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JOINT FAO/WHO PRE-COORDINATING COMMITTEE FOR ASIA (CCASIA) WORKSHOP

**Summary Report: Joint FAO/WHO pre-CCASIA workshop on
food recall/traceability within the risk analysis framework -
prevention of food safety emergencies**

**Tokyo, Japan
2 November 2014**

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1. INTRODUCTION

1.1. Pre-CCASIA workshop

Based on the needs expressed by many of the CCASIA countries, FAO and WHO organized a one-day workshop prior to the 19th session of the CCASIA (the 2nd of November, 2014 in Tokyo, Japan), entitled “Food recall/traceability within the risk analysis framework – prevention of food safety emergencies” with the overall objective to provide technical guidance and support to CCASIA delegations on the topic of establishing and implementing an effective national food recall system to respond to food safety events.

The workshop was attended by 45 participants from 20 countries: Afghanistan, Bangladesh, Bhutan, Cambodia, China, India, Indonesia, Japan, Lao PDR, Malaysia, Maldives, Mongolia, Myanmar, Nepal, Pakistan, Philippines, Singapore, Sri Lanka, Thailand, Vietnam and other observers. The complete list of participants is attached as Annex 1.

A short summary of the workshop was prepared and made available to CCASIA participants as Conference Room Document 28. CRD 28 is available at:

ftp://ftp.fao.org/codex/meetings/CCASIA/CCASIA19/CRDs/as19_CRD28x.pdf.

1.2. Background

Food safety emergency response preparedness is a key element in food safety emergency risk management. Food recall is one of the fundamental tools in the management of risks in response to food safety events. Some countries are still in need of an effective recall system and the necessary infrastructure to support it. For example, a robust legal basis, regulatory framework, effective pre-established protocols and the necessary collaboration between competent authorities and food business operators are required.

In addition, foods and the ingredients in food products are increasingly grown, processed and consumed in different locations around the globe. This poses new challenges in the conduct of key activities associated with food recalls, such as the trace-forward and trace-back activities required for a food suspected or confirmed to be unsafe. Many countries have expressed their needs to have their capacity strengthened in this area.

Therefore, FAO and WHO have developed:

- 1) a guide for emergency planning to assist countries in the formulation and implementation of national food safety emergency response plans (<http://www.fao.org/docrep/013/i1686e/i1686e00.pdf>);
- 2) a guide to the application of risk analysis principles and procedures during food safety emergencies (<http://www.fao.org/docrep/014/ba0092e/ba0092e00.pdf>); and
- 3) a guide on food recall to assist countries in the establishment and implementation of an effective national food recall system which may also be used during food safety emergencies (<http://www.fao.org/docrep/017/i3006e/i3006e.pdf>).

The workshop focused on two publications (#2 and #3) above.

1.3. Objectives

The objectives of the workshop were as follows:

- Share knowledge on the basic concept of risk analysis and relation between risk management and crisis management in food safety;
- Enhance understanding on application of food recall and traceability systems in the national food control system with specific reference to food safety events and emergencies;
- Raise awareness on the FAO/WHO guides for applying risk analysis during food safety emergencies and for developing and improving national food recall systems;
- Discuss a possible roadmap for introducing traceability and food recall in emergency scenarios in participating countries;
- Strengthen regional collaboration on the topic.

2. WORKSHOP PROCEEDINGS

2.1. Opening session

Mr Mbuli Charles Boliko, Director, FAO Japan Liaison office, opened the workshop and welcomed all participants and thanked the government of Japan for hosting this workshop. He stated that the capacity development in food safety emergency response preparedness is a key element in preventing food safety emergencies and he hoped that this workshop would provide technical guidance and support to CCASIA delegations on the topic of implementing an effective national food recall system to respond to food safety events. He also highlighted some recent activities in the subject of risk analysis specifically in relation to emergencies as well as other activities on food safety and control in the region.

On behalf of WHO, Dr Li Ailan, Director, Health Security and Emergencies, WHO Regional Office for the Western Pacific, gave opening remarks. She noted that food safety emergency management is a vital part of the overall health security work. She also noted that we need to have effective mechanisms for regional and international collaboration to manage food safety incidents and emergencies and emphasized the importance of the International Food Safety Authorities Network (INFOSAN) and the International Health Regulations (IHR).

Ms Yayoi Tsujiyama, Director for International Affairs, Ministry of Agriculture, Forestry and Fisheries (MAFF) Japan, also gave opening remarks. She welcomed participants and thanked FAO and WHO for support in enhancing food safety. She stressed the importance of making informed decisions in food safety emergency and noted that food recall should be determined carefully. She highlighted the usefulness of the tabletop training exercise used in the workshop to guide authorities in decision-making during food safety emergencies.

Ms Shashi Sareen, Senior Food Safety and Nutrition Officer, FAO Regional office for Asia and the Pacific, introduced the objectives and workshop outline. The detailed programme of the workshop is attached in Annex 2.

2.2. Presentation 1: Managing food safety emergencies: role of INFOSAN and IHR

The presentation on “Managing food safety emergencies: role of INFOSAN and IHR” was delivered by Dr Li Ailan, WHO Western Pacific Regional Office. She noted that food safety is seen as an important aspect of health security work in this highly interconnected world. Countries are legally obliged to comply with the IHR (2005) obligations, including meeting core capacity requirements for surveillance and response. The IHR set rules and procedures to detect, assess and respond to any potential public health emergencies of international concern (PHEIC), including those caused by food-borne diseases and food safety incidents.

Managing food safety emergencies requires rapid exchange of information at national and international levels. INFOSAN is a global voluntary network of national food safety authorities that promotes the exchange of food safety information, shares information on important food safety related issues, promotes partnerships and collaboration between countries and networks, and helps countries strengthen their capacity to manage food safety risks. It is vital to ensure close interaction between INFOSAN and IHR at global, regional and national levels. Lastly, she emphasized that health security depends on the capacity of each country to act effectively and contribute to the security of all countries. The presentation is available for download at:

http://www.fao.org/fileadmin/user_upload/agns/pdf/CCASIA_2014/1._Managing_Food_Safety_Emergencies_WHO_Li_Ailan.pdf

2.3. Presentation 2: Preventing food safety emergencies: FAO EMPRES Food Safety

FAO has established an Emergency Prevention System for Food Safety (EMPRES Food Safety) to serve as a key international system to assist in the prevention and management of global food safety emergencies.

Dr Masami Takeuchi, FAO Food Safety and Quality Unit, presented an overview on FAO EMPRES Food Safety. First, she noted that the work and activities to assist member countries in ensuring food safety is a core mandate of FAO as one of the important pillars of Food Security. She explained the key components of FAO EMPRES Food Safety; early warning, emergency prevention and rapid response. Engagement with the joint FAO/WHO INFOSAN is one important activity to provide technical assistance to member countries in strengthening capacity to provide early warning of food safety threats.

Tool development is also a key activity and so far FAO, in collaboration with WHO, has developed 3 tools on food emergency response planning, risk analysis during emergencies and food recall systems. Two more tools will be published soon on the topics of risk communication and early warning. Several short documents on “lessons learned” from some past emergency cases are also providing good food safety emergency prevention scenarios. The website: <http://www.fao.org/food/food-safety-quality/empres-food-safety/> can be referred to for more information about FAO EMPRES Food Safety. The presentation is available for download at:

http://www.fao.org/fileadmin/user_upload/agns/pdf/CCASIA_2014/2._EMPRES_Food_Safety_FAO_Masami_Takeuchi.pdf

2.4. Presentation 3: FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies

Ms Viengxay VANSILALOM, Lao PDR, elaborated the FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies.

In the first part, she described preliminary risk management activities such as preparedness for food safety emergencies (criteria, decision trees, example templates for a risk assessment) and initial steps after identifying a food safety event. She explained the three principles of risk analysis: (1) risk assessment, (2) risk management and (3) risk communication, which may be very different from usual approaches.

She concluded that application of risk analysis follows the same principles as in normal situations but the factors that affect the decision-making are different; time pressure, increased uncertainty and need for multiagency collaboration and a strong demand for timely communication. Lastly, she emphasized the preparedness is the key to respond to food safety emergencies. The presentation is available for download at:

http://www.fao.org/fileadmin/user_upload/agns/pdf/CCASIA_2014/3._Guide_for_application_of_risk_analysis_principles_Lao_Viengxay_VANSILALOM.pdf

2.5. Presentation 4: Food recall and traceability: Codex work

Ms Annamaria Bruno, Codex Secretariat, explained the main work of Codex on food traceability/product tracing which had been carried out by the Codex Committees on General Principles (CCGP) and on Food Import and Export Inspection and Certification Systems (CCFICS).

The two Committees have respectively developed the definition, included in the Procedural manual of the Codex Alimentarius Commission, and the Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CAC-GL 60-2006).

Traceability/product tracing should not be intended as an objective but rather a tool that countries may use to demonstrate that imported or exported foods meet safety and quality requirements.

The Principles, developed by CCFICS, are intended to assist competent authorities in utilising traceability/product tracing as a tool within their food inspection and certification system. The Principles apply to food safety and to non-safety areas (e.g. the prevention of economic fraud and consumer deception).

Key messages are that the use of traceability/product tracing as a tool:

- does not of itself improve food safety outcomes or promote fair practices in food trade, i.e. it must be applied in combination with a measure or requirement;
- can contribute to the protection of consumers against deceptive marketing practices and the facilitation of trade on the basis of accurate product description.

The concept of traceability/product tracing is also included in a number of other Codex texts even if the term “traceability/product tracing” has not been used. In most cases it is linked to product identification and recall procedures. The presentation is available for download at: http://www.fao.org/fileadmin/user_upload/agns/pdf/CCASIA_2014/4_Food_recall_and_traceability_Codex_work_Codex_Annamaria_Bruno.pdf

2.6. Presentation 5: *FAO/WHO guide for developing and improving national food recall systems*

Ms Shashi Sareen, FAO Regional Office for Asia and the Pacific, gave a presentation on the “FAO/WHO guide for developing and improving national food recall systems”. She started her presentation by providing the background to food recalls and explaining their importance. She highlighted the purpose of food recalls which is primarily to protect the public health.

She introduced the FAO/WHO guide with its seven sections. The preliminary four steps for developing and/or improving national food recall systems are: (1) understanding the importance of shared responsibilities, (2) reviewing the current national food recall system, (3) considering general issues and (4) considering country-specific issues.

The elements of the national food recall systems that include, most importantly, the legal framework and powers, as well as clearly defined roles and responsibilities of the competent authorities and those of the food business operators, all make food recall a shared responsibility of governments and the food business operators. Effective communication through international and national channels, including notification and accurate record keeping by both the competent authorities and the food business operators are important, she added.

Equally important are the guidance materials for the development of robust food recall plans and review of the national food recall system. Traceability in the context of a food recall is of considerable importance and she stressed the importance of data collection, their proper analysis and exchanging the information so gathered. In addition, she noted that setting up and operating a national food recall system prior to a food recall was absolutely critical.

She further covered the various elements of a food recall management plan with an example of a food recall workflow. Four scenarios of recall episodes triggered by: 1) contaminated food; 2) contaminated ingredients; 3) an outbreak of a food-borne disease; and 4) an international source, were elaborated with the help of charts. The presentation is available for download at:

http://www.fao.org/fileadmin/user_upload/agns/pdf/CCASIA_2014/5_Guide_for_developing_food_recall_system_FAO_Shashi_Sareen.pdf

2.7. *Q and A session*

Following the presentations, several participants asked questions regarding ‘clarification on food safety as a health security concern’, ‘explanation on the synergies between INFOSAN and EMPRES’ and ‘credibility of scientific information and data to be shared during emergencies’.

Ms Shashi Sareen replied that food safety is a health security issue, and is also more than a health security concern because food safety is related to food availability and accessibility is affecting and being affected by economic concerns such as global markets, social development and a number of other aspects.

With regard to the difference between INFOSAN and EMPRES, Dr Masami Takeuchi explained that INFOSAN is the FAO/WHO network for food safety authorities for information sharing that can be also effectively utilized during food safety emergencies, while EMPRES is an FAO programme for strengthening national/regional emergency prevention systems for food safety focusing on preparedness for emergencies. Dr Li Ailan stated that each information collection system can complement others as each system has its strengths and weaknesses.

In relation to the last question, Ms Annamaria Bruno explained about the two CODEX Principles and Guidelines documents and plan for the revision, the Principles and Guidelines Exchange of Information in Food Safety Emergency Situations, which describes the credibility of the information, and the Guidelines for the Exchange of Information between Countries on Rejection of Imported Foods.

2.8. Tabletop exercise

Introduction and objectives for the tabletop training exercise were provided to the participants by Mr. Takuo Sukigara with support from Mr. Fusao Kamikubo, both from the Ministry of Agriculture, Fisheries and Forests, Japan. The introductory presentation for the exercise is available for download at:

http://www.fao.org/fileadmin/user_upload/agns/pdf/CCASIA_2014/6_Tabletop_training_exercises_Japan_Takuo_Sukigara.pdf

A set of working group sessions was then held for participants to work on a hypothetical scenario to discuss and consider the needs and possible processes of risk assessment, communication and risk management options including food recall (see the scenario in Annex 3).

Participants were divided into four groups. Two groups were tasked to work on the scenario from the exporting country's point of view, and the other two were tasked to work on it from the importing country's point of view. In addition, the participants were encouraged to also consider their real country situations and experiences when conducting the simulations.

After the group exercise, the representative of each group presented a discussion result on various risk management options based on risk assessment and effective risk communication strategy including risk communication messages and target groups. Following the group presentations, there were in-depth discussions on other required considerations and feasibility of each risk management option. The discussion summary of each group is attached in Annex 4.

2.9. Discussions and conclusions

In the last session of the workshop, Dr Kazuaki Miyagishima chaired the structured discussions for participants so that some concrete action items could be considered for the participants to take home and discuss with their colleagues in order to strengthen the food recall and traceability aspects of national food control systems. These action points included the following:

- Identification of clear roles and responsibilities of all relevant government authorities and stakeholders involved in risk analysis and food recalls;
- Review of the national legal frameworks to ensure that the system captures all elements for a food recall and is functional in case an urgent food recall is required;
- Review of the existing traceability and food recall systems in place and, based on the same, consider any improvements needed;
- Assessment of the national food recall systems to identify possible gaps in managing and implementing effective food recalls;
- Addressing the aspect of strengthening multisectoral communication and coordination mechanisms;
- Capacity development of professionals on risk analysis, especially on traceability and recall systems;
- Strengthening of institutional capacities including imported product inspections, specifically in view of cases in which a recall is required for imported products; and
- Sensitization of stakeholders on effective traceability and recall systems.

Participants stressed the importance to continue strengthening the capacity needed to take action on food recall and traceability including manpower, technical expertise and institutional capacity. Further training on food safety including risk analysis and traceability are needed. FAO and WHO will consider how best to respond to such requests for technical assistance in these areas.

2.10. Closing remarks and workshop evaluation

The workshop was concluded with a great appreciation being expressed by FAO and WHO to the participants, resource persons, colleagues from FAO/WHO and the Government of Japan for providing in-kind contributions for the venue and refreshments, administrative assistance and IT support. The FAO/WHO Codex Trust Fund provided financial support to allow many of the participants to attend the workshop.

At the end of the workshop, the participants completed a workshop evaluation aimed at allowing participants to give their perspective on the organization, conduct and value of the course, as well as feedback on topics of interest for future FAO/WHO training courses. The results of the evaluation are used by FAO/WHO to ensure the highest standards of training, to ensure that future training meets the needs of participants, and to identify follow-up to the training that might be needed to further build capacity at country level. Results of end of workshop evaluations are also included in the monitoring and evaluation reporting of the Codex Trust Fund.

Some key results of the evaluation included:

- Participants were highly satisfied with the workshop.
- They highly appreciated the workshop presentations, group discussions and the high quality tabletop exercise.
- Participants thought that the materials provided were useful to understand the risk management options in a food safety emergency situation based on risk analysis framework and importance of strengthening traceability and recall systems.

- Challenges that were highlighted included the overall workshop duration which was found to be too short for the objectives and exercises and, related to this, the time restriction for effective group exercises. They suggested extending the workshop duration, or allocating more time for interactive sessions.

The breakdown of the workshop evaluation results is attached in Annex 5.

Annex 1

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Annex 2

WORKSHOP AGENDA

Time	Item
09:00 – 09:30	Meeting registration
09:30 – 10:00	<p>Opening session</p> <p>Welcome and introduction</p> <ul style="list-style-type: none"> • Mr Mbuli Charles Boliko, Director, FAO Japan Liaison office (on behalf of Mr Hiroyuki Konuma, Assistant Director General, FAO Regional office for Asia and the Pacific) • Dr.Li Ailan, Director, Health Security and Emergencies WHO Regional Office for the Western Pacific (on behalf of WHO) • Ms. Yayoi Tsujiyama, Director for International Affairs, Ministry of Agriculture, Forestry and Fisheries (MAFF) JAPAN • Objectives of the workshop, Ms Shashi Sareen, Senior Food Safety and Nutrition Officer, FAO Regional office for Asia and the Pacific •
10:00 – 10:15	Managing food safety emergencies: role of INFOSAN and IHR: Dr.Li Ailan, WHO
10:15 – 10:25	Preventing food safety emergencies: FAO EMPRES Food Safety: Dr Masami Takeuchi, FAO
10:25 – 10:45	FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies : Ms Viengxay VANSILALOM, Lao PDR
10:45 – 11:00	Q & As
11:00 – 11:20	Coffee/tea break
11:20 – 11:30	Food recall and traceability: Codex work: Ms Annamaria Bruno, Codex Secretariat
11:30 – 11:50	FAO/WHO guide for developing and improving national food recall systems: Ms Shashi Sareen, FAO
11:50 – 12:00	Q & As
12:00 – 13:00	<p>Tabletop Training Exercises (Session 1) - Mr. Takuo Sukigara with support of Mr. Fusao Kamikubo</p> <ul style="list-style-type: none"> • Scenario proposals and explanation of scenario • Explanation of preliminary risk assessment for scenario • Estimation of risk
13:00 – 14:15	Lunch
14:15 – 15:30	<p>Tabletop Training Exercises (Session 2) - Mr. Takuo Sukigara with support of Mr. Fusao Kamikubo</p> <p>Group work</p> <ul style="list-style-type: none"> • Consideration of management options (food recall and other options considering situation of traceability, risk communication etc.)

15:30 – 15:45	Coffee/tea break
15:45 – 16:35	Tabletop Training Exercises (Session 3) Group presentation - Dr Kazuaki Miyagishima to facilitate with support of Mr Takuo Sukigara and Mr. Fusao Kamikubo
16:35 – 17:25	Facilitated Group discussion on Roadmap for introducing traceability and food recall : FAO/WHO
17:25 – 17:35	Completion of evaluation proforma
17:35 – 17:45	Closing remarks: FAO (Ms Shashi Sareen) /WHO (Dr.Li Ailan)

Annex 3

TABLETOP TRAINING EXERCISES

1. Objectives

The objectives of the tabletop training are:

- 1) to **assess the degree of risks** associated with an identified hazard quantitatively, using available information or data, in a food safety emergency situation;
- 2) to **identify risk management options**, taking into account the risk assessment results; and
- 3) to **consider communication approaches** that are appropriate to the individual risk management options that have been determined.

2. Expected outcomes of the training

At the completion of the tabletop training exercises, participants are expected to have:

- 1) enhanced capacity for conducting a **preliminary risk assessment** and making **risk management decisions** during a food safety emergency; and
- 2) enhanced capacity to plan and carry out **food safety emergency drills** in a country, including a **review of each country's food safety emergency plan**.

3. A case scenario

1) A food-borne illness outbreak in country A

Country A has mild weather and moderate rainfall in spring and summer and dry weather in the autumn. Thus the climate of country A is suitable for the production of various fruits; grape cultivation and its secondary products is an important industry of country A. Grapes cultivated in country A are not only consumed domestically but also exported to other countries in the form of fresh fruit, raisins, grape juice and wine.

From spring to summer of the past year, country A was blessed with good weather; the grape crop grew favourably and the cultivation progressed as usual. But in early autumn, an unusual rainfall prior to harvest time enabled certain types of mould to grow on the grapes.

Some moulds produce XYZ toxin just below the skin of grapes, but that type of toxin does not deteriorate the quality or the appearance of grapes. The grape farmers tried to prevent the mould from spreading across their vineyards, but vineyards across the country were affected.

The XYZ toxin can adversely affect human health; although it is not a genotoxic carcinogen, it can trigger immunotoxicity or reduce growth. The XYZ toxin does not break down in food processing except during the fermentation. Food safety authorities need to pay particular attention to the presence of XYZ toxin in food products that young children might consume, such as grape juice, which they drink in greater volume than persons in other age groups.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a **tolerable daily intake (TDI) of 0.02 mg per kg body weight**. Acute toxicity of the digestive organs, resulting in vomiting or diarrhea, was observed in animal tests; thus, an acute reference dose (ARfD) of **0.1 mg per kg body weight** was established for humans.

The Department of Health of country A requested the National Health Science Laboratory to analyse the XYZ toxin in grapes and grape products, such as raisins, juice and wine, distributed within country A after many patients, mainly children, presented a range of symptoms, from fever and nausea to vomiting and diarrhea (similar to the symptoms of XYZ

toxin) eating grapes and grape products. According to the analysis results, **XYZ toxin of 2.4–45.0 mg per kg** was detected in raisins, **0.3–4.0 mg per kg** was found in fresh grapes, **0.4–7 mg per kg** appeared in the grape juice and **0.2–2.1 mg per kg** was found in the wine.

Because country A had exported a large amount of grapes and grape products to its neighbouring countries, the government of country A notified the respective governments of the analysis results, through **INFOSAN**. They wanted them to be aware of possible XYZ toxin contamination. Through the quarantine and inspection authorities, country A directly reported the incident to country B, which had been a major importer of its grapes and grape products.

In country A, meanwhile, the food safety authority decided to carry out responses to prevent the spread of the damage. Based on the scientific data, such as the level of XYZ toxin concentration in food and its toxicity (see the fact sheet), the food safety authority need to consider how to respond.

2) **Imported fresh and processed grapes in country B from country A**

Country B does not grow any grapes but relies on the importing of grapes and also imports many grape products; approximately 70 percent of those imports are from country A.

After the imported-food inspection agency in country B received the report from country A, it launched an inspection of the grapes and grape products that had been imported from country A between September 2013 and January 2014. The test results proved to be similar as what country A found and reported. For that time period, the records indicated that country B had imported 12 000 tonnes of fresh grapes and 5 400 tonnes of raisins from country A, with which it made and sold secondary products.

There have been no reports of patients suffering any symptoms related to grapes or grape products contaminated with the XYZ toxin. Nonetheless, the food safety authority of country B have decided to consider preventive measures, based on scientific data (see the fact sheet), to guard against the possible occurrence of any health issues caused by grape products contaminated with the XYZ toxin.

4. **Exercise**

Exercise 1 (individual work)

- 1) **Estimate the daily XYZ toxin intake amount** (the mean and the 99th percentile values) using the concentration data of XYZ toxin in each product (fresh grapes, raisins, grape juice and wine) and the provided consumption data, body weight for adults and infants (please see note below). In table 1, fill in the blank spaces with your calculations.
(Note; the word of infants in this text is translated from original Japanese text in which “infants” means children of 12-24 month old)
- 2) **Conduct risk characterization of XYZ toxin**, by comparing the daily XYZ toxin intake amount estimated in the previous step with the tolerable daily intake (TDI) and the acute reference dose (ARfD) values. Insert those TDI and ARfD values into the table 1 also.

Exercise 2 (group work)

1) **Discussion themes**

- i) What options should **the government of country A** take as a producer and exporter of grapes, based on the risk assessment results? (for groups A and B)
- ii) What should **the government of country B** do as an importer of grapes and grape products, based on the risk assessment results? (for groups C and D)
- iii) What type of information should be released to the public? And how? (for all groups)

2) Points of concern

- i) In determining options to protect the public from health problems, several practices should be followed (when identifying possible risk management options during a food safety emergency):
 - **The initial source of information** regarding a food safety event in the country should be recognized, such as media reports, official food inspector reports, laboratory test results, alerts from international partners or consumer complaints.
 - If a **food recall is required** or implemented, the specific means suitable for the national legal and institutional systems should be considered (see the fact sheet further on).
 - In addition to a food recall, **other possible risk management options** to prevent the distribution and public consumption of contaminated food should be considered (for this exercise, assume that there is a **mechanism to trace food items** in the country).
 - When considering risk management options, it is essential to make use of all **available scientific data**. Also, other factors such as public perceptions and socio-economic conditions of the country must be considered.
 - When estimating the degree of adverse impact to public health, the **worst case should be assumed**. In this situation, that infants are most susceptible to the XYZ toxin should be recognized and all implications should be considered.
 - **Not taking any action** should also be considered as a viable option.
- ii) When preparing to communicate public risk information to key stakeholders, such as consumers and food industry operators, the government's message must be provided at the most appropriate time, taking into account the priority of the information.

Fact sheet

1. Country A

A. Information on food

Grapes are cultivated nationwide.

Production volume of grapes and grape products

(September 2013 to January 2014)

Food item	Amount of production	Amount of export
Fresh grapes	20 900 tonnes	17 400 tonnes
Raisins	71 000 tonnes	49 700 tonnes
Grape juice	186 200 kilolitres	121 100 kilolitres
Wine	371 200 kilolitres	232 900 kilolitres

B. Legal and institutional systems

National agencies involved in the food safety emergency response: Food and Drug Administration (FDA), Department of Medical Science (DMSC), Department of Health (DOH), Department of Disease Control (DDC), National Bureau of Agricultural Commodity and Food Standards (ACFS), Department of Agriculture (DOA), Department of Livestock Development (DLD), Department of Fisheries (DOF), Department of Rice (DOR), Bureau of Food Safety Extension and Support (BFSES).

The **Food Safety Law** covers the following points of the national food safety policy:

- appropriate public health measures to protect human health at each stage of the food supply process;
- responsibilities of the central and local governments;
- responsibilities of food-related business operators;
- registration required for all food-related business operators;
- food recall system; and
- traceability standards system (At present, use of the traceability system is largely on a voluntary basis and is limited. Specifically, tracing fresh fruits cultivated in the country is voluntary, while tracing fruit products throughout the food supply chain is mandatory. Export products are traced voluntarily by the export business operators, according to requests from authorities in the importing countries.)

Maximum residue levels (MRLs) of the XYZ toxin

Food items	MRLs (mg/kg)
Fresh grapes	2
Raisins	5
Grape juice	1
Wine	-

2. Country B

A. Information on food

Grapes are not grown in country B. The amount of imported grapes from country A accounts for about 70 percent of the grapes consumed within country B.

**Import volume of grapes and grape products
(September 2013 to January 2014)**

Food item	Amount of import
Fresh grapes	5 400 tonnes
Raisins	12 000 tonnes
Grape juice	36 600 kilolitres
Wine	91 200 kilolitres

B. Legal and institutional systems

National agencies involved in the food safety emergency response: Food Safety Commission (FSC), Ministry of Health (MOH), Ministry of Agriculture (MA), Ministry of Economy, Trade and Industry (METI), Consumer Affairs Agency (CAA), Ministry of the Environment (MOE) and local governments.

The **Food Sanitation Law** covers the following points of the national food safety policy:

- appropriate public health measures to protect human health at each stage of the food supply process;
- responsibilities of the central and local governments;
- responsibility of food-related business operators;
- registration required for all food-related business operators;

- food recall system; and
- traceability standards (Traceability is mandatory nationwide. Specifically, fresh fruits grown in the country and fruit products distributed throughout the food supply chain are required to be traced by business operators. In addition, labelling on imported products are required to include place of the origin but not their lot number.)

Maximum residue levels (MRLs) of XYZ toxin

Food items	MRLs (mg per kg)
Fresh grapes	2
Raisins	5
Grape juice	1
Wine	-

C. General information on the XYZ toxin

- **TDI:** 0.02 mg per kg body weight
- **ARfD:** 0.1 mg per kg body weight
- **Toxicity:**
According to animal tests, the following adverse health effects are recognized:
 - a. Acute toxicity: high-level XYZ toxin exposure leads to vomiting and/or diarrhea.
 - b. Long-term toxicity can lead to eating disorders, weight loss, growth delay and/or kidney function disorder; but there is no evidence of genotoxic carcinogenicity.
- **Physical property:**
Molecular weight: 183.5
Melting point: 112–113°C
Solubility: XYZ toxin, which is a polar molecule, is soluble to water, alcohol, ethyl acetate and acetone. The XYZ toxin is not destroyed during normal heating and cooking, but 60–90 percent reductions have been reported during the alcohol fermentation process for grape juice.
- **Analytical methods:** Analytical methods using gas chromatography–mass spectrometry (GC–MS) and gas chromatography with an electron capture detector (GC–ECD) are available. Enzyme-linked immunosorbent assay (ELISA) kits are also available, but measurement uncertainty of the method is relatively large. The limits for the quantification and detection with GC–MS are 0.1 mg per kg and 0.03 mg per kg, respectively. The limits for the quantification and detection with ELISA are 0.5 mg per kg and 0.2 mg per kg, respectively.

D. Human body weight

**Human body weight
(Mean value, countries A and B in common)**

Adult	Infant
60 kg	10 kg

E. Daily food intake

- **Daily food intake for adults**

unit: g/day/adult

Food items	Mean (50th percentile)	99th percentile
Fresh grapes	15	50
Raisins	5	15
Grape juice	20	40
Wine	50	450

- Daily food intake for infants**

Infants drink grape juice more than adults.

unit: g/day/child

Food items	Mean (50th percentile)
Fresh grapes	10
Raisins	5
Grape juice	150
Wine	0

F. Analysis results

Food items	Number of samples	Number of positive samples in country A	Number of positive samples in country B	Detection range (mg per kg)
Fresh grapes	20	20 (7)	12 (3)	0.3–4.0
Raisins	20	20 (11)	15 (5)	2.4–45.0
Grape juice	30	30 (10)	21 (4)	0.4–7.0
Wine	30	28 (-)	15 (-)	0.2–2.1

Note: The figures in parentheses indicate the number of samples above MRLs.

Table 1. Memo template for individual assignments
(for conducting a preliminary risk assessment during a food safety emergency)

Food items	Age category	Concentration of XYZ in the food items (maximum) (mg/kg)	Average daily intake of the food items per person (kg)	Average amount of XYZ intake per person (mg)	Body weight (mean) (kg)	TDI (mg/kg bw)	TDI per person (mg)	TDI ratio (%)	ARfD (mg/kg bw)	ARfD per person (mg)	ARfD ratio (%)
Fresh grapes	Adult (mean)										
	Adult (99%ile)										
	Infant (mean)										
Raisins	Adult (Mean)										
	Adult (99%ile)										
	Infant (mean)										
Grape juice	Adult (mean)										
	Adult (99%ile)										
	Infant (mean)										
Wine	Adult (mean)										
	Adult (99%ile)										
	Infant (mean)										

Table 2. Memo template for group work assignments
(for considering risk management options during a food safety emergency)

Fresh grapes

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
	Status quo (no new measures)	

2) Communication

Priority	Information content and target

Raisins

1) Management

Priority	Countermeasures (scope and target)	Pros and cons

	Status quo (no new measures)	

2) Communication

Priority	Information content and target

Grape juice

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
	Status quo (no new measures)	

2) Communication

Priority	Information content and target

Wine

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
	Status quo (no new measures)	

2) Communication

Priority	Information content and target

Annex 4

SUMMARY OF GROUP DISCUSSION

Group A

(the exporting country's point of view)

Fresh grapes

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
Moderate	<ul style="list-style-type: none">• Further monitoring• Collect more samples and analyses in order to get more information• To secure export consignments and also domestic• Identify potential measures to control the production of toxin at farm level and educate farmers to improve their practices on these for an effective implementation.	<ul style="list-style-type: none">• Give further insights into the contamination problem• Ensure safe production in future for grape juice and raisins and other similar products.• Long term strategy

Grape juice and raisins

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
Very high	<ul style="list-style-type: none">• Public notices, alerts and warnings that the product is not fit for infantsi) Domesticii) Importing countries	<ul style="list-style-type: none">• Effectively protect infant health• Consumer panic
High	<ul style="list-style-type: none">• Recall the implicated producti) Re-labelling the product that it is not fit for infantsii) Re-conditioning to reducing the toxin upto safer level	<ul style="list-style-type: none">• Health protection• Costly exercise• 100% recovery of the product is not practicable
Moderate	<ul style="list-style-type: none">• Suspend exports unless the detoxification measures and system has been established and further monitoring reveals that the product is safe	<ul style="list-style-type: none">• Prevent any emergency in importing country• Loss of reputation
	<ul style="list-style-type: none">• Identify potential measures to control the production of toxin at farm level and educate farmers to improve their practices on these for an effective implementation.	<ul style="list-style-type: none">• Ensure safe production in future for grape juice and raisins and other similar products.• Long term strategy

2) Communication

Priority	Information content and target
	<ul style="list-style-type: none">• Public notices, alerts and warnings that the product is not fit for infants<ul style="list-style-type: none">i) Domesticii) Importing countries

Group B

(the exporting country's point of view)

Fresh grapes

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
1	Enhance routine inspection at the wholesale as well as retail	
2	Pre-export checks	
3	Inform consumer	
4	Promote GAP	

2) Communication

Priority	Information content and target
1	Public advice on washing grapes
2	Advice farmers on good practises to be followed

Raisins

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
1	Recall the product and relabeling with adequate statutory warning	cons <ul style="list-style-type: none"> • additional cost on trade pros <ul style="list-style-type: none"> • reputation as responsible country enhanced • increasing consumer confidence
2	Enhanced monitoring of the recall effectiveness	cons <ul style="list-style-type: none"> • additional cost on CA and industries pros <ul style="list-style-type: none"> • greater confidence on traceability system
	Post public alerts and warnings through social communication (hotline,	cons

3	social media &etc.)	<ul style="list-style-type: none"> negative consumer perception pros <ul style="list-style-type: none"> proactive communication strategy may offset the negative impact
4	Collect and analysis affected product for long terms perspectives(climate change)	cons <ul style="list-style-type: none"> additional cost on CA and industries pros <ul style="list-style-type: none"> increase public-private partnership for long term solutions increase thrust on R&D

2) Communication

Priority	Information content and target
1	The communication strategy would be devised to sensitise the parents and medical practitioner about the consumption of the product, electronic , social media hot lines and websites
2	Inform INFOSAN

Grape juice

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
1	Recall the product and relabeling with adequate statutory warning	cons <ul style="list-style-type: none"> additional cost on trade in terms of finances as well as human resources pros <ul style="list-style-type: none"> reputation as responsible country enhanced increasing consumer confidence
2	Enhanced monitoring of the recall effectiveness	cons <ul style="list-style-type: none"> additional cost on CA and industries pros <ul style="list-style-type: none"> greater confidence on traceability system
3	Post public alerts and warnings through social communication (hotline, electronic media, websites, social	cons <ul style="list-style-type: none"> negative consumer perception public panic

	media &etc.)	pros <ul style="list-style-type: none"> proactive communication strategy may offset the negative impact
4	Collect and analysis affected product for long terms perspectives(climate change)	cons <ul style="list-style-type: none"> additional cost on CA and industries inadequate laboratory infrastructure pros <ul style="list-style-type: none"> increase public-private partnership for long term solutions Increase focus on GAP increase thrust on R&D

2) Communication

Priority	Information content and target
1	<ul style="list-style-type: none"> The communication strategy would be devised to sensitise the parents and medical practitioners Also, monitor symptoms, if any, in case the products have been consumed Information to be disseminated through electronic and print , social media, hot lines and websites
2	<ul style="list-style-type: none"> Inform INFOSAN

Wine

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
	<ul style="list-style-type: none"> Increase awareness of public on wine produced from grape varietals of the Sep 2013-Jan 2014 Routine inspection 	Cons: <ul style="list-style-type: none"> dip in sales Pros <ul style="list-style-type: none"> Increase consumer confidence.

Group C

(the importing country's point of view)

Fresh grapes

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
1	Close monitoring at the entry points	
2	Require certificate of analysis for every shipment/consignment from the exporter	
3	Advise the public	
4	Inform the INFOSAN	
5	Require GAP Certificate	

2) Communication

Priority	Information content and target
1	Inform the public to check the condition of the fresh grapes before buying
2	The public must inform the Health Authority if any symptoms of toxicity after consuming the product

Raisins

1) Management

Priority	Countermeasures (scope and target)	Pros and cons	
1	Stop importation of the product; Recall of product	<ul style="list-style-type: none"> • Safe guarding the public health, especially infants 	<ul style="list-style-type: none"> • Insufficient supply of raisins in country B; • Increase in price of similar product;
2	Ban on sale		
3	Destruction of recalled products by		

	the competent authority		
4	Public alert by the Ministry of Health (in schools, etc.)		
5	Require a certification (eg. Certificate of Analysis) for every batch/ consignment from the exporting country		
6	Require GMP and HACCP Certificate		

2) Communication

Priority	Information content and target
1	Inform the public, in particular the parents, guardians, child care institutions, regarding the recall of the product and the information for the particular toxin, symptoms that will occur after consumption.
2	The public must inform the Health Authority if any symptoms of toxicity after consuming the product.

Grape juice

1) Management

Priority	Countermeasures (scope and target)	Pros	Cons
1	Stop importation of the product; Recall of product	<ul style="list-style-type: none"> Safe guarding the public health, especially infants 	<ul style="list-style-type: none"> Insufficient supply of grape juice in country B; Increase in price of similar product;
2	Ban on sale		
3	Destruction of recalled products by the competent authority		
4	Public alert by the Ministry of Health		

5	Require GMP and HACCP Certificate		
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2) Communication

Priority	Information content and target
1	Content of the message – all information related to the contaminated product such as country of origin, batch number, hazard/s, etc.
2	Inform the public, in particular the parents, guardians, child care institutions, regarding the recall of the product and the information for the particular toxin, symptoms that will occur after consumption.
3	The public must inform the Health Authority if any symptoms of toxicity after consuming the product.

Group D

(the importing country's point of view)

Fresh grapes

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
Low	Increase frequency of testing of fresh grapes from Country A to ensure that the toxins are within the MRLs.	Pros <ul style="list-style-type: none"> • Pro-trade initiative, safer food Cons <ul style="list-style-type: none"> • Budget implications
	Monitor data collected from the sampling for further risk assessment	Pros <ul style="list-style-type: none"> • better data for assessment and re-course the actions

2) Communication

Priority	Information content and target
Low	Inform food processors to monitor the toxins level present in their fresh grapes from Country A and products made from these fresh grapes. Food processors should inform the authorities of any irregularities.

Raisins

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
High	Require testing of the toxins for every batch of raisins from Country A, to restrict import of failed batches	Pros <ul style="list-style-type: none"> • Ensure safety for every batch Cons <ul style="list-style-type: none"> • Budget implications
	Request import documentation from importers	Pros <ul style="list-style-type: none"> • Reduce the economic burden for importing country Cons <ul style="list-style-type: none"> • Document forgery

2) Communication

Priority	Information content and target
	To traders(importers) of raisins from Country A on the monitoring process
	Advice care-takers to restrict the consumption raisins (from Country A) by infants

Grape juice

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
High	Recall of products that are already distributed in the market because 1/3 of the samples have failed the analysis	Pros <ul style="list-style-type: none"> • Consumers protection Cons <ul style="list-style-type: none"> • Unnecessary food wastage, reduce consumers' trust
	Require testing of the toxins for every batch of grape juice from Country A and locally manufactured grape juice from grapes obtained from Country A, to restrict import of failed batches	Pros <ul style="list-style-type: none"> • Ensure safety for every batch Cons <ul style="list-style-type: none"> • Budget implications
	Request import documentation from importers	Pros <ul style="list-style-type: none"> • Reduce the economic burden for importing country Cons <ul style="list-style-type: none"> • Document forgery

2) Communication

Priority	Information content and target
High	Issue recall alert for consumers and retailers
	Public health advisory to general public to inform the public on observable symptoms especially for infants and seek medical assistance

Wine

1) Management

Priority	Countermeasures (scope and target)	Pros and cons
Low	Status quo	<p>Pros</p> <ul style="list-style-type: none">• No budget implications, do not create unnecessary fear for consumers <p>Cons</p> <ul style="list-style-type: none">• Safety unknown

Annex 5

WORKSHOP EVALUATION RESULT

Note: Comments are transcribed as presented and spelled by the participants in the original evaluation form.

1. Workshop administration and organization

	Satisfaction % (I agree or I agree completely)
Travel arrangements were satisfactory	82
The workshop facilities were conducive to learning	100
The workshop was well organized	100

2. Objectives of the workshop

	Satisfaction % (I agree or I agree completely)
The objectives of the workshop were clearly explained	100
The objective of sharing knowledge on the basic concept of risk analysis and relation between risk management and crisis management in food safety was achieved	95
The objective of enhancing understanding on application of food recall and traceability system in the national food control system with specific reference to food safety events and emergencies was achieved.	95
The objective of raising awareness on the FAO/WHO guides for applying risk analysis during food safety emergencies and for developing and improving national food recall systems was achieved.	95
The objective of discussing a possible roadmap for introducing traceability and food recall in emergency scenario in participating countries was achieved	79
The objective of strengthening regional collaboration on the topic was achieved	86

3. Learning from the workshop

	Satisfaction % (I agree or I agree completely)
The topic of the workshop was relevant to furthering establishing and implementing an effective national food recall system to respond to food safety events.	98
The workshop was relevant to my workplace needs	95
The trainers were of high quality	100
The workshop materials aided my comprehension of the course	98

There was sufficient time for group work and questions	63
As a result of my participation, I feel confident to provide technical input to support my country to establish and implement an effective national food recall system to respond to food safety events.	93
As a result of my participation I feel confident to facilitate better in-country communication and coordination between ministries involved in establishing and implementing an effective national food recall system to respond to food safety events.	91

4. Which of the following workshop sessions were most useful to you

	Satisfaction % (Useful or Very useful)
Information sharing during international food safety emergencies: INFOSAN	90
Preventing food safety emergencies:FAO EMPRES Food Safety	95
FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies	93
Food safety incidents and emergencies: relevant Codex definitions and common terminologies	90
FAO/WHO guide for developing and improving national food recall systems	95
Table-top Training Exercises	100
Facilitated Group discussion on Roadmap for introducing traceability and food recall	95

5. Please note your three most important take-home messages from this workshop?

- Lessons learned to manage risk in an emergency situation based on the risk analysis approach.
- Traceability of recall guidelines as essential in managing food safety issues.
- Importance of traceability and recall plans and systems.
- Too strict counter measures, or ones without scientific evidence to support them, will not be accepted at the SPS committee.
- Coordination of many national authority, industry, stakeholders, consumers and other international agencies is important in alert and emergency recall.
- Increase capacity of relevant authorities on risk assessment and management.

6. What specific priority actions you will take upon return to your country? (describe 2-3)

- Disseminate guidelines and information to relevant staff.
- Share information from workshop to colleagues and other relevant officers.
- Enhance capacity building in the area of risk analysis.
- Review current risk analysis framework and assess effectiveness of risk communication among of stakeholders.
- Strengthen multisectorial collaboration for traceability and recall systems.
- Work on legislative framework for food recall/ IT based traceability system.
- Strengthen national food safety control systems for better food recall based on risk assessment.
- Strengthen communication between relevant authorities, not only on food emergencies, but also on potential food safety problems.
- Encourage and promote establishment of food recall procedures.

- Strengthen existing INFOSAN activities at national level

7. Additional comments ?

Positive Comments	Comments for improvement
<ul style="list-style-type: none"> • Very useful and informative workshop • Very useful workshop and materials • Very good, only need more time • I express my thank you to organizer WHO/FAO and Japan to assist us attend this important event 	<ul style="list-style-type: none"> • The workshop was very good, however, this subject requires more in-depth inputs. More table top exercise should be included. • Overall was good, but the available time for the exercises for risk assessment and management was too short. • Introduction for new person is less guided. • Risk analysis workshop like this should be conducted for more than 2days. One day is too short. • Please plan a workshop for a longer duration.

8. Recommended topics for future pre-Regional Coordinating Committee workshops

- Similar detailed and exhaustive workshop and food recall and traceability
- Same topic in more detail (taking more time, so that participants would be able to learn more)
- Collecting data, sampling techniques for making risk analysis decision
- Exercise food safety topics on food borne disease example
- Food supply chain approach
- The exposure assessment
- Updating a recall/traceability system
- Food setting and training for food testing in emergencies
- Training on the development of national food control system based on guide 82/2013 of Codex
- Implications for developing countries of sharing information and notification

