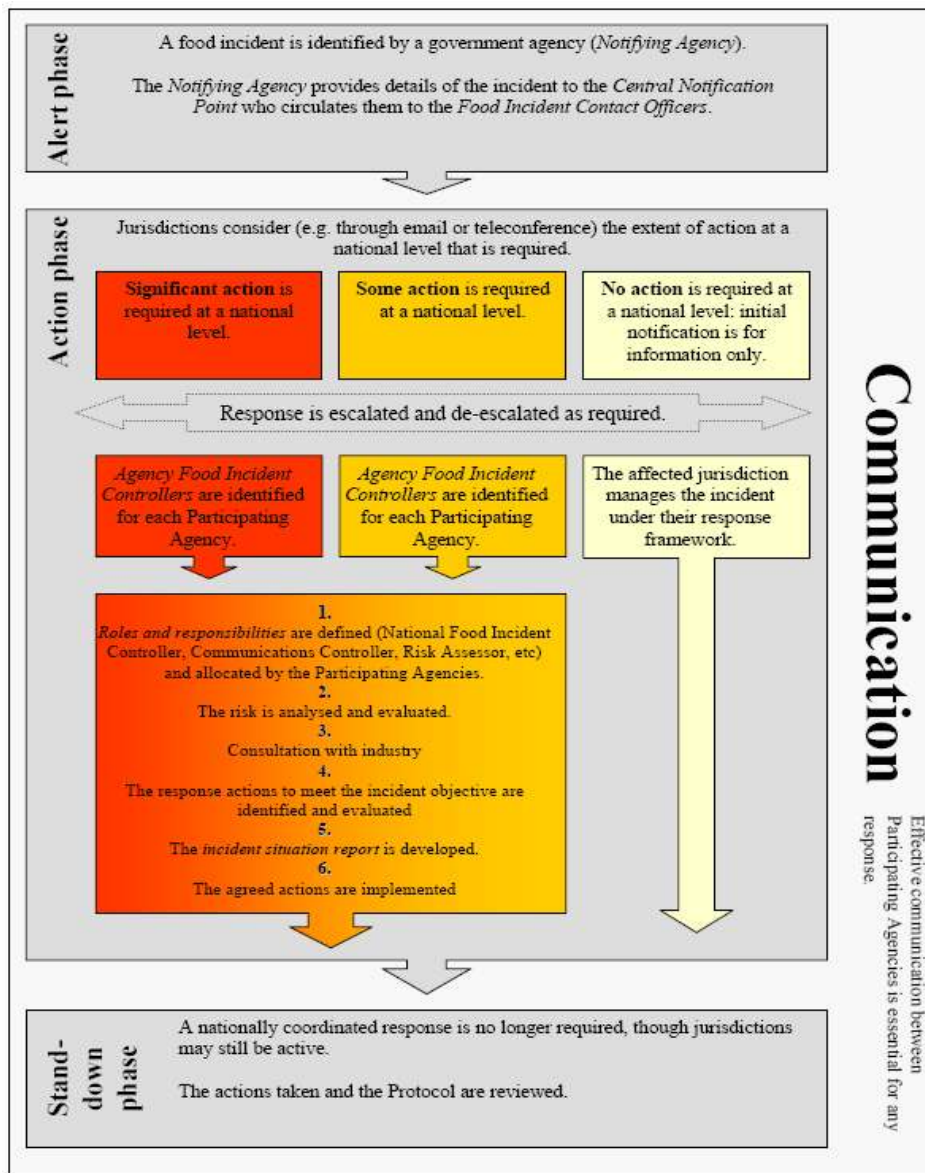


Figure 5. Outline of the steps in the National Food Incident Response Protocol<sup>5</sup>

enough. However, for food incidents that require significant activity at the national level, may have to go through the complete process of risk assessment. The risk assessment advice is needed by States and Territories and Australian Quarantine Inspection Service (AQIS) for enforcement. Additionally at this phase, after the risk is evaluated, they consult the industry, usually a committee, or a specific industry. They do survey of similar products related to the recalled product to gather more information. This survey is part of the incident response protocol and the information gathered is published through a website and may also be part of information sent through INFOSAN. The survey serves several other purposes, and it may also be used to review the existing protocol. At this stage, a media release may be developed by all stakeholders including the industry opinion.

<sup>5</sup> National Food Incident Response Protocol.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-isc.htm>

In the stand-down phase, the participating agencies agree that a nationally coordinated response no longer required and the incident is deemed to be over. Here the participating agencies should do a debrief or conduct a post-review and the Incident Response Working Group may make recommendations to ISC<sup>6</sup> on changes to the Protocol. Her complete presentation on food incident management is attached as **Appendix 11**.

During the open forum, Dr Butow was requested to give an update on the *bonsoy* incident. In reply, Dr Butow explained that the company which produces the *bonsoy*, totally recalled the product. Apparently, the milk has a strong following, so they reformulated it and just recently is back in the market. Dr Butow also responded to inquiry why Australia developed the food incident protocol and how hard they get the ministers to agree with it. She explained that more and more people are getting interested in emergency management and realized that after several events, a uniform national action must be developed. It's a painful and successful process, but eventually everyone seemed in agreement with it.

### **Meat and Poultry Recalls**

Ms Lisa Volk, Director of Recall Management Staff, Office of Food Operation, USDA-FSIS gave the lecture on meat and poultry recalls in the United States. She initially gave a background distinction between USDA and USFDA's jurisdiction. The USDA has the authority over meat and poultry and processed egg products while USFDA covers all other products.

The USDA has a succinct definition of "food recall." It is a firm's removal of distributed meat or poultry products from commerce when there is reason to believe they are adulterated or misbranded under the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). Recall does not include a market *withdrawal* or a *stock recovery*. Market withdrawal means a firm's removal or correction by its own initiative of a distributed product that involves a minor regulatory infraction that would not cause the product to be adulterated or misbranded. Here, there is no violation of FMIA or PPIA and no health hazard has been identified. Stock recovery means a firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm. She also noted that FSIS has no mandatory recall authority, however, should the company refuses a recall as per FSIS recommendation, the latter may resort to detention and seizure of the products as long as FSIS can justify in the court of law that there is a clear violation of the Acts (FMIA or PPIA). Also, FSIS can go for a media release should company still did not agree for a voluntary recall.

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<sup>6</sup> The Food Regulation Standing Committee's Implementation Sub-Committee (ISC) was established to develop guidelines on food regulations and standards implementation and enforcement activities. ISC comprises representatives from the Commonwealth, each State and Territory jurisdiction and New Zealand and includes representation from the Australian Quarantine and Inspection Service, Food Standards Australia New Zealand and a representative of Australian local government. ISC members are responsible for food safety and food issues and include the government agencies in each jurisdiction with statutory responsibility for food safety.

There are several ways FSIS identifies the problem. First, more often the quality assurance department of the company discovers the problem. They will immediately prepare the documents and notify FSIS that they will voluntarily recall their product. FSIS also gets information from their in-plant Inspection Program Personnel (IPP). FSIS conducts routine microbiological sampling, requesting companies to hold their product until the result comes out. Moreover, FSIS identifies the problem from several consumer complaints and epidemiological investigation or other data gathered by other Federal, State, or local agencies, but the latter takes a while.

During an outbreak, preliminary investigation will be conducted. FSIS interviews case patients and collects all relevant information from the company that made the product. Likewise, FSIS has District Recall Officers (DRO) that coordinate with the company directly during this investigation. However, when imported product is involved, the Office of International Affairs (OIA) takes in charge. It assigns an Import Recall Coordinator (IRC) to direct these preliminary investigations. Some important information that are gathered includes contact information of the establishment, company recall coordinator, media contact and consumer contact, brand and product names, packing type/size, dates, codes (use by/sell by), production dates, distribution areas etc. Same information is required from imported products. Once enough information had been gathered, FSIS convenes the Recall Committee chaired by the Recall Management Staff (RMS).

Additionally, Ms Volk specified that FSIS has three recall classifications. Class I means there is a reasonable probability that consumption of product will cause serious, adverse health consequences or death. Examples are if *Listeria monocytogenes* is found in ready-to-eat food or *E. coli* O157:H7 is present in raw ground beef. Class II means if there is remote probability of adverse health consequences from the consumption of the product. Examples are very small amounts of allergens typically associated with milder reactions, such as wheat or soy products or if there are extraneous, non-sharp edged, material such as pieces of plastic found in the food. Class III if the use of product will not cause adverse health consequences, but FSIS believes that the situation warrants some public notifications, like mislabeling of products. FSIS Congressional and Public Affairs Office (CPAO) handles the public notifications. Recall release is issued for Class I and II recalls. This is posted at the FSIS Web site and distributed to wire and media services in area of product distribution. Recall Notification Report (RNR) on the other hand is issued for Class III recall, including Class I & II where products are distributed only to the wholesale level which not likely to be sold directly to consumers.

Ms Volk further explained that FSIS personnel also conducts effectiveness checks to verify the recalling firm has been diligent and successful in contacting and advising the consignees of the need to retrieve and control the recall product, and that consignees have responded accordingly. The DRO take a lead on this activity. These checks are done throughout the distribution chain and they are risk based, dependent on the class of the recall, the number of consignees, and other relevant factors. For instance, for Class I recall *with* illness, if the number of consignees falls between, 1-200, say 40 consignees, FSIS will conduct a 100% effectiveness checks, however for Class 1 *without* illness, if there are 40 consignees, FSIS will only conduct 20 effectiveness checks. Her presentation attached as **Appendix 12**

provides the complete guidance on this routine effectiveness checks. In the event the recall was found to be ineffective, FSIS will take further appropriate action to mitigate the risk to the public, including detention, seizure, or other action within the rules of practice. The DRO then summarizes the recall activities and provides Final Recall Effectiveness Report to RMS which includes a summary of findings of the recall effectiveness and product disposition verification checks and any supporting documentation voluntarily provided by the firm, including information about the amount of recalled product recovered.

The following figure shows FSIS recalls in 2009 by Class:

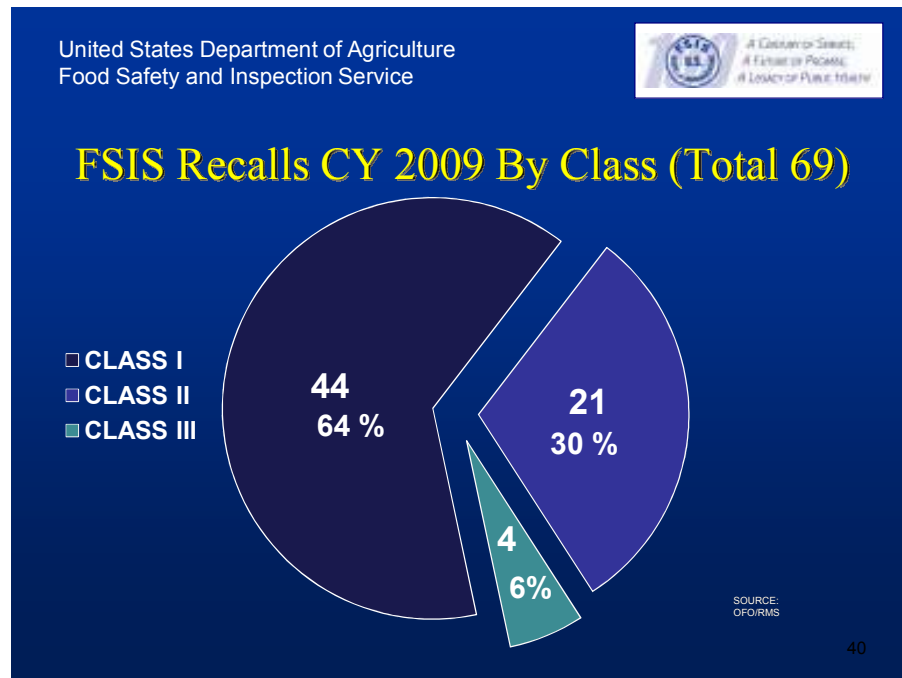


Figure 6. FSIS Recalls CY 2009 by Class (Source: OFO/RMS)

After her presentation, Ms Volk entertained some questions from the participants. Issues raised were conducting a recall when the illness cannot *directly* link the evidence to the food, compensation to the victims, propaganda by competitors, method of disposing recalled product. Ms Volk, in response to the first query explained that epidemiological evidences shall be enough reason to connect the ill patients to the suspected product and if there are other means to exclude other potential sources for the illness, then FSIS will initiate the recall. As regards compensation for the victims, FSIS doesn't get involve with the compensation; this is taken care of by lawyers. In making sure the information is not a hoax or just a mere propaganda by competitors, Ms Volk reiterated that when FSIS gets only one complaint, most likely FSIS does not take action. She also clarified that FSIS does not act based on hearsay. There are verification procedures to be followed. FSIS has field officers to get information from the company and that there is a systematic way in doing the investigation and that there is a legal basis for conducting a recall. On the verifying that the products is properly disposed, Ms Volk restated the effectiveness check that FSIS conducts like doing the physical check and looking at landfill records.

Asked what FSIS does to media reports who exaggerate the information about the recall. Ms Volk explained that FSIS can only do so much. But they continue their outreach with consumer and media group to explain to them the scenario as best as they could possibly do. They are limited however on the information that still remains in the web even if the recall was actually terminated. About the question on heavy metal testing, Ms Volk clarified that FSIS does not routinely test heavy metals. If faced with a situation where it lacks expertise, in this case on heavy metals, it consults the Health Hazard Evaluation Board. It does not normally works with recall, but they are subject matter experts. It is the one that advices whether product needs to be recalled because of high public risk. Regarding reprocessing of recalled products. If the product is recalled and has not gone overseas, the product may be still reprocessed. She cited an *E. coli* contaminated ground beef, where the bacteria can still be destroyed by further processing, but it needs to be cooked under federal supervision.

### **USFDA Food Recall System**

Dr Aurora Saulo, Professor from the University of Hawaii Manoa spoke in behalf of USFDA. According to her, the primary goal of the food industry is to produce safe and wholesome food, and in order to do that, they must develop and follow food safety programs including traceability so in times of crisis, companies can respond immediately. It's a given, that no matter how established the system, things can still go wrong, sometimes at very inconvenient times. And this trouble is even exacerbated by media sensationalizing the event, hence things become worse. She then enumerated some high profile outbreaks in the United States, namely: Jewell Dairy *Salmonella* (1985), Jalisco Cheese (1985), Jack-in-the Box *E. coli* 0157:H7 (1993), Schwann's Ice Cream *Salmonella* (1994), Japanese Radish Sprouts (1996), Odwalla Apple Juice (1998), Pre-Cut Spinach (2007) and Tomatoes then peppers (2008).

The US Food and Drug Administration policy on food recall can be found at Title 21 Code of Federal Regulations (21CFR7.40 – 21 CFR7.59) where it defines food recall as “...removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration.” Hence, it is the prompt removal of contaminated, mislabeled products, or sick animals from the market, including its proper disposal in “...to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.” The document also sets the guidance, policy, and industry responsibilities. According to Dr Saulo, food recall in the US is still voluntary or FDA may request for a recall, however, should the firm refuses to undertake the recall when it's needed, or when a recall is found to be ineffective or when violation continues, then FDA may initiate some seizures and or some court actions.

During the recall process, FDA organizes an Ad Hoc Committee that will work on the risk assessment and will then classify the type of recall depending on the degree of hazard identified. Class I indicates that there is a reasonable probability that the use of, or exposure to, a violative product causes serious adverse health consequences or death. Example under this class are pathogen-contaminated foods and allergens. Allergen according to Dr Saulo is a serious concern in the US and hence falls under

this category. Here, there will be public warnings and likelihood of maximum efficacy check will be conducted. Class II involves products that may cause temporary or reversible health consequences. At this class the probability of serious adverse health consequences is remote. There may likely be a public warning and only an intermediate effectiveness checks will be done. Under Class III, affected products have no health hazards, may not involve public warning, and effectiveness checks are minimal. Often, under this category are mislabeling cases.

A recall may be FDA-requested or firm initiated. A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration with relevant information. Such removal will only be considered a recall if FDA regards the product as involving a violation that is subject to legal action, e.g., seizure. FDA may request a firm to recall their products, depends on the result of the risk assessment. Except in limited circumstances (e.g., infant formula), a firm need not initiate a recall even at FDA's request. In both cases, a recall strategy should be developed by the agency for a FDA-requested recall and by the recalling firm for a firm-initiated recall. Essential elements for the strategy include the depth of recall, public warning and effectiveness checks. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. Table 1 summarizes FDA's recall practice:

<b>CLASSIFICATION</b>	<b>RETRIEVAL LEVEL</b>	<b>EFFECTIVENESS CHECKS</b>	<b>PUBLIC WARNING</b>
Class I	Consumer	100% at retail	Yes
Class II	Retail or more	90 – 100% at retail	Yes
Class III	Wholesale or more	Variable	Sometimes
Withdrawal	Company Criteria	Company Assessment	No

Table I. USFDA Recall Classification

During public notification of recall, the FDA will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was FDA-requested or firm-initiated, and the specific action being taken by the recalling firm. A recall will be terminated when the FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. A recalling firm may request termination of its recall by submitting a written request to the FDA.

Dr Saulo also presented recall program that a company may develop. According to her, it is very important to have the top management support in developing this recall program. There should be a Recall Action Team composed of one Recall



Coordinator, technical representatives from Quality Assurance, Research and Development, Laboratory, Contractor, Legal and Communication representatives as well as from Warehouse and Distribution department. Representatives from top management may also be represented in the team. Dr Saulo also highlighted the importance of establishing a traceability program in complementing the recall program. Likewise, it is also important for the company to make a simulation or mock exercise of this program. This should somehow mirror what would happen in the event a real recall happens. The standard according to Dr Saulo on this mock exercise should be a 100% product tracked within 4 hours.

She was asked to explain further how is effective mock recall is done. Dr Saulo explained that mock recall was done unannounced, usually has top management support, and should as much as possible emulate a real recall. Likewise, during the exercise, training will be done per section. The purpose of the mock recall is to observe how fast the company can recall the product, afterwards the recall team will reconvene and discuss the loopholes of their recall program. Mock recall is also documented.

Asked about the certification, Dr Saulo explained that it is not related to food recall program rather to the prerequisite programs. She focuses on the prerequisite programs because it is where violations really happen. She also warned that there are lots of HACCP instructors, but make sure to check on their credentials, the manual was checked by the International HACCP Alliance. According to her, not all HACCP certificates are equal. It is also important to check who issues the certificates. There are lots of HACCP impostors who use the certification as a revenue scheme.

### **USFDA Food Recall Case**

She used the *Salmonella* in Hydrolyzed Vegetable Protein (HVP) as the Case Study. HVP is a flavor enhancer used in a wide variety of processed food products, such as soups, sauces, chilis, stews, hot dogs, gravies, seasoned snack foods, dips, and dressings. It is often blended with other spices to make seasonings that are used in foods. In February 2010, a customer of Basic Food Flavors alerted the FDA that it had detected *Salmonella* in the company's HVP product they had purchased from Basic Food Flavors. The company made the report through the FDA's new Reportable Food Registry (RFR), prompting the FDA to begin its investigation which led to an inspection at Basic Food Flavors that began on Feb. 12. That inspection led to the FDA's positive findings of *Salmonella* in the manufacturing facility. On 9 March 2010, the FDA issued to the company Form FDA 483 Inspectional Observations, detailing the Agency's inspectional observations at the facility where contamination with *Salmonella Tennessee* was found. The form did not include the final FDA determination of the company's compliance with the Federal Food, Drug, and Cosmetic Act, but rather, it details the observations made during the inspection by the inspection team some of which are problems with the cleaning and sanitizing procedures of equipment and work areas where food meant for human consumption is processed, as well as plumbing and drainage issues. To date, no illness has been reported yet.

Dr Saulo highlighted some lessons learned. The case has the potential to be the largest recall in US history should the FDA did not immediately began investigations after report of detection of *Salmonella* on RFR. Moreover, it is very important to have communications with the company, issued press release about the recall, to set up online Q&A for consumers, Q&A for the industry, to set up online database of recalled products and brands, to post online public documents about the investigation and recall as well as appropriate contacts. For the company, the problem should have been immediately lessened had it voluntarily recalled all involved products in timely manner, ceased production and distribution while confirming lab results, had an experienced crisis management program and a trained crisis management team, had it known what to do when the investigators knock and promptly returned media calls (only by designated company communication persons).

Asked why despite an excellent food safety system in a developed economy like the US and even if HACCP is in place, this incidence still occurred. Dr Saulo commented, not because it's in the US, there will no longer be violations of the system. The HACCP plan should have worked to prevent the incident, has it been developed properly. Looking at the FDA report, it can be observed that the violations have come from the prerequisite program. The company may have their CCP in place, but ignored their sanitation protocols, their Good Manufacturing Practices (GMP) etc. Her presentation can be found in **Appendix 13**.

### **Outbreak to Recall: A Case Study**

Dir Lisa Volk stated that given the number of reported recall cases from different food and non-food products, 2007 was a year of recall. Of the 21 meat recalls for *E. coli* O157:H7 in 2007, ten are associated with illnesses. She used the frozen beef patty as her case study. Initially, FSIS learned the incident from their Consumer Complaint System, that there was a case patient in Florida that illness was likely to be associated with *E. coli*. Investigators tested both samples from remaining beef patties consumed by the test patient and beef patties from the production plant. Both samples are from the same code date but only the former was tested positive, hence, it was inferred that the one consumed by the patient may have just been cross-contaminated and therefore FSIS did not act on the case. This has also been the weakest link, so despite subsequent cases in several US States, the Recall Committee did not move forward. However, the New York health agencies have been more aggressive and proactive in solving the case, testing intact products from the commerce, and later on were able to link the *E. coli* contamination to the product. Recall was initiated afterwards and the plant operation was suspended after the Food Safety Assessment. Eventually, additional cases in Canada with *E. coli* isolates similar to the US outbreak strain and further investigation finally lead the source to the Canadian slaughter house that supplied the American company that produced the beef patties. The recalls then expanded to 21.7 million pound (or equivalent to one year production), making it the largest beef recall in US history. There were 43 case patients from 8 states, 21 hospitalizations, but no deaths were reported and the firm ultimately went out of business. Because of the magnitude of the recall, it heightened the interest of the US Congress, media and the public. Consequently, with the recommendations from the Office of the Inspector General, FSIS has made

some policy changes like expansion of sampling programs (e.g. aside from sampling of raw ground beef, routine sampling now includes trim, source materials other than trim such as two-piece chuck, sub-primals, LFTB or lean finely-textured beef, and bench trim), FSA scheduled at all firms with a reported positive FSIS sample result. Likewise, FSIS has developed some documents for the industry for reassessment of *E. coli* controls to take into consideration more importantly on the sporadic nature of the organism (e.g. checklist/survey to catalog industry practices, draft compliance guidelines issued in 2008, criterion for high event periods, and verifying sanitary dressing procedures). Some future initiatives of the agency are to initiate rulemaking to identify tenderization as a material fact that must be identified on labeling, to propose mandatory ‘test and hold’, begin earlier traceback activities to identify all affected product and suppliers and respond more rapidly to protect the public health, mandatory record keeping requirements that would facilitate traceback at retail when a product is recalled and develop new N60 sampling instructions. For details, see **Appendix 14**.

### **Food Recalls in Australia**

Mr Elliot Hill, Principal Food Recall Coordinator of FSANZ presented the food recall process in Australia. He reiterated that FSANZ is the central notification point for all food recalls in Australia.

A company conducting a recall has a legal requirement under the Food Standards Code. Under clause 12 Standard 3.2.2, *a food business engaged in the wholesale supply, manufacture or importation of food must – (1) have in place a system to ensure the recall of unsafe food; (2) set out this system in a written document and make this document available to an authorized officer upon request; and (3) comply with this system when recalling unsafe food.*

Mr Hill emphasized that FSANZ only coordinates and correlates the information and disseminates it to relevant parties involved in the process. The decision whether or not to recall a food rests with the State and Territory Health Department. The FSANZ role of coordination is carried out between Australia’s States and Territories and the sponsor which is the company that manufactures or imports the food product. The sponsor remains responsible for all aspects of food recall. Once recall is warranted, the sponsor needs to contact all their customers whom they distributed the product, to remove the product from sale, and also to provide their customers with further instruction on its isolation and subsequent disposal. Likewise, within two days of initiating a recall, the sponsor is asked to contact the Minister for Consumer Affairs, although FSANZ offers this service to reduce the workload of the sponsor. FSANZ also disseminates information to relevant food industry organization, hence it requires essential information from the sponsor such as food type, brand name as it appears on the packaging, Best Before or Use by Dates, packaging type and size, sponsor details, domestic and overseas distribution list. Other crucial details include category and sub-category of the hazard risk (e.g. microbial, labelling, tampering), the proposed recall level (consumer or trade), action proposed by the company, Australian Product Number (APN) or other code number, method of disposal (sponsor may request to return the products to them), and country of origin. And while FSANZ may draft press advertisements, it is necessary for the company to

book its own press advertisement in the daily paper of each affected state or territory. Advertisement comes with standard layout, for instance, a recall notice will always appear in a newspaper with a hatched border and a triangle in the top left hand corner, with the following information: Name size and description of the product, reason for the recall, identify, quarantine, disposal, hazard, and company contact details. Eventually, once the recall was carried out, the sponsor is asked to provide post recall reporting including destruction certificates.

Mr Hill likewise outlined some of the challenges FSANZ has encountered dealing with different States and Territories and issues that may slow down food recall. He discussed that when conducting a recall, FSANZ was endeavoured to process it within 24 hours but in some cases this process takes longer. FSANZ has found that some smaller businesses are unsure or unprepared how to conduct a recall. They usually don't have recall plan, so when a recall does occur, the sponsor is ill-equipped and unprepared which in turn places undue stress on the owner of the business. Lack of preparation also slows down recall, as the sponsor cannot get all the information together in a quick phase during the actual incidence. Inaccurate details and knowledge about the implicated product including a broad list of distribution list may exacerbate the recall process.

He also enumerated some recent and famous food recalls in Australia that caught a lot of media and political issue. One shows a major Australian supermarket recalling a very common milk product concerning yet common microbial contamination. This recall gained a lot of political concern as this company distributes milk over a vast distance and to many shops. FSANZ's senior officials were contacted and asked for their opinion on the subject. Another is the *bonsoy* recall. It caught a lot of media attention because it has a lot of following. Some food incidents overseas also triggered recall in Australia. In April 2009 the USFDA recalled pistachios from Setton Pistachio due to a potential contamination with *Salmonella*. FSANZ was made aware that pistachio products had been exported to Australia. Subsequently the importer recalled their product which in turn triggered two other recalls with companies who had received the same product. The sharing of information assisted FSANZ in the effective tracing and recall of these contaminated products.

In addition, FSANZ developed the Food Industry Recall Protocol as a tool for business so they could develop their own recall plan. The protocol is an effective guideline on how to conduct a recall and the roles government and industry. FSANZ is constantly looking to improve and refine the food recall process. It also continues to provide after hours training for volunteer officers and recently updated the Industry Food Recall Protocol. FSANZ has distributed this booklet out to States and Territories to be disseminated on to industry within their jurisdiction.

After his presentation, question was asked how FSANZ gathers, consolidates or shares information with other states/territories about the products including those that coming in from overseas. Mr Hill explained that FSANZ shares information within the organization and with other Australian federal departments. They also share information with other international government agencies. Once they are made aware of the product, they simply consolidate and discuss the level of risk, then they coordinate with AQIS, the Customs and also of Department of Health and Ageing. His presentation is found at **Appendix 15**.

## Member Economy Presentations

### Brunei Darussalam

Ms Mahani Muhammad presented the food recall system in Brunei Darussalam. She initially gives a background of Brunei food sector. It imports about 80% of food from all over the world but the government is now currently gears towards self sufficiency and food security. She then explained that the Ministry of Health is the one responsible for food safety either imported or locally produced, while the Agriculture Department and Agri-food is under the Ministry of Industry and Primary Resources which assists local entrepreneurs in developing their production and how to improve their products and labeling.

Regarding Food Recall System in Brunei. They receive alerts from various reporting system like INFOSAN. Both the Focal Point and Emergency Contact Point are from the Ministry of Health. They also subscribe from food safety authorities website overseas like Food Safety Authority United Kingdom, FSANZ, Canadian Food Inspection Agency (CFIA). Brunei also gets information from their bi-lateral trading partner like Malaysia and Singapore. Information from these sources is carefully analyzed. There are ways to alert the public in case of a recall: (1) verbal & written notifications to importers/traders, (2) press releases will be issued if required, (3) post updates with Ministry of Health website, and (4) media updates. The Ministry of Health also does the checks and investigations, to make sure unsafe products are no longer available at commerce, properly disposed and new batch of same products are re-sampled. They also carry out frequent and regular inspections to further ensure that appropriate actions are taken. Some of challenges Brunei face in their food regulation are limited manpower with specialized skills, lack of laboratory facilities (citing the absence of equipment to analyze melamine during the incident) hence they have to rely information from Malaysia and Singapore, and the increasing number of cottage food industries (people making food based on orders only).

In summary, in Brunei, there is no formal protocol on carrying food recall, but it's part of the standard food safety control. Her presentation is at **Appendix 16**.

### Chile

Mr Marcelo Ulloa, Adviser from Department of Food and Nutrition, Ministerio de Salud (MINSAL), presented the food recall system in Chile. The first part of his report talks about the agencies in Chile that involve in food control and inspection. The Ministry of Health is the national sanitary authority in charge of sanitary administration and control on food products for domestic use, both from imported food and local production. The other two major regulatory bodies in charge of the food sanitary administration regarding international trade agreements on food products for export are the Agricultural and Livestock Service (SAG), under the Ministry of Agriculture and the National Fisheries Service (SERNAPESCA) under the Ministry of Economy.

All food control and inspection works are implemented under the Sanitary Code which is the main official regulatory document on sanitary matters, assigning responsibilities and authority to the different regulatory bodies, and constitutes the basis for the more specific regulations. The Food Sanitary Regulation is the document that dictates regulation in all those matters concerning manipulation, storage and manufacture of food products. It also specifies the minimal nutritional qualities, and the maximum levels permitted of chemical and biological residues. These two regulations apply to imported food products and local production and are executed by the Regional Health Secretariats (SEREMI) through their inspection and analytical divisions.

MINSAL is responsible for protecting the consumer's health and assuring the safety and quality of food in the commerce. The Ministry takes permanent sanitary control and inspection measures appropriately at each stage of the food chain, both at the central (national) and regional level.

Figure 6 shows the recall flows and actions in Chile:

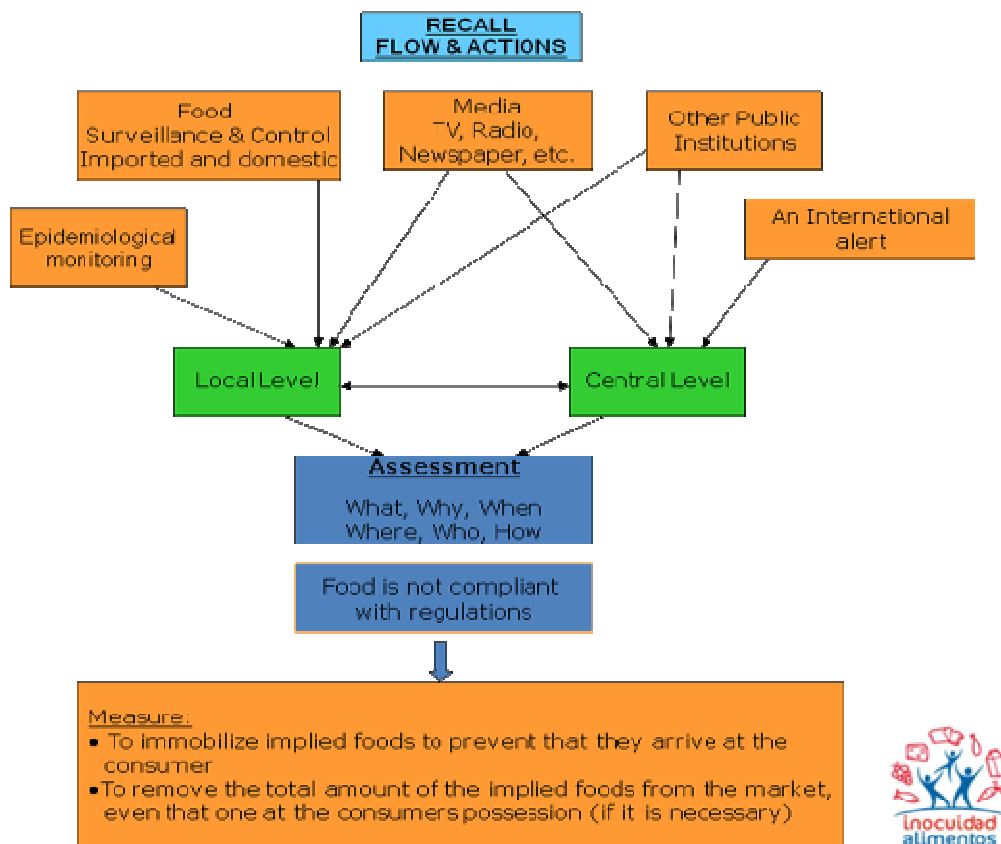


Figure 7. Food Recall Flow and Action in Chile

Information about food alert may come from various sources namely, epidemiological monitoring, food surveillance & control, media, other public institutions in Chile, and also coming from international notifications like INFOSAN and European Union's Rapid Alert System for Food and Feed (RASFF). All this information is received at the local and central level. If the food in question was found not to be compliant to regulations after the risk assessment, common

measures include prevention and removal of food from the market and or from the consumers possession if necessary. Other measures to be taken may include suspension of the company's operation, confiscation of implicated food at the company and market. Confiscated food may be destroyed. Mr Ulloa also emphasized the importance of communication with consumers because they need their cooperation in averting the problem. He cited one incident in Chile in 2008 regarding the recall of ADN, a food for children. All information about the food incident was published at the Ministry's website including a 24hour hotline where consumers can call to get advices and the recent information. Mr Ulloa noted that even though their sanitary regulation does not explicitly mention any indications how to develop a recall protocol, it is strong enough to protect and provide consumer protection. His presentation can be found at **Appendix 17**.

### Chine Taipei

Mr Fang-Ming Liu, Section Chief of Taiwan Food and Drug Administration (TFDA) represented Chinese Taipei. At the outset, he introduced the new TFDA under the Department of Health. Four agencies were combined to form the new TFDA. It officially started to operate just last January 1, 2010.

The Chinese Taipei food recall guidelines are available through the Department of Health website. It is both available in Chinese and English versions. Food recall is initiated in Chinese Taipei if the food violates the existing hygiene or other applicable regulations and the defects are deemed necessary for a recall. Recall can be both initiated voluntarily by the company or by the request of the competent health authority. Moreover, food recall is classified into three subject to the degree of harm the food causes to public health: Class I, if the food is expected to have a probability to cause death or serious harm to public health; Class II if the food is expected to have a low probability to cause harm to public health; and Class III, if the food is expected not to cause harm to public health but is not in conformity with the quality regulation (e.g. labeling requirements). The recall level also depends upon the extent by which the food reaches a point in the food chain, whether be it at the consumers, retailers or manufacturers. The recall operation can be summarized in the following diagram:

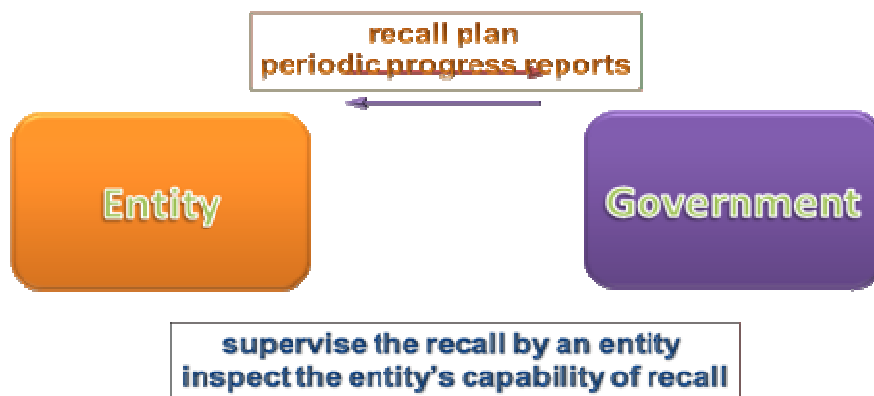


Figure 8. Chinese Taipei Recall Operation

Here, prior to the conduct of the recall, an entity (or company) shall devise a *recall plan* to be submitted to the local competent health authority. At the same time, the entity shall submit *periodic progress reports* in the course of food recall.

The recall plan shall include among others (1) name, address and telephone number of the responsible entity of the food to be recalled; (2) reason of the recall and nature of the potential hazard; (3) product name, packaging, form, or special distinguishing features or signs of the food to be recalled; (4) date, lot number, code, or other identifying information and number specified on the food to be recalled; (5) total production volume of the food to be recalled; (6) total volume of the food to be recalled in the sales channel; (7) distribution record of the food to be recalled; (8) recall measures to be adopted, including the level of recall, instruction on stopping the sale of the particular food, and other actions which shall be taken, prescribed time limit for the recall, etc.; (9) subsequent safety or destruction measures to be adopted, for instance, sterilization, recondition or correction etc.; and (10) warning issued to consumers.

He also elaborated the contents of the periodic progress reports. These reports shall include the basic essential information, among others: (1) number of downstream entities or individuals being notified, and date and manner of notification; (2) number of entities responding to the notification and quantity of the particular food in their possession; (3) number of companies or individuals not responding to the notification; (4) quantity of recalled food; (5) number of times and result of investigation; and (6) anticipated time limit for completion. Likewise, these reports shall be kept for future reference as well as for inspection and verification by the competent authorities.

By and large, the central government develops the recall guideline and oversees each local competent health authorities to ensure they execute their responsibility to supervise the recall by the entity and inspect the entity's capability of recall and where necessary, may assess the relevant reports submitted by the entity and give instructions.

A comment was raised for Mr Liu to elaborate on their Traceability System. Mr Liu, explained that the nature of food and type of company affect the traceability process. Citing the melamine-contaminated coffee powder incident, he said, the traceability was easier to implement because it was a big company who helped in the traceability process using their available resources. The nature of food as well is a challenge. Chinese foods usually are composed of different ingredients from different sources (especially if coming from overseas), therefore traceability may be very difficult. His presentation is at **Appendix 18**.

## Indonesia

Ms Dyah Setyowati of National Agency of Drug and Food Control (NADFC), presented the Indonesia food recall system.

Some of the recall guidelines developed were the General Guidelines on the Control of the Implementation of Product Recall established on 1997 and the Code of Practice for Food Products Recall in 2008. The revision of the latter is still in process.



In developing standards, guidelines, and codes of practices, Indonesia uses Codex as the main reference, however since Codex has not developed guidelines specifically for food recall, the NADFC refers to some references such as Food Industry Recall Protocol of FSANZ, the Canadian Food Safety System – Food Recall by the CFIA, and Code of Federal Regulation of USFDA. Food recall in Indonesia is classified into three classes based on the relative degree of health risk presented by the products. Food recall can be initiated and conducted by the government, manufacturer, wholesaler, distributor, or importer. It can either be voluntary or mandatory recall. Voluntary Recall means a recall that is initiated and carried out by the food businesses without ministerial order. The food business with primary responsibility for the supply of a food product initiates the action for implementing a voluntary recall. This action may be taken as a result of reports the business receives from a number of sources e.g. a manufacturer, wholesaler, retailer, government agency or a consumer. Mandatory Recall on the other hand must be done by the food businesses if the voluntary recall was not effective. Mandatory recall and the destruction of affected product must be done on the instruction and supervision of NADFC. NADFC is the government agency which has the authority in coordinating food recall in Indonesia. Figure 9 summarizes the steps of mandatory recall.

## Step of Mandatory Recall

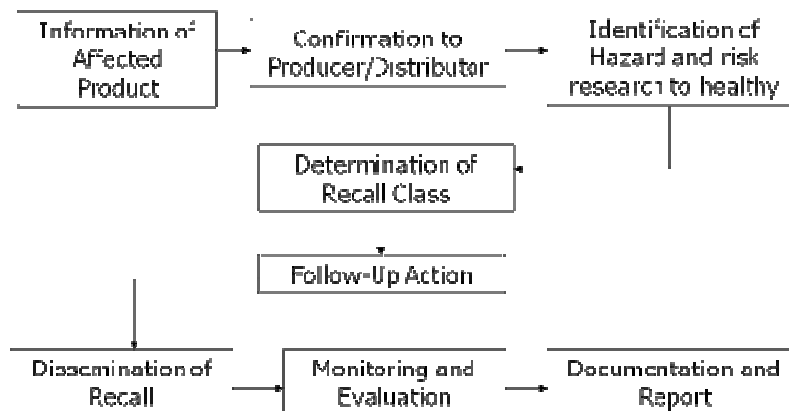


Figure 9. Steps of Mandatory Recall in Indonesia

Information of affected product can be received from manufacturer, consumer, food inspector, other institutions and other countries. Confirmation is done by collecting information about the manufacturer/distributor, sampling of affected product, and if necessary product examination. Identification of hazard and risk analysis are done with emphasis to disease or disease symptoms appeared after consuming the affected product and to children or high risk population. Then based on the evaluation, the incident is classified to what type of recall should be made. At this point NADFC has to secure the entire affected product. Follow up action by NADFC includes monitoring of food recall implementation and coordination with NADFC's regional officers to investigate the distribution facilities (market) and secure products and act as witnesses when products are destroyed. Press release is disseminated with consideration to the whole range of product distributions, product characteristic, and consumer targets. Monitoring and evaluation are necessary to ensure the effectiveness of recall implementation as well as the products are disposed in accordance with the regulations. Documentation and report must describe all of

recall activities detailing the step by step process of food recall. Her presentation is attached as **Appendix 19**.

## Malaysia

Dr Mektir Singh presented the food recall in Malaysia. In Malaysia both the Ministry of Health (MOH) plays a primary role in food recall. But the Ministry of Agriculture (MOA) and Agro-Based Industry-Department of Veterinary Services (DVS) also play an important function in the food recall system though mostly on the farm side and imported meat products.

The legislations in place to support the recall system with MOH are Food Act 1983, Food Regulation 1985, and Food Hygiene Regulation 2009. On the other hand, legislations with MOA (DVS) that sustain food recall are Animal Act 1953 (Revised 2006), Animal Rule 1962 and Custom Act of 1967.

Dr Singh emphasized that each regulatory agencies designated at entry points should ensure that all products entering Malaysia should meet their requirements. Though there are some variations in implementation from department to department, the aim is both to prevent unsafe food from entering the food chain. In DVS, the detained product is either sent back or destroyed depending on the severity of the risk. Confiscated products are reported to the police and a court order is then issued where the detained product will be returned or destroyed. The cost is borne by the company.

He also introduced, FoSIM - Food Safety Information System of Malaysia. It is an intelligent web-based information system to enhance the management of food safety surveillance. FoSIM emphasizes the establishment of food import surveillance system. The system having interfaced with Custom Information System (*Sistem Maklumat Kastam* - SMK) which allows importer/agents and authorized officers at entry points to manage food importation activities electronically using ICT.

The system uses risk based approach in determining food safety hazard of imported food. The risk attributed to the food is determined by six levels of examination. The levels of examination are: a) Level 1 (Auto Clearance); food automatically is released without inspection; b) Level 2 (Document Examination) food released after satisfactory document inspection; c) Level 3 (Monitoring Examination) food is released after inspection and samples may be taken for analysis; d) Level 4 (Surveillance Examination) food is released after inspection with samples taken for analysis; Level 5 (Hold, Test & Release) food is detained pending results of sample analysis; and f) Level 6 (Auto Rejection) food automatically rejected.

In the event of food recall, it is necessary to notify the relevant regulatory authority and provide the reason for the recall as well as the affected product identification and product name, lot numbers, date of production, date of importation / exportation, quantity distributed, quantity remaining in stock on the premises and area of distribution of the recalled goods with name and address of clients shall be described and stock accounted for. Moreover it is important to keep some records like end

product distribution records, stock control records including ingredients and work in progress, production records and ingredients preparation records

He summarized his report by making some recommendations to strengthen food recall system by reviewing and updating food legislation and it's important to continuously strengthen food safety infrastructures, including food inspection capabilities, sampling, laboratory facilities and ICT (Information, Communication and Technology). His presentation can be found at **Appendix 20**.

## **Mexico**

Ms Miriam Munguia Murillo, Inspector of Federal Commission for the Protection from Sanitary Risks (COFEPRIS), presented the food recall system for Mexico. She initially introduced the institutional framework and organizational structure of Cofepris. It is under the Ministry of Health with technical, administrative and functional autonomy, which makes it a de-concentrated organization. Its mandate is to protect the population from sanitary risks caused by the use and consumption of goods and services, as well as from exposure to environmental and occupational factors, through prevention, regulation and sanitary inspection. Likewise, it is involved in the assessment, regulation, control, surveillance and analysis of risks related to food, health products, medical services, sanitary emergencies, occupational health, environmental and other products and services like tobacco, alcohol, cosmetics, cleaning products etc. The emergency attention project which aims to protect the population from different health risk is a vital activity of the Sanitary Enforcement Commission under the operation of the Federal Sanitary System. Cofepris also works in coordination with other authorities like the National Center of Preventive Programs and Disease Control (CENAPRECE y DGEpi), Customs Authorities (SAT), Secretary of Agriculture, Livestock Production, Rural Development, Fishery and Food (SAGARPA, SENASICA). It also coordinates with different chambers and associations like the National Association of Department Stores, National Association of Drug Stores (ANAFARMEX) and Self Services Stores like (COSTCO, WALMART).

As regards sanitary alerts, cofepris monitors several web pages (official health pages and producers or sellers pages), including news of health authorities from other countries, receives e-mails from USFDA, USDA, CFIA, Health Canada, RASFF, INFOSAN which Cofepris classifies these e-mails into: Notice, Warning or Alert. They classified information as Notice when the product is not traded within the border of the states of Mexico. The information is categorized as Warning, if the products is commercialized in borders of the states of Mexico but with no evidence that is being traded within Mexico, however, Cofepris still sends official notification to the border states like Baja California, Sonora, Chihuahua, Coahuila, Nuevo Leon, Chiapas, Tabasco, Campeche and Quintana Roo. Notification is classified as Alert if there is evidence that the product is already traded or produced in Mexico. Here several measure controls are being undertaken, like if the product is imported, check visits in stores and plants, secure the product for analysis, destruction or return of the product. Cofepris eventually develops the report for the Health Secretary.

She also enumerated some food recalls in the Mexico like the Melamine-tainted milk from China in 2007. Cofepris got the report from INFOSAN of the cases where babies got ill because of the contaminated infant formula. Cofepris did some plant visits, secured products from the market, did some laboratory analyses of the products, but no traces of melamine were found, hence the ban on imported products from China's was lifted in 2009.

Another case was the *Salmonella Saintpaul* contaminated tomatoes produced in Mexico in 2008. The United States and Mexican cooperated on the investigation, making inspection visits at harvest fields and packing companies. No reported cases of illness associated with the products in Mexico. Though few samples were tested positive for *Salmonella*, no *S. saintpaul* species was found. Other notable food recall cases were the *E. Coli H7:O157* contaminated ground beef and *Salmonella Typhimurium* contaminated peanut butter from the United States in 2009. No cases of illness associated with the consumption of the products were reported in Mexico. Her presentation is attached as **Appendix 21**.

### Papua New Guinea

Mr Terry Daniel, Chief Executive Officer, Food Sanitation Council Secretariat of the Ministry of Health reported in behalf Papua New Guinea. He introduced the Food Sanitation Council (FSC) as the food safety and quality authority in Papua New Guinea. It is an independent, expertise-based authority which comprises of stakeholders in various government organizations & agencies and operates under the Ministry of Health. FSC aims to protect public health and safety by maintaining a safe food supply, provide consumers with proper information about the food so they can make choices, and to prevent misleading and deceptive practices.

He also introduced the Food Regulatory System in Papua New Guinea composed of standard setting body, policy and enforcement agencies. FSC is under the policy development.

## FOOD SAFETY REGULATORY SYSTEM

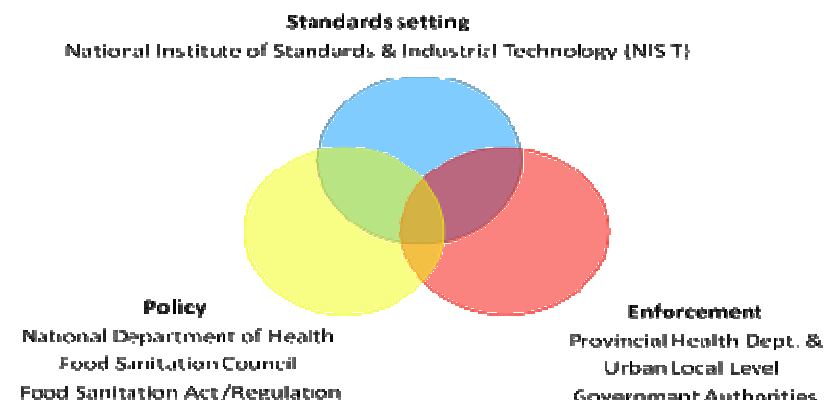


Figure 10. Structure of Food Regulatory System in Papua New Guinea

According to Mr Daniel, food recall procedure documents are with the Independent Consumer & Competition Commission (ICCC), however, enforcement of such

procedure was not effective. But officers from other enforcement agencies are still mandated by their laws and may enforce food recall and seize products when found to be non-compliant to national standards. During the melamine incident, information was received from INFOSAN then a Melamine Task Force was created. The task force developed a Plan of Action, press release was given to daily news papers and the Customs office ban all importation of infant formula, milk and milk products from China. Milk and milk products were likewise removed from shelves and information about melamine was distributed to different stakeholders. His presentation is attached as **Appendix 22**.

## Peru

Maria del Carmen de la Colina Ochoa, Food Engineer from the Ministry of Health reported the Food Recall System in Peru. She explained food recall is the main responsibility of the manufacturer. The recall plan is usually part of the provider's control system like HACCP, lot identification, and traceability program. It is the manufacturer's responsibility to maintain an effective traceability and recall system, and to always make the process and traceability documentation available.

The provider's responsibility is to inform any food safety incident to the competent authority, however, there's no legal requirement if it is a quality issue. In the event the incident is detected by a regulatory authority through market surveillance, and complaints, the provider is immediately notified to provide necessary information in order to evaluate appropriate intervention. If alert or notification comes from overseas usually received by the chancellery, the INFOSAN contact point, relevant authority will be contacted and will identify the importers through sanitary registration. The Tributary Administration will have the affected lots disposed. The Sanitary Authority on the other hand is responsible for risk assessment, planning and coordination activities and for risk communication.

She also enumerated some food incidents in Peru namely the melamine in milk and milk products in 2009, where samples need to be sent in Chile because Peru has no laboratory capacity to do the analysis, *Bacillus cereus* in instant powder food for infants (2008 and 2009) and expired soybean oi (2009). Her presentation can be found in **Appendix 23**.

## Philippines

Ms Albina Mendoza of Food and Drug Administration, formerly the Bureau of Food and Drugs (BFAD) presented the food recall system in the Philippines. BFAD Bureau Circular No. 8 series 2001 also known as the Product Recall System details the guidelines in conducting food recall in the Philippines. Food recall can be both initiated by the company or at the request of BFAD. A recall is as Class I if a situation in which there is a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death, this is usually during pathogen-contamination of food; Class II if a situation in which use or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health

consequences is remote; and Class III if the situation in which the use or exposure to a violative product is not likely to cause adverse health consequences like mislabelling.

Figure 11 highlights the general procedure in conducting food recall in the Philippines. Here, the BFAD Committee for Product Recall, upon receipt of a case report, will assess the hazard presented by a product being recalled or considered for recall. Such case report may come from the company (if company initiated), BFAD technical divisions, DOH or other government offices, or consumer complaints. Likewise a public health alert will be issued within twenty-four (24) hours for cases that have been determined as Class I or Class II Recall. For a Class I recall, notices and warnings shall be issued, by tri-media, to the general public, health professionals, health institutions, industry associations, distribution outlets for such products and all other concerned parties; Class II recall, notices and warnings shall be issued to groups and institutions that are identified as those who generally use or are exposed to the product and to those who could help remove such violative products from the market or prevent such products from being used; and Class III recall - notices and warnings shall be issued to concerned parties and distribution outlets.

Moreover, in case the concerned firm refuses to conduct a product recall, regulatory action and/or other measures will be pursued by FDA like seizure, multiple seizure or court action. The concerned FDA inspection division will audit the recall operation by developing and implementing a recall audit program so in case the product is to be destroyed, the destruction should be witnessed by a FDA representative. It will also determine when a recall will be terminated and upon such determination, provide written notification of the termination to the recalling firm.



### General Procedure for Product Recall:

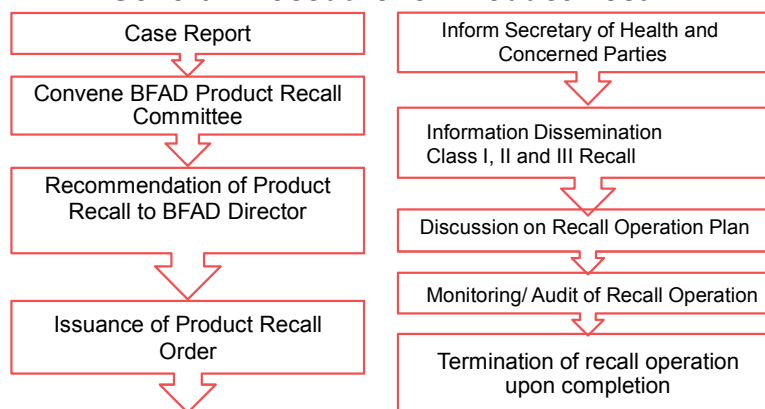


Figure 11. General Procedure in conducting food recall in the Philippines

Ms Mendoza noted in developing a recall strategy the duration to complete the recall operation should also be considered. It is recommended that completion of a recall operation should be seven (7) days for Class I, fifteen (15) days for Class II and thirty

(30) days for Class III. Asked why seven days for Class I when the situation is very urgent, Ms Albina explained that for Class I, public alert will be issued within 24 hours at the same time, recall has already been undertaken. Recalling *all* products should be completed within 7 days only. Her presentation is attached as **Appendix 24**.

### Republic of Korea

Mr Kyoung-Mo Kang presented the food recall system in the Republic of Korea. Food recall in Korea can be both voluntary or as per request by the Korea Food and Drug Administration (KFDA), but mostly KFDA-initiated. Recall process starts with recall announcement through KFDA's website, daily newspapers, TV subtitle advertisement, and SMS texts, indicating the title of the recall, reason for recall, brand and product name, production dates, details of the manufacturers etc. Recall monitoring involves checking the implementation of the recall by the company on site. The firm reports the recall results including the amount of uncollected products during the termination of the recall. KFDA also verifies the effectiveness of the recall process.

He highlighted the two electronic systems established by Korea for urgent recall. One is the Urgent Notification System whereby details of the unsafe food (e.g. firm's details, inspection history and reason for recall etc) are transmitted to the Urgent Recall center which then disseminates the information via the electronic system to related organizations and retail stores including mid/small-sized distributors and retailers nationwide. Figure 11 shows the flow of information, from the center to the distributors. Another is the POS data system that disallows recalled products to be sold to the costumers. POS is the place in a shop where a product is passed from the seller to the customer.

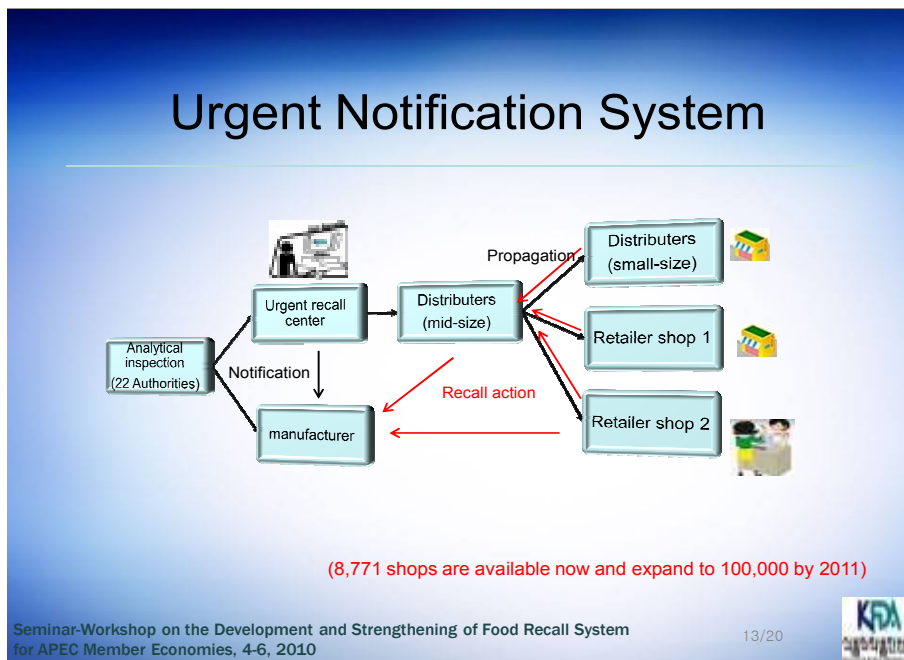


Figure 12. Korea Urgent Notification System

Despite of the presence of these computerized systems, Korea is faced by the complicated distribution channel of companies including that of Small and Medium Enterprises (SMEs) in effectively implementing a recall strategy. Keeping a balance between transparency and honestly informing the public of the actual incidents as well as the concern to the company's image is carefully considered by KFDA. Other details of Korea's recall system can be found in **Appendix 25**.

### **Russian Federation**

Mr Andrey Shirkov of Social and Industrial Foodservice Institute presented the food recall in Russian Federation. He clarified that in Russia, there is no distinction between food withdrawal and food recall, hence may be used interchangeably.

Some of the legislations that contain provisions on food recall are the law of quality and safety of food products, law of consumer protection, and recently adopted law of technical regulation. He mentioned that some sectors of Russia are regulated by this technical regulation which is in compliance with the requirement of the World Trade Organization (WTO) and some sectors are still regulated by the old system.

He noted that in the old system, they have state standards which are obligatory to all. Now standards are voluntary. There are distinctions between safety and quality provisions. During Soviet time, there were no regulations, there were standards for all kinds of products hence there was no difference between quality and safety standards. After joining the WTO, Russia has implemented some technical regulation reforms. He noted the importance of these reforms on creating an environment that promotes not just strengthening of technical capabilities but cooperation of manufacturers in implementing an efficient food recall strategies.

According to Russian laws, during food outbreaks or emergencies, there are certain responsibilities that must be observed at different stages of the food chain. If the hazard was identified at the production, the producers or the manufacturers are responsible for everything. They will shoulder all expenses that will be incurred during the food withdrawal. At transportation and storage, organizations that handle the food will inform the manufacturers which in turn will be responsible for the recall. At point of sale, the owners, retailers or distributors will be the one responsible for recall process. During outbreaks, it is required by the law to have a laboratory investigation to be done within a week. Samples are to be taken by state authorities and products in question are isolated from the commerce. Assessment will be done by experts to determine if the products should be destroyed or reprocessed. Reprocessing or disposal of contaminated food should be coordinated with state control authorities. These food control agencies are also mandated by the law to have selective investigation, at least once in three years of food manufacturers as part of their reaction or response function.

Moreover, should there be reports or information of food production that are non-conforming with technical regulation particularly by manufacturers, state authorities have ten days to verify the accuracy or validity of the information. During this period, a program should be designed to prevent possible harmful impact of this non-conforming production practice. If the information was confirmed, another measure



should be done to prevent harmful impact of this non compliance. If harm can no longer be eliminated, production is suspended, food produce is recalled and purchasers are compensated. Should the company ignored compulsory withdrawal of food, state authorities can go to court and file administrative and criminal charges to the manufacturers.

The strength of Russia is not just on food recall but on food control as a whole. Russia has the scientific and intellectual resources as well as technical experts available for food control. Weakness lies on the lack of responsibility or initiative of producers or manufacturers for a recall when found to be non-compliant with regulation. They care less for public opinion and rely more on state action. He sees some opportunities in strengthening more of the traceability capability, creating more incentives for companies with good food safety management system and reinforcing penalties to those who do comply with regulation.

A question was raised how Russia check imported food at the border, Mr Shirkov affirmed that Russia has efficient border control or checks of food that are brought to Russia. This is being implemented by the agency for protection of consumers. Likewise, state control agencies constantly negotiate with foreign companies before importing foods to Russia to make sure state regulations are strictly followed. He further explained that the agency for consumer affairs in this case, is under the Ministry of Health. Its main leverage is to give certification on food safety and quality. It has no police power but it can file case to court in the event that it finds any violation to technical regulations. Asked to elaborate more of the traceability system conference held in Russia, he expounded that the purpose of the conference is to introduce new technology for traceability system and Russia is now considering of reinforcing their recall system similar to that of European Union. His complete presentation is attached as **Appendix 26**.

## Thailand

Ms Surewan Pattanawongyuenyong, Senior Inspector of Food and Drug Administration presented the food recall system for Thailand. She first enumerated agencies in Thailand the deal with food and food safety:

The Police Crime Suppression Division on Consumer Protection is under the Prime Minister's Office, which aims to protect consumer rights, which involves food safety, advertisement and product labeling.

The Ministry of Agriculture and Cooperatives (MOAC) is responsible for the control of imports and the safety of raw and semi-processed meat, plants, and fish products as well as the certification of exports. Under MOAC is the National Bureau of Agricultural Commodity and Food Standards (ACFS) which is tasked to (1) the control and safety monitoring of fresh and processed agricultural products and foods by certifying and enforcing standards within the production and processing industry; (2) development of agricultural commodity and food standards; (3) serving as the national accreditation agency for certification bodies for standards, hazard analysis as well as supervision of both public and private agricultural commodities and food laboratories to be in line with prescribed standards; (4) representing Thailand in

international standard-setting organizations; (5) SPS risk assessments and negotiation with international partners in order to reduce technical barriers to trade; and (6) improvement and enhancement of the competitiveness of Thai agricultural and food standards.

The Ministry of Public Health has three departments and one food center that are concerned with food safety and human health (i) the Food and Drug Administration (FDA); (ii) the Department of Medical Sciences (DMSc); (iii) the Department of Health (DOH); and (iv) the Food Safety Operation Center. The FDA is the principal department in charge of consumer safety in the consumption of foods, use of drugs and chemicals. It is also in charge of national food regulations which lay down mandatory measures based on risk analysis principle. These are the pre-marketing measures in the form of registration of process and ingredients, labeling and licensing requirements and post-marketing control measures which include inspection and food safety in the market place on food. Additionally, FDA is made up of two divisions, the Food Control Division (FCD) which undertakes among others the development of standards and rules and regulations relating to control measures including food recall. It supervises food sold in the market. The post-marketing group of the FCD evaluates the information it receives from various sources like consumer complaints, news items and from food surveillance inspection. It may audit manufacturers, detain products of the form and take samples for analysis during investigation of the problem. The group may decide whether to stop the production of the product or initiate recall for further treatment, destruction, downgrading or re-exportation. The following summarized the FCD recall procedure:

### Food Recall Process -Food control Division

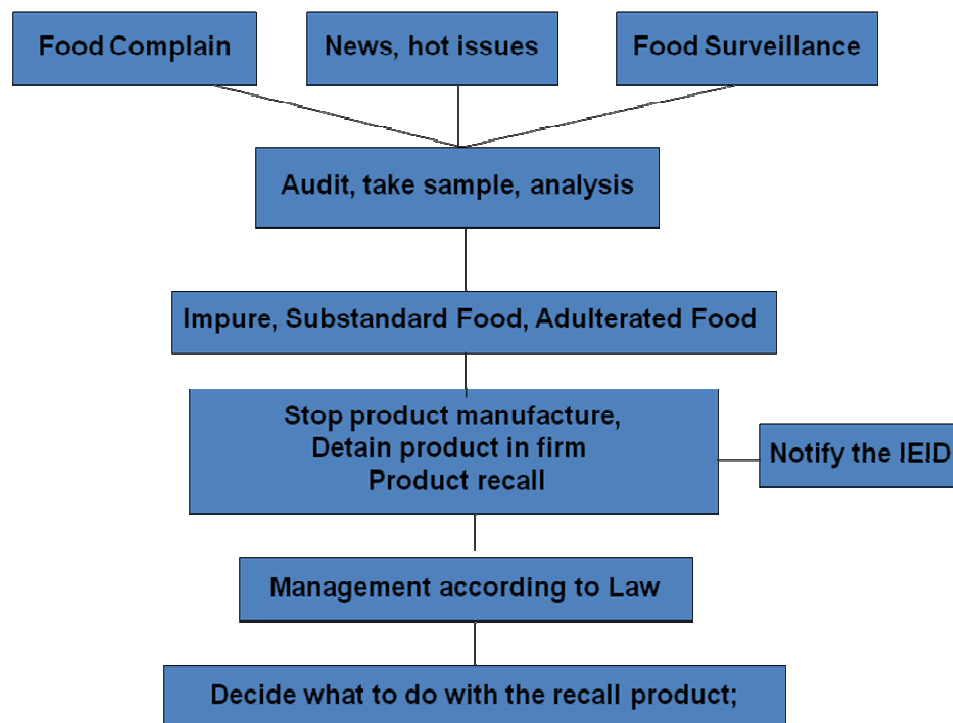


Figure 13. Thailand FDA's Food Control Division Recall Procedure

The post-marketing group may also request the Import and Export Inspection Division (IEID) of FDA for further inspection. The latter manages imported food. Samples of quarantine food items are subject for analysis prior for release to market. Non quarantine food items are released in the market, but will be subjected for recall if found not to be compliant to standards during surveillance. Some recent food recalls that were undertaken in Thailand are the melamine-tainted milk products and bamboo tissue with high sulfur content, both from China. Her complete presentation is found at **Appendix 27**.

## Viet Nam

Ms Tran Minh Thanh, Product Officer of Department for Products and Good Quality Control presented food recall process in Viet Nam. Products that violate the Food Hygiene and Safety Quality may be recalled. Some violations, among other, may include selling beyond expiration date, mislabeling, and new products that have yet given the permission to be sold. Food recall in Viet Nam may also be voluntary and mandatory. Companies may recall their products voluntarily in order to protect their brand name. Compulsory recall if authorities find the products, proven or otherwise, to be high risk for consumption. Food recall in Viet Nam is also classified to different levels. Level 1 Recall is applied to food products that cause serious consequences that may even lead to death of consumers; Level 2 if the food products may only cause temporary or immediate but not serious consequences and Level 3 is applied only to suspected product. Recalled products may be reprocessed, reused for other purpose, destroyed or returned to exporting economy depending on the level of risk and the circumstances.

The Vietnam Food Administrator (VFA) and the Department of Health in cities and provinces under central authority will decide on the recalled products. Other authorities like the Ministry of Agriculture and Rural Development, the Ministry of Industry and Trading, etc. also have the rights to recall products under their jurisdiction. Her presentation is attached **Appendix 28**.

## Risk Communication

Dr Barbara Butow talked about Risk Communication in Australia, public perceptions of risk and went over some communication strategies and tools during the conduct of recall. Looking at the Risk Analysis framework (Figure 14), it can be observed that Risk Assessment and Risk Management is enveloped by Risk Communication.

According to Codex, Risk Communication is *the interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions*(Codex, 2001). It is not just an add-on at the end, it is an active part of the process of Risk Analysis. It is a two-way process (talking and listening) and it is about opportunities for public involvement in decision making. It is about internal communication as well. Everybody in the team should know what's going on,

everyone should be informed, updated, and briefed about the situation, so just in case somebody asks for any information, anybody can provide timely and accurate details. Risk communication is everyone's responsibility.

On the other hand, Risk Communication is *not* just about the sole responsibility of communication specialists or communicating risk and telling people what's wrong or simply selling decisions to the public. It is *not* a crisis-related process, but risk communication also conveys positive messages, building relationship or partnership with stakeholders, listening to their problems, and talking to industry and knowing their attitudes and motivations. Risk communication is also about maintaining contacts, networking and keeping people on the loop.



Figure 14 Risk Analysis Framework<sup>7</sup>

In communicating the risk, it's important to take into consideration the public perceptions of the risk. People have different mind sets and see the world differently. Risk communicators should be aware of differences on people, but it is important to explain though that we cannot live risk-free lives and it is generally accepted that zero-risk is impossible and that there is no such thing as risk-free environment. Hence, as risk managers, it is important to be aware of how to approach risk issues with the public, because of the *fear* factor and how risk is perceived.

As shown in Figure 15, the acceptability of the risk by stakeholders is negotiated and established. It is important to understand expert and consumer risk perceptions to develop effective communication during a food incident or recall. Experts prefer quantitative algorithms for risk acceptability e.g. risk-benefit calculations, risk comparisons, risk probability is more important to risk magnitude. Consumers focus on the magnitude of risk, the uncertainty, distribution of risk, the dread factor and the catastrophic potential – the outrage factor. Trust in the risk assessors and risk managers, is the most important factor whether stakeholders define if the risk is acceptable.

<sup>7</sup> FAO/WHO. 2006. **Food Safety Risk Analysis. A Guide for National Food Safety Authorities** - FAO Food and Nutrition Paper 87.



Figure 15. Perception of risk

Dr Butow also specified some communication strategies and tools during food incident or recall (Table 2). The implementation of these different types of strategies can be realized through a communication action plan. This needs to be set up at the outset of the Risk Analysis process and requires a cross-section of skills and knowledge – although most probably will be driven by food regulators.

Low risk – Low perceived risk, eg allowed microbial contaminant levels	<b>PASSIVE</b>
Low risk – High perceived risk, eg. <i>E. coli</i> , in yet-to-be-cooked meat	<b>RESPONSIVE</b>
High risk – Low perceived risk, eg <i>Campylobacter</i> in chicken	<b>EDUCATIVE</b>
High risk – High perceived risk, High risk – High perceived risk eg. <i>E. coli</i> O157 H7, in salami	<b>PROACTIVE</b>

Table 2. Communication Strategies

Moving on to risk communication during food safety incidents, Dr Butow explained some communication methods like having a spokesperson either a Chief Scientist or communication lady to give the message depending on the emphasis, press conferences for major crises, making messages updated, for instance, FSANZ has full time staff to keep the website updated, scripts for enquiry staff. She also enumerated some conventional and modern communication tools, like having an emergency plan, regular internal meetings in incident room, using existing networks/structures, knowing everyone before the emergency, establishing an emergency contact list, having established media contacts, keeping a media log especially during debriefing, mobile phones (blackberries), website, emails, google news and chatrooms.

understanding risk. Dr Butow said that FSANZ is constantly looking to improve things, updating techniques. The comment may be a good suggestion for the social science unit of FSANZ to take into consideration in their research. Asked how FSANZ reached its consumers. FSANZ has Consumer Liaison Committee that meets three to four times a year with representation from different interested publics not necessarily food safety experts all over Australia including NGOs to get involved and get perception of FSANZ works.

## WORKSHOP

During the workshop, participants were grouped into two. Group A was composed of Brunei, Indonesia, Chile, Malaysia, Papua New Guinea, Republic of Korea, Mexico and the United States. Group B was comprised of Peru, Philippines, Chinese Taipei, Russia, Viet Nam, Thailand and Australia. Based on the lectures and experiences of each member economies, each group was asked to identify and enumerate some *common* Strengths, Weaknesses Opportunities Threats (SWOT) among their recall protocols. The groups are also requested to recommend some future action plan for possible joint follow up projects that will sustain the output of the Seminar.

Dr Mektir Singh presented the work of Group A. Some common strengths among member economies are the (1) presence of multinational companies that can afford to establish a recall system along with other food safety management systems. These companies have the ability to invest and employ the right people; (2) Products are being registered before being marketed, hence regulatory agencies are able to monitor and identify who are the wholesalers, importers or distributors. This also means that regulatory agencies have (4) some control over imported and exported foods. (5) Surveillance system on all foods. Likewise, it is observed that commonly, the Ministry of Health is the lead agency for food recall among member economies.

He also enumerated some common weaknesses, like (1) complexity of distribution channel (traceability) for products; (2) geographical distribution including weak infrastructure, transportation and communication system of a member economy; (3) insufficient human resources which is apparent both in developing and developed economies; (4) numerous small scale industries who are comfortable with the current system and maintaining the status quo. These industries are more focus on the profit than be convinced on having documentation or recall plan strategies as part of their business operation; (5) limited technical support; (6) no guidelines and protocols to involve all stakeholders. There must be rules and responsibilities. He explained that at the end of the day, somebody has to play a role. (7) Companies do not take responsibility. Most of the times, when problem strikes, they just let the government do its job alone; (8) lack of products information; (9) lack of government support and commitment. Some economies change government very often, hence a change in prioritization as well. (10) Complex enforcement and (11) farm to table bio security risk. It is important to have recall system at the farm level, to make the system holistic, covering the entire food chain. One of the opportunities that needed to be tapped is developing template or standard operating procedure for crisis management. So when problem strikes, no time is wasted on organizing people,

finding solution, and planning action in abating the crisis. The template will serve as the guide and expedite the appropriate response. Some of the threats highlighted are the outdated legislation, smuggled food products, rampant unregulated internet sales of food items and lack of defined role of responsibilities in agencies. The complete Group A output is attached as **Appendix 30**.

Meanwhile, Ms Edna Begino of the Philippines, reported for Group B. Common SWOT among the member economies of the group are highlighted in red text (see **Appendix 31**). Among the strengths are laws and guidelines, consumer awareness, strong scientific foundation and expertise. Weaknesses include lack of financial resources, lack of coordination among agencies involve in the recall and absence of enforcement powers. Some of the opportunities needed to be tapped are the availability of trainings from international bodies to continue strengthening regulatory agencies, Asian single window policy may increase in exchange information of hazardous product between Asian economies, GSI recall portal. Among others, some of the threats political interventions, bureaucracy, emerging new products with many ingredients and globalization in general.

Group B also identified some possible Joint APEC programs related to food recall, namely information system/web base, common draft recall protocol guidelines, comprehensive training risk communication, national information center on food recall and best practices, establishment of a food model that could be used for a food recall plan and establishment of a traceability system on an economy scale (for small and medium industry).

## CLOSING PROGRAM

Dr Sonia de Leon, the Project Consultant summarized the main points of the seminar-workshop. Despite diversity, different social cultural habits, different governmental and political system, there are still common elements among APEC economies and that is to take the mission of food safety and food recall seriously. She emphasized that regardless of the food group, the threats to food safety system are everywhere and that it is prudent to be watchful. The plans according to her are not to remain as plans and resolutions but are to be implemented in the near future by the individual economies. She also hoped that some joint programs can ensue from this networking on food recall for consumer safety worldwide.

Dir. Gilberto Layese officially closed the Seminar and acknowledged all the speakers, participants, and the people behind the project.

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