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
May 2010

Committee on Trade and Investment (CTI)/Sub-Committee on Standards and Conformance (SCSC)
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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 DVELOPMENT AND STRENGTHENING OF FOOD RECALL SYSTEM FOR APEC MEMBER ECONOMIES

Project No. CTI 55/2009T
The Richmonde 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 Richmonde 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 situationer 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[1] 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.**

[1] 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 or 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.

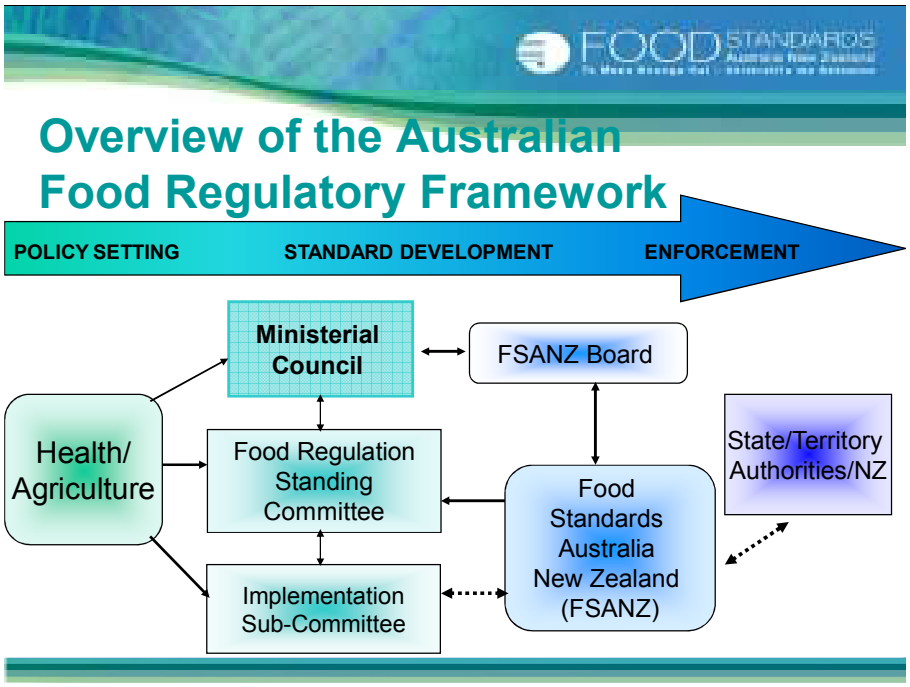

Figure 1. Overview of the Australian Food Regulatory Framework

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 mislead 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.

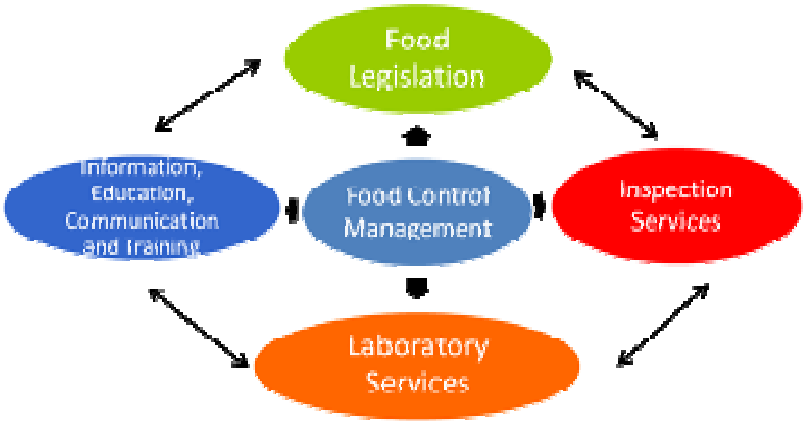

Figure 2. FAO/WHO Key Components of National Food Control Systems

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.[2]

[2] 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 identity 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

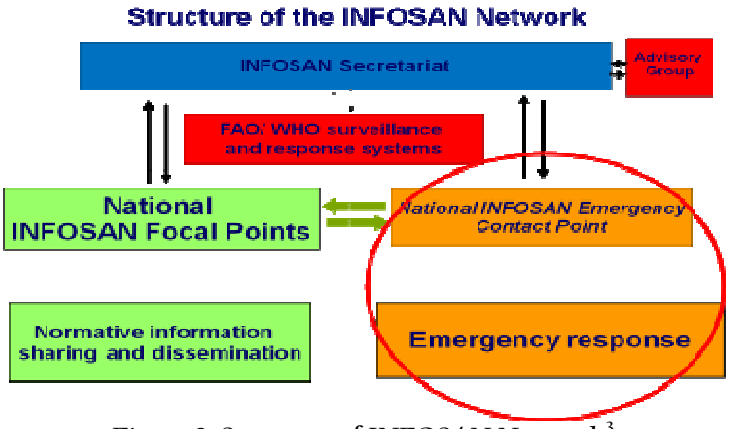

Figure 3. Structure of INFOSAN Network[3]

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.

[3] **INFOSAN**. http://www.who.int/foodsafety/fs_management/infosan/en/

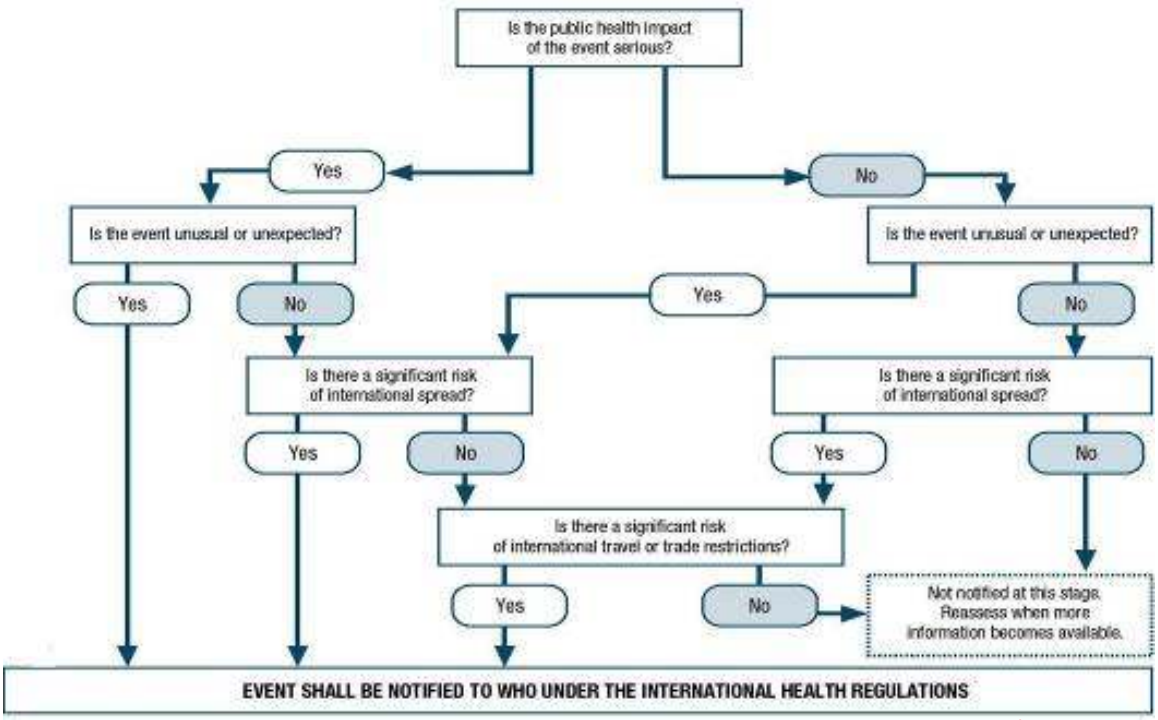

Figure 4. Decision Instrument for the Assessment and Notification of Events[4]

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 means 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*

[4] 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 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

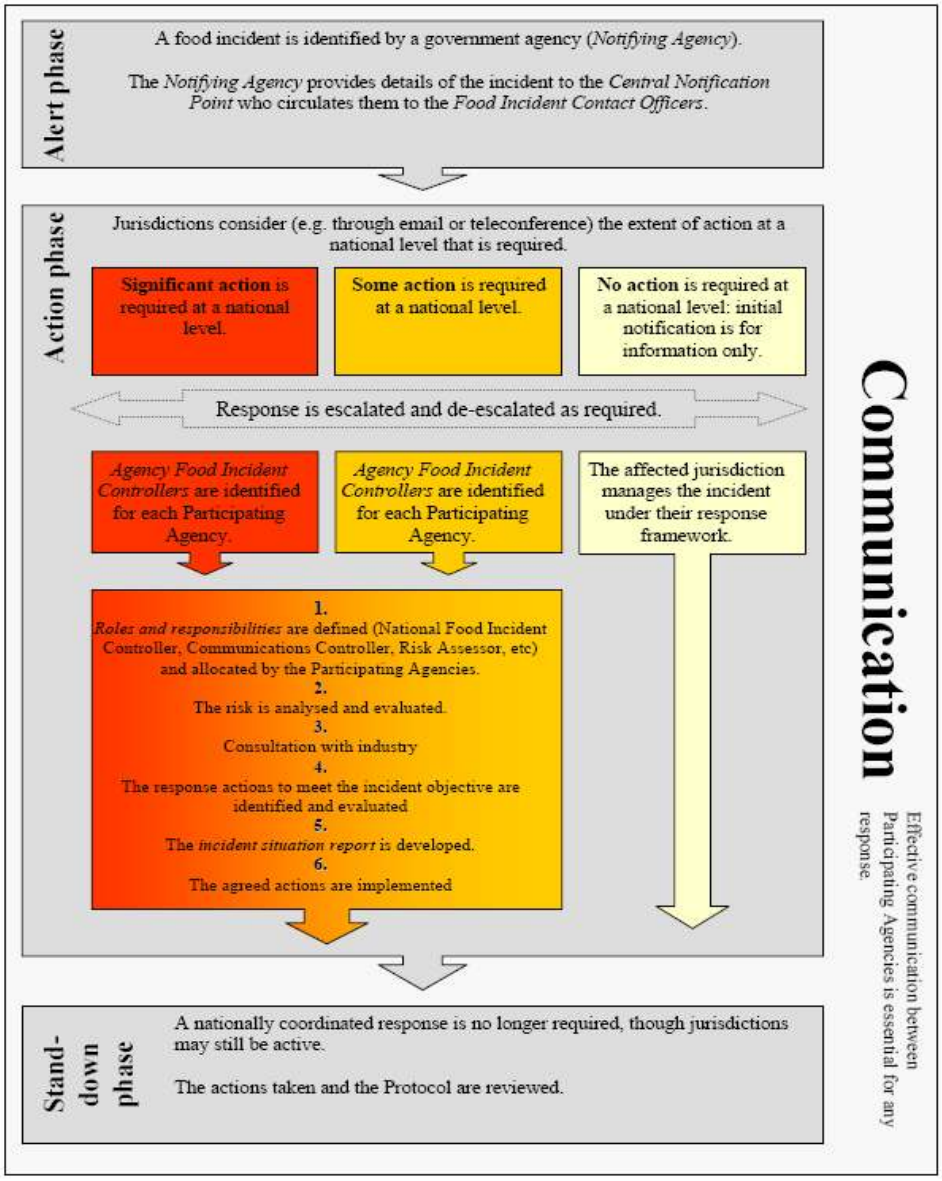

Figure 5. Outline of the steps in the National Food Incident Response Protocol[5]

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.

[5] **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[6] 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.

[6] 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 indentifies 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:

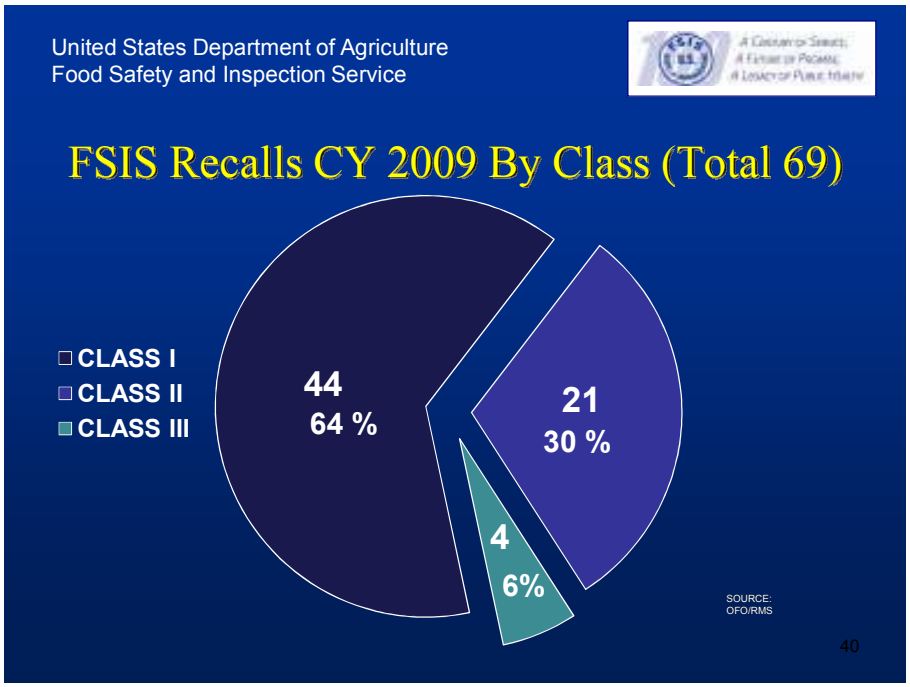

Figure 6. FSIS Recalls CY 2009 by Class (Source: OFO/RMS)

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:

CLASSIFICATION	RETRIEVAL LEVEL	EFFECTIVENESS CHECKS	PUBLIC WARNING
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 1. 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 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 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 at 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**.

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:

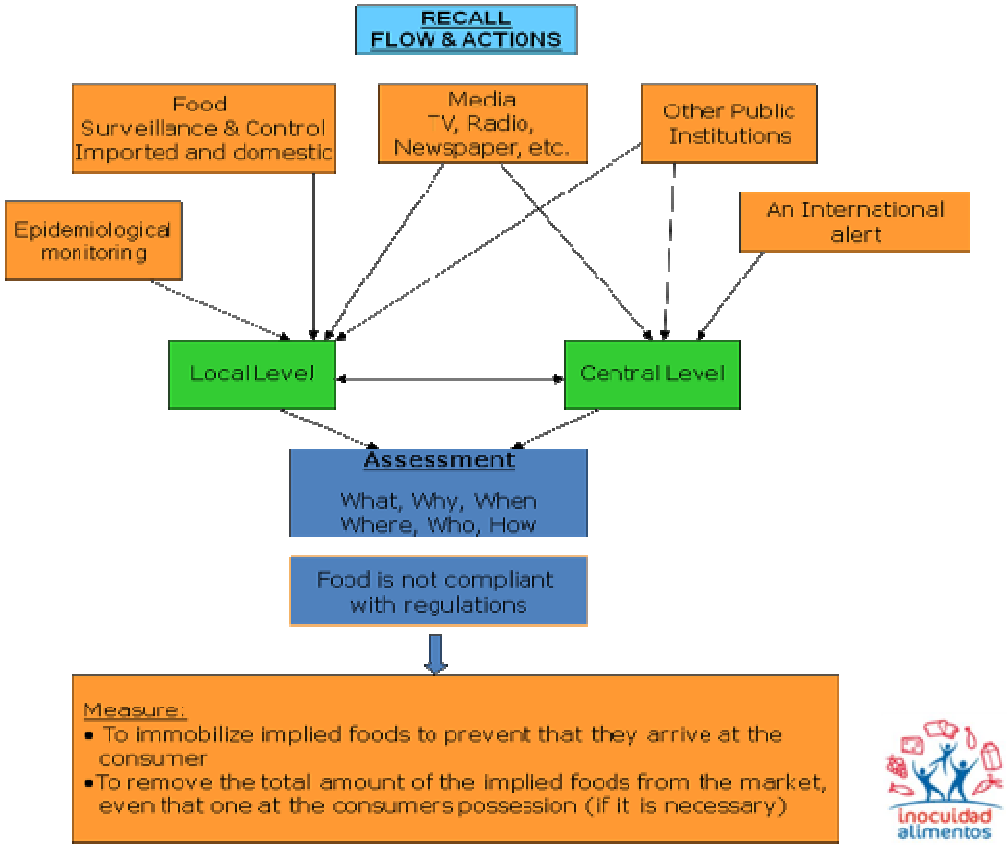

Figure 7. Food Recall Flow and Action in Chile

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:

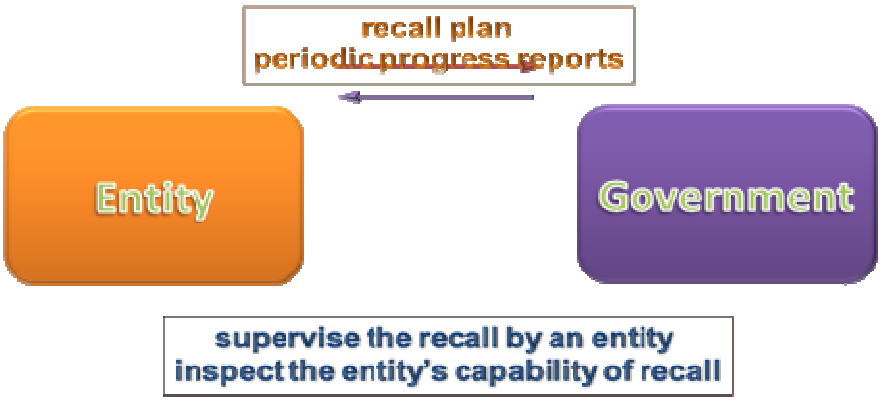

Figure 8. Chinese Taipei Recall Operation

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.

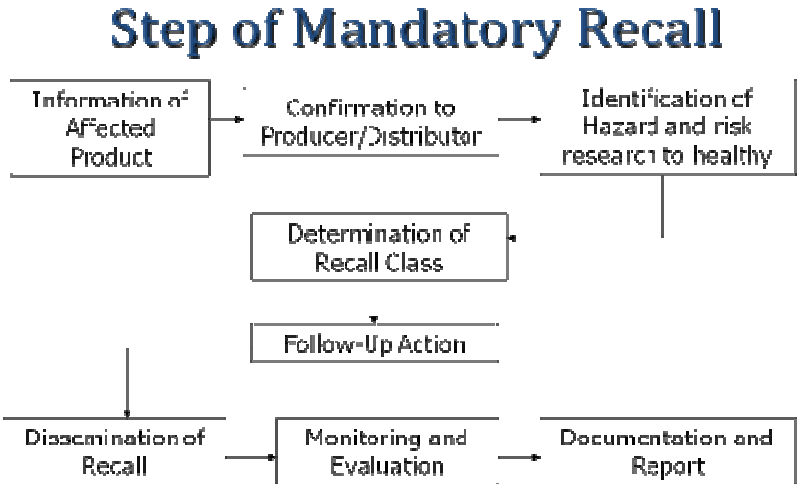

Figure 9. Steps of Mandatory Recall in Indonesia

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 Moktir 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 involves 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.

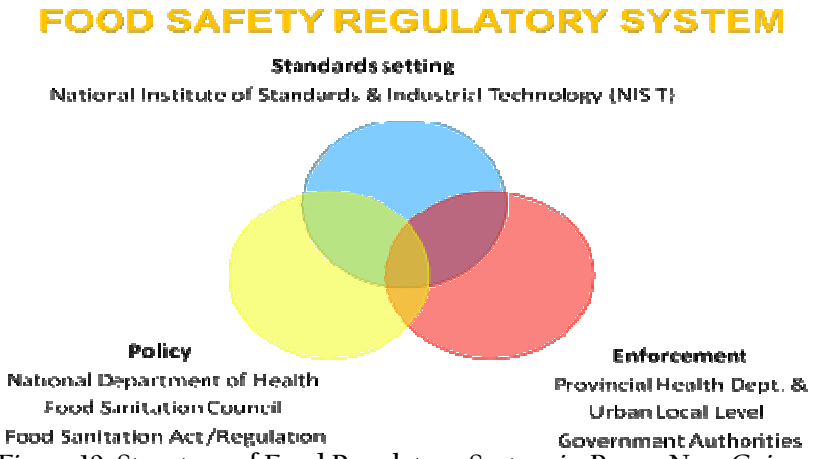

Figure 10. Structure of Food Regulatory System in Papua New Guinea

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.

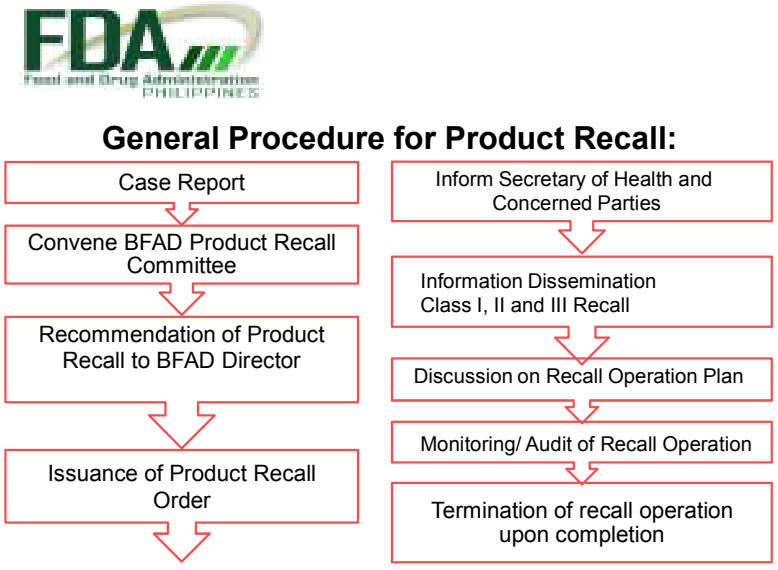

Figure 11. General Procedure in conducting food recall in the Philippines

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.

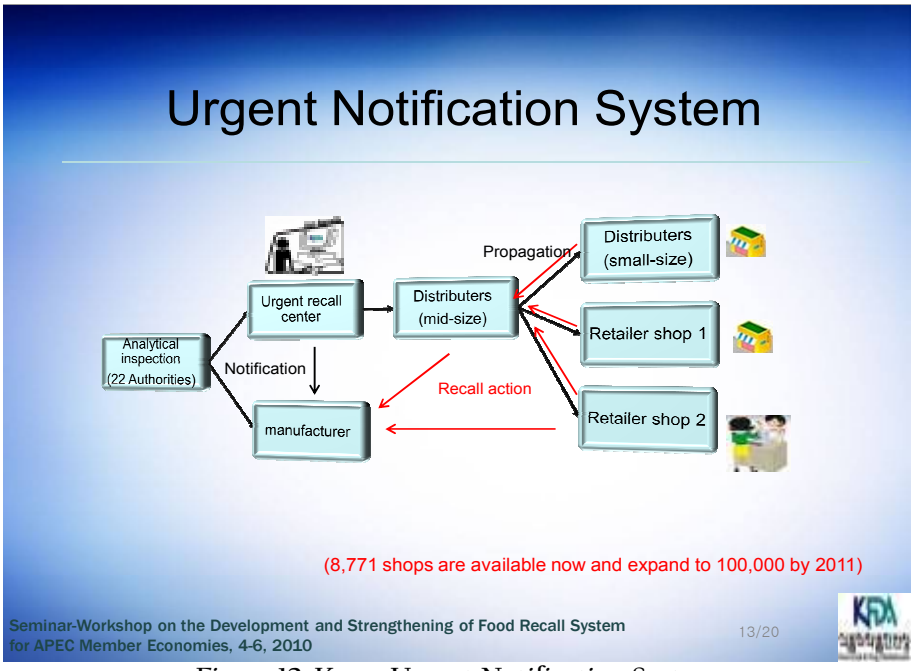

Figure 12. Korea Urgent Notification System

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 Sureewan 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:

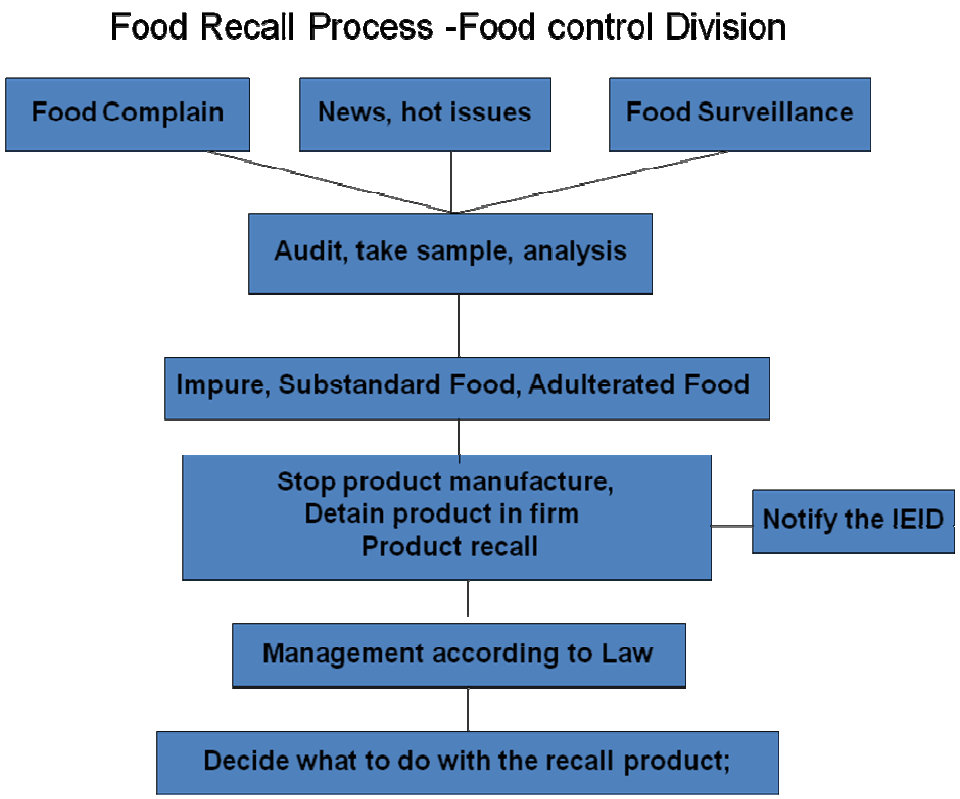

Figure 13. Thailand FDA's Food Control Division Recall Procedure

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[7]

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.

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

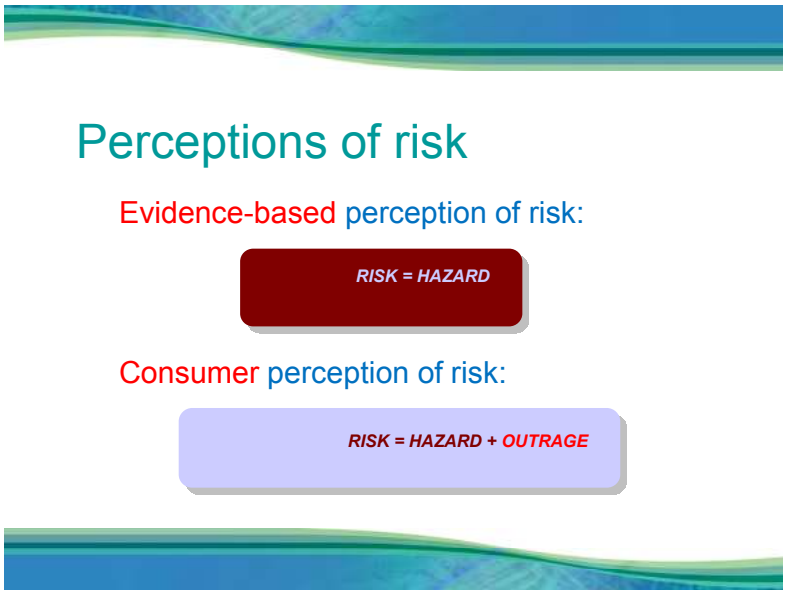

Figure 15. Perception of risk

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	**PASSIVE**
Low risk – High perceived risk, eg. *E. coli*, in yet-to-be-cooked meat	**RESPONSIVE**
High risk – Low perceived risk, eg *Campylobacter* in chicken	**EDUCATIVE**
High risk – High perceived risk, High risk – High perceived risk eg. *E. coli* O157 H7, in salami	**PROACTIVE**

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.

During the open forum, Dr Butow was asked whether in the past decade FSANZ is using risk communication techniques, if there was a change in Australian public in

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 Moktir 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.

-xoxo-

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APPENDIX 2

PROGRAM OF ACTIVITIES

Time	Day 1 (Tuesday)	Day 2 (Wednesday)	Day 3 (Thursday)
Morning Session			
9:00 – 9:30am	***Opening Program*** **Welcome Address** – Asec. Preceles H. Manzo, Department of Agriculture **Message** – Dr. Soe Nyunt-U, WHO Representative, Philippines **Message –** Ms Emiko Purdy, Agricultural Counselor, USDA, Philippines **Photo Session**	**USFDA Food Recall Policies** Dr Aurora Saulo – University of Hawaii at Manoa	***Member Economy Experiences on Food Recall (cont.)*** Russia Thailand
9:30 – 10:30am	**Introduction of speakers/participants** **Mechanics of the Seminar-Workshop –** Mr Israel Q. Dela Cruz, Project Manager and Over-all Project Coordinator **Food Recall Overview –** Dr Sonia Y de Leon, Project Consultant	**USFDA Recall Case Study** Dr Aurora Saulo – University of Hawaii at Manoa **Outbreak to a Recall, A Case Study** – ***Overview of Food Safety Inspection Service (FSIS/USDA) Recall Process*** Dir. Elizabeth Volk, USDA-FSIS	***Member Economy Experiences on Food Recall (cont.)*** Viet Nam **Overview of Risk Communication in Australia during Food Emergencies** Dr Barbara Butow - FSANZ
Coffee Break			
10:45 – 11:45am	**Food Recalls Australia** Dr Barbara Butow – FSANZ	**Case Studies:** Australia Experience on Food Recall Mr Elliot Hill - FSANZ	**Workshop Mechanics** – Dr. Sonia Y. de Leon, Project Consultant **Workshop Groupings:** Group A (USA Moderators): Brunei, Indonesia, Chile, Malaysia, Papua New Guinea, Republic of Korea, Mexico Group B (Australia Moderators) Peru, Philippines, Chinese Taipei, Russia, Viet Nam, Thailand
11:45 – 12:00nn	***Open Forum***		
Lunch			
1:30 – 3:30 pm	**UN Programs on Food Recall** **Food and Agriculture Organization** – Ms Sashi Sareen **World Health Organization** – Ms Jennifer Bishop **Awarding of Certificate of Appreciation –** Project Overseer **Food Incident Management** – the Australian Experience Dr Barbara Butow – FSANZ	***Member Economy Experiences on Food Recall (cont.)*** Brunei Darussalam Chile Chinese Taipei Indonesia Malaysia Mexico Papua New Guinea Peru	**Participants presentation of workshop outputs and plan of action** **Synthesis Project Consultant** **Closing Ceremonies** **Awarding of Certificates** – Project Overseer **Reminders –** Project Manager and Over-all Coordinator
Coffee Break			
3:45 – 4:45pm	**Meat and Poultry Recalls –** Dr Elizabeth Volk, USDA-FSIS	***Member Economy Experiences on Food Recall (cont.)*** Philippines Republic of Korea	
4:45 – 5:00pm	**Open Forum**		
6:00 – 8:00pm	**Welcome Dinner**		

KEYNOTE SPEECH

PRECELES H. MANZO
Assistant Secretary, Office of Policy and Planning
Department of Agriculture
Republic of the Philippines

Seminar-Workshop on the Development and Strengthening of Food Recall System for APEC Member Economies
May 4-6, 2010

It is my pleasure and distinct honor to welcome you all in the Philippines on behalf of Her Excellency Gloria Macapagal-Arroyo and the men and women of the Department of Agriculture headed by Atty. Bernie G. Fondevilla to this three day Seminar-Workshop on the Development and Strengthening of Food Recall System for APEC Member Economies.

We, at the Philippine Department of Agriculture – through the Bureau of Agriculture and Fisheries Product Standards (BAFPS) – extend our sincerest gratitude to APEC for favorably considering our proposal to serve as host of this important activity.

In time with different current events happening left and right around the globe, food safety concerns somehow manage to be a headliner. Despite its increasing popularity, 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. With growing concerns on this predicament come along different campaigns regarding health awareness. These are being offered on the market by government and non-government organizations hoping to minimize if not totally address the problem.

Recently, several dramatic incidences of food accidents and outbreaks, like Melamine tainted milk and peanut butter contaminated by *Salmonella,* were observed which led to raise 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 discomfort over microbiological and chemical contaminant of food chain as well as heightened consumer interest in diet-related health issues, have contributed to the augmentation of the profile of food safety control systems.

In return, such occurrences led to improvement and strengthening of risk management actions requiring constant vigilance from the government bodies as well as different industries and consumers.

In relation to this, sharing the fame of food safety concern and considered part of food control system, is the food recall which presently being carried out to remove from the market the food that poses risk to public health and safety. This action should be given importance as this offers significant impact in trade, locally and internationally, requiring effective implementation.

With this three-day seminar workshop, it is aimed to give focus on the issue, help improve one's awareness on the topic and develop a competent strategy on implementation of food recall.

It is a challenging job indeed, but as what they say, challenges make life interesting, overcoming them makes life meaningful. Again, a warm welcome to all you. I wish you all a good stay in the country, and may you have a productive seminar ahead of you. Thank you for this privilege Mabuhay!

MESSAGE

Dr Soe Nyunt-U
WHO Representative to the Philippines

Colleagues, magandang umaga po and welcome to the Philippines. Thank you to the organisers for inviting WHO to be part of this important seminar.

Improvements in food and transportation technologies, together with the globalization of the marketplace, and changes in work expectations and hours, have led to an increase in consumer demand for readily accessible and easily prepared processed food. Associated with this is an increase in the international distribution of raw materials, food ingredients, food additives and food products. While international distribution adds to the diversity of food available to consumers, it also has the potential to result in the cross-border distribution of food that is not safe. Every week, new outbreaks of foodborne disease are reported in the media. With the increase in international trade and travel, outbreaks which were once limited to local communities, can now affect several countries.

WHO estimates that foodborne and waterborne diarrhoeal diseases kill about 2.2 million people annually; 1.9 million of them are children. The World Health Assembly, the highest governing body of the WHO, adopted a resolution in 2000 to recognize food safety as a significant public health concern. This resolution is as important today, as it was a decade ago, with significant public health, economic and societal impacts associated with foodborne disease evident in both developed and developing countries.

WHO aims to work with Member States to develop their national food control programmes with the overall goal of improving public health through the reduction in foodborne disease. This is an enormous ongoing task and working in partnership with other UN organizations such as FAO and UNICEF, and other forums such as APEC and ASEAN, is important for success. Developed countries also have a vital role in sharing information, experiences and expertise with developing countries. Only through these partnerships will we see improvement in national food control systems.

As the saying goes, ‘an ounce of prevention is worth a pound of cure’, and this is true in food safety. Effective food safety programmes, based on Good Hygienic Practices and Hazard Analysis Critical Control Point System (HACCP) and risk-based imported food programmes are important preventive features of national food control systems to avert foodborne disease caused by unsafe food. However, it is acknowledged that from time to time, such systems do fail. Therefore, it is of the utmost importance to have effective food recall systems in place, to ensure the removal of unsafe food from sale, and to also inform consumers of the risk so that appropriate preventative action can be undertaken.

The 2000 resolution also encouraged Member States to develop and implement systematic and sustainable preventive measures aimed at significantly reducing the occurrence of foodborne disease. The development and implementation of food recall systems is considered sustainable and preventive in reducing foodborne disease.

I wish you a fruitful seminar on this important topic and thank you all for the partnership approach displayed in this seminar.

Maraming salamat po.

MESSAGE

Ms Emiko Purdy
Agricultural Counselor
United States Department of Agriculture in the Philippines

Magandang umaga sa inyong lahat. Good morning everybody and welcome to Manila.

There have been recent and growing programs established to strengthen different national food safety systems among APEC member economies.

This seminar-workshop in Manila on the Development and Strengthening of the Food Recall System for APEC Member Economies is another step forward.

During the November 2008 APEC Ministerial Meeting in Lima, Peru, a joint statement was issued which expressed support for the APEC Food Safety Cooperation Forum (FSCF).

The statement likewise gave recognition to the efforts and commitment of APEC member to pursue more cooperation in relation to product safety.

And during the succeeding 6th APEC Economic Leaders' Meeting held also in Peru, we further "reaffirmed our commitment to improve food and product safety standards and practices to facilitate trade and ensure the health and safety or our populations."

As we all know, instituting the appropriate food recall process goes hand-in-hand with any food safety program.

Today's exercise will help us individually and as a group in developing recall protocols for a food industry that is widely perceived to be very diverse, unique and sometimes even exotic.

The sharing of experiences by the more advanced economies with established and effective recall systems will be useful in streamlining existing and established food recall processes.

This will save us time, effort and resources.

More importantly, it is a means to a more open trade regime that will promote and ensure food safety.

With your enthusiasm and active support, this seminar-workshop in Manila will help us get there.

Mabuhay kayong lahat!

Description of the Workshop

- **APEC Food Safety Cooperation Forum (FSCF)** under APEC SCSC and APEC CTI
- This project also complements the works of Codex Alimentarius Commission particularly 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).

Description of the Workshop

- **Project Objectives:**
  (1) To explore the current situationer on Food Recall Systems in place among APEC Member Economies;

  (2) To develop and/or update recall standards among participating regulatory agencies and private enterprises in APEC Member economies;

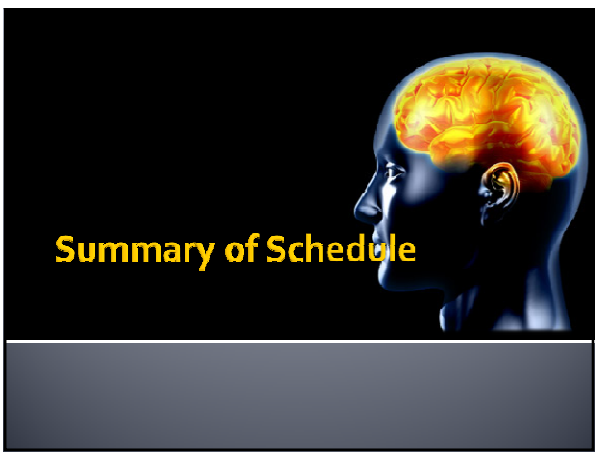
  (3) To assist participants from APEC Member economies in the development of recall procedures for food industry stakeholders (e.g. importers, distributors, retailers and manufacturers)

Seminar Workshop Components

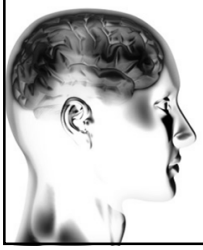
- **Lectures**
- **Member Economy Experiences**
- **Workshop**

Deliverables

- Information detailing current recall practices, recall programs/regulation, experiences from the member APEC economies
- Workshop output – SWOT
- Recommendations for APEC (Project Design)



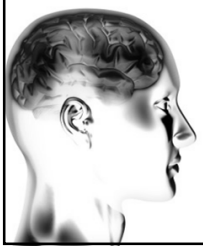
Day 1 (Tuesday)



Morning Session
- Overview of Food Recall
- Food Recalls Australia

Afternoon Session
- United Nations Program on Food Recall – FAO & WHO
- Food Incident Management – the Australian Experience
- Outbreak to a Recall, A Case Study –
- *Overview of Food Safety Inspection Service (FSIS/USDA) Recall Process*

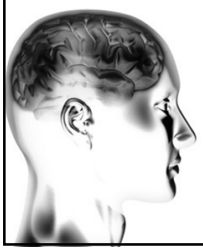
Day 2 (Wednesday)



Morning Session
- USFDA Food Recall Policies
- Meat and Poultry Recalls
- Case Studies:
- Australia Experience on Food Recall
- Member Economy Presentation: Brunei, Chile

Afternoon Session
- Member Economy Presentation:Chinese Taipei, Indonesia, Malaysia, Mexico, PNG, Peru, Philippines & Korea

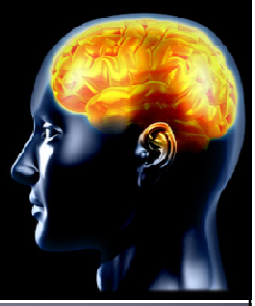
Day 3 (Thursday)



Morning Session
- Member Economy Presentation: Russia, Thailand, Viet Nam
- Overview of Risk Communication in Australia during Food Emergencies
- Workshop

Afternoon Session
- Group Presentation
- Consultant Synthesis
- Evaluation
- Closing Program

Workshop



Workshop

APEC Member Economies will be grouped into two. Group A is composed of Brunei, Indonesia, Chile, Malaysia, Papua New Guinea, Republic of Korea, Mexico and the United States. Group B will be composed of Peru, Philippines, Chinese Taipei, Russia, Viet Nam, Thailand and Australia. Based on the lectures and experiences of each member economies, each group shall identify and enumerate *common* Strengths, Weaknesses Opportunities Threats (SWOT) among their recall protocols.

Workshop

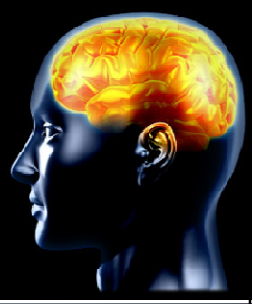
Recommendations:

- What's next to be done after the seminar-workshop? What are the possible follow up APEC projects to sustain the initial seminar workshop?

Resource Speakers

Food and Agriculture Organization – Ms Sashi Sareen
World Health Organization – Ms Jennifer Bishop
Food Standards Australia New Zealand – Dr Barbara Butow and Mr Elliot Hill
US Department of Agriculture – Dir. Elizabeth Volk
University of Hawaii at Manoa – Dr. Aurora Saulo

Reminders



- Welcome Dinner
- Meals
- Correction participant list
- Confirmation of flights
- Information about the area
- Any handouts that are unreadable
- Other additional information about the place or other places that you would like to visit
- Be sure to keep every receipts of any documents for your reimbursement as stated in your travel undertaking
- Hotel-airport transfer
- Other matters

Sonia Y. de Leon, Ph.D., M.B.M
President,
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E-mail: fafst@yahoo.com

I. Introduction

"Globalization has changed the system of food and trade"

✓The amount and variety of food trade has increased tremendously

✓Safeguarding safety has become difficult

✓Rapid spread of foodborne diseases

Leon & Divina
casabas

I. Introduction

1.1 Demand for regulated safe food and information

- Food poisoning is possible everywhere e.g. jack in the box hamburger (E.coli poisoning), milk plants poisoning in Japan

1.2 Prevention of Rapid Spread of food and waterborne diseases

- Dr Yasmine Motarjemi: food poisoning is like airplane crushes. "Swiss cheese" model

I. Introduction

1.3 Improve chances of facing national and transboundary food safety emergencies

- BSE or Madcow disease, FMD, dioxin, avian influenza, BADGE and bioterrorism

1.4 Need to develop capacity to network to address current and future food safety issues

* The world has to think of innovative ways of defending the food safety of its population

Food Recall

- 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
- Every year many food manufacturers, distributors, retailers and importers within the APEC region are faced with the prospect of conducting a recall.

Food Recall

- 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.
- Recalling a product is a planned action. This will help you remove unsafe or violative products

Objectives of Food Recall

- Remove potentially dangerous product from the market
- Properly inform the public of the problem
- Stop distribution and sale of unsafe product
- Stop further spread of contaminated/unsafe product

What triggers a recall?

Possible Scenario

-Testing or inspection by a regulatory authority shows some problem

-Routine testing by the company

-Consumer complaint and/or illness

-Overseas authorities detect and report a problem with imported food

Why are products recalled?

- Food products can be recalled for many reasons, including the presence of :
- pathogens (*listeria, salmonella*),
- chemical contaminants,
- undeclared allergens,
- extraneous matter (glass, shell fragments),
- non-permitted food ingredients.

Food Recall Classifications

- Depends on the country, food recall is classified into:
  - **"Class I"** is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death
  - **Class II"** is a situation in which the use of, or exposure to, a violative product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.
  - **Class III"** is a situation in which the use of, or exposure to, a violative product is not likely to cause any adverse health consequences.

Before conducting the recall

Ask yourself these questions:

- If you needed to remove a product from the market right now, would you be able to do it?
- Would you be able to remove the product quickly?
- Would you be able to remove all the product?


THANK YOU
GOOD DAY!

Food Recalls in Australia

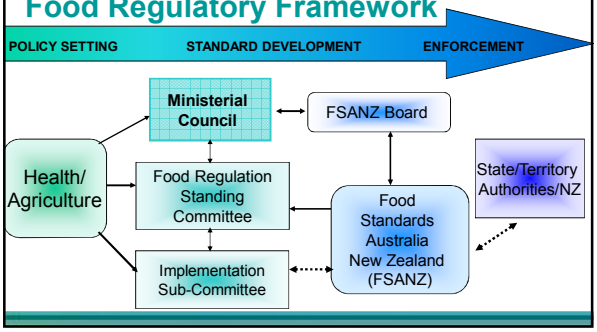
Dr Barbara Butow

APEC Recall Workshop, Manila
4th – 6th May, 2010

Australian System

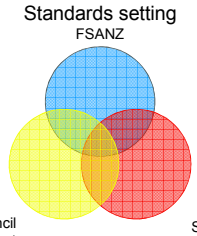
- Federal system
- Comprises Commonwealth Government,
- 6 States, and
- 2 Territories
- > local Government Authorities

Overview of the Australian Food Regulatory Framework



Who Does What?

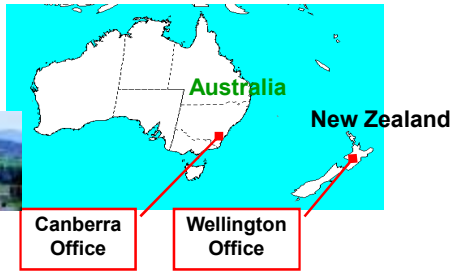
Food regulatory system depends on effective collaboration.



Food Standards Australia New Zealand (FSANZ)

FSANZ is a bi-national, independent, expertise-based statutory authority that develops food standards

FSANZ Set Up



What does FSANZ do?

FSANZ develops food standards for the composition and labelling of foods sold in NZ and Australia.

In Australia, FSANZ also develops food standards for food safety and primary production.

Standards are included in the **Food Standards Code**

FSANZ objectives when developing or reviewing food standards

- ✓ Protects public health and safety by maintaining a safe food supply.
- ✓ Provides consumers with information about food so they can make informed choices.
- ✓ Prevents misleading and deceptive conduct.

What does FSANZ do?

- FSANZ coordinates national food surveillance in Australia
- FSANZ coordinates **incidents** and **food recalls**
- FSANZ works closely with the Australian Quarantine and Inspection Service (AQIS) to ensure imported food is safe in Australia
- FSANZ works closely with other government food regulatory bodies to ensure consistency in standards setting

Australia New Zealand Food Standards Code

- Chapter 1 General Food Standards
- Chapter 2 Food Product Standards
- Chapter 3 Food Safety Standards (Australia only)
- Chapter 4 Primary Production Standards (Australia only)

Standards Setting Process

- Evidence based
- Based on risk analysis model – risk assessment, risk management and risk communication
- Consultative
- Economic and Social Analysis
- International

Food Standards Enforcement

- Health authorities in the Australian States and Territories
- New Zealand Food Safety Authority
- Australian Quarantine and Inspection Service - imported foods

The Role of States and Territories

- State Territory Food Acts adopt the Code as a regulation or as a standard
- Food standards are enforceable under State and Territory Food Acts
- A breach of the Food Standards Code is an offence

Food Recalls…

Food Recalls

- May involve one, or a number of government agencies
- Can occur at any time
- Can range from fairly simple, localised problems to complex, multi-jurisdictional (national and international)
- Are managed under an agreed set of structures, processes and protocols

Outline

- Objectives of a recall
- Food recall implementation – key elements
- The food recall system in Australia

Definitions

- Recall - Action taken to remove from sale, distribution and consumption foods which may pose an unacceptable risk to public health and safety
- Withdrawal - Product withdrawn from sale for either:
  - Quality defect
  - Before an official recall, pending further investigation

Objectives of a Food Recall

- Stop distribution and sale of affected product
- Inform the appropriate authorities and the public of the problem
- Effectively and efficiently remove potentially unsafe product from the marketplace

Legal Requirements

The *Australia New Zealand Food Standards Code*

A food business engaged in the wholesale supply, manufacture or importation of food must:

- Have in place a system to ensure the recall of unsafe food
- Set out this system in a written document and make this document available to an authorised officer upon request
- Comply with this system when recalling food

Standard 3.2.2 (clause 12)

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Level of recall

1. TRADE

- Food has not been available for direct purchase by the public
- Recovery of food from wholesalers, distribution centres, supermarkets/grocery stores, hospitals, restaurants

Level of recall

2. CONSUMER

- More extensive than trade recall
- Recovery of food from the production and distribution network (trade/retail outlets, grocery and health stores, supermarkets, consumers
- The public must be informed through the media

Other terms...

Voluntary

- Occurs when the sponsor initiates the recall and voluntarily takes action to remove food from the market place
- All of the affected food must be removed from the market place

or

Mandatory

- Commonwealth, State or Territory Government **orders** a food to be recalled
- Only occurs when the sponsor will not voluntarily recall the product

Key Elements of a Food Recall

- A Plan
- A Trigger
- Initiate
- Undertake
- Evaluate (report/review)

Key Elements of a Food Recall

A PLAN
– needs to be fully documented

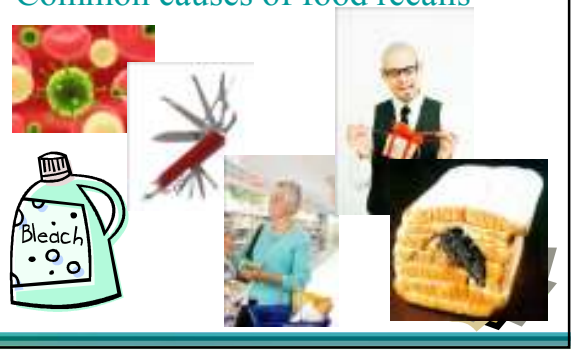
Example of information required:
- Contact phone number for the relevant food authority (Department of Health
- Customer contact details
- Recall management
- Recall advice

What Triggers a Recall?

Possible Recall Situations

- Routine testing by a food company
- Testing or inspection by a regulatory authority shows problem
  - Incorrect labelling (e.g. undeclared allergens)
- Consumer complaint and/or illness
- Overseas authorities detect and report a problem with imported food

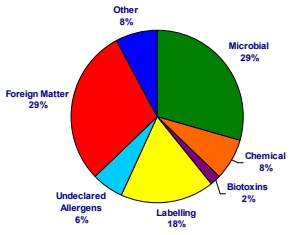
Common causes of food recalls



Common Causes of a Recall

• Microbiological	• Processing
• Foreign matter	• Labelling
• Chemical	• Tampering
• Biotoxin	

Food Recall Statistics - 2009



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Number of Recalls

Year	Domestic Foods	Imported Foods
2002	34	24
2003	57	29
2004	51	19
2005	42	18
2006	45	23
2007	49	5
2008	42	9
2009	40	20

Key Elements of a Food Recall

INITIATE

Key Elements of a Food Recall - Undertaking a Recall

- **Notify Relevant Parties – stop distribution**
  - discussions with recall coordinator/health authorities
  - inform distribution network and customers
  - media advertisement

Undertaking a Recall

- **Retrieve and dispose of product**
  decide on disposal with approval of government authority

Key Elements of a Food Recall – Report/Evaluation

- Report on progress of recall
- Review company processes
  - plans, systems, training etc
  - implement preventive strategies
- Measures to prevent recurrence of problem

Food Recall Review

- Review in consultation with government and industry stakeholders
- Training of after hours recall officers has been revised and improved
- Updated versions of the Food Industry Recall Protocol and Government Authority Food Recall Protocols published in 2008

Conclusion

- FSANZ's role is one of coordination and monitoring
- FSANZ assists in the recall process, but the decision whether or not to recall foods rests with the States and Territories
- Prompt and effective recall action ensures safety of the food supply and promotes consumer confidence in a company's products

Questions?

UN Programmes on Food Recall

at

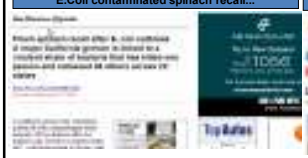
WS on the Development & Strengthening of Food Recall System for APEC Member Economies

(Manila, 4-6 May 2010)

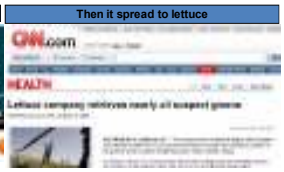
Ms Shashi Sareen
FAO Regional Office for Asia & the Pacific, Bangkok
E-mail : shashi.sareen@fao.org

Product Recalls – Some Recent Egs

E.Coli contaminated spinach recall...



Then it spread to lettuce



China Milk Recall

China Milk Recall – Some Details

Sanlu China

Saturday, 2nd August 2008

BEIJING

- Suppliers are believed to have added melamine, a banned chemical normally used in plastics, to diluted milk to make it appear higher in protein.
- Melamine was first found in baby milk powder made by the Sanlu Group.
- In total, melamine has been found in products made by 22 companies.
- 13,000 babies in hospital
- 53, 000 people affected and milk recalled around the world.

Product Recalls – Some more recent egs

Europe – Belgium- Coca Cola Recall

- 5 months to recover the sales
- 249 cases of illnesses in Belgium
- Recall of 15 million cans and bottles
- Crisis cost $200 million in expenses and lost profit

EU – Sudan 1 Crisis (Red chillies)

- Led to ~600 food product recalls in UK
- Sudan I & IV classified as carcinogens by Int Agency for Research on Cancer
- Dye detected in chilli powder used to make Worcester sauce
- Imported from India in 2002 & recall issued in 2005

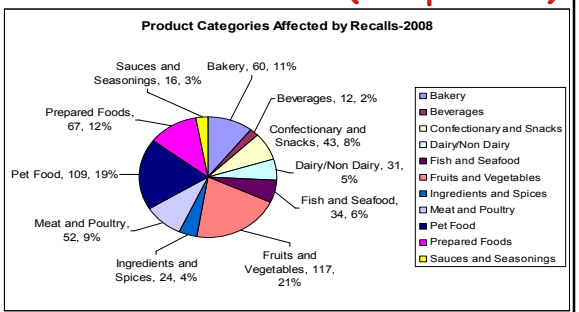
Data of Published Worldwide Food Product Recalls (US)

Year	Recalls
1999	279
2000	384
2001	393
2002	396
2003	266

Year	Recalls
2004	293
2005	255
2006	240
2007	338
2008	565

Food Institute Report, 2009

Recalled Food Products (565 products)



As compared to 2007, recalls due to:

- Salmonella, ↑ by 800%
- Listeria, ↑ by 20%
- E. Coli, ↓ by 22%
- Undeclared ingredients ↑ by 16%

Food Institute Report, 2009

Recall

- Recall means action taken to remove a marketed food product that may pose a health & safety hazards/ risk to consumers, from distribution, sale and consumption

- Recalls are undertaken to : (Objectives)
  - ➢Minimize risk of injury to consumers (food safety)
  - ➢Ensure compliance with legal requirements
  - ➢Other quality related issues such as labelling, BB date
  - ➢Protect company assets including brand reputation

Causes of Recall

- **Health & safety** concerns – which include
  - ➢Residues & contaminants – pesticides, vet drugs, heavy metals, toxins, cleaning chemicals, food additives adulterants
  - ➢Pathogens & spoilage micro-organisms
  - ➢Zoonotic diseases
  - ➢GMO issues
  - ➢Irradiation issues
  - ➢Physical contaminants – glass/ metallic pieces, grit, vermin fecal matter /body parts
  - ➢Persistent organic pollutants – eg dioxins
  - ➢Food allergens
  - ➢Labelling & claims – incorrect, past BB date

Pre-requisites to Operate a Recall

- Targeted and accurate information concerning the implicated product
  - ➢Linking to the **origin** for a root cause & thereby decision on batches to be recalled
  - ➢Product **location** or the customer (s)

TRACEABILITY

Traceability – Important Concepts

❑Traceability refers to "one step forward" & "one step backwards" approach to

➢Identify immediate **customers** & **suppliers**

Customers

Downstream tracing refers to ability to establish where products went to - important to identify & recall contaminated products & not safe ones –so minimize size of recall – loyalty progs

Suppliers

Upstream tracing refers to ability to identify where products came from – need to investigate & rapidly establish the source of problem & rectify the same, prevent further occurrences & resume production

Codex/FAO Work in area of Food Recall

Codex/FAO Work in area of Food Recall

- Recommended international Code of Practice – General principles of food hygiene
- Principles & guidelines for exchange of information in food safety emergency situations
- Principles for traceability/ product tracing as a tool within a food inspection & certification system
- Assuring food safety & quality: GL for strengthening national food control systems. FAO Food & Nutrn Paper 76
- FAO Technical Guidelines for responsible fisheries - Aquaculture Devt – 1. Good Aquaculture feed m/f practices
- FAO/WHO Framework for Developing national food safety emergency response plans (recent document)
- Food Recall Guidelines –under preparation

1. Recommended International Code of Practice – General Principles of Food Hygiene

- Fourth revision (2003)
- **"5.8 Recall Procedures requires food businesses to have effective procedures in place to deal with any food safety hazards and to enable the complete, rapid recall of any implicated lot of the finished food from the market. "**

  Where product withdrawn because of an immediate health hazard, **other products produced under similar conditions to be evaluated** & may need to be withdrawn

  Recalled products to be **held under supervision till disposed off**, used for purposes other than human consumption, determined to be safe or reprocessed into a safe product

2. Principles & GL for Exchange of Information in Food Safety Emergency Situations

- CAC/GL 19-1995; rev 1 2004
- Purpose is to enable countries to assess & decide on their risk management/ communication strategies (recall would be part of strategy)
- Annex gives standard format for information exchange covers information on actions taken such as to recall food from markets (mandatory & voluntary)

3. Principles for Traceability/Product Tracing as a Tool within Food Inspection & Certification Systems

- CAC/GL 60-2006)
- **Definition** - Traceability/product tracing: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution
- Traceability does not make a food safe but is a **risk mgmt tool** for use to **assist in containing a food safety problem**
- Traceability is meant to ensure that
  - ✓ targeted & accurate withdrawls or recalls are undertaken
  - ✓ appropriate **information** given to consumers & Food Business Operator,
  - ✓ **risk assessment** carried out by control authorities &
  - ✓ unnecessary **wider disruption of trade** avoided

4. Assuring Food Safety & Quality: GL for Strengthening National Food Control Systems

- FAO Food & Nutrition Paper 76
- Elements of a food control system under *food laws & regulations* requires 'provision of tracing of food products and for recall in case of problems'
- 'Principles of food control' gives recall of products as an eg under establishing emergency procedures for dealing with particular hazards

5. FAO Technical Guidelines for Responsible Fisheries

- Aquaculture Development – 1. Good Aquaculture feed manufacturing practices – cl 14 deals with recalling defective or mislabelled products
  - ➢ Based on feed quality or labelling errors
  - ➢ Recall to be handled quickly, properly & be well documented
  - ➢ Detailed procedure at Annex 1

6. FAO/WHO Framework for Developing National Food Safety Emergency Response Plans

- Very recent (26/04/2010)
- Key elements - reinforcing preparedness & responding rapidly to emergencies
- Covers - incident identification, incident mgmt, post incident review & evaluation, communication
- **Under incident management** requires procedures for traceability, withdrawal & recall amongst others
- **Under communication strategy** covers recall/withdrawal notices

7. Food Recall Guidelines

- A guidance manual for introducing effective food recall systems into national food control programs (under preparation)

Some Important Points in a Food Recall -1

- Legal basis – legislation applicable across food chain, authority & responsibility, disposals, communication, etc; covers recall by authorities/ business
- Implemented by govt, industry, jointly
- Recall by food business otherwise withdrawal
- Food business recall plan to be part of food safety control system (linkage with HACCP-based systems)
- Involvement of consumers in a recall – communication, public notice
- International involvement in a food recall – imports/ exports, INFOSAN networks
- Planning in advance – Risk basis, mock withdrawals/ recalls – to ensure system is effective

Some Important Points in a Food Recall 2

- **Plan** of recall - also relevant in an emergency, shared with all involved
- **Information** from various sources – food industry, consumer, labs, surveillance programmes, hospitals - INFOSAN
- **Level** of recall depends on distribution in food chain
- **Disposal** of products
- **Rectification** of problem or Corrective action
- **Communication** systems - (authorities/food businesses); website, mob phones, toll free phones
- Lot **identification & traceability** – only effected lots, reduced impact of lots
- **Data** system & flow of data

Procedure for a Product Recall (Feed)

- Potential product recalls to be quickly **reported** & **investigated** by a **responsible decision-maker** who has **authority** to assign the recall classification to the situation.
- When warranted, a Recall Committee to be appointed & quickly convened when a Class I, II, or III situation exists.
  - Class I Recall - A serious emergency recall situation involving product which may have an immediate or long range effect on the life or health of aquatic animals or human consumers.
  - Class II Recall - A priority situation involving product which may be a potential hazard to human or animal life or health.
  - Class III Recall - A situation involving product which does not pose a health threat, but which may have serious or wide-spread customer or public relations implications.

Procedure - 2

- When potential for a recall is evident, the production & QC manager to be informed immediately
- The QA manager to immediately investigate & determine if situation is a Class I, II, or III recall or is of lesser priority.
- If it is a Class I, II, or III recall, QC manager to immediately convene Recall C
- Chair then co-ordinates all recall activities, keeps C informed
- A lesser priority situation may be handled at plant level without committee being convened.
- The Recall C to include persons with expertise in: Regulatory, Production, Sales, QC, PR, Legal, Purchasing, Nutrition
- The Recall C to decide quickest & best overall procedure for handling recall

Procedure - 3

- As each situation is unique, following guidelines are useful:
  - Determine suspect product's identif codes & dates of m/f
  - Determine entire product location
  - Immediately notify all locations. Mandate a “stop sale.”
  - If product sold to consumers, procure customer details from distributors
  - Get Recall Committee input on handling all contacts outside company, eg consumers, agents, dealers, media
  - Decide if media to be notified. PR dept to handle.
  - Decide if govt agencies to be notified (may make matters worse if officials feel concealment attempted)

Procedure - 4

- Assign responsibility (production manager) for records of production, shipments & disposals. Also a record of recall actions with date & time (for legal protection).
- All samples secured to be properly identified & safeguarded;
- Refrigerate to prevent degradation . If analysis required, do expeditiously (retaining duplicates).
- Communication critical. Keep the Recall C, plant manager, any customers, & news media (if necessary) informed, so that no inaccurate information
- A 24-hour hotline ph no for any queries from consumers.
- Yearly review of recall policy & procedures

For Further Details Please Contact

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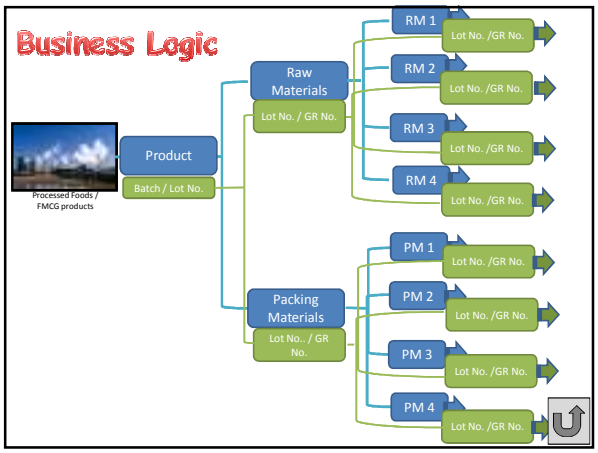
Any Questions?

Business Logic



The World Health Organization's Food Recall Activities

Jenny Bishop
for the WHO Western Pacific Regional Office programme on Food Safety

World Health Organization

National and Global Activities associated with Food Recalls

National Level Activities

In the absence of a food recall system – a case study

2007 Cacuaco, Angola

- 467 cases of bromide intoxication
- Drowsiness, blurred vision, walking difficulties and difficulties in muscular control

In the absence of a food recall system – a case study

- Sodium bromide sold as salt was identified as the cause

No recall system in place =

- Delay in action
- Massive resource input
- Additional cases

WHO assistance at a National Level for Food Recalls

- Working
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  - Guide
  - Assist

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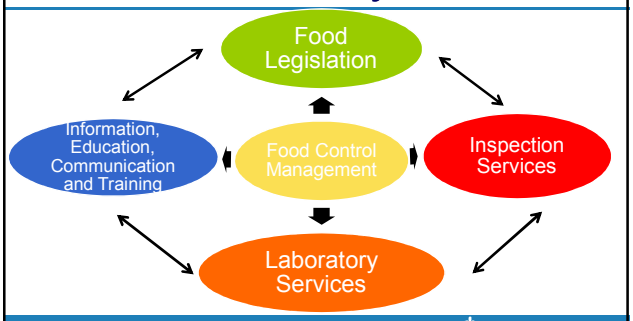
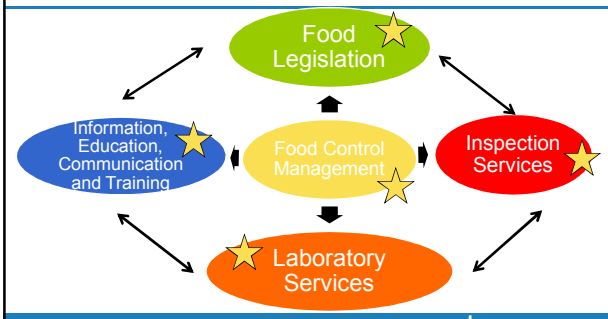
Western Pacific Regional Office of the World Health Organization

FAO/WHO Key Components of National Food Control Systems



Western Pacific Regional Office of the World Health Organization

FAO/WHO Key Components of National Food Control Systems – associated with food recalls

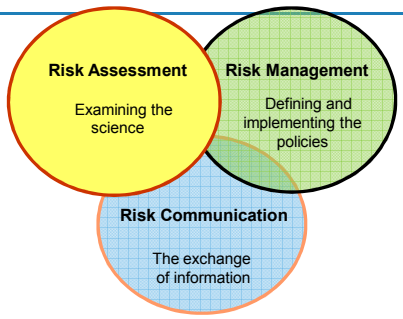


Western Pacific Regional Office of the World Health Organization

Food Recall Key Principles - Prevention

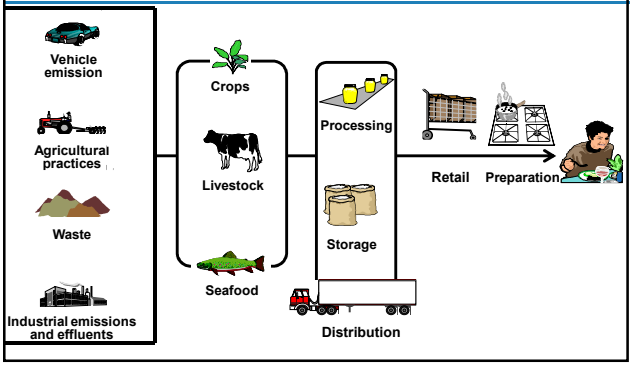
Western Pacific Regional Office of the World Health Organization

Food Recall Key Principles – Risk Analysis



Western Pacific Regional Office of the World Health Organization

Food Recall Key Principles – Farm to Fork



Food Recall Key Principles – System needs to reflect local situation

Food Recall Key Principles– Meet International Obligations

WPRO Food Recall Guidelines

- Developed in 2007 and has been subject to international peer review.
- Not yet published, but available for use by National Governments.
- Outlines key components of a recall system.
- All input is welcome!

WPRO Food Recall Guidelines

- Legal basis
- Risk assessment
- Role and responsibilities
  - Food business
  - National authority
  - Consumer
  - International obligations

WPRO Food Recall Guidelines

- Planning, implementing and reviewing a food recall
  - Planning a recall
  - Implementing a food recall
  - Reviewing a food recall
  - Inspector skills
- Guidance questions to be considered when drafting or reviewing food legislation
- Food business recall plan
- Recall plan for National Authorities
- Checklist for public notices

Food recall systems in WPRO countries and areas

Case Study: Fiji

- Fiji is a small island developing state in the Pacific
- Population of 850,000
- WHO supported Food Recall Protocol developed in 2002:
  - The roles and responsibilities of involved stakeholders
  - Who should be notified of the recall
  - Notification procedures
  - Post recall reporting

Challenges in developing recall systems

- Risk assessment in urgent situations
- Action proportionate to risk
- Defining the scope of a recall
- Action in time critical situations
- Development of communication mechanisms
- Management of 'informally traded foods'

Global Action – INFOSAN

International Food Safety Authorities Network

International foodborne disease outbreaks: Rapid spread worldwide by movement of food

Globalisation of Food Trade

Chicken Kiev

Herb Butter:	Salted butter	- Ireland
	Garlic puree	- China, USA, Spain
	Garlic salt	- China, USA, Spain
	Lemon	- USA
	Parsley	- France, UK
	Pepper	- Indonesia
	Water	- Ireland
Chicken Breast:	Chicken	- Ireland, Belgium UK, France etc.
Batter:	Flour	- Belgium, France
	Water	- Ireland
Bread Crumb:	Bread crumb	- Ireland, UK
	Rape-seed oil	- EU, Australia Eastern Europe

Courtesy A. Reilly, FSAI, Ireland

What is INFOSAN?

A global network of national food safety authorities that…

- Promotes the rapid exchange of information during food safety related events
- Shares information on important food safety related issues of global interest
- Promotes partnership and collaboration between countries, and between networks
- Responds to requests for assistance during international food safety events
- Helps countries strengthen their capacity to manage food safety risks

As of today, there are 177 country members of INFOSAN

Mandate for INFOSAN

World Health Assembly (WHA) Resolutions

Codex Guidelines

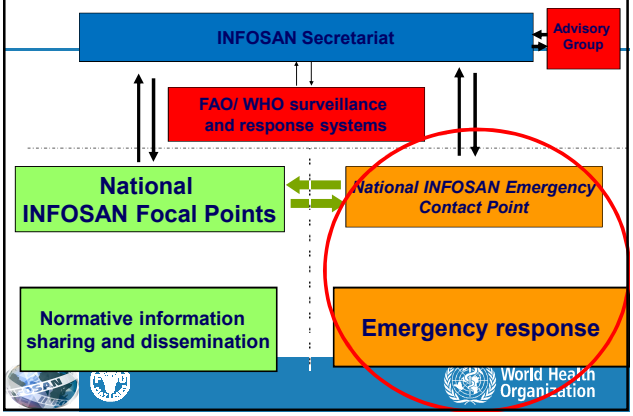
Principles and Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL19-1995 Rev.1-2004)

International Food Safety Conferences

Reinforced by the Beijing Declaration on Food Safety (2007)

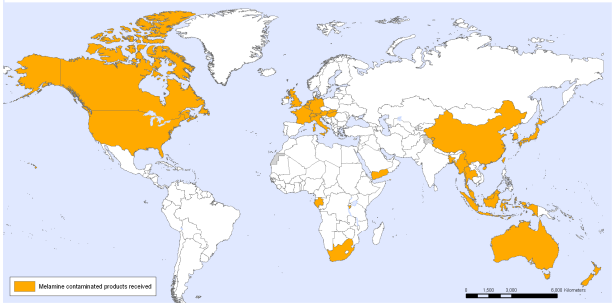
World Health Organization

Structure of the INFOSAN Network



World Health Organization

Country received melamine contaminated products

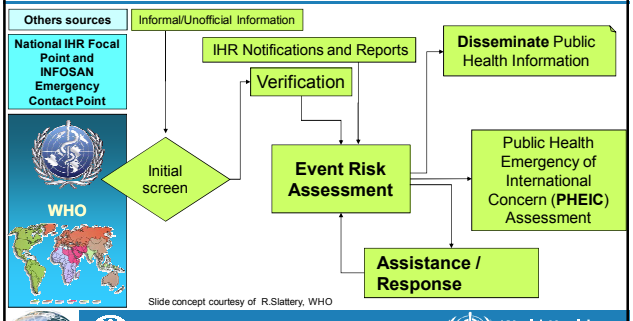


International Health Regulations (IHR)

- Old IHR (1969) only covered Yellow Fever, Cholera and Plague
- New IHR (2005) include *all public health emergencies of international concern* - including those caused by food
- IHR (2005) entered into force on 15 June 2007
- All WHO Member States are obliged to declare all public health emergencies of international concern to WHO

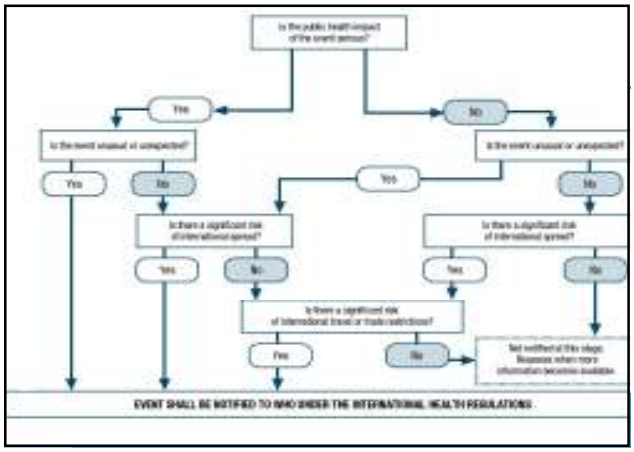
World Health Organization

The International Health Regulations and INFOSAN



Slide concept courtesy of R.Slattery, WHO

World Health Organization



Examples of INFOSAN Emergency Alerts

- *August 2009 - Listeria monocytogenes* associated with chicken wraps served on an aeroplane
- *December 2009* – Excessive levels of iodine in an internationally distributed seaweed product causing illness
- *January 2010* - Multi-state outbreak of *Salmonella* Montevideo infections in the United States of America linked to internationally distributed salami
- *November 2009 – March 2010* Possible link between Hepatitis A and semi-dried tomatoes

World Health Organization

INFOSAN Emergency and National Food Recall Systems

- Relevant national food recalls should notified to WHO via the INFOSAN Emergency Contact Point or the National IHR Focal Point
- Food recalls maybe triggered by INFOSAN Alerts
- Reflect this in the recall procedures
- Please let me know if you would like the contact details of the INFOSAN Emergency Contact Point for your country

World Health Organization

INFOSAN – The International Food Safety Authorities Network

"Only if we act together can we respond effectively to international food safety problems and ensure safer food for everyone"

Dr Margaret Chan – Director-General

Food Safety Incident Management

Dr Barbara Butow

APEC Recall Workshop, Manila
4th – 6th May 2010

Food Safety Incidents

- Usually involve a number of government agencies
- Can occur at any time
- Can range from fairly simple, localised problems to complex, multi-jurisdictional (national and international)
- Are managed under an agreed set of structures, processes and protocols

Outline

- What is a food safety incident?
- What is incident management?
- Why develop a system?
- Features of an incident management system

Food safety incidents

- No single definition
- Common characteristics
  - Risk (actual or potential) to human health
  - Involves a physical, chemical or microbiological hazard
  - Can occur at any stage of the food supply chain
  - Requires some form of action
- Incidents will happen!

Food Safety Incidents – what we know

- Public health and safety risks
- Consumer concerns…
- Usually do not have all of the information at the start
- Scientific uncertainties
- Involve more than one agency/organisation
- Inconsistent responses
- Impact at a number of government levels
- Disruption to domestic and international trade
- May last for weeks, or months!

'Pre-washed' salads in bags aren't as clean as you may think

Food Safety Incidents – what we know

- Public health and safety risks
- Consumer concerns
- Usually do not have all of the information at the start
- Scientific uncertainties
- Involve more than one agency/organisation
- Inconsistent responses
- Impact…
- Disruption to domestic and international trade
- May last for weeks, or months!

Impact

Consumers responded to the Food and Drug Administration's September 2006 warnings to avoid eating spinach because of possible contamination with *E. coli* O157:H7.

Food Safety Incidents – what we know

- Public health and safety risks
- Consumer concerns
- Usually do not have all of the information at the start
- Scientific uncertainties
- Involve more than one agency/organisation
- Inconsistent responses
- Impact at a number of government levels
- Disruption to domestic and international trade
- May last for weeks, or months!

Is this a food incident?

- Non-compliance with food standards.
- Perception of a risk to public health and safety.
- Specific level of risk to public health and safety.
- 'Routine' food recalls (e.g. voluntary recalls initiated by industry)
- Differences in enforcement activities across different jurisdictions.
- An incident in only one or two jurisdictions
- Terrorism and food tampering.

Challenges for Responding to incidents

- New and emerging hazards
- Uncertainties in science
- Perceptions
- Legal liabilities
- Political sensitivity

Response should be …

- Scientifically based
- Effective
- Consistent
- Legally sound
- Balanced – public health, social impacts, cost-benefit
- Well communicated

What is incident management?

- Measures to manage the risk to consumers from unsafe/unsuitable food
- A management framework that is:
  - Comprehensive and can address all hazards
  - Integrated at all levels of government and with industry
  - Contains prevention, preparation, response and recovery elements

Why develop a system?

- Frequency and complexity of incidents have increased worldwide
- Impacts to governments, industry and consumers can be significant
- Several agencies may need to respond
- Need for a consistent and timely response

What is required in a system?

- Robust
- integration of activities and resources of multiple agencies
- Operate effectively for any type of incident (imminent or actual)
- System and supporting principles can be applied broadly to food safety management

Response Protocols

- Operation, coordination and communication between agencies/jurisdictions
- Builds on existing individual organisation protocols
- Emergency management principles
- Roles and responsibilities
- Response and review phase and activities

Summary

- System need to be in place
- Networks need to be in place
- System need to be integrated
- Common command and control and coordination system
- System and roles need to be known and exercised
- Protocols need to be reviewed

An Overview of Australia's National Food Incident Response Protocol

Why have a Protocol?

- Ensure response and communication is timely, consistent, appropriate, coordinated
- Formalise current arrangements and link Commonwealth and State/Territory protocols
- Manage incidents for widely distributed foods

Scope

- A guidance document for coordinating the response of food regulatory agencies during a food incident

"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 or foods."

"A food incident that could, or is expected to, impact on multiple government jurisdictions."

Structure of the Protocol

- Single coordination point
- Roles and responsibilities defined
- Consultative mechanisms involving government and industry
- Response actions designed to minimise disruption to industry/consumers while protecting public health and safety
- Graduated responses depending on the incident
- Integration of food incident and public health incident response processes

Roles and Responsibilities

- Notifying Agency
- Central Notification Point
- Food Incident Contact Officer
- Lead Agency
- National Food Incident Coordinator
- Agency Food Incident Controller
- Participating Agencies
- Risk assessor
- Communications controller

How Does the Protocol Work?

Three phases:

ALERT

ACTION

STAND DOWN

Alert Phase

- Awareness of incident from variety of sources
- Notifying agency notifies the Central Notification Point (CNP) – early notification encouraged
- CNP circulates a Food Incident Notification, including to National Incident Room (International Health Regulation obligations)
- May be only response for many incidents

Action Phase

- If more than initial info circular is required, then response moves to Action Phase.
- Actions may be restricted to the Notifying Agency or affected jurisdiction for minor incidents
- For other incidents – agencies notified of expected activities (e.g. a teleconference)
- Allocation of roles and responsibilities
- National Food Incident Coordinator
- Agency Food Incident Controllers nominated
- Lead Agency nominated

Action Phase Response Activities

- Incident Objective established
- Risk analysed and evaluated
- Consultation with industry – early as practical
- Response action to meet Incident Objective determined (e.g. recall, communication, survey)
- Best endeavours to reach an agreed response action
- Situation Reports circulated
- Implement agreed actions
- Communication activities – developed by National Food Incident Controller
- Escalation/De-escalation – participating agencies decide depending on the changing complexity of the issue

Stand-down phase

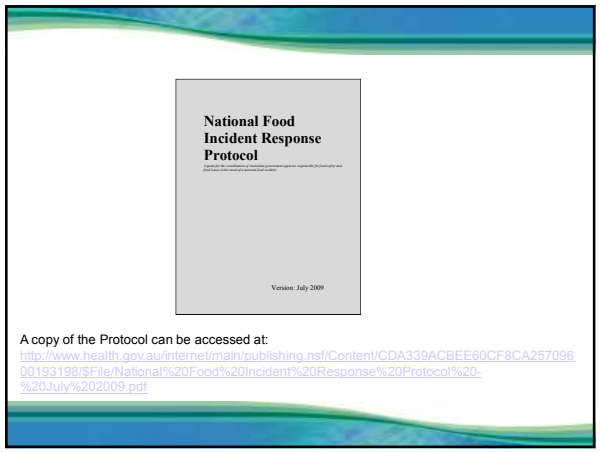
- Participating Agencies agree that a nationally coordinated response no longer required and incident deemed to be over
- Participating Agencies should do de-brief or conduct after action review
- Outcomes considered by Incident Response Working Group, who may make recommendations to ISC on changes to the Protocol

Protocol Annexes

- Intentional interference
- Chemical contaminants
- Environmental investigation/traceback

Incidents

- 2007 – 01: *Clostridium botulinum* type A, nachos
- 2007 – 02: plastic contamination, chocolate bars
- 2007 – 03: wheat gluten
- 2007 – 04: apple juice contamination
- 2007 – 05: *Listeria monocytogenes*, meat products
- 2008 – 01: cyanogenic glycosides, vegetable crackers
- 2008 – 02: metal contamination, meat and frozen products
- 2008 – 03: Melamine contaminated baby formula from China
- 2008 – 04: Dioxin contaminated pork from Ireland
- 2009 – 01: Hepatitis A in semi-dried tomatoes
- 2010 – 01: Bonsoy milk suspected link to thyroid dysfunction



A copy of the Protocol can be accessed at:
http://www.health.gov.au/internet/main/publishing.nsf/Content/CDA339ACBEE60CF8CA257096
00193198/$File/National%20Food%20Incident%20Response%20Protocol%20-
%20July%202009.pdf

Questions?

United States Department of Agriculture
Food Safety and Inspection Service

Meat and Poultry Recalls

Lisa Volk
Director, Recall Management
USDA FSIS
May 2010

United States Department of Agriculture
Food Safety and Inspection Service

Recall

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.

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Market Withdrawal

- 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.
- No violation of FMIA or PPIA
- No Health Hazard

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Stock Recovery

- A firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm.
- Example: Product is located at company warehouse and no portion of the lot has been released for sale or use.

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Why Recall?

A Recall is a fast and effective method of removing distributed products, particularly when many lots of product have been widely distributed. A recall may be an alternative to FSIS detention or seizure.

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Who Recalls?

- Manufacturers and distributors of product
- FSIS does not have mandatory recall authority.
- However, FSIS may initiate the recall process by informing a firm that adulterated product has been identified in commerce .

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Recall Process

- **Problem Identification:**
  - The company discovers the problem
  - FSIS microbiological sampling
  - Information from in-plant inspection program personnel (IPP)
  - Epidemiological or other data gathered by other Federal, State, or local Agencies
  - Consumer complaints

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Recall Process

- Preliminary Investigation
  - FSIS program personnel begin the preliminary inquiry by gathering product and contact information, and any additional relevant information.
  - For domestic production, FSIS contacts the plant and works with the firm to complete recall worksheets. The District Recall Officer (DRO) directs these activities and forwards the information to RMS.
  - If imported product is involved, Office of International Affairs (OIA) assigns an Import Recall Coordinator (IRC) to direct these activities.

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Preliminary Investigation

- Contact Information for Official Est.
  - Est. number, name, and address
  - Company Recall Coordinator, Media Contact, and Consumer Contact (name, title and phone number)
- Contact Information for Imported Products
  - Import and Foreign Est. identification and contact information
  - Importer of Record (IOR), IOR Recall Coordinator, IOR Media Contact, IOR Consumer Contact (name, title, and telephone number)

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Preliminary Investigation

- Product Information (for all products)
  - Reason for recall
  - Brand and Product names
  - Packing type/size, dates, codes (Use by/Sell by), Case Codes, Count/Case
  - Production dates, Distribution areas
  - Whether or not the products were part of School Lunch, DoD, or internet/catalog sales

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Preliminary Investigation

- Additional Information (all products)
  - Amount produced/imported (pounds/cases)
  - Amount held at Est./Import Est.
  - Amount distributed (pounds/cases)
  - Distribution level (Depth of Recall, if known)

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FSIS May Also

- Collect and verify information about suspect product
- Document chronology of events
- Contact manufacturer/distributor for additional information
- Interview consumers who allegedly became ill or injured from suspect product
- Collect/analyze product samples
- Contact other Federal, State, or local Agencies
- Analyze any available epidemiological data

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FSIS Recall Committee

- Consist of representatives from various FSIS offices and staffs assembled to respond to potential or real health hazard incidents reported to Recall Management Staff (RMS)
- Recall worksheets and any other information is gathered by RMS, who forwards the relevant materials to the Recall Committee
- RMS makes every effort to ensure the five primary members of the committee are available

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FSIS Recall Committee

- Chaired by Recall Management Staff
- Includes personnel from:
  - DRO and other district staff as appropriate
  - Microbiology/Toxicology/Public Health
  - Policy Office
  - Media Relations/Communications
  - Other (OIA, OPEER, ODIFP)
  - Other Federal or States agencies as appropriate (FDA, CDC, FNS)

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FSIS Recall Committee

- Evaluates Hazard, Circumstances, and Statutory basis for recall
- Reviews FSIS and Plant Data
- Reviews Recall Worksheet
- Classifies Hazard
- Evaluates Scope (product lots involved)
- Recommends Recall
- Evaluates Firm's Recall Strategy

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Recall Classification (Health Risk)

- Class I: Reasonable probability that consumption of product will cause serious, adverse health consequences or death
- Examples:
  - Pathogen in ready-to-eat product
  - *E. coli* O157:H7 in raw ground beef

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Recall Classification (Health Risk)

- Class II: Remote probability of adverse health consequences from use of the product
- Examples:
  - Very small amounts of allergens typically associated with milder reactions, such as wheat or soy products
  - Extraneous, non-sharp edged, material such as pieces of plastic

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Recall Classification (Health Risk)

- Class III: Use of product will not cause adverse health consequences
- Example: Undeclared, non-allergenic, Generally Regarded As Safe (G.R.A.S.) ingredient such as excess added water

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Public Health Alerts

Product presents a public health risk

- Specific class of product implicated, rather than a specific product brand
- Human illness associated with a common, but unidentified source
- Product is long out of date

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Recall Process

- The plant recall coordinator is contacted by the recall committee and advised of the recommendations
- Questions from both FSIS and the plant are discussed
- Although not required, FSIS expects the firm to provide the Committee its recall strategy, including how it intends to notify and instruct its consignees to retrieve or dispose of recalled product

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Firm's Recall Action

- Promptly Notify Each Consignee about Recall
  -Telephone followed by Fax, Letter, and/or Email
- Identify Exact Product, Lot(s), Codes, Sizes
- Explain Reason for Recall and Hazard Involved
- Explain how recalled product is to be handled/disposed

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Public Notification

- **Recall Release** – for Class I & II recalls, post to FSIS Web site and distribute to wire and media services in area of product distribution
- **Publish Recall Notification Report (RNR)** on Web site – Class III recalls or Class I & II distributed only to the wholesale level (not likely to be sold directly to consumers)
- Subscribers receive email notification of all recalls
- If MOU with a state - share distribution records
- **Publish Retail List** – for Class I Recalls only

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Recall Verification Activities

FSIS personnel conduct **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.

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Recall Verification Activities

- Effectiveness checks are conducted throughout the distribution chain
- Risk Based and dependent on the class of the recall, the number of consignees, and other relevant factors

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DRO/IRC Responsibilities

- Primary contact for recalling firm
- Request product distribution information
  (names, addresses, and phone numbers of consignees)
- Coordinate Effectiveness Checks
- Request assistance from other DDMs, Regional Import Field Supervisors, Office of Program Evaluation, Enforcement and Review (OPEER) Regional Managers to conduct effectiveness checks and gather any additional distribution information from consignees
- Develops sampling plan based on distribution

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Field Recall Responsibilities

- DRO (DDM) coordinates and directs Enforcement Investigations and Analysis Officers (EIAOs) to conduct effectiveness checks
- IRC coordinates and directs Import Surveillance Liaison Officers (ISLOs) or Compliance and Investigation Division (CID) Investigators to conduct checks if recalling firm is an importer

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EIAO/CID/ISLO Responsibilities

- Randomly conduct effectiveness checks
- Verify consignees are handling product in accordance with regulatory requirements and instructions of recalling firm
- Take action, if necessary, to detain product
- Submit findings to DRO/IRC
  - Identify process or product failures/trends?
  - Determine whether distributor or consignee failed to appropriately address recalled product
  - Issue Prohibited Activity Notice as appropriate
  - Consider other enforcement actions, if necessary

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Verification Process

Determine the risk

Determine the hazard (class of recall) and exposure

Recall classification	FSIS verification activities begin as soon as possible within a period of:	FSIS verification activities should be substantially completed within:
Class I	3 Days	10 Days
Class II	5 Days	12 Days
Class III	10 Days	17 Days

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Verification Process

Number of Effectiveness Checks

Class I recalls with illness, outbreak, or school lunch implications

Number of Consignees	Number of Effectiveness Checks to Make	Deviations for Recall to be Considered Ineffective
1 to 200	100%	0
201 to 10,000	200	0
10,001 – 500,000	800	1
Over 500,001	1250	2

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Verification Process

Class I recalls without illness, outbreak, or school lunch implications.

Number of Consignees	Number of Effectiveness Checks to Make	Deviations for Recall to be Considered Ineffective
1 to 20	100%	0
21 to 150	20	0
151 to 1,200	80	1
1,201 to 2,300	125	2
2,301 to 10,000	200	3

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Verification Process

Class II recalls

Number of Consignees	Number of Effectiveness Checks to Make	Deviations for Recall to be Considered Ineffective
1 to 5	100%	0
6 to 25	5	0
26 to 150	20	1
151 to 280	32	2
281 to 500	50	3

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Verification Process

Class III recalls

Number of Consignees	Number of Effectiveness Checks to Make	Deviations for Recall to be Considered Ineffective
1 to 8	100%	1
9 to 50	8	1
51 to 90	13	2
91 to 150	20	3
151 to 280	32	5

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Findings of Product in Commerce

1. Findings of product in commerce are those occurrences where recalled product remains available to the consumer
2. DDMs should immediately inform DRO when recalled products are encountered in commerce, so that the recalling firm can be informed
3. DRO determines if the findings follow a pattern or trend.

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Effectiveness Determinations

The objectives of verification activities are to evaluate:

1. The overall effectiveness of the recall
2. The recalling firm's process

If the recall is **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.

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Verification Follow-up

- The objective of verification follow-up is to determine that product has undergone proper disposition in accordance with regulations.
- Is conducted on a subset of consignees. The same tables used to determine the number of recall effectiveness checks are also used to determine the number of verification follow-ups.
- Disposition includes return to recalling firm, destruction, lethality treatment, relabeling. Verification is on-site by FSIS personnel, independent verification, or may be a records review.

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Verification Result Summaries

The DRO summarizes 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.

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Verification Result Summaries (Continued)

- State the total number of effectiveness checks and disposition verification checks performed and the numbers conducted both on-site and by telephone
- Assign an overall effectiveness rating to the recalling firm's recall activities (effective or ineffective)
- Determine how many consignees may still have product on sale
- Identify other deficiencies in the firm's recall process (if applicable)
- Summarize actions taken by FSIS in the case
- Description of corrective actions for each deficiency found

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Recall Termination

- When the establishment completes the recall, it notifies the DRO of amount recovered and disposition of product
- FSIS verification: recall effectiveness checks
- Recommend close-out following reasonable efforts to recover product

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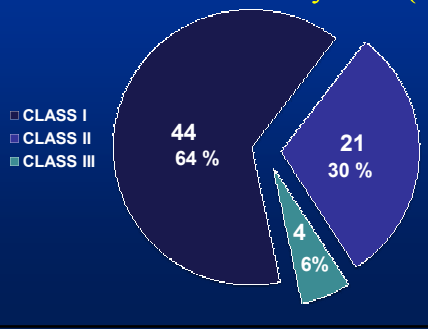
FSIS Recalls CY 2009 By Class (Total 69)



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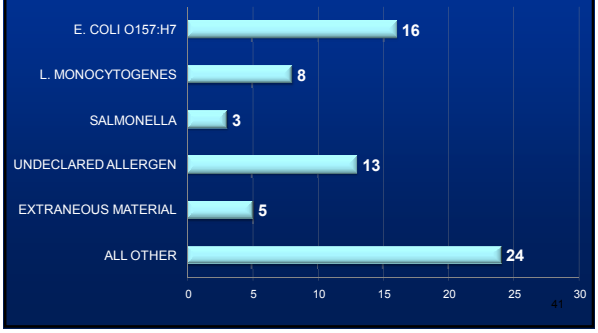
FSIS Recalls CY 2009 by Problem Type



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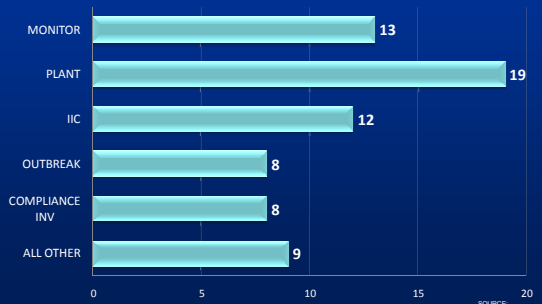
FSIS Recalls CY 2009 by Source



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Questions ?

- For more information on FSIS recalls, visit our website (www.fsis.usda.gov)

Thank you!

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RECALL – The word that brings shudders to the food industry

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May 4-6, 2010
Manila, Philippines

C/T/A/H/R
College of Tropical Agriculture and Human Resources
University of Hawai'i at Mānoa

Goal of the Food Industry

- To produce safe and wholesome foods



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How to Insure Safe Food is Distributed

- Develop and follow programs
  - Identify products accurately
  - Document procedures
  - Validate results with third-party audits
- Know where your products come from and where they go (traceability)
  - Trace forward; trace back (product identification is key)
  - Raw materials, ingredients, packaging
- During crisis, respond quickly

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But sometimes, things go wrong…

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And When Things Go Wrong

- Usually at very inconvenient times


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Then It Hits the News (Noose)!

- Adverse publicity almost instantaneously

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And Even If The Story Is Inaccurate, or Not Even True

You still get unwanted exposure:

"A lie can travel halfway around the world while the truth is putting on its shoes. "
(Mark Twain)

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Public Health Issue-Botulinum Toxin

Bolthouse Farms Carrot Juice, 450-ml and 1-l bottles, *"Best if used by"* November 11, 2006

- Improper refrigeration may have caused the development of *C. botulinum* toxin

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Public Health Issue-Salmonella

- Outbreaks: 2001, 2004
- Resulted in mandatory pasteurization of raw almonds by September 1, 2007

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2006 Spinach Outbreak

Over 200 illnesses and one death….

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Salmonella typhimurium
691 cases in 46 states with latest confirmed, most recent reported illness beginning on February 24, 2009, making this one of the largest food recalls ever in the USA.

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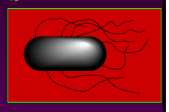
High Profile Outbreaks



- 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)
- Tomatoes then peppers (2008)

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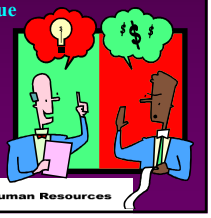
Costs of Recall

- Direct costs
  - Product and package loss
  - Retrieval
  - Destruction
  - Cleaning
  - Potential health risks
  - Lawsuits and legal issues
  - Human time
- Indirect Costs
  - Potential reduction in demand and sales
  - Decrease in share value



Source: Resende-Filho *et al.*, June 19, 2007

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$ Losses To The Industry

Produce	Est. Revenue Loss
Spinach 2006 *E. coli* O157:H7 	$350 million (shippers & growers)
Peanut butter 2007 *Salmonella* 	$140 million ($55 million in lost sales)
Tomatoes/Peppers 2008 *Salmonella* 	>$100 million (growers)

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Recalls are expensive!

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US FDA Recall Policy 21CFR7.40

- Recall: "*…removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration.*"
- Therefore, recall is the
  - Prompt removal of contaminated, mislabeled products, or sick animals from the market (includes proper disposal)

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US FDA Recall Policy 21CFR7.40 (cont'd)

- Objective of a recall: *"…to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective."*

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US FDA Recall Policy 21CFR7.40 (cont'd)

- Voluntary action by food manufacturers and distributors
- *"…an alternative to a FDA-initiated court action…"*

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Different from Seizures or Other Court-Actions

- That are done by US FDA when
  - Firm refuses to undertake a recall
  - A recall is ineffective
  - The agency believes a recall would be ineffective
  - Violation is continuing

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US FDA Enforcement Policy

- 21CFR7.41 – 21CFR7.59 (Guidance on policy, procedures, and industry responsibilities)
  - Sec 7.41 Health hazard evaluation and recall classification
  - Sec 7.42 Recall strategy
  - Sec 7.45 FDA requested recall
  - Sec 7.46 Firm initiated recall

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US FDA Enforcement Policy (cont'd)

- 21CFR7.41 – 21CFR7.59
  - Sec 7.49 Recall communications
  - Sec 7.50 Public notification
  - Sec 7.53 Status Reports
  - Sec 7.55 Termination
  - Sec 7.59 General industry guidance

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Health Hazard Evaluation and Recall Classification (21CFR7.41)

- Ad Hoc FDA committee will determine
  - Has disease or injury occurred?
  - Are there conditions that will expose humans or animals to a health hazard?
  - Will humans or animals be exposed to a health hazard?
  - Who are expected to be exposed?
  - How serious are the hazards?
  - What is the likelihood of occurrence?
  - What are the consequences of occurrence?

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Health Hazard Evaluation and Recall Classification (21CFR7.41)

- Based on the assessment, a recall classification will be assigned relative to the degree of health hazard:
  - Class I
  - Class II
  - Class III

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Types of Recall

- Product Recalls
  - Class I
  - Class II
  - Class III
- Not included in public notifications
  - Market Withdrawals
  - Stock Holds
  - Mock Recalls

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Class I Recalls

- Reasonable probability that the use of, or exposure to, a violative product cause serious adverse health consequences or death

- Examples: food pathogens, allergens
- Public warnings

- Maximum efficacy check likely

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Class II Recalls

- Involve products that may cause temporary or reversible health consequences
- Probability of serious adverse health consequences is remote
- Public warning likely
- Intermediate effectiveness checks

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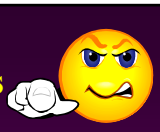
Class III Recalls



- May not involve public warning
- Wholesale or retail level
- Effectiveness checks are minimal
- Affected products have no health hazards

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Market Withdrawals

- This is a situation where no violation is involved or the violation is minor and product is not subject to seizure under current FDA or USDA policy or guidelines.

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Stock Recovery

- Involves the recovery of products that remain under the ***complete*** control of the manufacturer and its clients, regardless of the severity of the problems.
- For example, most of Multiple Organics products are dried, shelf stable ingredients. Such a retrieval could be possible.

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Recall Summary

CLASSIFICATION	RETRIEVAL LEVEL	EFFECTIVENESS CHECKS	PUBLIC WARNING
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

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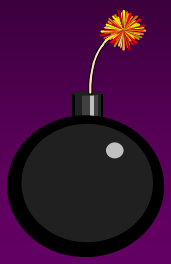
Who Identifies the Problem?

- Regulatory Agency
- Consumer
- Physician
- Field Sales Staff
- Customer Service
- Others



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Who Determines the Severity of the Problem?

- Quality Assurance or Technical Group evaluates the concern
- Is the concern of public health significance?
- Their evaluation results determine the next steps.

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If Product is a Suspected Health Concern

The following actions must be started simultaneously:

- Confirm the presence or absence of a health concern
- Notify management
- Trace all suspect products

- Collect & review production or quality records
- "HOLD" product in company control

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If Product is a Confirmed Health Hazard

- Initiate recall
- Sales & Marketing - Notify buyers; pick up product; isolate product
- Confirm coverage with insurance company
- Marketing - Public relations
- Purchasing - Work with suppliers if issue is supplier-related
- Human Relations - Work with staff
- Production - Assist in investigation; stop operations

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Firm-initiated Recall (21CFR 7.46)

- Firm should notify FDA with required information.
- Firm action will be considered by FDA as a recall when product involves a violation subject to legal action.

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FDA-requested Recall (21CFR7.45)

- Except in limited circumstances (e.g., infant formula), a firm need not initiate a recall even when at FDA's request.

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Recall Strategy (21CFR7.42)

- = Recall Plan (entails a Recall Program)
- Should include
  - Depth of recall: level in the distribution chain (consumer, retail, wholesale)
  - Public warning: general or using specialized media
  - Effectiveness checks: level A (100%), level B (10-99%), level C (10%), level D (2%), level E (0)

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Recall Program

- Documented procedures developed and maintained by a Recall Coordinator
- Staff training
- Must be practiced regularly as a company
  - Goal: to have recalled products within 24 hours of first alert

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Recall Program => Addresses Recall Needs

- Assesses personnel needs
- Needs management support
- Needs a Recall Action Group
  - Recall Action Coordinator
- Requires team effort

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Recall Action Team or Retrieval Team

- Coordinator
- Technical Representative
  - QA, R & D, Laboratory, Contractor
- Warehouse & Distribution
  - Warehouse, receiving, distribution, marketing, customer service
- Communication
- Legal

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Recall Action Team or Retrieval Team (cont'd)

- President/CEO
- Financial Staff
- Public Relations
- Legal Staff
- Outside Help (if needed)

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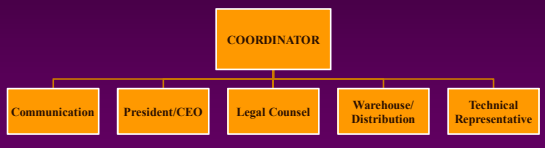
Recall/Retrieval Structure



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How to Recall the Product

- When out-of-compliance food inadvertently reaches any part of the food chain, including the consumer, the product needs to be recalled.
- Traceback or tracking systems or traceability
  - Used to trace the route of contaminated food or sick animals in the food chain

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Traceback or Tracking Systems or Traceability

- Initiated by the food producer or manufacturer
- Offer additional safety reassurances to food
- Used in post-market monitoring (e.g., unintended health effects)
- Important in insuring liability and compensation

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Recall & Traceability

- Statutorily required of some products but all products must involve these.
- Protect the business
- Different issues for distributor than a producer
  - Reliance on vendors & warehouse operations
  - Lot sizes may be variable
  - Mixed pallets

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Commitment to Traceability

- Needs total management support

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How to Trace the Product

- Product identification is critical in tracing the product through distribution from supplier to consumer.
- Rigid coding system preferred
- Test the system through mock recalls
  - Evaluate performance at post mock-recall meetings

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Product ID ➡ Tracking ➡ Recall

- Proper identification of product is a prerequisite to tracking & recall.
- Plan ahead. A crisis is not the time to find that your recall program doesn't work.

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Required Label Information

- Legibility
- Establishment
- Product
- Pack Date
- Pack Year
- Shift or Period

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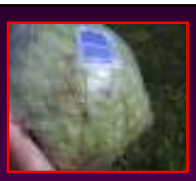
Identifying Initial Source



- Critical information
- Use accurate and recorded product identifications linking successive packaging and transport/storage configurations.

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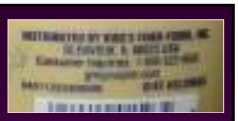
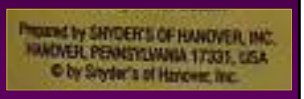
Product Labels



- Code allows traceability to date of production, but labels allow the manufacturer or distributor to be contacted
  - Manufactured by:
  - Distributed by:
    - Distributors work with manufacturers to put their labels on items.



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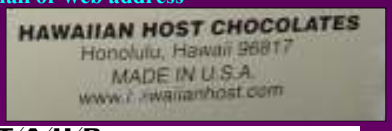
Product Labels (cont'd)

- Clear contact information including;
  - Company name
  - Phone, preferably an toll free number
  - Address
  - Email or web address



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Other Product Information

- Product type
- Packaging
- Labeling
- Shelf life
- Lot number
- Date processed/received/rotated
- Inventory
- Shipping and handling information

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Facility Designation

- Differentiate plants
- Needed for troubleshooting

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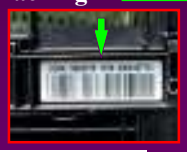
Case Codes & Pallet Tags

- Case codes should be the same as for individual product containers
- Universal Product Codes (UPC) & scanners may be used for tracking
- Pallet tags should delineate what is in pallet



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Tracking Finished Product

OBJECTIVE: *To ensure that all products shipped by the firm may be tracked to the customer in the event that there are problems. This procedure shall be used for tracking products as part of a recall exercise.*

DEVELOP & USE YOUR TRACKING FORM

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RECALL AND TRACKING FORM

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TOTALS

PERCENTAGE RECOVERY

COMMENTS ON THE TRACKING EXERCISE

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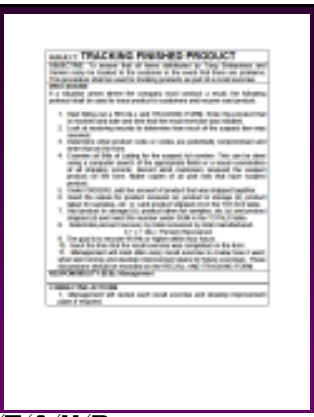
TRACKING FINISHED PRODUCT

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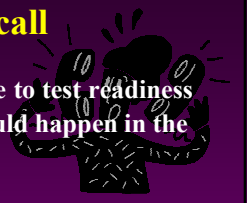
Mock Recall



- Simulated recall exercise to test readiness
- Should mirror what would happen in the event of a real recall
- Standard:
  - 100% of product tracked within 4 hours
- Recall Action Team shall meet and review exercise when it is complete
- Records of discussions shall be maintained

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Mock Recall (cont'd)

- Be proactive
- Seamless, not a fire fighting exercise
- Have backups

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Recall Communications (21CFR7.49)

- Lists the necessary information for a recall
- Gives instructions on product handling

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Role - Communications

- Responsible for communicating with the media, consumers, and regulatory Agencies
- Instructs all employees to refer all questions to Communications
- Statements are pre-evaluated and pre-approved by the Recall Action Team and Legal Counsel

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Contact List

- Detailed contact lists shall be developed, documented and maintained on a regular basis.
- Quarterly at least
  - All team members
  - All warehouse and distribution centers
  - All clients
  - All vendors

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Communicating the Problem

- Radio, television, & print media
- Full details on product
- State what is known and NOT known and what the company is doing to address uncertainties
- Instructions on how to handle suspect product
- Be open & honest

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Group Exercise

- Recall Action Team Members:
  - Take 15 minutes to jot down your duties
  - Include types of documents, locations and key contacts
  - This will become the basis of your work instruction.
  - Discuss the duties

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Public Notification (21CFR7.50)

- Published in the weekly FDA Enforcement Report
  http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm
- Then click on Recalls, Market Withdrawals, & Safety Alerts

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Recall Status Reports (21CFR7.53)

- By the initiating firm to the FDA usually at 2-4 week intervals
- Discontinued upon termination of the recall

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Recall Termination (21CFR7.55)

- Depends on the hazard
- By FDA when all reasonable efforts had been made to remove or correct the product
- Requested by the firm demonstrating effectiveness of the recall

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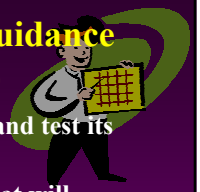
General Industry Guidance (21CFR7.59)



- Prepare a contingency plan and test its effectiveness
- Use product identification that will positively identify the lot and facilitate effective removal of violative lots
- Keep records beyond product shelf life and expected use (e.g., 3 years total)

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A Case Study

Salmonella in Hydrolyzed Vegetable Protein (HVP)

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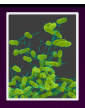

Salmonella in HVP

- Considered a major product recall due to public health impact (*Salmonella* Tennessee)
  - Used worldwide in many products
- Given expanded coverage on
  http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/default.htm
- February-April 2010
- Some say it is potentially the largest recall in US history

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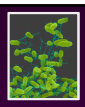

Salmonella Tennessee

- Symptoms
  - Fever
  - Diarrhea (may be bloody)
  - Nausea
  - Vomiting
  - Abdominal pain
  - If the organism enters the bloodstream, may cause arterial infections
- Can survive in dry products

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Basic Food Flavors, Inc.

- Manufacturing HVP since 1980
- HVP is a flavor enhancer
  - Imparting meaty or savory taste (umami)
  - Available in liquid, paste, vacuum dried granules, spray dried powder, Identity Preserved Non-GMO forms
  - Found in ~10,000 packaged, processed foods

Source: http://www.basicfoodflavors.com/

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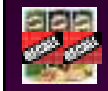

Some HVP Applications

- Beef
- Chicken
- Pork
- Snacks
- Soups
- Stews
- Gravy
- Sauces
- Dips
- Salad dressings
- Spice rubs
- Seasonings

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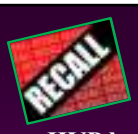

The HVP Recall

- HVP by Basic Food Flavors, Inc.
  - in liquid and paste forms manufactured after September 17, 2009
  - Including foods using this HVP if not cooked before serving (e.g., snacks, dips)
- As of March 24, 2010, no foodborne illness from this HVP or products using this HVP had been reported.

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Inspection History of Basic Food Flavors, Inc.

- 1990: by US FDA; no violations
- 1996: by US FDA; one violation; company took voluntary action
- 2009: by a State contractor; no violations

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New Law on Reporting Problems with Food

- September 2009: US FDA established the Reportable Food Registry (RFR) that mandates food industry to report within 24 hr of detection any problems with a food product
- February 5, 2010: Upon testing HVP purchased from Basic Food Flavors, Inc., a customer reported detection of *Salmonella.*

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Inspecting Agency's Response

- February 12, 2010: US FDA and the Nevada State Health Department began investigations
  - Later found contamination of one lot with *Salmonella* Tennessee
  - Also found *Salmonella* in the processing plant
- Set up a database of products containing this HVP

http://www.accessdata.fda.gov/scripts/HVPCP/

Inspecting Agency's Response (cont'd)

- March 4, 2010: US FDA issued a press release about the firm-initiated recall
  - Industry must destroy or recondition recalled this bulk HVP
  - Recall foods containing this HVP
  - Issued consumer instructions
    - Check list of recalled products on FDA website
    - Follow cooking instructions for all foods
    - Report symptoms of foodborne illness

Inspecting Agency's Response (cont'd)

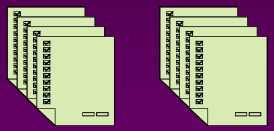
- April 1, 2010: about 177 products containing this HVP have been identified
  - Database is searchable by brand name, product name, or a combination
  - Each product (e.g., bouillon, frozen food, gravy mix, sauce and marinade, etc.) may have been manufactured by several processors.

Inspecting Agency's Response (cont'd)

- Brands included
  - McCormick
  - Durkee
  - French's
  - Pringles
  - Quaker
  - Safeway
  - Fresh Food Concepts
  - Hawaiian
  - Great Value
  - Trader Joe's
  - Herbox
  - Garden Harvest
  - Publix
  - Kroger
  - Dean's
  - Great Nut Supply

Inspection Form 483

- Observations of the inspection team, not a final FDA determination
- Listed FDA's own *Salmonella* findings



Source:http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/ucm203784.htm

Inspection Form 483 (cont'd)

- January 21, 2010: company received COA showing positive for *Salmonella*
- January 21-February 15: company continued distribution
- January 21-February 20: company continued manufacture under the same conditions without microbial contamination control

Source:http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/ucm203784.htm

Inspection Form 483 (cont'd)

- Detailed significant issues in the plant
  - Lack of microbial contamination control during manufacture, packaging, and storage of foods
  - Failure to conduct cleaning and sanitation procedures
  - Inadequately installed plumbing and inadequate drainage
  - Plant construction and design do not allow floors to be adequately cleaned and kept in good repair.

Source:http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/ucm203784.htm

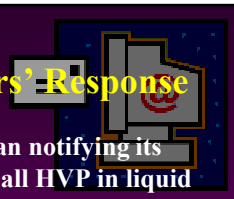
Basic Food Flavors' HACCP Plan

BASIC FOOD FLAVORS - HACCP PLAN SUMMARY 2009

CCP HACCP Plan Summary			Review Date March 2009 SUPERCEDES				PRODUCT HVP – VACCUM DRIED POWDER PAGE 1 of 1		
Critical Control Point (CCP)	Hazard	Critical Limits	Monitoring				Corrective Action	CCP Verification Procedures	Records
			What	How	Frequency	Who			
Treatment CCP:1	C: S-MCPD	≥ 8 hours ≥ pH 8.8	pH & Time during treatment . Check the pH	Sample is taken and pH checked using pH meter	Before treatment and then after every 4 hours	Reaction Operator	If pH is < 8.7 raise pH by adding more Caustic (NaOH). If Treatment time is less than 8 hours treat it to 28 hours.	-Calibrating the pH used in determining the pH; - Observing monitoring activities to ensure the records are completed and to verify that the documented values are within the set limits; -Observing corrective actions to ensure that records are complete and appropriate action taken; - Reviewing records including verifying signatures and dates for completeness.	-Treatment Log - pH Calibration Log.

Source: http://www.basicfoodflavors.com/pdf/HACCP_PLAN_1CCP_2009.pdf

Basic Food Flavors' Response



- February 26, 2010: began notifying its customers of a recall of all HVP in liquid and paste forms it had manufactured from September 17, 2009
  - February 27, 2010: Kroger recalled products
- Mid-March 2010: Company still refused to comment on the recall

Source: http://www.foodproductiondaily.com/Quality-Safety/Basic-Food-Flavors-denies-wrongdoing-in-HVP-recall

Basic Food Flavors' Response (cont'd)

- Company's sales and marketing manager hoped media freeze "would help publicity of the recall to pass quickly."

  "Quite honestly, we didn't bother answering the press because we just wanted it to go away," he said. *"…It's working. It's beginning to die down."*

  The recall affected *"only 10,000 lb of 10 million"* or 0.1% of the production volume of the company.

Source: http://www.foodproductiondaily.com/Quality-Safety/Basic-Food-Flavors-denies-wrongdoing-in-HVP-recall

Basic Food Flavors' Response (cont'd)

- March 17, 2010: Company broke its media freeze to FoodNavigatorUSA

  "While it is unclear whether FDA is suggesting in the Form 483 that Basic Foods knowingly shipped adulterated product, the language used by the agency and reported by the press has created that implication. We, therefore, consider it important to clarify that Basic Foods has not knowingly shipped into commerce any product the Company believed had the potential to contain Salmonella."

Source: http://www.foodnavigator-usa.com/Financial-Industry/Basic-Food-Flavors-denies-wrongdoing-in-HVP-recall

Basic Food Flavors' Response (cont'd)

- Form 483 of the company issued March 9, 2010 by the US FDA (FoodNavigatorUSA)

  "After receiving the first private laboratory analytical results [dated January 21] indicating the presence of Salmonella in your facility, you continued to distribute HVP paste and powder products until 2/15/2010. Furthermore, from 1/21/2010 to 2/20/2010, you continued to manufacture HVP paste and powder products under the same processing conditions that did not minimize microbial contamination."

Source: http://www.foodnavigator-usa.com/Financial-Industry/Basic-Food-Flavors-denies-wrongdoing-in-HVP-recall

Basic Food Flavors' Response (cont'd)

- Their website does not contain any progress report on the recall. There is no information on:
  - Company responses to the recall
  - What the company is doing to insure no product contamination in the future
  - What stage the recall is at

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Unwanted Exposure (cont'd)

- The Daily Green, April 27, 2010. *"HVP, a Non-Food, Continues to Cause More Food Recalls"*

thedailygreen the consumer's guide to the green revolution

- *"…the industrialized food system and how easily it can sicken us, rather than nourish us."*
- *"…food manufacturers, it doesn't sound like a farm, does it?"*
- *"…how weirdly disgusting our food system is."*

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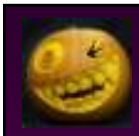

Unwanted Exposure (cont'd)

- March 13, 2010 Pacifica Riptide

"They documented dirty utensils and equipment-mixers and tubing coated with brown residue-and cracks and fractures in the floor, as well as standing water on the floor-all conditions where bacteria can breed. In one area where paste mixers and belt dryers were positioned, FDA inspectors noted "standing, grey/black liquid" in the drain near the area where the hydrolyzed vegetable protein was turned from paste to powder. "We sensed an odor in the vicinity of this drain," the inspectors wrote. Enough said? "

Source: http://www.pacificariptide.com/pacifica_riptide/

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Unwanted Exposure (cont'd)

- March 12, 2010 Care2 Healthy and Green Living

"We will now attempt to scare you into walking away from the processed food. "

"Thousands of types of processed foods–including many varieties of soups, chips, frozen dinners, hot dogs and salad dressings–may pose a health threat because they contain a flavor enhancer that could be contaminated with salmonella. "

Source: http://www.care2.com/greenliving/hvp-biggest-food-recall-in-us-history.html

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Lessons Learned

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How the US FDA Minimized the Risk of Foodborne Illness

- Immediately began investigations after report of detection of *Salmonella* on RFR
- Communicated with the company
- Issued press release about the recall

FDA U.S. Food and Drug Administration

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How the US FDA Minimized the Risk of Foodborne Illness (cont'd)

- Set up online Q&A for consumers, Q&A for the industry
- Set up online database of recalled products and brands
- Posted online public documents about the investigation and recall
- Posted online appropriate contacts

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How the Company Minimized the Risk of Foodborne Illness

- Voluntarily recalled all involved products but not sufficiently timely
  - Form 483 cited their continuing to manufacture and distribute for more than 3 weeks after receiving confirming lab results of *Salmonella*

Basic Food Flavors, Inc.

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To Minimize the Risk of Foodborne Illness, the Company Should Have…

- Known what to do when the investigators knock
- Ceased production and distribution while confirming lab results
- Had a tested Crisis Management Program and a trained Crisis Management Team

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To Minimize the Risk of Foodborne Illness, the Company Should Have…

- Had tested Recall Program and a trained Recall Team
- Announced recall to the industry and the consumers immediately upon verification (in different languages)
- Publicized on their website events and activities related to the recall

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To Minimize the Risk of Foodborne Illness, the Company Should Have…

- Promptly returned media calls (only by designated company communication persons)
- Within the company
  - Checked coverage of insurance policy
  - Reviewed supplier qualification procedures and supply contracts
  - Obtained criminal law advice

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Communicating the Problem

- Radio, television, & print media
- Full details on product
- State what is known and NOT known and what the company is doing to address uncertainties
- Instructions on how to handle suspect product
- Be open & honest

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Group Exercise

- Recall Action Team Members:
  - Shall we do a mock recall?
  - Use your notes from the first exercise and let's go.
  - Select a product to track.

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Thanks to Jennifer Thomas of US FDA for her kind assistance.

C/T/A/H/R
College of Tropical Agriculture and Human Resources
University of Hawai'i at Mānoa

Mahalo nui loa!
Maraming salamat po!

Aurora A. Saulo, Ph.D.
Professor and Extension Specialist in Food Technology
University of Hawaii at Manoa
aurora@hawaii.edu

May 4-6, 2010
Manila, Philippines

C/T/A/H/R
College of Tropical Agriculture and Human Resources
University of Hawai'i at Mānoa

United States Department of Agriculture
Food Safety and Inspection Service

Outbreak to Recall
A Case Study

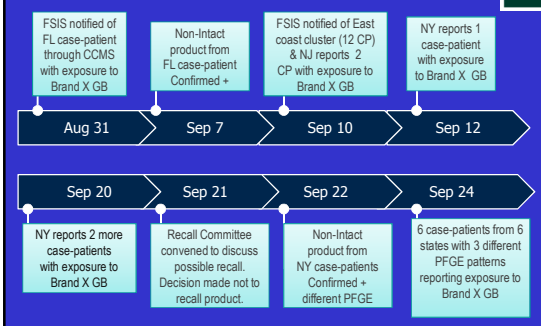
United States Department of Agriculture
Food Safety and Inspection Service
Lisa Volk, Director of Recall Management

United States Department of Agriculture
Food Safety and Inspection Service

Tainted-Beef Recall Sparks Consumer Concerns

- "2007- year of the recall"; peanut butter, pet food, toys, cribs....
- Of 21 meat recalls for *E. coli* O157:H7 in 2007, 10 are associated with illnesses.
- E. coli fears trigger large beef patty recall.

United States Department of Agriculture
Food Safety and Inspection Service



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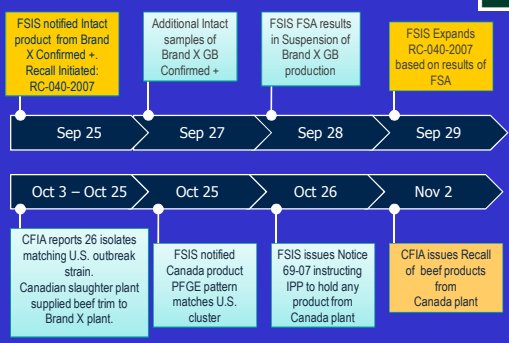
United States Department of Agriculture
Food Safety and Inspection Service



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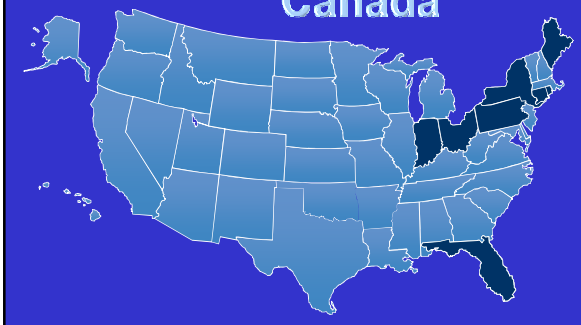

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United States Department of Agriculture
Food Safety and Inspection Service


Recall Release

- Recall expands to 21.7 million pounds (1 years production)
- Distribution Nationwide retail and Exports
- Impacts 11 Brands and 1 other Federal Establishment
- Occurred on a Friday!

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United States Department of Agriculture
Food Safety and Inspection Service

Consequences

- 43 case patients from 8 states
- 21 hospitalizations; 2 HUS; no deaths
- Add'l cases in Canada
- Firm ceased operations
- 2.2 million lbs recovered/destroyed
- At the time, 5th largest recall;
  - Largest beef recall

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United States Department of Agriculture
Food Safety and Inspection Service

Outcomes

- Heightened interest in all recalls by Congress, media, and general public.
- OIG audit to evaluate FSIS recall procedures


Audit Report
Food Safety and Inspection Service
Recall Procedures for Adulterated
or Contaminated Product

United States Department of Agriculture
Food Safety and Inspection Service

Recommended Actions

- Final OIG report issued August 2008
- 1.Collect and analyze greater number of representative samples during outbreak investigations.
- 2.Implement new Directive for investigating foodborne illness and for handling recalls. (FSIS Directive 8080.3)

-Revised Recall Directive 8080.1 issued Nov. 2008

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United States Department of Agriculture
Food Safety and Inspection Service

Policy Changes

- Notices to expand sampling programs
  - -Sampling of raw ground beef based on volume
  - -Routine sampling of trim and source materials other than trim, such as two-piece chuck, sub-primals, LFTB, and bench trim
  - -Includes follow up sampling of component materials at all suppliers to a positive event
- FSA scheduled at all firms with a reported positive FSIS sample result
- Focus on getting available best practices to establishments
- Reassessment of E. coli controls
  - -Checklist/survey to catalog industry practices
  - -Draft compliance guidelines issued in 2008
  - -Criterion for high event periods
  - -Verifying sanitary dressing procedures

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Food Safety and Inspection Service

Proposed Next Steps

- Initiate rulemaking to identify tenderization as a material fact that must be identified on labeling
- 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
- Develop new N60 sampling instructions

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Food Safety and Inspection Service

Published Guidance

- FSIS Directive 10, 010.1 Revision 2 July 31, 2009 Verification Activities for Escherichia coli O157:H7 in Raw Ground Beef Products
- Posted on Significant Guidance Page at http://www.fsis.usda.gov/Significant_Guidance/index.asp

  -Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for Escherichia coli O157:H7

  -Draft Compliance Guideline for Sampling Beef Trimmings for Escherichia coli O157:H7

  -Draft Guidance for Small and Very Small Establishments on Sampling Beef Products for Escherichia coli O157:H7

  -Draft Label Policy Guidance for N-60 Testing Claims for Boneless Beef Manufacturing Trimmings ("Trim") Concerning E. coli O157:H7

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United States Department of Agriculture
Food Safety and Inspection Service

Thank you

Food Recalls in Australia

Mr Elliot Hill

APEC Recall Workshop, Manilla
4th – 6th May, 2010

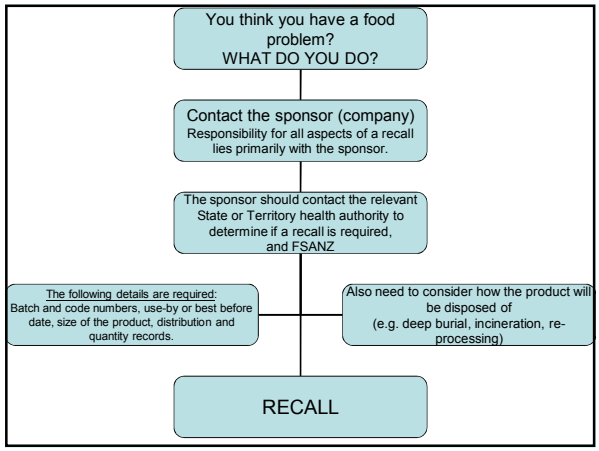
Key Elements of a Food Recall

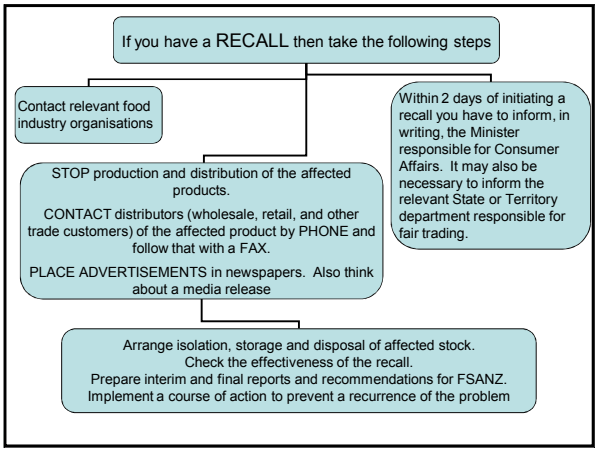
The FSANZ Recall Process

- FSANZ's role is one of coordination and monitoring
- Process supported by legislative requirements for food businesses to act and report
- FSANZ assists in the recall process, but the decision whether or not to recall foods rests with the States and Territories

The FSANZ Recall Process

- FSANZ is notified of a potential recall situation
- The Home State or Territory determines whether a recall is warranted
- FSANZ collects information concerning the recall and disseminates it





Product Information Required

Details required:

- Food Type
- Brand Name
- Use By or Best Before Dates (as they appear on packaging)
- Packaging and size
- Sponsor Details
- Distribution

Other Relevant Details

- Category and sub category of the hazard risk
- Proposed recall level (consumer or trade)
- Action proposed by the company
- Australian Product Number (APN) or other code number
- Method of disposal
- Country of origin
- Domestic and overseas distribution

Post Recall Reporting

- Reports used to show recall carried out satisfactorily and consumers have been protected
- Examples of questions asked
  - Circumstances leading to recall
  - How widely were the relevant batches distributed
  - How much manufactured? Recovered?
  - How was stock disposed of? Provide destruction certificates

State/Territory Challenges

- Dealing with different State/Territory can be a challenge
- Each State/Territory deals and assess food recalls differently
- One State/Territory would recall a product while another may just withdrawal
- FSANZ is working with each State/Territory to develop better continuity for food recalls

Issues that may slow down a recall

- How to conduct a recall
- Lack of preparation
- Distribution Lists
  - Accuracy – Contact details of those that received implicated product
  - Knowledge – whether a company received the implicated product
- Timeliness – sponsor carries on with the day to day running of the business

Mistaken use of the recall process

- Garlic Bread Recall – 2008
  - Sponsor recalled garlic bread because of blue colouration
  - FSANZ advised that this was not a public health and safety risk
  - Sponsor went ahead with recall
  - Later the sponsor admitted that the product was recalled for aesthetic reasons

Recalls and Media Attention

- Some recalls get a lot of media attention
  - Woolworths Fresh Milk Lite 2 L – 2009
    - Microbial – *Escherichia coli*
  - Bonsoy Soy Milk - 2009
    - very high levels of Iodine due to Kombu
    - World wide recall

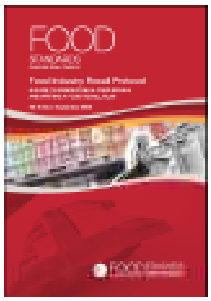
International Recalls and Australia

- Food Incidents overseas have triggered recalls in Australia
- Recall of Pistachios from Setton Pistachio of Terra Bella Inc in the US resulted in 3 recalls in Australia
- FSANZ receives information from overseas agencies about recalls and investigates possible imports

Food Industry Recall Protocol

What is the purpose of this protocol?

Guidance for food businesses on
- Developing a written recall plan
- Conducting a food recall
- Roles of government and industry



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Food Recall Review

- Review in consultation with government and industry stakeholders
- Training of after hours recall officers has been revised and improved
- Updated versions of the Food Industry Recall Protocol and Government Authority Food Recall Protocols published in 2008

Conclusion

- Prompt and effective recall action ensures safety of the food supply and promotes consumer confidence in a company's products

FOOD RECALL BRUNEI DARUSSALAM EXPERIENCE

Presented by:
Mahani Muhammad
Ministry of Health, Brunei Darussalam
May, 2010

INTRODUCTION

- Brunei Darussalam imports about 80% of food from all over the world
- Minimal Production
- Brunei Darussalam gears towards self sufficiency and producing local food products

ALERTS

Receives alerts through various reporting systems such as:

- INFOSAN – International Food Safety Authority Network
- Food Authorities – Subscription to websites
- Bi-lateral Agreement - Exchange of information between two countries

ANALYSIS OF INFORMATION

Information received is analyzed

ALERTING THE PUBLIC

- Verbal & written notifications to importers / traders
- Issue press releases if required
- Post updates to MOH Web site regularly to alert people
- Media updated

CHECKS

- Carry out checks and investigation a
- Product destroyed
- Re-sampling

SURVEILLANCE

- Carry out frequent and regular inspections
- Take enforcement action

CHALLENGERS

- Human resources:
  Constraint of manpower, lack of speciality training,
- Capacity building:
  Recruitment of manpower, training on enforcement
- Laboratory capability and facility
- Cottage food industries: Increasing numbers
- Meeting food standard

THANK YOU FOR YOUR ATTENTION

Food Safety & Quality Control Division
Environmental Health Services
Department of Health Services
Ministry of Health
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Tel. No.: 673 2 331100-10 Fax. No.:673 2 331107
e-mail : fsqc@moh.gov.bn

GOBIERNO DE CHILE

RECALL SYSTEM IN CHILE

DEVELOPMENT AND STRENTHENING OF FOOD RECALL SYSTEM FOR APEC MEMBER ECONOMIES
MANILA, PHILIPPINES 4-6 MAY 2010

CHILE:

On the western coast of South America (4.200 km long and 152 km wide on average)
Inhabitants: 17.094.275
Urban: 86.6%
Life expentancy at birth (y): 75.5 M / 81.5 F

Electricity:	99.5 %
Tap water:	98.1 %
Sewerage:	82.8 %
Literacy:	95.8 %

ORGANIZATION AND SYSTEMS RELATED TO FOOD CONTROL AND INSPECTION

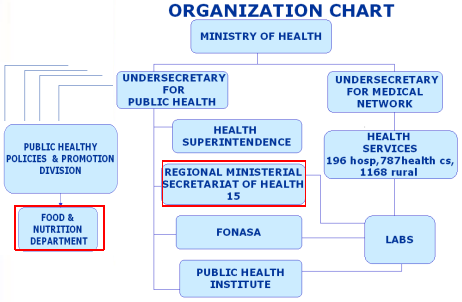
The Ministry of Health is the national sanitary authority in charge of sanitary administration and control on food products for domestic use (imported food and local production).

Two other major regulatory bodies are in charge of the food sanitary administration regarding international trade agreements on food products for export. The Agricultural and Livestock Service (SAG), depending on the Ministry of Agriculture; and the National Fisheries Service (SERNAPESCA), depending on the Ministry of Economy.

MINISTRY OF HEALTH

The mission of Ministry of Health (MINSAL) is to contribute to elevate the level of the population's health; to develop the systems of health harmoniously, centered in people; to strengthen the control of the factors that can affect the health and to reinforce the administration of the national network. All this to collect opportunely needs of the people, families and communities, with the obligation of to render accounts to the citizenship and to promote the participation of the same ones in the exercise of their rights and their duties.

ORGANIZATION CHART



MINISTRY OF HEALTH

Food Safety Area:

MINSAL is responsible of protecting consumers health, promoting healthful nutritional habits and it has legal attributes in reducing all kind of contaminants in foods, assuring the safety and quality of them. To comply with this role, the Ministry takes permanent sanitary control and inspection measures appropriately at each stage of the food chain.

MINSAL carries out a range of work to make sure that food is safe to eat. Some activities to achieve these goal are:

From the central level:

- Developing, updating and harmonizing the food regulation, according current requirements and international guidance.
- Coordinating policies in food sanitation, according to strategies indicated in the Public Health National Plan.

From regional level, through regional offices (SEREMI).

- Food establishment authorization
- Sanitary inspection on Food establishments
- Control and surveillance of food
- Meat and poultry inspection
- Control of Food Imports
- Monitoring, Investigation and control of food poisoning
- Control of labeling
- Monitoring and controlling poisonings by Red Tide.

GENERAL CONDITION OF FOOD CONTROL AND INSPECTION

- **The Sanitary Code** 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 regulates 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.

This regulation applies to imported food products and local production, and is executed by the Regional Health Secretariats (SEREMI) through their inspecting and analytical divisions.

The Public Health Institute (ISP) is the appointed reference laboratory for the analytical laboratories of the public health system.

The monitoring programs are mainly directed to the most sensitive issues, according to the specific needs of the different regions.

SANITARY CODE

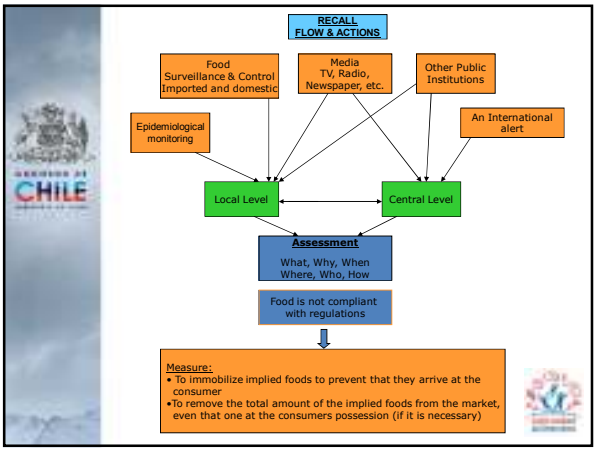
TITLE III

ABOUT SANCTIONS AND SANITARY MEASURES

Article 178 (169).: The authority, as sanitary measure, will be able to order in justified cases the closing, prohibition of operation of houses, premises or establishments, paralyzation of tasks, seizure, destruction and denature of products.

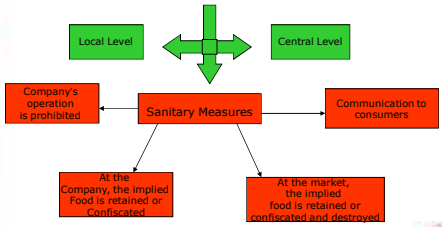
FOOD SANITARY REGULATION
TITLE II
FOODS
General provisions

Article 102.- The manufacture, import, possession, distribution, marketing or transfer for any reason of foods that are altered, contaminated, adulterated and falsified is prohibited.



RECALL FLOW & ACTIONS

Measure:
- To immobilize implied foods to prevent that they arrive at the consumer
- To remove the total amount of the implied foods from the market, even that one at the consumers possession (if it is necessary)



Minsal prohibits manufacture and sale to any kind of foods "ADN"

•Hotline

- In spite of sanitary regulation does not consider any indications about how to develope a Recall, regulation frame is strong enought to give us support on different sanitary measures to avoid consumer exposition.
- The following points must be our challenge the next coming years:

  - Plants are not maintaining enought time the records or documents or they are not sufficient

  - Communication between stackeholders and sanitary authority must be more fluently

  - Stackeholders are understanding that their own recall procedures are an important part of pre requirement programs

  - Information about food incidents may not be clear for consumers

  - Exist a delay to close food events and make the final evaluation.

THANK YOU

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Ministry of Health
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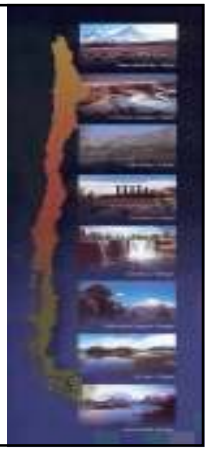


Food Recall Guidelines of Chinese Taipei

TFDA
Section Chief
Fang-Ming Liu

TFDA

Food Recall Guidelines Purpose

- These Food Recall Guidelines are established to provide a guide for carrying out food recall in order to ensure the hygiene, safety and quality of food and to protect health of consumers.
- http://food.doh.gov.tw/english/english.asp

Purpose

- These Food Recall Guidelines are established to provide a guide for carrying out food recall in order to ensure the hygiene, safety and quality of food and to protect health of citizens.

Scope

- These Guidelines apply to the recall of food, which will or probably will cause hazard to the diet safety of the public or, whose quality does not conform to regulations.

Initiation of Food Recall

- The responsible entity shall proceed with recall where the food:

  (1) by law shall be recalled for violating hygiene or other applicable regulations; or

  (2) is of defect that it is deemed necessary for a recall.

Initiation of Food Recall

- Food recall is initiated under the following two circumstances:

(1) Where an entity launches the recall on its own initiative as required by law or where it deems recall necessary; and

(2) Where the competent health authority orders the entity by law to conduct the recall.

Classes and Levels of Recall

- Recall is divided into the following three classes subject to the degree of harm the food causes to public health:

(1) Class 1:

The food is expected to have a probability to cause death or serious harm to public health.

Cyanide causing one death

Classes and Levels of Recall

(2) Class 2:

The food is expected to have a low probability to cause harm to public health .

Pb:174 ppm

Classes and Levels of Recall

(3) Class 3:

The food is expected not to cause harm to public health but is not in conformity with the quality regulations（ex. Labeling）

Do not meet the requirement of Health Food Claim (Catechins)

※Usually relabel

Classes and Levels of Recall-II

- Recall is divided into the following three levels depending on the extent sales channels are involved in food recall:

(1) Consumers:

to the extent of individual consumers

※News release

Classes and Levels of Recall-II

(2) Retailers:

to the extent of sales premises.

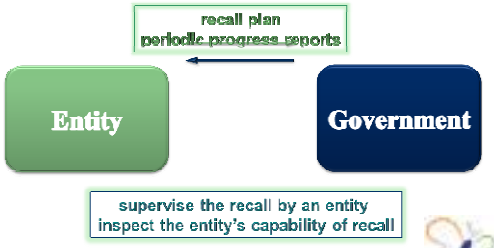
(3) Wholesalers:

to the extent of importer and wholesaler premises etc. where the food is not directly sold to consumers.

Operation of Recall System

- Class 1 recall, the recall plan of the responsible entity shall specify the recall being extended to the consumer level and such entity shall issue a press release.
- Class 2 or 3 recall, the responsible entity initiating the recall shall propose the level of recall taking into consideration the nature of the potential hazard caused by the food to public health, and report to the local competent health authority prior to finalizing the recall proposal according to the instructions of such authority.

Operation of Recall System

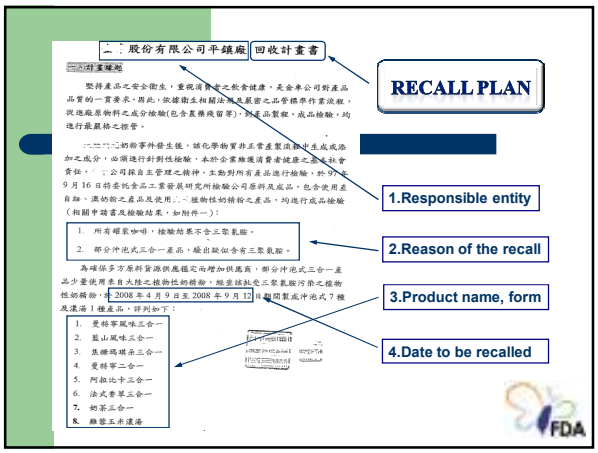


Responsibilities of entity – recall plan

- An entity shall devise a recall plan at least covering, inter alia, the following information:

(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;



Responsibilities of entity – recall plan

(3) Product name, packaging, form, or special distinguishing features or signs of the food to be recalled;

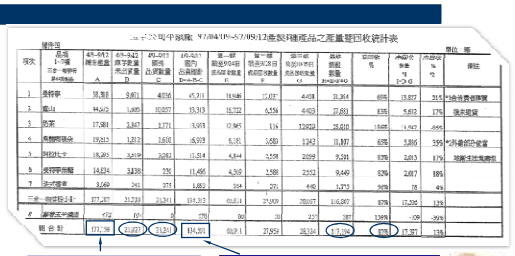
(4) Date, lot number, code, or other identifying information and number specified on the food to be recalled;

Responsibilities of entity – recall plan

(5) Total production volume of the food to be recalled;

(6) Total volume of the food to be recalled in the sales channel;

Responsibilities of entity – recall plan



5.Total production volume to be recalled

6.Total volume to be recalled in the sales channel

Responsibilities of entity – recall plan

(7) Distribution record of the food to be recalled;

Responsibilities of entity – recall plan

(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.;

Responsibilities of entity – recall plan

(9) Subsequent safety or destruction measures to be adopted, for instance, sterilization, recondition or correction etc.; and

(10) Warning which shall be issued to consumers, and the contents thereof.

Responsibilities of entity

- An entity shall present its recall plan to the local competent health authority for the file and, where necessary, issue a press release, prior to the recall of food.

Responsibilities of entity – periodic progress reports

- An entity shall submit periodic progress reports to the local competent health authority in the course of food recall, covering at least the following information:

  (1) Number of downstream entities or individuals being notified, and date and manner of notification;

Operation of Recall System

(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;

Operation of Recall System

(4) Quantity of recalled food;

(5) Number of times and result of investigation;

(6) Anticipated time limit for completion.

Responsibilities of entity

- An entity shall, upon completion of food recall, report the process and result of the recall in writing to the local competent health authority and, where necessary, to the central competent health authority, for placing the matter on the file for future reference.
- An entity shall properly retain complete documentation on food recall for inspection and verification.

Responsibilities of Government Authority

- The local competent health authority shall supervise the recall by an entity and inspect the entity's capability of recall. The work of such authority shall include the following:

(1) inspect the violating food, take action by law, and advise the entity to recall such food;

Responsibilities of Government Authority

(2) give instruction on the class and level of the recall proposed by the entity, and file the entity's recall plan for future reference;

(3) request the entity having submitted an incomprehensive recall proposal to make improvement;

Responsibilities of Government Authority

(4) give instruction on the frequency of reporting the condition of recall, subject to the urgency of the case, and monitor the entity's recall progress;

(5) supervise the entity in its completion of recall;

(6) assess the entity's recall report;

(7) offer follow-up guidance to the entity;

Responsibilities of Government Authority

(8) conduct periodic inspections to ascertain the extent of recall accomplished; and

(9) file relevant recall information and issue the necessary press release.

periodic inspections

supervise the completion of recall

Responsibilities of Government Authority

- The central competent health authority shall supervise the local competent health authority in the execution of the above work and, where necessary, may assess the relevant reports submitted by the entity and give instructions.

Challeges

- Responsibility of recall：
  ingredients already made in food ?
- Class of recall：
  media pressure + public confidence
  vs. risk assessment + risk communication

Thank You For Your Attention !!!

INDONESIA FOOD RECALL SYSTEM

APEC SEMINAR-WORKSHOP ON THE DEVELOPMENT AND STRENGTHENING OF FOOD RECALL SYSTEM FOR APEC MEMBER ECONOMIES
PHILIPPINES, 4-6 MAY 2010

INDONESIA REGULATION

General Guidelines for the Control of the Implementation of Products Recall
(established on 1997)

Code of Practice for Food Product Recall
(established on 2008)

Draft Revision of Code of Practice for Food Products Recall
(under development)

Referenses

- Food Industry Recall Protocol, Food Standards Australia New Zealand (FSANZ)
- The Canadian Food Safety System – Food Recall, The Canadian Food Inspection Agency (CFIA)
- Code of Federal Regulation, FDA
- etc.

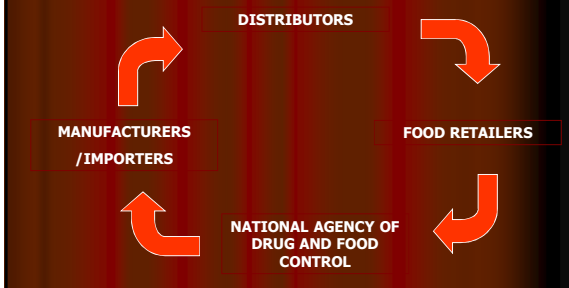
classes of food recall

Class I
- Product is suspected to cause serious adverse health effect or even death because of pathogen (e.g. *Clostridium botulinum, Salmonella, Vibrio cholerae,* etc) or chemical hazards (boric acid, formaldehyde, prohibited coloring, etc)

Class II
- Product is suspected to cause temporary adverse health effect because it does not comply standards (e.g. chemical contamination exceeds its maximum limit)

Class III
- Product is not likely to cause any adverse health effects but in violation of legislative (e.g. incorrectly labelled, illegal products)

Role and Responsibilities



Responsibilities :Manufacturers/Importers

- remove the unsafe food from sale
- maintain records and establish procedures that will facilitate a recall (records should be in a form that can be quickly retrieved)
- have a written recall plan
- initiate the action for implementing a recall
- in the case of a consumer level recall, notify the public (generally by press advertisement)
- for imported product, contact overseas supplier/manufacturer when initiating recall action

Responsibilities :Distributors

- maintain distribution records, and
- establish procedures that will facilitate a recall

Responsibilities :Food Retailers

- remove all recalled products from sale.
- Return the product to the distributors.

Responsibilities :National Agency of Drug and Food Control

- monitor supervise the implementation of recall and ensure that the implementation is taken in the appropriate manner.
- ensure that recalled products secured or reconditioned in the appropriate manner.
- evaluate sufficiency of food recall implementation
- act as witnesses when the products are destroyed.
- investigate the cause of affected product

Implementation of Food Recall

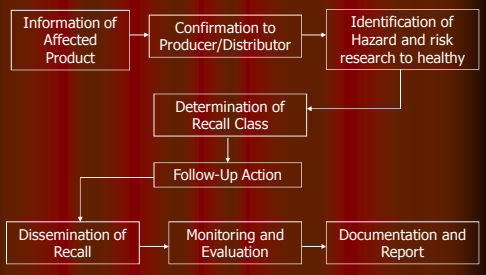
- Voluntary Recall

= a recall that is initiated and carried out by the food businesses without ministerial order

- Mandatory Recall

= a recall done by the instruction/order of Head of NADFC

Step of Mandatory Recall



Information

- Information of affected product can be received from manufacturer, ditributor, consumer, food inspector, other institution, other country, etc.

Confirmation

- Confirmation is done by collecting information about the manufacturer/distributor, investigation to the manufacturer/distributor location, collect information on the affected product, sampling and product examination.

Identification of hazard and risk analysis

- Disease or disease symptoms appeared after consuming the affected product
- Hazard identification and risk analysis to children or high risk population
- Hazard level identification

Determination of recall class

- class I, class II or class III

Follow-Up Action

- coordinate with NADFC's regional officer on supervision of implementation food recall of affected product
- prepare and issue recall instruction letter to manufacturer/distributor/importer
- monitor the food recall implementation.

Currently, there are 30 NADFC's regional offices, Responsibilities of NADFC's Regional Officer in the food recall implementation

- Investigate the distribution facilities (market) and secure products and act as witnesses when products are destroyed.
- Provide report to NADFC not later than 2 months.

Dissemination of recall information (Press Release)

- whole range of product distributions
- Product characteristics
- Consumer targets
- Precautionary measure that should be done.
- Type of Media Release

Monitoring and Evaluation

- Food recall conducted effectively and in accordance with the regulations
- Recalled product are treated in accordance with the regulations

Documentation and Report

- Documentation and report must describe all of recall activities. Report can be provided step by step based on the process of food recall. Period for providing report are determined by NADFC and or NADFC's regional officer.

Example of Products Recall in Indonesia

No	Date	Subject
1	27/09/2008	NADFC Press Release on products containing milk from China tainted melamine
2	12/12/2008	NADFC alerts to recall Munchy's Lexus Peanut Butter for tainted of melamine
3	20/03/2009	NADFC alerts to recall all Munchy's and Apollo biscuit products tainted melamine
4	01/06/2009	NADFC Press Release on beef jerky tainted pork (halal concern)
5	05/01/2010	NADFC alerts to recall "Terasi Udang cap Rambutan" for the use of prohibited coloring agent of Rhodamin B
6	08/01/2010	NADFC alerts to recall Yeo's Drink based on cancellation of product registration approval

No	Date	Subject
7	12/01/2010	NADFC alerts to recall Marquisa Syrup for the use of sodium benzoic exceed the maximum levels
8	15/01/2010	NADFC alerts to recall Mentalk – Coffe and Ginseng Coffee based on cancellation of product registration approval
9	02/02/2010	NADFC alerts to recall Orens Orange Syrup for the use of sodium cyclamate and sodium benzoic exceed the maximum levels
10	02/02/2010	NADFC alerts to recall Prigo Strawberry Jam for the use of sodium benzoic exceed the maximum levels
11	02/02/2010	NADFC alerts to recall Seprit Ice for the use of sodium cyclamate exceed the maximum levels
12	05/02/2010	NADFC alerts to recall Zamghua Bottled Water based on legality of product registration approval

CTI 55/2009T

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

MANILA,PHILIPINES

4th MAY 2010

DR.MOKTIR SINGH

MALAYSIA

FOOD RECALL SYSTEM

- Ministry Of Health
- Ministry of Agriculture & Agro Based Industry (DVS)

FOOD SAFETY OBJECTIVES

- To protect consumer's health
- To ensure fair trade practices

Product Recall/Withdrawals

Objectives:

- Stop production and distribution of effected product lot
- Notify the public and relevant government agencies
- Enable a voluntary withdrawal or recall of product from market place
- Response time in determining affected product withdrawn or recalled is critical.

Product Recall/Withdrawals

Recovered products:

- Shall be secured or held under supervision until they are
  - destroyed or
  - used for purpose other than originally planned or
  - if can be determined to be safe for the same (or other) intended use or
  - reprocessed in a manner to ensure they become safe

ACTIVITIES: ENFORCEMENT

Import Control

- Inspection based on:
  - Document
  - Physical inspection
  - Sampling
- Priorities based on:
  - Past violations (black listed items)
  - Food entering for the first time
- Approach undertaken
  - Hold-test-release
  - Undertaking letter

ACTIVITIES: LEGISLATIVE SUPPORT

- **Food Act 1983**
  - gazetted on 10 March 1983
- **Food Regulations 1985**
  - gazetted on 26 September 1985
- **Enforced together on**
  - 1st October 1985
- Food Hygiene Regulations 2009

Legislation – Animal Quarantine/Import-Export

- **Animal Act 1953 (Act 647)- West Malaysia**
  Revised 2006.
- **Animal Rules 1962**
- **(Custom Act 1967)**

Legislations

1. **Animal Act 1953**

- Part II(Importation and Exportation of Animals and Birds)

  Exportation (sect 14,15,16 & 17)

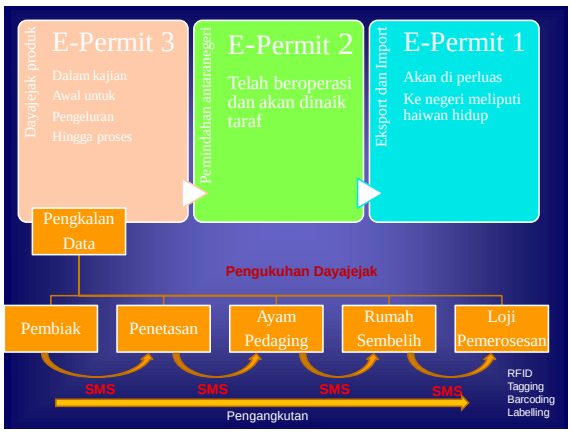
  - No person to export any animal without licence
  - Exportation to Singapore
  - Examination before exportation
  - Exportation of diseased animal or bird

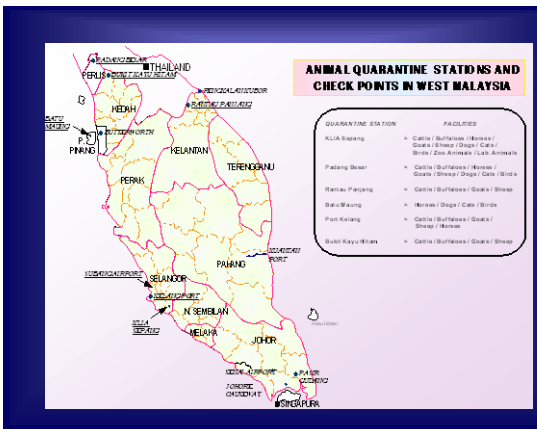
- Sect 83 (Certificate of freedom of State from disease)

Legislations(cont)

2. **Animal Rules 1962**

   - Prescribed landing place (entry & exit point) for importation/exportation of animals and animal products
   - Issuance of health certificate





ENTRY POINT

Airport

ENTRY POINT

PORT

ENTRY POINT

LAND

WORK PROCESS- DETAIN PRODUCTS

Work Proses	Approving Officer/ Ref.
Record animal and animal product held	PPV/PV Senior
Inform importer and prepare report for HQ DVS using appropriate form (Borang Laporan Kes Penahanan/Rampasan/Penyakit di Pintu Masuk/SKH)	Peg. Vet/PPV/PV Enforcement Officer DVS
Animal or animal products held will be sent back or confiscated	
If confiscated do a police report together with enforcement officer	
Obtain and carry out Court Order	
Complete Forms (Laporan Kes Penahanan/Rampasan/Penyakit di Pintu Masuk/SKH)	

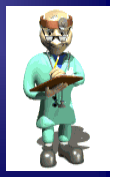
PROCESS FLOW – DETAIN PROUCTS

DISPOSAL

- Animal Act 1953 (Part II – Seksyen 9)
  - Disposal Cost – Born by Owner
  - No reimbursement (Tiada Pampasan)
- Action – Court Order
  - Destroy
  - Auction
  - Hapuskira

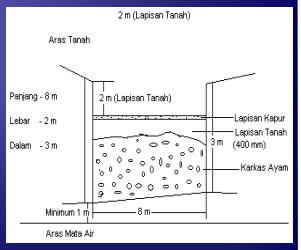
Disposal Method

- Bury
- Rendering
- Incinerator)
- Dispose at allocated site (Need Supervision)
- Include proper disinfectant



Method - Bury

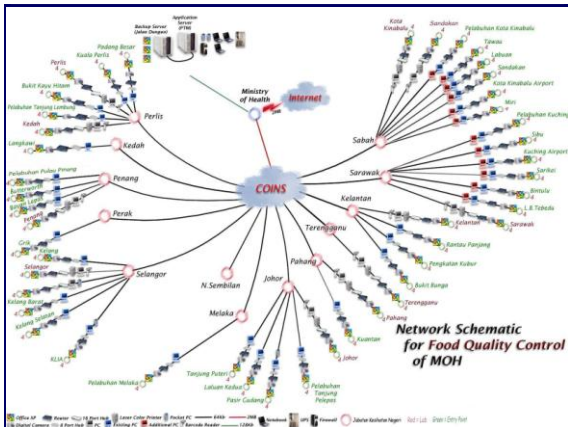
- Specify Disposal Hole
- To cover hole filled with carcass



METHOD – BURY

Food Safety Information System of Malaysia (FoSIM)

- Development of a web-based system linking all 36 entry points to control food import to ensure speedier clearance, consistent scrutiny and greater transparency
- Launched in Aug 2003
  - to be integrated with Custom's system
- Adapted from FAIINS (Food Automated Import Inspection Network System) of Japan with customization to FSQ existing procedures
- In-built intelligent/knowledge databases
- Automated examination levels, food codes, analytical parameter codes, electronic references



MAIN PAGE

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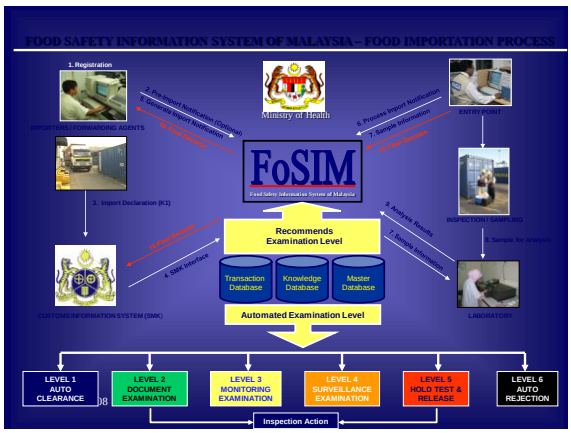
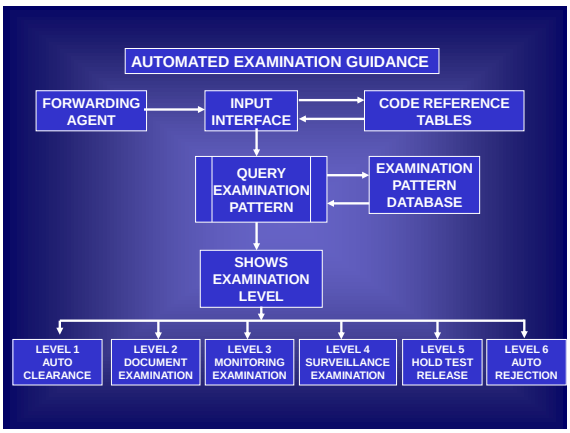
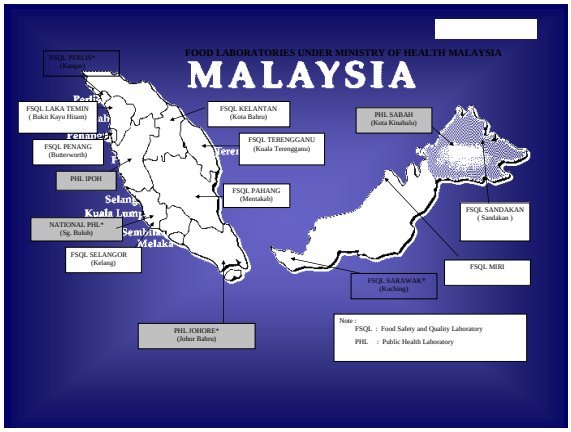
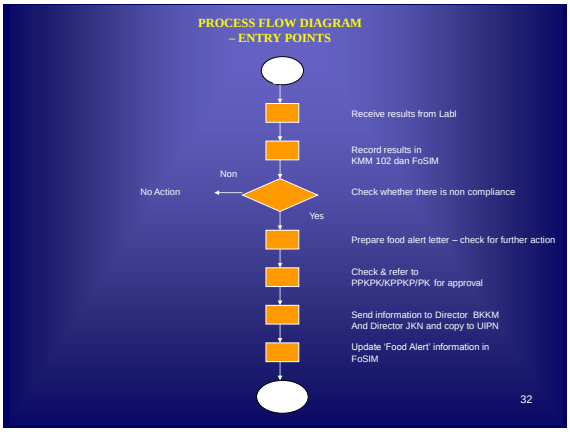
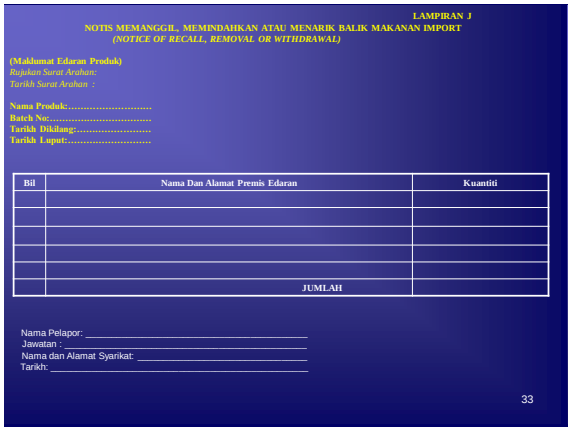










LAMPIRAN J

NOTIS MEMANGGIL, MEMINDAHKAN ATAU MENARIK BALIK MAKANAN IMPORT
(NOTICE OF RECALL, REMOVAL OR WITHDRAWAL)

(Maklumat Edaran Produk)
Rujukan Surat Arahan:
Tarikh Surat Arahan :

Nama Produk:.....
Batch No:.....
Tarikh Dikilang:.....
Tarikh Luput:.....

Bil	Nama Dan Alamat Premis Edaran	Kuantiti
	JUMLAH	

Nama Pelapor: _____
Jawatan : _____
Nama dan Alamat Syarikat: _____
Tarikh: _____

33

LAMPIRAN M

AKUAN PENERIMAN NOTIS MEMANGGIL, MEMINDAHKAN ATAU MENARIK BALIK MAKANAN IMPORT *(NOTICE OF RECALL, REMOVAL OR WITHDRAWAL)*

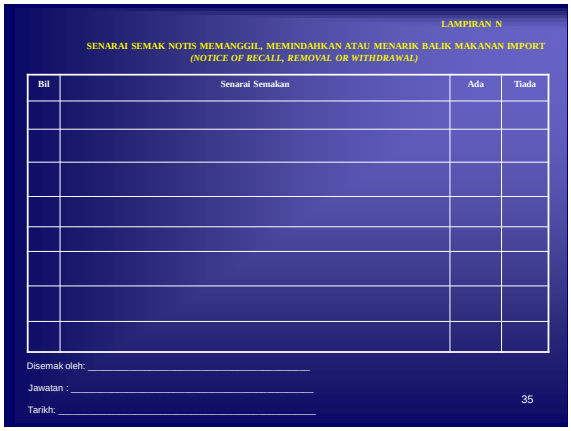
Saya.....**No.K/P**.....**pada**.....
telah menerima notis memanggil dan menarik balik surat rujukan bil ( )dlm UIP/KKM bertarikh
.....**untuk produk (nama dan jenama produk)**
.....
dari negara asal:.....

Tandatangan penerima notis: .....

Nama penerima: .....
Jawatan : .....
Nama Syarikat: (cop syarikat): .....
Tarikh dan Masa: .....

Nama Penyampai Notis: .....
Jawatan: .....
Pejabat: .....
Tarikh dan Masa: .....

34



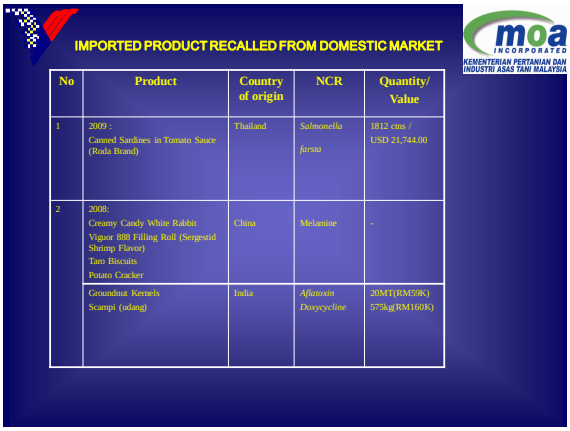
LAMPIRAN N

SENARAI SEMAK NOTIS MEMANGGIL, MEMINDAHKAN ATAU MENARIK BALIK MAKANAN IMPORT
(NOTICE OF RECALL, REMOVAL OR WITHDRAWAL)

Bil	Senarai Semakan	Ada	Tiada

Disemak oleh: _____
Jawatan : _____
Tarikh: _____

35



IMPORTED PRODUCT RECALLED FROM DOMESTIC MARKET

No	Product	Country of origin	NCR	Quantity/ Value
1	2009 : Canned Sardines in Tomato Sauce (Roda Brand)	Thailand	*Salmonella farsta*	1812 cins / USD 21,744.00
2	2008: Creamy Candy White Rabbit Vigour 888 Filling Roll (Sergestid Shrimp Flavor) Taro Biscuits Potato Cracker	China	Melamine	-
	Groundnut Kernels Scampi (udang)	India	*Aflatoxin* *Doxycycline*	20MT(RM59K) 575kg(RM160K)

moa INCORPORATED
KEMENTERIAN PERTANIAN DAN INDUSTRI ASAS TANI MALAYSIA

DOMESTIC FOOD RECALLED FROM LOCAL MARKET

No	Product	Country of origin	NCR	Quantity/ Value
1	2005 - 2008 : Biscuits : Puff (Square,Lemon, Creamy Choclate, Cocoa), Cracker (Supercrown,Tasty)etc	Malaysia	Melomine	-

RECOMMENDATION/ STRATEGIES

- **Establish, Review, & Update Food Legislation To Ensure Safe Food Supply Domestically And Internationally.**
- **Continuous Strengthening of Food Safety Infrastructures Including Food Inspection Capabilities, Sampling And Laboratory Facilities & ICT To Ensure Food Safety.**

Thank You

COFEPRIS

FEDERAL COMMISSION FOR THE PROTECTION FROM SANITARY RISK

EMERGENCY RESPONSE MANAGEMENT

SPECIAL PROGRAMS EXECUTIVE DIRECTORATE

4-6 MAY, 2010

1

COFEPRIS

•Governmental office under the Ministry of Health with technical, administrative and functional autonomy, which makes it a de-concentrated organization.

• Its authority comprises regulation, control and sanitary promotion under a unique coordination, operated by processes.

2

Mission

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.

Vision 2012

Mexico will have a reliable and efficient national authority for the protection against sanitary risks, outstanding for its technical, operational and regulatory capacity, as well as for its commitment to the human and professional development of its personnel.

3

OUR MAIN OBJECTIVES

• Offer suitable protection to the population.

• Collaborate on competitiveness improvement of the industries in order to direct them into the foreign trade stream.

• Prevent conflicts for the national productive industry.

4

Institutional Framework

Assessment, regulation, control, surveillance and analysis of RISKS related to:

1. Food
- Processed goods
- Slaughter houses
- Mollusk shellfish
- Red tide
- Genetically modified organisms

2. Health Products
- Drugs
- Phrmacosurveillance
- Expired and counterfeit drugs

3. Medical Services
- Infectious and pathologic hospital residues
- Transplant centers
- Blood bank
- Tissues

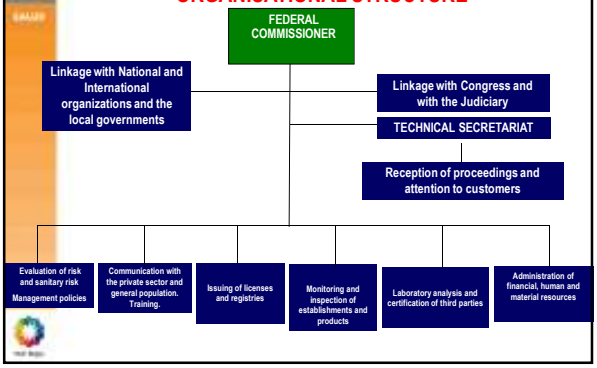
4. Other products and services
- Tobacco
- Alcohol
- Cosmetics
- Cleaning products
- Sanitary control of publicity

5. Sanitary Emergencies
- Basic Sanitation

6. Occupational Health
- Radiological Protection
- Pesticides

7. Environmental
- Air
- Water
- Soil

ORGANISATIONAL STRUCTURE



Operation of the Federal Sanitary System

Strategic Administration

Processes

- Evidence and Management of Sanitary Risks
- Sanitary Authorization
- Sanitary Enforcement
- Sanitary Promotion
- Analytical Control and Coverage Extension

Administrative office

EMERGENCY ATTENTION PROJECT

BACKGROUND

THE EXECUTIVE DIRECTION OF SPECIAL PROGRAMS OPERATES THIS PROJECT OF EMERGENCY ATTENTION PROJECT. IT STARTED IN 2003. IT IS, OF COURSE AN IMPORTANT AND VITAL ACTIVITY AT SANITARY ENFORCEMENT COMMISSION

OBJECTIVE

TO GUARANTEE THAT THE SYSTEMS, PROCEDURES AND RESOURCES ARE EFFICIENT AND SUFFICIENT.

TO PROVIDE WITH A QUICK AND PROFESSIONAL ASSISTANCE

IMPACT INDICATOR

PROTECTED POPULATION

MEXICAN POLITICAL CONSTITUTION.

ARTICLE 4.- "ALL CITIZENS HAVE THE RIGHT TO HEALTH PROTECTION"

Political Constitution, General Health Law and its regulations

- Juridical Basis
- Procedures
- Intrasectorial Actions

General Model

- Multisectorial activities
- Establishment of plans and programs
- Attention and response

The National Committee for Health Security

22 September 22, 2003

- Natural Disasters
- Exposure to dangerous substances
- Outbreaks
- Preventive Actions
- Outbreak at hospitals

- Identify areas and vulnerable groups
- Sanitary and Epidemiologic surveillance
- Define programs for risk communication
- Health promotion
- Security and control measures

INTERSECTORIAL COORDINATION

- COFEPRIS
- CENAPRECE
- CENSIA
- Health Secretariat
- Health Promotion
- Mental Health

MULTISECTORIAL COORDINATION

- COUSTOM AUTHORITIES
- CENAPRECE
- INTERNATIONAL AGENCIES
- COFEPRIS
- ASOCIATIONS AND CHAMBERS
- SAGARPA

10

• Organization and Response

- **Coordination with all administrative areas from COFEPRIS**
  - Evidence and Risk Management Commission
  - Sanitary Promotion Commission
  - Sanitary Authorization Commission
  - Sanitary Enforcement Commission
  - Analytic Control and Expansion of Coverage Commission
  - General Coordination of the Federal Sanitary System
- **Coordination whit other Authorities**
  - 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)
- **Coordination whit Chambers and associations**
  - -National Association of Department Stores (ANTAD, ASACHOC, ETC.)
  - -National Association of Drug Stores (ANAFARMEX)
  - -Self Services Stores (COSTCO, WALMART)
- **Others**
  - Importers (COUSTOM AGENTS)
  - Direct contact whit sellers

• Procedure for the attention of sanitary alerts

- Monitoring of several web pages including news and Health Authorities from other countries.
- Reception of e-mails from FDA, USDA, CFIA, Health Canada. RASFF, INFOSAN
- Classifies the e-mails from other countries in to:
  - Notice
  - Warning
  - Alert
- Investigation in web pages
  - Official health pages
  - Producers or sellers pages

Notice

MONITORING

E-MAIL NOTIFICATION

ANALYSIS OF INFORMATION

NOTICE

WHEN THE PRODUCT IS NOT COMERCIALIZATED IN BORDER OF STATES WITH MEXICO

Warning

MONITORING

E-MAIL NOTIFICATION

ANALYSIS OF INFORMATION

WARNING

COMUNICATES FROM THE INVOLVED COMPANY

MONITORING OF CONTROL AND DESEASES PAGES

ASK FOR INFORMATION TO ALL ADMINISTRATIVE UNITS FROM COFEPRIS

FEEDBACK WITH HEALTH AUTHORITIES

ASK FOR INFORMATION TO WHOLESALER

WHEN THE PRODUCT IS COMERCIALIZATE IN BORDER OF STATES WITH MEXICO BUT DO NOT HAVE EVIDENCE OF COMERCIALIZATION IN MEXICO

SEND AN OFFICIAL NOTICE TO BORDER OF STATES (BAJA CALIFORNIA, SONORA, CHIHUAHUA, COAHUILA, NUEVO LEÓN, CHIAPAS, TABASCO, CAMPECHE Y QUINTANA ROO)

Alert

MONITORING

E-MAIL NOTIFICATION

ANALYSIS OF INFORMATION

ALERT

COMUNICATES FROM THE INVOLVED COMPANY

MONITORING OF CONTROL AND DESEASES PAGES

ASK FOR INFORMATION TO ALL ADMINISTRATIVE UNITS FROM COFEPRIS

FEEDBACK WITH HEALT AUTHORITIES

ASK FOR INFORMATION TO WHOLES ALER

COODINATION WITH COUSTOM AUTHORITIES AND SAGARPA

ANALYSIS OF INFORMATION

PRODUCT PROSSECED OR DISTRIBUTED IN MEXICO

SEND OFICCIAL NOTICE TO ALL STATES IN MEXICO

PROGRAMMING OF CHECK VISIT

SANITARY CONTROL MEASURES

ANALYSIS OF INFORMATION

FINAL REPORT

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EXAMPLES

- MELAMINE IN MILK PRODUCTS FROM CHINA 2007
- *Salmonella Saintpaul* IN TOMATOES FROM MEXICO 2008
- *E. Coli H7:O157* IN GROUND BEEF FROM USA 2009
- *Salmonella Typhimurium* IN PEANUT BUTTER USA 2009

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Melamine in milk products

- After the report from INFOSAN were babies get ill for the consumption of infant formula COFEPRIS ask CENAPRECE for cases and did not report any case of illness.
- COFEPRIS did 10,485 visits and did not find infant formula from China.
- COFEPRIS secured the profit of 700 kg of white rabbit candy, 12 kg of cookies and 120 pieces of chocolate.
- COFEPRIS analyzed 5 samples of candy and no traces of melamine were found.
- In February 1, 2009 the restriction of the imported products from China was ended.

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SALMONELLA SAINTPAUL IN TOMATOES FROM MEXICO

- FDA reports 57 cases of salmonelosis associated to the consumption of tomatoes from Mexico.
- CENAPRECE did not report any cases of illness associated to the products.
- FDA, SAGARPA and COFEPRIS worked coordinated to make inspection visits at harvest fields and packing companies, they took samples from water, products, surfaces and farmland in 4 companies in different states of Mexico.
- Less than 10% out of 130 samples taken, resulted whit the presence of *Salmonella*, but not *Saintpaul* specie.
- FDA said that tomatoes in the market were not associated to the outbreak and therefore a new warning for jalapeños and chile serrano was launched
- The institutions worked coordinated again and visited 3 companies and took similar samples from tomatoes.
- As a result of different visits and analysis, specific evidence from *Salmonella Saintpaul* was not found.
- Mexico reiterated its cooperation and its support by allowing these investigations.
- Several companies were put on the white list because FDA found Salmonella however Saintpaul specie was ***never*** found.

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E. Coli H7:O157 IN GROUND BEEF FROM USA

- After SAGARPA's notification about the recall of ground beef in the USA.
- CENAPRECE did not report any cases of illness
- COFEPRIS did 35 visits and did not find any products for sale
- COFEPRIS had found that 2 companies processed meat in Mexico and both companies had acquired this meat, but in different plants from the involved company.
- The USA Embassy sent a document giving guaranties of safety products.
- COFEPRIS and SAGARPA worked coordinated with USDA to make an inspection at the involved plant of the recall of such product .
- SAGARPA has developed a program for the sample taking from imported beef.

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SALMONELLA TYPHIMURIUM IN PEANUT BUTTER FROM USA

- CENAPRECE did not report any cases of illness associated to the consumption of the product.
- COFEPRIS asked the customs authorities to deny the entrance of products that contain peanut butter from USA.
- COFEPRIS did 2,396 visits and did not find any products for sale from the FDA list
- COFEPRIS designed an importation scheme so every company has to notify the entrance of products with previous documental analysis. Then COFEPRIS takes samples of products for the *Salmonella* test. When the importer accumulates 10 negative sample results the scheme changes from 1 to 5 shipments
- Under this scheme, 4 companies are operating at this moment
- There has been 94 negative results to *Salmonella* so far.
- In this moment the importation scheme is in evaluation for improvement.

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THANK YOU

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DEVELOPMENT & STRENGTHENING OF FOOD RECALL SYSTEMS FOR APEC MEMBER ECONOMIES

4 – 6 MAY 2010

MANILA

PHILIPPINES

1

FOOD RECALL SYSTEM IN PAPUA NEW GUINEA

Terry Daniel
a/CEO
Food Sanitation Council Secretariat

2

CONTENT

- Food Sanitation Council
- Food Safety Regulatory System
- Food Laws
- Purpose
- How the purpose is achieve
- Food Recall Procedures
- Food Recall PNG Experience

3

FOOD SANITATION COUNCIL

- **FSC was established under the Food Sanitation Act 1991, Part II – Section 3 (1)**
- **It was established on the 17 April 2002**
- **Food Sanitation Council is an independent, expertise - based authority which comprises of stakeholders in various government organizations & agencies which addresses food safety and quality in the country.**

4

- Operates under the Ministry of Health
- Reports to the Minister for Health on all matters related to food safety and quality
- Meets at least 4 times a year

5

- Members are appointed by notice in the National Gazette by the Minister for Health
- Appointed for a period of two (2) years
- Members are eligible for re - appointment
- Elected Chairman to be appointed as Chairman by notice in the National Gazette

6

FSC MEMBERSHIP

1. NDOH
2. Dept. of Finance & Treasury
3. DAL
4. Dept. of Commerce & Industry
5. NISIT
6. PNG Chamber of Commerce
7. UNITECH
8. Food Inspector (NCDC)
9. Food Analyst (CPHL)
10. IMR
11. ICCC
12. CIMC – Informal Economy
13. DEC

7

SUB - COMMITTEES

- Review Committee
- Food Fortification Committee

8

FSC SECRETARIAT

- Oversees the functions & affairs of the FSC

9

ROLE OF FSC

- The role of the FSC is to protect the public health and safety of the people of Papua New Guinea by maintaining a safe food supply.

10

OBJECTIVES

(a) Protect public health and safety by maintaining a safe food supply

(b) Provide consumers with information about food so they can make inform choices

© Prevents misleading and deceptive conduct

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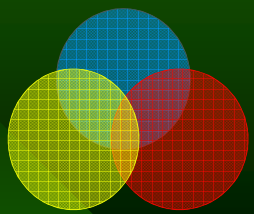
FOOD SAFETY REGULATORY SYSTEM

Standards setting
National Institute of Standards & Industrial Technology (NISIT)



Policy
National Department of Health
Food Sanitation Council
Food Sanitation Act /Regulation

Enforcement
Provincial Health Dept. & Urban Local Level Government Authorities

12

FOOD LAWS

- Food Sanitation Act
- Food Sanitation Regulation
- Food Safety Code

13

PURPOSE

The main purpose of the Food Laws are as follows;

(a) To ensure food for sale is safe & suitable for human consumption

(b) To prevent misleading conduct relating to sale of food

(c) To apply the food safety code

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HOW THE PURPOSE IS ACHIEVE

The main purpose are to be achieved primarily by;

(a) Providing for the licensing of particular food businesses &

(b) Requiring particular licenses to have an accredited food safety program &

(c) Providing for the accreditation and auditing of food safety programs; &

(d) Providing for the monitoring & enforcement of compliance with this food laws & food safety code.

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Food Recall Procedures

- Food Recall Procedures document are with the Independent Consumer & Competition Commission (ICCC)
- Their Officer's enforce this legislation but not effective
- We (EHOs)use our powers in the laws to enforce / recall food of none compliance

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Food Recall PNG Experience on Melamine

- EVENTS
  - Receive of information on Milk & Milk Products tainted with melamine
  - Melamine Task Force formed
  - Task Force develop Plan of Action

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- EVENTS (cont')
  - Plan of Action included;

✓Press Release in daily news papers

✓ Ban on importation of all infant formula, milk & milk products made from China

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- Plan of Action (cont')
- ✓ Circular instruction for EHOs to remove all milk & milk products from shelves of food shops.
- ✓ Information on Melamine & its health effects sent to CEOs, PHAs, Paediatricians & all Clinicians

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THANK YOU!

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FOOD RECALL NATIONAL SYSTEM

PERÚ
2010

Food Recall - Peru

- Part of the provider's auto control system (HACCP, lot identification, traceability program).
- The manufacturer is responsible of maintain an efective traceability and recall system, and keep process and traceability documentation available.

Food Recall - Peru

- The provider must inform about the food safety incident to the competent authority (fishery, manufactured and primary products)
- There's no legal requirement if it is a quality issue.

Food Recall - Peru

- If it is detected by the Regulatory Authority (market surveillance, complains or food incidents), the provider is notified for giving further information in order to evaluate an intervention.

Food Recall - Peru

- If there is part of an external sanitary alert noticed by the Chancellery, the Authority identifies the importers (Sanitary Register) and through the Tributary Administration, the lots that have been imported to dispose the recall.

Food Recall - Peru

- Depending on the localisation and the distibution area the regional and local governments are informed and update.
- Role of the Sanitary Authority:
- Risk asses
- Planing and coordination for activities
- Risk communication

Food Recall - Peru

Peruvian experience:

- Melamine in milk derivative products (2009)
- *Bacillus cereus* in instant powder food for infants (2008 and 2009)
- Soybean oil with date expired (2009)

Relevant Legislation

- Regulation on Fiscalization and Sanitary Control of food and beverages (1998).
- Sanitary Regulation on the HACCP System aplication for food and beverages manufacturing (2006).
- Food Safety Law (2008).
- Food and Beverage Sanitary Alerts Attention (2009).

PRODUCT RECALL SYSTEM
In the Philippines

Presented by:
Albina M. Mendoza
Food Drug Regulation Officer
Food and Drug Administration

Workshop on the Development & Strengthening of Food Recall System for APEC Member Country
4-6 May 2010 Manila, Philippines

LEGAL BASES

Republic Act 3720
Foods, Drugs, Cosmetics, and Devices Act
Bureau Circular No. 8 series 2001
Product Recall System

Bureau Circular No. 8 s. 2001

Guidelines To Be Observed On The Implementation Of Product Recall System

SCOPE:

This guideline shall apply to the recall of all types of products regulated by BFAD.

BFAD Committee for Product Recall:

- **Chief of Product Services Division**
- **Chief of Laboratory Services Division**
- **Chief of Legal Information Compliance Division**
- **Chief of Regulation Division I and II**
- **Medical Consultant / Deputy Director**

BFAD Committee for Product Recall:

- *Created to evaluate the health risk presented by a violative product*
- *In case a product recall is agreed upon, a written concurrence shall be submitted to the BFAD Director for approval and proper issuance of recall order.*

Who will initiate Recall?

Manufacturers and Distributors of a violative product:

1. at any time on their own initiative
   - Firm Initiated Recall
2. in response to a recall order by BFAD
   - BFAD Ordered Recall

General Procedure for Product Recall:

- Case Report
- Convene BFAD Product Recall Committee
- Recommendation of Product Recall to BFAD Director
- Issuance of Product Recall Order
- Inform Secretary of Health and Concerned Parties
- Information Dissemination Class I, II and III Recall
- Discussion on Recall Operation Plan
- Monitoring/ Audit of Recall Operation
- Termination of recall operation upon completion

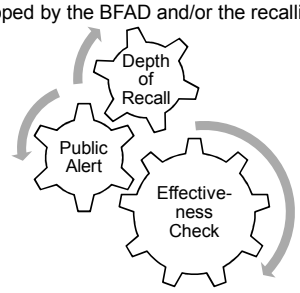
Public Health Alert:

To be issued by BFAD within 24-hours after issuance of Order for Product Recall.

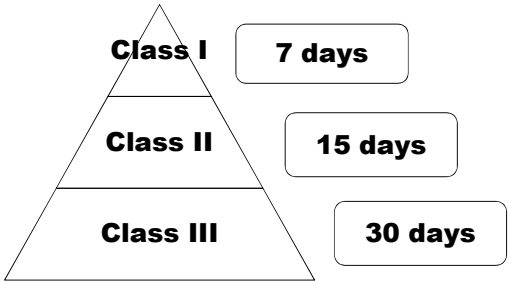
Class I Recall	• Notice and warnings shall be issued by tri-media to the general public, health professionals, health institutions, industry associations, distribution outlets for such products and other concerned parties.
Class II Recall	• Notices and warnings shall be issued to : 1) groups and institutions that are identified as those who generally use or are exposed to the product, and 2) those who could help remove such violative products from the market or prevent such products from being used.
Class III Recall	• Notice and warnings shall be issued to the concerned parties and distribution outlets.

Recall Strategy:

Shall be developed by the BFAD and/or the recalling firm



Completion of Recall Operation



Recall Status Report:

- The recalling firm is mandated to submit Periodic Recall Status Reports to BFAD so that the agency may assess the progress of the recall.
- Frequency of such reports will be determined and specified by BFAD in each recall case relative to the urgency of the recall.

Content of the Recall Status Report:

- Number of consignees notified of the recall, and date and method of notification;
- Number of consignees responding to the recall communication and quantity of products on hand at the time it was received;
- Number of consignees that did not respond (if needed, the identity of non-responding consignees may be requested by the BFAD)

- Number of products returned or corrected by each consignee contacted and the quantity of products accounted for;
- Number and results of effectiveness checks that were made;
- Estimated time for completion of recall.

Disposition of Recalled Products:

- The recalling firm will notify BFAD of the final disposition:
  1. For destruction.
     Submit Procedure for the disposal of recalled products
     Destruction should be witnessed by BFAD representatives
  2. For reprocessing
     Reprocessed products shall be allowed for distribution and sale only upon recommendation by BFAD

     .

Thank you !

Food Recall in Korea

Kyoung-Mo Kang
(e-mail:kmokang@kfda.go.kr)
Korea Drug and Food Administration

Overviews

- What is recall and how it runs in Korea
- Electronic system for urgent recall
- Obstacles in recall activity

What is recall ?

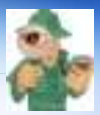
Recall

- An appropriate alternative method for removing marketed consumer product,
  - as a result of self-inspection by firm,
  - a violation of the laws administered by the Korean Food and Drug Administration

Recall Situations

- Routine testing by firm
- Inspection by regulatory authority
  - Violation of Food safety standard etc.
- Reporting of a problem with imported food
- Manufacturer's decision to fit for it's purpose

Recall Initiation



- Voluntary recall
  - Firm noticed its violations as a result of self-inspection
- Request by KFDA
  - When firm responsible do not undertake recall on its own
  - Problems occur during on-site inspection
  - Investigation authority found risky factor in food provided by collection authority

➢ Mainly initiated by KFDA

Recall process

1. Recall announcement
   - KFDA's website, newspapers
     - Title of recall activity & Reason for recall
     - Brand and product name, Lot No.
     - Production dates and shelf life
     - Details of manufacturer : telephone number, address etc.
   - Publish in a daily newspaper
   - TV subtitle advertisement, SMS Text

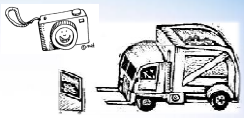


Recall process

2. Recall monitoring
   - Check on-going recall activities
3. Recall termination
   - Firm reports the recall results
     - based on it's initial recall plan, amount of uncollected products
4. Recall verification
   - effectiveness check
     - firm's communication system with their dealer
5. Corrective action and preventive action
   - The cause of the recall, and disposal etc.

Disposal of Recall product

- ❖ Discard of recall products
  - Secure objective evidence. e.g. photos of disposal scene
- ❖ Return of recall products
  - Send recall products back to exporting countries
- ❖ Conversion for use other than food
  - e.g. animal feed or fertilizer




Firm's duty

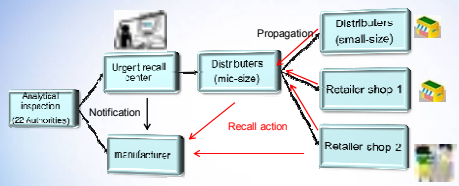
- ❖ The firm report result of recall to KFDA or regional office
  - Date of announcement
  - Media to which announcement through
  - Number of announcement performed
  - A copy of announcement and its contents
  - Proper Disposal of recall product

Electronic system for Urgent recall

Urgent Notification System

- ❖ Unfit food's details are notified to Urgent recall center
  - e.g. firm's details, inspection history and reason for recall etc.
- ❖ Then the center propagates the message via the system to….
  - related organizations and retail stores across the nation
  - mid/small-sized distributors, retailers nationwide

Urgent Notification System



(8,771 shops are available now and expand to 100,000 by 2011)

Sales Ban System

- Recall products are blocked by POS data system
  - Related organizations and retail stores across the nation
  - mid/small-sized distributors, retailers nationwide
    - POS is the place in a shop where a product is passed from the seller to the customer

POS data system in retail shop

Challenges in recall enforcement

Recall Statistics

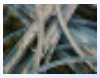
Year	Number of Recall Products	Result (%)
2005	84	
2006	45	
2007	106	> 40%
2008	227	
2009 (1/4)	74	

High turnover rate of food

- Short-term distributed products take up majority of recall
  - account for 42.5 % of total recall cases in Korea
    - KFDA Statistics (05~07.6)
  - e.g. Kim chi, seafood

Complicated distribution channel

- Small and medium enterprises(SMEs) and importers take up the majority of recall
  - Vulnerable distribution channel
    - Manufacturer (207,172), restaurants (718,092) nationwide
- Difficulties of product tracing in companies
  - Distribution channels with many stages
  - manufacturer → 1st wholesaler → 2nd wholesaler → retailers



Other issues

- Firm's concerns over decline in their image due to recall
  - Call for easing criteria on announcement to media
- Consumer has a right to know the result of recall
  - release the recall statics officially ?
  - Just focus on identifying the exact cause of recall and recall statics is not announced officially ?

Summary

- KFDA makes an effort to ensure that consumer warned about hazardous products ubiquitously
- We develops Sales Ban system for liaison between headquarter and District, and POS data system for blocking hazardous food on-site of purchase
- We understand firm's concerns over decline in their image due to recall, so the recall strategies must be set up in a considerate way

Russian Federation
Social & Industrial Foodservice Institute

Food Recall in Russian Federation

Speaker: Shirkov Andrey

Contents

Why Food Recall?

- Efficient food recall system strengthens food safety and minimizes economic losses in emergency of food hazard
- Efficiency of food recall depend on creating environment (when producer is interested in recall) and technical capabilities (when producer can do it efficiently)
- Context of Russian Federation is the transition from old system of safety control to new model

Causes of food recall

- Non-conformance with technical documents
- Non-conformance with requirements for circulability of food products

Stages and responsibilities

What must be done if emergency of food hazard is identified on different levels

- Production level
- Transportation and storage
- Realization of goods
- Handling food during time of laboratory investigations
- Role of control authorities

Expertise, utilization and destruction

- Assessments in expertise
- Decision of control authorities on utilization or destruction
- Rules for utilization
- Rules for destruction

Reform of technical regulation

- Rationale for technical regulation reform (voluntary national standards and regulations in conformity with WTO rules)
- Coverage of new technical regulations in Russian economy

Procedures in case of information about non-conformance of food production with technical regulations

- Information transfer once information of non-conformance with technical regulation is received
- Check of validity of the information
- Designing of Program of prevention of harmful impact (for period of validity check)
- If information is valid — another Program of prevention of harmful impact
- If harm can't be eliminated — suspension of production, realization, recall
- and compensation of losses to purchasers
- Procedure of compulsory withdrawal
- Administrative and criminal responsibilities

Advanced practices: traceability and food recall procedures

- Systems HACCP and ISO 22000 as basis for strengthening traceability and food recall procedures in Russia
- System of traceability provides identification, records
- Established procedure of recall
- Efficiency of food recall procedures assessment

Food safety control and recall in government procurement sector

Government procurement sector in Russia (Armed Forces)

- Developing requirements for range, quantity and quality of food purchased
- Conducting of competitive tendering, making contracts
- Examination of food on level of production and acceptance
- Withdrawal in case of non-compliance
- Key findings: efficiency of the system because of contract requirements, lack of state control mechanisms

Features of food recall system in Russia

- **Weaknesses**: lack of responsibility for production of food non-compatible with requirements, lack of mechanism
- **Opportunities**: creating recall-stimulating environment, developing technical capabilities
- **Threats**: bureaucratization in case of strengthening control, low sensitivity to reputation losses

Thank you.

Thailand
Public Health Ministry
Food&Drug Administration
Import & Export Inspection Division

Sureewan Pattanawongyuenyong

Organisation in Thailand Dealing With Food

- Ministry of Public Health
- Ministry Of Agriculture and Cooperatives (MOAC)
- The police Crime Suppression Division on Consumer Protection.

The Police Office of Consumer Protection Board

Consumer Protection Board under the Prime Minister's Office to protect consumer rights, which involves food safety, advertisement and product labeling.

The Consumer Protection Act B.E. 2522 (1979)

- Consumer protection in the ad.
- Consumer protection in the label.
- Consumer protection in the contract.
- Actions on goods that could be dangerous.
- Actions instead of consumers.
- Association aims to protect consumers.
- The appeal of the business.

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**
- **Department of Fisheries.**
- **Department of Livestock**
- **Department of Agriculture**
- **Office of Agricultural Commodity and Food Standards National** (ACFS)

The National Bureau of Agricultural Commodity and Food Standards (ACFS)

The ACFS is responsible for six key tasks

- (i) the control and safety monitoring of fresh and processed agricultural products and foods by certifying and enforcing standards within the production and processing industry;
- (ii) development of agricultural commodity and food standards;

- (iii) 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; With the assistance of JAS-ANZ.
- (iv) representing the country in international standard-setting organizations;

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

- Contravention of the standards or orders issued by the **ACFS** constitutes a **criminal offence** which is punishable by imposition of fines and/or imprisonment, apart from the administrative measure of licence revocation

The Ministry of Public Health (MOPH)

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)
- (iv) the Food Safety Operation Center

The FDA

- in charge of national food regulations
- based on the risk analysis principle
- under the Food Act B.E. 2522 (1979)
- the FDA has the power to prosecute violators of the Act and its secondary legislations and to impose administrative sanctions such as licence revocation

- FDA inspectors conduct site-inspection of processing plants and imported food products that need to comply with GMP for domestic supply and HACCP for export.
- The inspection procedure is based on risk analysis,
- The FDA acting as the national risk manager sets up the food mandatory regulations and enforcement activities under Food Act B.E. 2522 (1979).

The FDA

- Food Control Division
- Import & Export Inspection Division

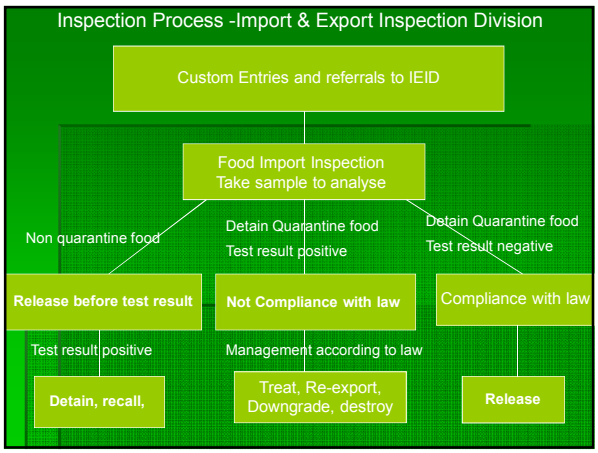
Food Control Division

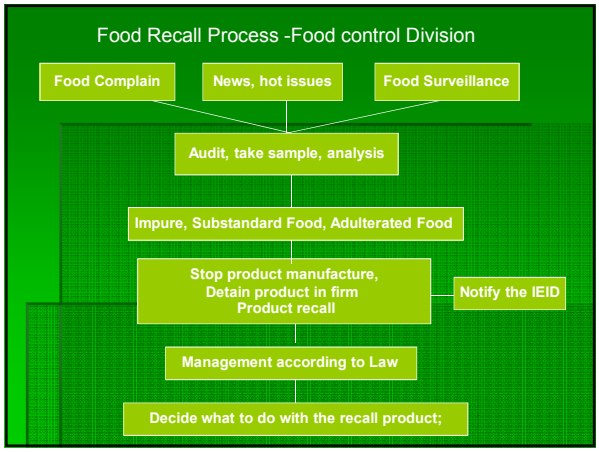
- Development standards and rules and regulations relating to control measures. Regulatory quality. And food safety standard
- Development of audit supervision of food surveillance. Food establishments and food advertising to be in the same legal standards consistent with national and international
- Corporate control food safety standards and in accordance with law.

- Capacity Development for the import and manufacture food for quality and Safety standards.
- Recommendation for academic knowledge. Research and development data to provide information on food
- Networks and sought support from all sectors to participate.
- Coordination and cooperation with foreign partners and building networks.

Import & Export Inspection Division

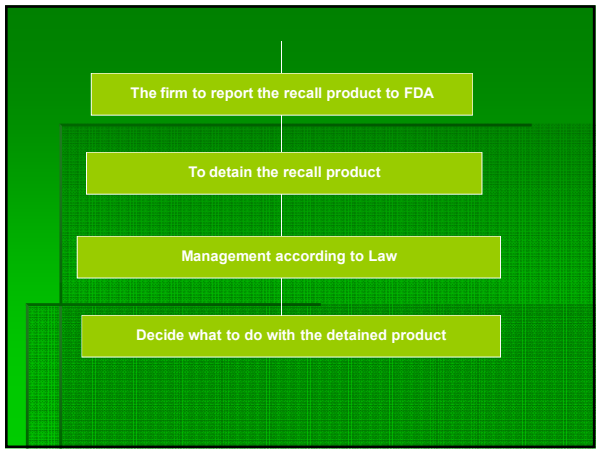
- To supervise the import and export product to meet the standards quality for health safety In accordance with the law

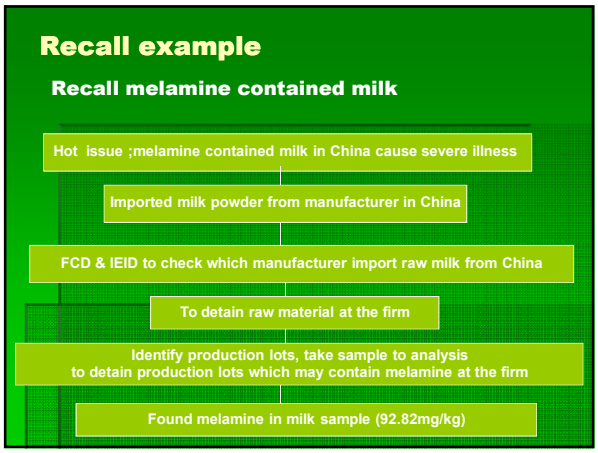


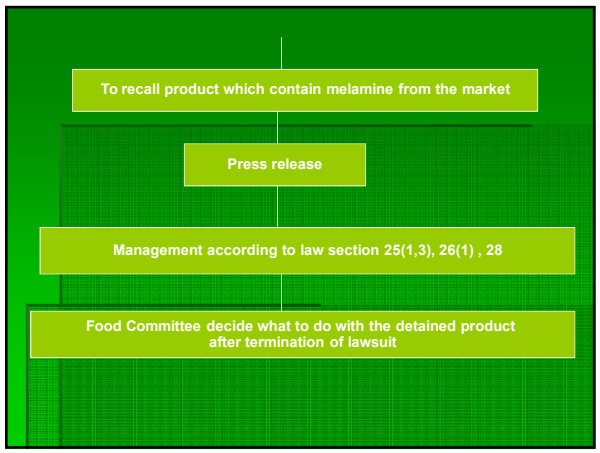


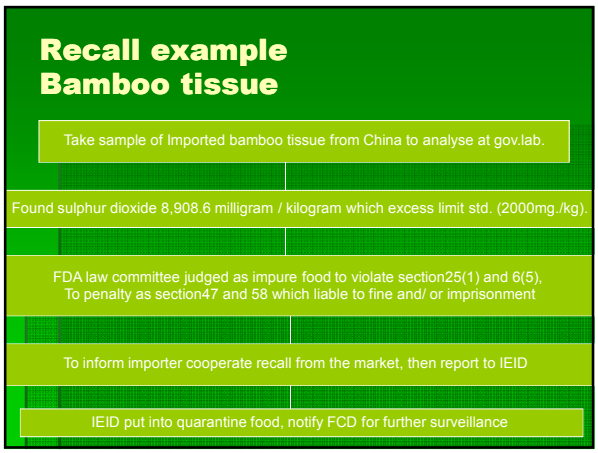
Recall Process

- Decision to Recall the Product (by Food Committee)
- Identify products to be recall
- To detain products at the firm
- to recall products from the market by the firm, voluntary
- Prepare the Press Release (if require)









Food Acts B.E.2522 (1979)

- SECTION 15 No one may import food for sale except receiving licence from the authority.
- SECTION 25 No one may produce, import for sale or distribute the following foods:
  (1) impure food;
  (2) adulterated food;
  (3) substandard food;
  (4) other food which specified by the Minister.

- SECTION 26. Food of the following description shall be deemed impure;
  (1) Food which contains anything likely to be dangerous to health
  (2) Food in which a substance or chemical substance has been mixed which could deteriorate the quality unless such admixture isnecessary to the process of production, the production and has been authorized by the competent officer

(3) Food unhygienically produce, packed or stored.

(4) Food produced from animals having disease which might be communicated to man.

(5) Food in containers made of materials which are likely to be dangerous to health.

- SECTION 27. Food of the following description shall be deemed adulterated:

(1) Food for which other substances are partly substituted or inwhich valuable substances are wholly or partly removed and which isslod as or under the name of the genuine food.

(2) Substances or food produced as substitutes for any food and distributed as being genuine food.

(3) Food Which is mixed or prepared in any way to conceal defects or inferior quality of the food.

- (4) Foods labelled in order to deceive or try to 'deceive the purchasers in matters of quality, quantity,, usefulness or special nature or place or country or production
- (5) Food not up to the quality or standard prescribed by the Minister under Section 6(2) or(3) and the quality or standard of that food deviate from the upper or lower specified limit more than thirty percent or its deviation may harmful to the consumer.

- SECTION 28 Substandard food is a food not up to the quality or standard prescribed by the Minister under Section 6(2) or(3) but its deviation is not as high as in Section 27(5).

- SECTION 29 Food of the following description shall be deemed food under Section 25(4)

(1) not safe for consumption;

(2) unreliable indication;

(3) value or usefulness is not appropriate to the consumer.

- The Food Act B.E. 2522 (1979) is currently subject to amendment. Its final content will depend on the National Food Commission Act. A proposal is submitted to increase liabilities for those who violate the Act, with emphasis on product, premises and advertisements and scope for improved traceability.
- The FDA is taking part in the process of the Act's revision

- The ACFS takes the leading role for coordination while field works are undertaken by various line departments such as the DOA, the FDA, and the DLD. The ACFS has the coordinating role for the ASEAN Food Safety Network and maintains, develops and improves the website (http://www.aseanfoodsafetynetwork.net).

- Food Safety has been part of the national policy since 2003 with a view to strengthening food control strategies along the food chain more effectively, hence the promulgation of the National Food Commission Act (2008) and the revision of the Food Act.

Tran Minh Thanh

Department for Goods, Products Quality Management
Directorate for Standards, Metrology and Quality
Vietnam

Legislation document system about goods, product quality management

1. Law on goods and product quality No.05/##
2. Decree No.132/2008/NĐ-CP dated 31/12/2008 laying down the details of the execution of the goods, product quality management rules
3. Food Hygiene and Safety Ordinance
4. Decree No.163/NĐ-CP dated 7/9/2004 laying down the details of the execution of some of the parts of the Food Hygiene and Safety Ordinance

Recalling products that violate the Food Hygiene and Safety Quality

- This is the method of protecting the rights and legal benefits of consumers
- Vietnamese government is now composing the circular about banning, recalling food that violate the Food Hygiene and Safety Quality and it will soon be passed, promulgated and executed nationwide.

Example

- This information was issued at VN foods administrator's seminar on food safety and hygiene on Jan 1st 2010
- 147 occurrences with 33 deaths due to foods poisoning
- Most of the occurrences were discovered by the media channels
- General Assessment of the problem: It develops complicatedly and difficult to control as:
- Smuggled products in a small volume
- Home-made products, separated, using old techniques
- Policy System haven't reached the integrity, human resource is not adequate, Quality Standard System may needs modifying

Example (Continued)

- Another example from Vietnam is that the rumor that dried squid is made of rubber. When burned, it melts like burned rubber. Vietnamese Food Administrator is carrying out market surveillance, taking some samples and testing. But they haven't found out anything yet.

So the prerequisite is to pass a circular on procedures of food recall in Vietnam.

Products that must be recalled

- Products that violate the Food Hygiene and Safety Quality can be either:
  - Expired
  - Has one or more norms that are not qualified in comparison to the standards
  - Dishonest announcement
  - Hi-tech products that have not yet been given the rights to be circulated
  - Not reaching the quantitative standards
  - Illegal labeled

So the prerequisite is to pass a circular on procedures of food recall in Vietnam.

Products that must be recalled (continued)

- Products that need to be announced but not be announced
- Dud products
- Products recalled by the producer or foreign authorities

Banning the violating products

There exist 2 levels

1. Temporarily banning: applied to the products with no risk such as insufficient quantitative or illegal labeled
2. Banning the circulating permission: When having evidence about the usage or consuming of products with high risk to human health

Forms of recall

1. Self-recall: Businessmen, Organization discovering and recalling in order to protect their brand name
2. Compulsory recall: Authorities or businessmen applying to violating product with high risk (recognized or suspected) to consumers

Recalling Scales

1. Plot-Recall: When exactly defined the product plot
2. Recalling all products of the same type: applied when having objective evidence about the violation being popular and/or risky

Levels of Recalling

Lvl 1: Around 5 days, applied to violating products that cause serious consequences that may even lead to death

Lvl 2: Around 15 days, applied to violating product that only cause temporary or immediate but not serious consequences

Lvl 3: Around 30 days, applied to suspected product

Recalling Coercion

- Applied when businessmen have violated, received the recalling decision from the authorities yet have not executed the recalling before the deadline; or ones that have denied the decision of the authorities

Method of treatment

Recalled plots can be treated in one of the four following ways

1. Recycling: Applied to products with low risk to human health
2. Redirecting the purpose of using: Applied to products with risks to consumers yet do not need to be recycled or not recyclable and can be accepted for another purpose.

Method of treatment (continued)

3. Elimination: Applied to plots that have been affected by harmful bacteria, contain high rates of heavy metal or poisonous chemical content that is higher than the acceptable level. Those are products which is unable to redirect the purpose of usage
4. Re-exporting: Applied to imported plots that violate the terms of food safety

Authorities of making recalling decision

1. Vietnam Food Administrator (VFA) make the decisions to ban and recall products that was given the circulation license by the VFA itself and/or requested by related government bodies
2. Department of Health in cities and provinces under central authority make the decisions to ban and recall products that was given the certificate of qualification by the Department itself and/or requested by related government bodies

Authorities of making recalling decision (Continued)

3. Specialized inspecting agencies when discover false products will punish them in administrative way depending on their capacity and submit to their authorities to obtain permission to recall
4. Other authorities (not related to Health) (i.e. The Ministry of Agriculture and Rural Development, The Ministry of Industry and Trading, etc.) also have the rights to recall products related to their fields

Risk Communication

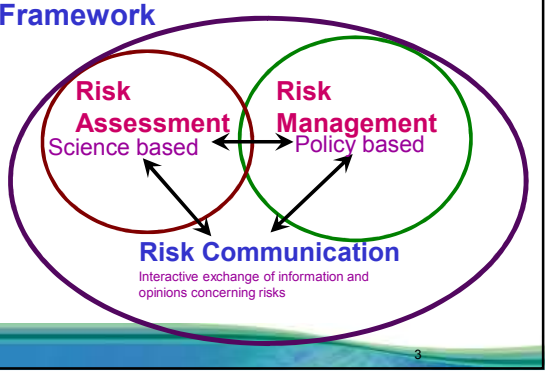
Dr Barbara Butow

APEC Recall Workshop, Manilla
4th – 6th May, 2010

Outline

- Risk communication
- Public perceptions of risk
- Communication strategies and tools
- Communication methods in an incident

Risk Analysis Framework



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Risk Communication

- Why are we communicating?
- Who is our audience?
- What do our audiences want to know?
- What do we want to get across?
- How will we communicate?
- How will we listen?
- How will we respond?

4

Risk communication is…

- Important part of both risk assessment and risk management
- active at the start of the process – not an add-on at the end
- everyone's responsibility

Risk communication is…

- two-way process
- understanding people's perception of risk
- opportunities for public involvement in decision making
- timely and accurate information
- internal communication

Risk communication is not…

- just about communicating risk;
- simply selling decisions to the public;
- a crisis-related process;
- the sole responsibility of communication specialists.

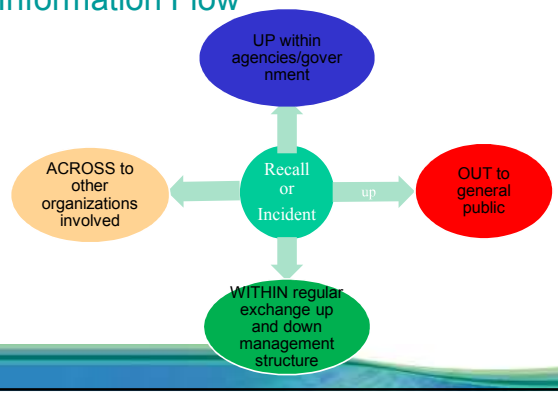
7

Risk communication is about..

- Relationship building – developing a feeling of partnership among stakeholders.
- Consultation – input from stakeholders, including attitudes and motivating factors.
- Maintaining the contact – keeping people in the loop.

8

Information Flow



Perceptions of risk

- We all see the world differently (mind sets).
- People of similar backgrounds tend to perceive risk in a similar way.
- Some gender differences.
- People with less control over their lives tend to see greater risk.

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What we worry about

- Kids crossing the road
- Air travel
- Avian Flu
- Smallpox
- Allergies
- Breast cancer
- Asthma – smog
- Secondary smoke

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Managing risk or fear?

- actual risk, and the perception of risk, often differ
- We're often managing fear more than we are risk
- "Fear management" can be minimised by good and timely communication

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Perceptions of risk

Evidence-based perception of risk:

RISK = HAZARD

Consumer perception of risk:

RISK = HAZARD + OUTRAGE

Some outrage factors affecting 'acceptability"

Lower risk	Higher risk
Natural	Man-made
Familiar	Exotic
Control	No control

Trust

- Public confidence in the safety of the food supply.
- Trust in industry and government regulators to ensure safe food.
- Hard to regain trust once it is lost.

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Trust

- Negative events are more noticeable than positive events.
- Sources of bad news are seen as more credible.
- Media is attracted to bad news.
- Special interest groups are skilful in using media.

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Communication strategies and tools

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10 ways to build trust

- Involve people in decisions that directly affect their lives.
- Release information as early as you can.
- Peoples' feelings – don't consider them to be irrelevant, irrational or an over-reaction.
- If you make a mistake, own up!
- If you don't know the answer, say so – it's OK to say "I don't know"

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10 ways to build trust

- Always follow up.
- Speak in plain language – don't use technical jargon.
- Avoid presenting yourself like a bureaucrat.
- Involve other organisations as soon as possible.
- If one of your people hates talking to the media or stakeholders, choose someone else. Adapted from New Jersey Department of Environmental Protection, 1987

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Communication strategies

Low risk – Low perceived risk — **PASSIVE**
eg. allowed microbial contaminant levels

Low risk – High perceived risk — **RESPONSIVE**
eg. *E. coli*, in yet-to-be-cooked meat

High risk – Low perceived risk — **EDUCATIVE**
eg. (*Campylobacter* in chicken)

High risk – High perceived risk — **PROACTIVE**
eg. *E. coli* O157 H7, in salami

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Communication action plan

- Build at outset of risk analysis process
- Team comprising government, industry and consumer representation
- Think of how and what want to convey (to whom?)

Communication tools

- Fact sheets, publications, advertising.
- Media releases, backgrounders.
- Telephone advice lines.
- Website, email bulletins.
- Conferences, seminars, meetings.
- Speeches, presentations, talks.
- Exhibitions, displays, launches.
- Education campaigns.
- Media relations.

Communication skills

- Listening.
- Writing (reports and material for lay audiences).
- Public speaking.
- Publishing (hard copy and web).
- PowerPoint presentations.
- Media relations.

Media

- Press, radio and television.
- Establish working relationships and credibility in non-crisis times.
- Know what messages you want to convey.
- Be open and honest… and available.
- Be helpful.
- Understand how the media works.

Risk communication and food safety incidents

Communication elements of your system

- Mechanisms of communication between organisations
- Communication tools required before, during and after a food safety incident (e.g. media releases, fact sheets).
- Responsibility for preparing and releasing communication tools and communicating with media.
- Timeframe and clearance process for communication tools.
- Communication responsibilities when the incident is spread across food, agriculture and health organisations.

Communication methods

- Spokesperson – who it is depends on emphasis
- Press conferences – more for major crises
- Messages developed and updated
- Webpage and fact sheets

Communication methods

- Scripts for enquiry staff
- Use press agencies to disseminate media
- quickly especially out of hours
- Travel advice
- Medical advice on doctors' website in case of symptoms

Communication tools (conventional)

- Have an emergency plan - keep a hard copy!
- Regular internal meetings in incident room
- Use existing networks/structures
- Know everyone before the emergency
- Establish emergency contact list

Communication tools (conventional)

- Have good established media contacts
- Keep a media log (a notebook is fine)
- Use print and electronic media
- Ethnic media
- Scripts for phone enquiry lines

Communication tools (new media)

- mobile phones and Blackberries (always be available)
- website essential – establish specialist web page for the subject and link to other experts
- Email media issues and updates to key stakeholders and influencers
- Use Google news to monitor the issue

Melamine contamination incident – Alert phase

- 12 September National Food Incident Response Protocol triggered
- 17 September INFOSAN Emergency alert reports 6,244 kidney stone cases in China
- 17 September China initiates a widespread recall of infant formula involving 22 producers

Action phase – "holding message"

23 September first Australian media interest

Key messages:

- Taking seriously
- Commenced National Food Incident Response Protocol
- Liaising with states and territories and AQIS and overseas agencies
- Mainstream dairy products, like milk, yoghurt and cheese - none imported since 2007
- Checking for imported foods with minor ingredients

Action phase – "targeted message"

Key messages:

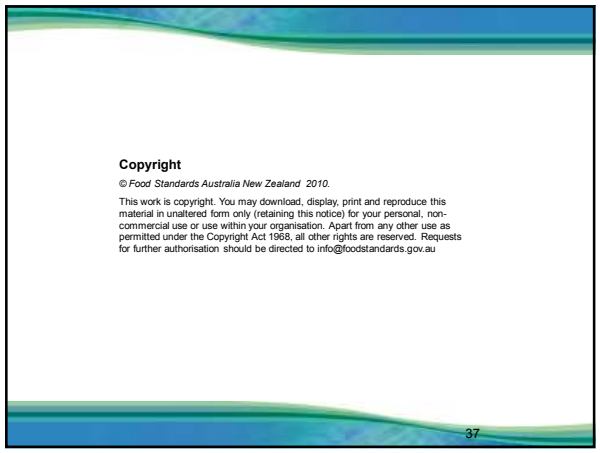
- 24 September withdrawal of white rabbit candy
- Product is being withdrawn
- Don't consume and dispose of out of reach of children and pets
- Would have to consume several bags a bay for many months for any ill effect

FSANZ **Media statement: Advisory on White Rabbit Brand Confectionery**

24 September 2008
Australian Food Regulators have commenced a formal request today to wholesalers and importers to voluntarily withdraw White Rabbit Brand Candies from shops pending further results of testing for melamine.
Testing in New Zealand released late today has confirmed that this product contains sufficiently high levels of melamine which may, in some individuals, cause health problems such as kidney stones if consumed in high quantities over a long period.
People are advised not to consume these milk-based sweets imported from China. This product is sold in retail packs through Asian retailers, supermarkets and restaurants.
Anyone who has the product should not to consume it. It is unlikely that there could be a problem if consumed in small amounts but people with concerns about the consumption of this product should seek medical advice.
The Australian State and Territory agencies will be working closely with wholesalers and importers to facilitate this voluntary withdrawal.
Australia does not import infant formula products from China and has not imported full-dairy products, such as yoghurt or condensed milk, from China since March 2007

Summary

- What is and is not risk communication
- Perceptions of risk
- Trust
- Communication strategies and tools
- Case study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SWOT ANALYSIS

GROUP A (Brunei Darussalam, Republic of Korea, Indonesia, Papua New Guinea, Malaysia, Chile, Mexico, the United States of America)

Strength - Big companies have recall in place - Register product before being marketed - Integrated network of all stakeholders - Import control of foods and register imported products - Surveillance system on all foods - Identity lead agency - Legislation in place - Record and Documentation in place - Traceability in place
Weakness - Complexity of distribution channel (traceability) for products - Country geographical distribution - Insufficient human resources - Small industries – no documentation - Limited technical support - No guidelines and protocols to involve all stakeholders - Companies do not take responsibility - Lack of products information - Lack of Government support and commitment - Complex of coordinated enforcement - From farm to table bio security risk
Opportunity - To develop guidelines and protocols - To obtain government commitment and support - To improve legislation - To accelerate exchange of information between stakeholder and agencies - To improve producer and consumer awareness - To improve technical support/services - To develop template/SOP for 1. crisis management 2. rapid response - Quality Assurance System demanded by vendors - More active participation in INFOSAN worldwide
Threats - Failure to take timely action - Fraudulent documents e.g. smuggling - Internet sales no control measures - Consumer misperception of low risk foods - Inaccurate distribution of imported food - Lack of defined role of responsibilities in agencies - Outdated legislation

RECOMMENDATION :

Information System
Draft Recall Protocol Guidelines Recommendation
Operational Plan
Comprehensive training Risk Communication
National Information Centre on Food Recall
Establishment of a Food Model that could be used for a food recall plan
Economical traceability system for small and medium industry
Food safety management response

APPENDIX 31

SWOT ANALYSIS GROUP B

	Philippines	Thailand	Viet Nam	Chinese Taipei	Russia	Peru	Australia
Strengths	1. Laws and guidelines are in place 2. Infrastructure and management support, technical manpower 3. Presence of analytical laboratories	1. Strong public relations strategies, good image of FDA 2. Public health Ministry have network in all provinces may help strengthen food recall policy. 3. Food safety is the country policy since 2003 4. Put GMP, HACCP as preventive measures. 5. well educated personnel(pharmacist, food chemist)	6. GMC-HACCP as preventive measures – public health ministry have network in all provinces may help strengthen food recall policy	1. Awareness of food safety issue	1. Strong scientific foundation	1. A good background in HACCP System implementation because of food exports	Central coordination part Expertise Networks with stakeholders
Weaknesses	1. Resources 2. Insufficient number of manpower/equipment 3. Policies not fully implemented 4. Rapid alert system is not well-organized 5. Lack of coordination between departments of health and agriculture 6. Weak risk communication 7. Weak monitoring at production (agriculture) 8. Frequent change in leadership 9. Delineation of duties and responsibilities amongst concerned agencies is not clear 10. Devolution 11. Lack of reporting on food	Less cooperation between organizations. Food Act not mention 'food recall', mostly are voluntary recall, low effective recall plan and management. Less technology due to limited of potential IT personnel. more workload Less personnel, Less training, Less budget	1. Less cooperation between organization 2. Policy system about recall on food haven't reached the integrity	1. Small food producer, long food supply chain	1. Lack of responsibility because not strong public pressure	Lack of statistics and laboratory capacity Lack coordination with the epidemiology area (information system)	Traceability No enforcement powers No input into risk assessment Sanctions lack of consistency and approach of jurisdiction

APPENDIX 31

SWOT ANALYSIS GROUP B

	borne illnesses						
Opportunities	1. Presence/available trainings from international bodies to continue strengthening regulatory agencies	revision of Food Act to mention 'food recall', more food recall training Asian single window policy may increase in exchange information of hazardous product between Asian country	1. Experience from APEC member economies; ASIAN single window my increase in exchange information of hazardous product between asian country	1. Because of the awareness of the different government agency, public entity and media, it strengthen the recall program	1. Creating environment 2. Creating technical capabilities	We have a permanent and multi sectorial commission on food safety (2008) Currently developing a project with EU in market surveillance	GSI recall portal Refine recall levels
Threats	1. Political interventions 2. Climate change	Political problem, changing government, changing policy. always changing key executive person due to political problem FTA policy increase workload, Economic problem effect to budget.	1. Always changing key executive person due to political problem	1. Public panic	1. Bureaucracy	Decentralization process to a local regional levels that need to improve not only the central level tasks but also the coordination	Emerging hazards/tampering Increase in processed foods with many ingredients which are hard to trace globalisation

Recommendations for Joint APEC Action Program

1. Information system/Web Base
2. Draft Recall Protocol Guidelines Recommendations
3. Operational Plan
4. Comprehensive training risk communication
5. National Information Center on food recall and best practice
6. Establishment of a food model that could be used for a food recall plan
7. Establishment of a traceability system on an economy scale (for small and medium industry)