

**CAP/REP 1**

**FAO/WHO Regional Conference on Food Safety  
for Asia and the Pacific**

24-27 May 2004  
**Seremban, Malaysia**

*“Practical Actions to Promote Food Safety”*

**FINAL REPORT**

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**FINAL REPORT**

**FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS  
Rome, 2004**

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**FOREWORD**

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Ensuring safe and healthy food is essential for improving human life in all countries, whether developed or developing. The World Food Summit, organized by FAO in 1996, recognized that access to safe food is in itself an element of food security. Rather than being a luxury of the rich, all people should have the right to an adequate supply of safe, nutritious food. The importance of safe food, whether domestically produced and consumed or that is imported or exported, is well known by the countries of Asia and the Pacific. However, the danger of food contamination and food related disease outbreaks is particularly acute in the region because of the proximity in which animals and people live and the way in which food is produced and distributed.

The countries of the region recognize the importance of developing practical actions and recommendations for capacity building to promote food safety in the region. Accordingly, at the request of the 13<sup>th</sup> Session of the Regional Codex Coordinating Committee for Asia (Kuala Lumpur, 17 to 20 September 2002), following the guidance of the FAO/WHO governing bodies, in line with the suggestions made by the participants at the first Joint FAO/WHO Global Forum of Food Safety Regulators in Marrakesh, Morocco, January 2002, and at the kind invitation of the Government of Malaysia, FAO and WHO jointly convened a Regional Conference on Food Safety for Asia and the Pacific in Seremban, Malaysia from 24 to 27 May 2004.

The Conference was held as part of a series of regional meetings that FAO and WHO are jointly organizing to meet the needs of member countries for policy guidance and capacity building in food safety, the first of which was held in Budapest in February 2002 for the European region. Over 230 delegates from 35 member countries and territories of the Asian and Pacific Region and observers from 10 international governmental and non-governmental organizations participated in this Conference, under the general theme of “Practical Actions to Promote Food Safety”.

The participants at the Conference affirmed that the countries of the region recognize the enormous gap between the scale and cost of food borne illnesses and their capacity to address them. Within this context, the Conference made numerous recommendations of practical actions to bridge this gap. It was generally recognized by the participants that although the convening of the Conference itself was successful, its true success can only be measured by the degree of implementation of the recommendations of the Conference and the improved safety of foods produced and consumed in the region.

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## **ACKNOWLEDGEMENTS**

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The Joint Secretariat of the FAO/WHO Regional Conference on Food Safety for Asia and the Pacific wishes to express its sincere thanks to all those that contributed towards the success of this Conference, in particular to the Malaysian authorities for their most efficient organization of the Conference and their warm hospitality; to the Government of the Netherlands and the International Life Sciences Institute for their financial assistance which facilitated the participation of many developing countries that would not have otherwise been able to participate in the Conference, and to all those member countries and international organizations that gave technical support during the preparatory stages. The Joint Secretariat also expresses its gratitude to the Chair, Vice-Chairs, and other members of the Conference Bureau for their dedicated hard work and the exceptional manner in which they conducted the meeting; to those who prepared and presented discussion papers for their outstanding presentations and interventions during the debates of the Conference; to those who organized and facilitated the excellent side events of the Conference; to all those who prepared Conference Room Documents and made interventions during the Conference; and last, but not least, to the members of the press for their excellent coverage of the event.

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**Final report of the FAO/WHO Regional Conference on Food Safety  
for Asia and the Pacific**

*Seremban, Malaysia, 24 to 27 May 2004*

**I. EXECUTIVE SUMMARY**

A Regional Conference on Food Safety for Asia and the Pacific, jointly convened by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), took place from 24 to 27 May 2004 in Seremban, Malaysia, at the kind invitation of the Government of Malaysia. Over 230 delegates from 35 member countries and territories of the Asian and Pacific Region and observers from 10 international governmental and non-governmental organizations participated in the Conference, which was designed to 1) provide a platform for broad co-operation in food safety among the countries of the region and to identify opportunities for regional cooperation; and 2) to promote increased exchange of information and expertise at all levels to improve transparency and facilitate capacity building.

Countries have recognized the enormous gap between the scale and cost of food borne illnesses and their capacity to address them. Within this context, the Conference made numerous practical recommendations to bridge this gap. The key recommendations made can be summarized as follows:

- The large majority of countries of the region must urgently give higher priority to building their capacity to respond to the unacceptable burden of illnesses caused by consumption of unsafe food. In particular, governments must ensure that good practices that minimize the risk of contamination are applied by producers, processors, and consumers alike.
- There is a need to establish or strengthen national food borne disease surveillance programmes in each country of the region and facilitate timely inter-country exchange of relevant information.
- Countries are urged to adopt a well coordinated, multi-sectorial approach to food safety risk analysis, including assessment, management and communication.
- Awareness of food safety risks and of opportunities to prevent or to mitigate food safety hazards must be created throughout societies, from producers to consumers. Governments, as well as the private sector should therefore engage in large scale communication and education campaigns.
- To supplement national actions, governments of the region should make better use of resources available in the region including, for example, specialized reference laboratories, established surveillance systems, and training capacities.
- FAO, WHO and other concerned international agencies and donors are called upon to support initiatives to address the food safety challenges, in particular in the poorer countries of the region.



## II. INTRODUCTION

1. The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) jointly convened the FAO/WHO Regional Conference on Food Safety for Asia and the Pacific (the Conference) in an effort to facilitate discussion on practical actions and recommendations to promote food safety in the countries of the Asian and Pacific region. The Conference was held in Seremban, State of Negri Sembilan, Malaysia from 24 to 27 May 2004 at the kind invitation of the Government of Malaysia. The Conference was attended by high ranking policy officers and technical experts from 35 Asia and Pacific member countries and territories of FAO and WHO. It was also attended by 10 international organizations as observers. A list of all participants is included in Annex 1.

2. This Conference is part of a series of global and regional meetings that FAO and WHO are convening to meet the needs of member countries for policy guidance and capacity building in food safety. This series began with the “First FAO/WHO Global Forum of Food Safety Regulators” in Morocco from 28 to 30 January 2002, followed by a “Pan-European Conference on Food Safety and Quality” in Hungary from 25 to 28 February 2002. The Conference was convened in light of the recommendations and feedback from these two events, direction from FAO/WHO governing bodies, and the request of the delegates at the 13th Session of the Codex Coordinating Committee for Asia, Kuala Lumpur, from 17 to 20 September 2002. In addition, inputs were received from two preparatory meetings held with representatives from countries of the Asia and Pacific region. The reports of the two meetings are available as Annex 2.

3. Further aims of the Conference were to 1) Identify opportunities for regional cooperation related to agriculture, agribusiness, post-harvest production, food processing, food trade, public health, and consumer protection; 2) Provide a platform for broad co-operation and mutual understanding; 3) Promote increased exchange of information at all levels to improve transparency and capacity building and to more effectively communicate with consumers, producers, and industries to improve food safety.

4. The Provisional Agenda for the Conference is found in Annex 3.

## III. OPENING CEREMONY (AGENDA ITEM 1)

5. The opening ceremony began with a statement from Dr Abd. Rahim bin Hj Mohamad, Director of the Food Quality Control Division, Malaysia on behalf of Dato’ Dr Shafie Ooyub, the Deputy Director-General of Health (Public Health), Malaysia, in which he reminded the participants of the importance of food safety for the countries of the region. The speaker also emphasized that all participants at the Conference are working towards the same objective, regardless of their differences in approaches to improving food safety, and that all participants are allies in the struggle against food hazards. The speaker stressed that safe food does not necessarily mean risk free food. He also expressed the desire that this Conference would provide the impetus for further collaborative efforts in the area of food safety, especially in building alliances for capacity building and scientific co-operation. The text of his speech is appended as Annex 4.

6. In his opening remarks on behalf of FAO, Mr Hartwig de Haen, Assistant Director-General, Economic and Social Department, informed the Conference of the series of regional

and global meetings that FAO and WHO are jointly organizing to provide fora for food safety officials to share information on national experiences in regulating and promoting food safety. He highlighted the importance of food safety for all people, in the interest of both public health and economic efficiency and competitiveness. He recalled the challenges for the countries of the region to improve the efficiency and effectiveness of their food control systems and the specific conditions of the region in relation to rapid urbanization, food trade opportunities and growing intensification of livestock production, which increase the potential of food safety risks. Mr de Haen further informed the Conference of various actions taken by FAO, in partnership with WHO and other organizations, to assist member countries in their efforts to improve food safety and quality and reiterated his Organization's readiness to further expand its capacity building programme to assist the countries of the region in this field, if funds become available. The text of his speech is appended in Annex 5.

7. The WHO Representative in Malaysia, Brunei Darussalam and Singapore, Dr Han Tieru, welcomed the participants on behalf of WHO. In his presentation, he reminded the Conference of the growing food safety concern in the world and of the burden food borne disease has on the world population. In the Asia and Pacific region, WHO's latest estimates show that every year, more than 700,000 people die from cases of food or water borne diarrhoea. He stressed that in the past, many problems have stemmed from our inability to ensure that all partners and government authorities involved in food safety work together. He expressed the hope that the present FAO/WHO collaboration in the joint convening of this Conference would inspire multi-disciplinary collaboration at the national level between agriculture, health and other sectors. The text of his address is appended as Annex 6.

8. The Conference was officially opened by the Honourable Datuk Dr Abdul Latiff Ahmad, Deputy Minister of Health, Malaysia, who thanked FAO and WHO for providing Malaysia with the honour of hosting this Conference. The speaker highlighted the changes that have taken place in the food production, trading, and consumption patterns in the countries of the Asia and Pacific region, and which continue to increase the challenges to food safety systems. The speaker emphasized that although great progress has been made in improving food safety, all stakeholders can and must do more to adapt food safety systems to respond to and prevent food borne illnesses. The speaker noted with pleasure the selected theme for the Conference, "Practical Actions to Promote Food Safety", which emphasizes the action oriented focus of the Conference. The text of his speech is appended as Annex 7.

#### **IV. DESIGNATION OF CONFERENCE CHAIRS AND RAPPORTEUR (AGENDA ITEM 2)**

9. The Conference designated Dato' Dr Shafie Ooyub of Malaysia as Conference Chairperson, Mr Zhang Yan Qiu of China and Dr Dennis Bittisnich of Australia as vice-chairpersons and Dr S.R. Gupta of India as Conference rapporteur. The Conference expressed their appreciation to these members for their agreement to serve in these roles.

#### **V. ADOPTION OF THE AGENDA (AGENDA ITEM 3)**

10. The Conference adopted the proposed agenda and agreed to the timetable as presented by the secretariat.

## **VI. KEYNOTE ADDRESSES (AGENDA ITEM 4)**

11. Dr Supachai Kunaratanapruk of Thailand presented the first keynote address, citing examples of the importance of improving food safety to foster health and economic development in the region and practical actions which can be implemented to do so. The speaker emphasized the need for regional collaboration and sharing of resources available within the countries of the region. He urged countries to increase harmonization of their food safety systems and standards, and to develop an “inter-country alert system” in addition to national surveillance systems. He emphasized the importance of adapting modern technology to suit local production systems, especially in developing countries. This applies to Good Agricultural Practices and the farm-to-fork approach. He further emphasized the importance of consumer education and awareness raising related to food safety. The text of his speech is available as Annex 8.

12. Mr Neil McLeod of New Zealand presented the second keynote address, presenting examples of practical actions implemented in his country to improve food safety, and the necessity of instilling trust and confidence in the safety of food, both for exports from their country and for the health of local consumers. The speaker described the vision of the New Zealand Food Safety Authority and its risk based approach to food safety management, which includes regulatory control of accredited verifiers who audit the food production, processing and retail/export industries. His presentation is appended as Annex 9.

## **VII. FOOD SAFETY LEGISLATION - SCIENCE AND RISK-BASED APPROACHES TO HARMONIZATION (AGENDA ITEM 5)**

13. Dr Dennis Bittisnich, of Australia, presented the contents of the first discussion paper on science and risk based approaches to effective food safety legislation. All the discussion papers and Conference Room Documents (CRDs) for the Conference are found in Annexes 10 and 11. The paper addressed the numerous benefits, as well as the difficulties in implementing a risk analysis framework for food safety legislation. The presenter briefly discussed the three components of risk analysis and the impact of each on the development and implementation of effective food safety legislation. Whole chain approaches to food safety legislation and the importance of performance-based, pro-active legislation were also presented. The importance of regional and international strategies for harmonization and alignment of food safety legislations was also presented.

14. The Conference welcomed the document, thanked Australia for preparing the paper, and highlighted that the enforcement of food safety legislation throughout the food supply chain is essential for an effective food control system that supports public health and safe food trade.

15. The Conference stressed the importance of utilizing the guidance documents on food safety legislation developed by FAO and WHO and that these agencies, in coordination with other relevant agencies, should continue to lead coordinated and integrated capacity building efforts in this area.

16. The Conference suggested that when developing food safety legislation, countries should not only give due consideration to their national needs, but should also take into account their obligations in respect to the World Trade Organization (WTO) agreements. In developing and reviewing food safety regulatory measures, governments should consider a

“farm to table” and preventative approach to food safety management and incorporate performance-based food safety standards. Risk based food safety control systems should be considered and priority should be given to high risk food.

### **VIII. THE APPLICATION OF RISK ANALYSIS IN FOOD CONTROL - CHALLENGES AND BENEFITS (AGENDA ITEM 6)**

17. Ms Melanie Fisher of Australia presented a paper on the application of risk analysis in food control and explained the structure of the food regulatory system in Australia. The importance and role of each of the three components of food safety risk analysis were highlighted. The presenter discussed the challenges of risk analysis, including the availability of data and required skills at both the national and international levels, and the benefits of risk analysis, including better use of resources and a better informed community. Four specific case studies were presented dealing with the following topics: chloropropanols, nitrofurans, *Listeria spp.*, and a new approach to capacity building in the region involving a training programme developed by Food Standards Australia New Zealand (FSANZ).

18. The Conference thanked Australia for preparing the paper and agreed on the importance of a comprehensive risk analysis framework to improve food safety.

19. The Conference expressed appreciation for the current training initiatives in food safety risk analysis, including the forthcoming FAO/WHO didactical manual and training pack on the subject.

20. The Conference noted the approach to treat issues of scientific uncertainty on a case-by-case basis, rather than using a generic approach to dealing with this uncertainty. The Conference noted that FAO/WHO provided guidance on the use of existing tools to assist in dealing with uncertainty. Countries must decide how to handle scientific uncertainty according to their national situations, taking into consideration their obligations under international agreements.

21. The Conference was informed of the upcoming FAO/WHO Technical Workshop on Substances without an Established Acceptable Daily Intake (ADI)/Maximum Residue Limit (MRL) to be convened in Thailand from 24 to 26 August 2004.

22. The Conference emphasized the need for countries to strengthen means of generating and collecting reliable data relevant to food safety risk assessments.

### **IX. PRIORITIZATION AND COORDINATION OF CAPACITY BUILDING ACTIVITIES (AGENDA ITEM 7)**

23. Dr S.R. Gupta of India presented the paper on the Prioritization and Coordination of Capacity Building Activities. The presenter highlighted the necessity of evaluating the capacity building needs related to each of the components of the food control system. The presenter emphasized that countries need to identify and prioritize their specific, urgent, and important capacity building needs in the area of food safety so that an effective capacity building programme can be implemented accordingly.

24. The Conference welcomed the paper from India and agreed that capacity building activities are essential for developing countries' efforts to establish and operate effective national food safety control systems.

25. The Conference noted the diversity in food safety situations and capacity building needs among the countries of the region. It recognized, however, that there are several common deficiencies requiring urgent attention and which could be addressed regionally. It emphasized the importance of political will and commitment as a prerequisite to any capacity building effort.

26. The Conference underlined the importance of basing capacity building on a careful analysis and prioritization of actual needs and linking them to available resources and noted that FAO/WHO were developing a set of guidelines to assist in this needs assessment. The Conference considered the implementation of a risk-based approach to capacity building activities where the most resources are assigned to the areas at greatest risk.

27. The Conference noted the on-going initiatives such as the Association of South-east Asian Nations (ASEAN) Expert Group on Food Safety and their ASEAN Food Safety Improvement Plan and ASEAN Task Force on Codex. The Conference considered that these sub-regional efforts could be extended to include all the countries of the Asian and Pacific region.

28. The Conference considered the importance of regional or sub-regional sharing of resources such as equipment and facilities, laboratory referral testing systems and for regional Centres of Excellence to be established in various areas of food safety. The possibility of establishing a regional training institute for food safety was also discussed. The Conference considered the usefulness of establishing a regional committee on food safety and the frequency of its meetings.

29. The Conference considered the need for building capacity to meet independent standards from an outside organization such as International Standards Organization (ISO) and for the need for those standards to be incorporated into the national and international food safety framework. The Conference also considered the need to discuss food safety capacity building in the context of the WTO.

30. The Conference was informed of the work of the Standards and Trade Development Facility (secretariat housed by the WTO) to provide a mechanism for the coordination of the Sanitary and Phytosanitary Agreement (SPS) related capacity building activities around the world through an internet based database of capacity building activities implemented by the relevant donor agencies. It encouraged countries and organizations to contribute to this database.

## **X. COMMUNICATION, INFORMATION EXCHANGE AND EDUCATION RELATED TO FOOD SAFETY (AGENDA ITEM 8)**

31. Mr Makoto Hirose of Japan presented a paper on Communication, Information Exchange, and Education Related to Food Safety based on the experiences of Japan. The recent incidents in Japan both directly and indirectly related to food safety were highlighted. The presenter discussed the changes in the structure of the food safety administration of Japan, which were caused by these food safety incidents. Deficiencies were evidenced in the

described cases in each of the following areas: information exchange, communication, consumer understanding, of a crisis management system, a lack of a sense of crisis, and insufficient co-operation between agencies. The presenter also noted that even though there was no data demonstrating that highly pathogenic Avian Influenza could infect humans through consumption of chicken and eggs, people still reduced their purchases of these commodities. He noted that Japan had improved its information collection and exchange activities with other countries and within Japan due to these incidents.

32. The Conference expressed its appreciation to Japan for preparing the paper and their honesty and transparency in describing these food safety incidents which occurred in Japan. The Conference noted the importance of communication, information exchange, and education in ensuring consumer health and protection and improving trade.

33. The Conference welcomed the proposed establishment of the International Food Safety Authorities Network (INFOSAN) and encouraged its development. The Conference noted that this network could allow for rapid exchange of information, including emergency information, between countries and across the food chain.

34. The Conference noted the initiatives in food safety education, communication, and information exchange implemented by various countries of the region. Important components of these campaigns include the collaboration of the various government ministries involved in food safety, academia, consumers, non-governmental organizations and industry, the involvement of mass media, establishment of sub-regional training programmes and education on food safety in elementary schools.

35. The Conference noted that many consumers erroneously think that highly pathogenic Avian Influenza presents a food safety risk and that food safety officials must clearly differentiate between issues related to animal health and those related to food safety when explaining them to the public, so as not to create unnecessary fears. Countries must emphasize that restrictive trade measures are taken for animal health reasons, rather than food safety reasons. The Conference noted the increased difficulty for transparency in sharing the disease status of a food exporting country due to the economic implications.

36. The Conference also emphasized the importance of using international standards and related texts for food safety and urged FAO, WHO, Codex, and the World Organization for Animal Health (OIE) to work together to provide a uniform source of information.

37. The Conference emphasized the importance of honesty, trustworthiness, accuracy, timeliness, transparency, scientifically based information and cooperation with all competent authorities in developing media campaigns to communicate complex food safety issues and avoid mis-information.

## **XI. FOOD BORNE DISEASE MONITORING AND SURVEILLANCE SYSTEMS (AGENDA ITEM 9)**

38. Dr Hasan Abd. Rahman of Malaysia presented the paper on food borne disease (fbd) monitoring and surveillance systems. The speaker highlighted that better understanding of the occurrence of food borne diseases should enable the countries of the region to lower the risk of food borne diseases to the population and that integrated food chain disease surveillance will be effective in detection and control of food borne pathogens. He emphasized that leadership, political commitment, interdisciplinary collaboration, and

coordinated activities at multiple levels with involvement from various agencies are the prerequisites for strengthening the existing fbd surveillance systems.

39. The Conference recognized the need to identify risks and establish priorities for fbd surveillance based on the actual problems faced by each country.

40. The Conference considered that the availability of data to establish the burden of food borne disease should help to influence decision makers in securing appropriate allocation of funds to improve food safety.

## **XII. PROCEEDINGS OF THE WORKING GROUPS**

41. The Conference agreed to discuss the following items in two concurrent working groups: Working Group 1) Food borne disease monitoring and surveillance systems and Working Group 2) Capacity building: use of expertise and resources in the region to enhance food safety. The two working groups were requested to discuss their respective themes and to propose concrete recommendations and practical actions to improve food safety in the region in these specific areas. The Conference designated Dr Dedi Fardiaz of Indonesia and Dr DongHa Lee of the Republic of Korea as co-chairpersons of the first working group and Dr Gilberto Layese of the Philippines and Dr Nu'ualofa Potoi of Samoa as co-chairpersons of the second working group. The Conference expressed their appreciation to these delegates for their agreement to serve in these roles.

42. The outcome of the two working groups have been incorporated in the Conference conclusions and recommendations as indicated below.

### **Launching of the International Portal on Food Safety, Animal and Plant Health**

43. The Conference witnessed the official launching of the International Portal on Food Safety, Animal and Plant Health through a live presentation by the FAO Secretariat and demonstration of its use and benefits for member countries and stakeholders involved in international food and agricultural trade. The Conference expressed appreciation to FAO and partner agencies for the establishment of the Portal. An information paper on the portal is available as Conference Room Document (CRD) 4.

### **Conference Side Events**

44. Three side events to the Conference on issues of interest to the region were held on Wednesday, 26 May, the report writing day of the Conference. The International Tropical Fruit Network gave a presentation on the activities of this initiative. An information document on this network is available as CRD 21. The International Life Sciences Institute (ILSI) South-East Asia organized a seminar on *Enterobacter sakazakii* in Infant Foods: Importance and Relevance to the Asia and Pacific Region. The agenda of this seminar and a background document are available as CRDs 3 and 14 respectively, and the executive summary of the seminar is appended as Annex 12. Consumers International organized a seminar on Food Safety in Street Vended Foods, the agenda of which is available as CRD 2. The summary of this event is appended as Annex 13.

### **XIII. RECOMMENDATIONS OF THE CONFERENCE**

#### *Food legislation and enforcement:*

45. The Conference recommended that, in order to successfully develop and enforce food safety legislation, member countries should:

- a) ensure the availability of technical, financial, and adequately trained human resources;
- b) establish national inter-agency committees to regularly review, update or revise legislation;
- c) conduct surveys and research in partnership with relevant national research institutions to ensure the availability of scientific data when establishing appropriate standards;
- d) continue to move towards the development of horizontal food standards, rather than product specific standards;
- e) take advantage of risk analysis and regulatory models developed by international agencies, in particular the Codex Alimentarius Commission, and establish mechanisms for sharing such information.

46. The Conference recommended that member countries of the region should:

#### *In the field of food safety policy:*

- a) work with FAO and WHO to develop improved food safety administrations, policies and national plans of action;
- b) work with FAO and WHO to strengthen the organization of food control administrations and activities at national level, including the review, drafting, and harmonization of food safety legislation and standards (regionally and with Codex);
- c) develop, with FAO, WHO and OIE, a means for encouraging transparency in sharing the disease status of a food exporting country.

#### *In the field of risk assessment:*

- d) share risk assessment data, especially among those with similar food consumption and preparation patterns, to avoid duplication of work and also take advantage of risk assessments available internationally;
- e) consider the cost and testing capabilities requirements when adopting Maximum Residue Limits (MRLs) established by international organizations or other parties. Such MRLs should be based on sound scientific evidence.

#### *In the field of information exchange and communication:*

- f) utilize national websites as a means of providing relevant food safety related information, e.g. crises management, alerts, listing of exporters, directory of experts in food safety, research data, training programmes and courses;
- g) collect and verify the food safety related information presented by the media and explore ways and means of making the media a partner in food safety education and awareness raising.



*In the field of stakeholder involvement:*

- h) ensure collaboration, cooperation, and coordination of activities among all stakeholders involved in food safety; including government, industry, academia and consumers, at the national, sub-regional, regional and international levels;
- i) develop and implement, in collaboration with the industry and other stakeholders, appropriate educational and awareness raising programmes on food safety addressed to consumers and the public in general;

*In the field of food testing:*

- j) further develop their capabilities in food testing through the acquisition of chemicals and modern laboratory equipment, the training of laboratory personnel and the seeking of international accreditation for their official testing laboratories.

*In the field of capacity building:*

- k) prioritize their food safety capacity building needs and develop capacity building programmes to meet these needs, using tools such as the soon to be released FAO/WHO Guidelines for Assessing Food Safety Capacity Building Needs.

*In the field of training of food producers and handlers:*

- l) make a special effort to promote the application of Good Agricultural Practices, Good Manufacturing Practices and HACCP throughout the food chain through provisions of proper infrastructure and training of food producers and handlers.

*In the field of food borne disease surveillance:*

- m) strengthen national fbd surveillance programmes and food contaminant data collection in order to provide more accurate information on their national food safety situation.

47. The Conference urged that all relevant stakeholders:

- a) submit relevant data on chemical contaminants and/or residues to the relevant FAO/WHO Expert bodies so that sound scientific advice can be provided to Codex and FAO/WHO member countries.

48. The Conference recommended that FAO and WHO:*In the field of policy advice:*

- a) support the countries of the region in the development of food safety policies, administrations and national plans of action;
- b) provide advice to member countries in strengthening the organization of food control activities at national level, including the review, drafting, and harmonization of food safety legislation and standards (regionally and with Codex);
- c) along with OIE, develop a means for encouraging transparency in sharing the disease status of a food exporting country.

*In the field of capacity building:*

- d) in collaboration with providers and donor agencies, continue to assist countries of the region in training of technical staff involved in various food safety related activities, including in the application of risk analysis, food contaminant analysis, analytical quality assurance systems and accreditation, food inspection, and HACCP;
- e) in collaboration with providers and donor agencies, assist countries in prioritizing their food safety capacity building needs and develop capacity building programmes to meet these needs, using tools such as the soon to be released FAO/WHO Guidelines for Assessing Food Safety Capacity Building Needs;
- f) assist countries of the region, through the Codex Trust Fund and relevant capacity building activities, to better understand Codex work and procedures so as to enhance the quality and effectiveness of their participation.

*In the field of information exchange and regional cooperation:*

- g) work, in collaboration with related regional bodies, such as the ASEAN Expert Group on Food Safety and the Pacific Public Health Surveillance Network (PPHSN), and the Standard and Trade Development Facility (STDF) Secretariat to develop a database of food safety experts, technical organizations/agencies and donors to better coordinate food safety capacity building activities to avoid duplication and ensure synergy;
- h) assist in the identification of those laboratories within the region that can play a role as regional reference laboratories and training centres in their respective fields of expertise;
- i) provide relevant, scientifically sound food safety educational materials to national governments so that they can disseminate them to large national audiences.

*In the field of food borne disease surveillance:*

- j) organize seminars/training sessions on the importance of fbd surveillance, involving all relevant stakeholders from all sectors;
- k) coordinate a working group to further discuss the details and logistics of a regional food borne disease surveillance network in Asia and the Pacific;
- l) invite member countries of the Asia and Pacific region to designate their representatives in the initial electronic working group on fbd surveillance;
- m) provide continued capacity building assistance to member countries in all aspects of fbd surveillance to ensure the timeliness, accuracy, and relevance of the data that is collected.

49. The Conference recommended that the Working Group on fbd surveillance should:

- a) clearly define the objectives of the fbd surveillance network;
- b) develop a survey to be completed by the member countries of the region which identifies the existing fbd surveillance data in the region and the capacity of each country to conduct fbd surveillance;
- c) evaluate the fbd surveillance systems and information currently available within and outside the region and take into account their strengths and weaknesses in designing the regional fbd surveillance network;
- d) determine the priority food borne diseases in the region and the format and type of data which should be collected regionally.

50. The Conference recommended that the fbd surveillance network should:
- a) recognise the importance of linking fbd surveillance data with food contaminants data in order to effectively reduce the burden of food borne diseases;
  - b) prioritize fbd surveillance initially, with inclusion of contaminant monitoring data and its linkages to disease once the fbd surveillance network is functioning adequately.

#### **XIV. ADOPTION OF THE REPORT**

51. The Conference discussed and adopted the report, agreed that it would be a public document and requested the Secretariat to publish it through the usual channels.

52. The Conference agreed to forward the report as an information document to the 27th Session of the Codex Alimentarius Commission (Geneva, 28 June to 3 July 2004) and to the Second FAO/WHO Global Forum of Food Safety Regulators to be held in Bangkok 12 to 14 October 2004.

#### **XV. CLOSING OF THE CONFERENCE**

53. The Conference expressed its warm thanks to the Government of Malaysia for the efficient organization of the Conference and for its generous hospitality. The Conference also expressed its appreciation to FAO and WHO for organizing the Conference. The Chairperson then closed the Conference.

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## ANNEX 2

**FAO/WHO Regional Conference on Food Safety for Asia and the Pacific**

Report of the First Preparatory Meeting  
FAO Headquarters Rome, Wednesday, 29 April 2003  
14.00 hours, Malaysia Room (B-227)

**Introduction**

The first preparatory meeting for the FAO/WHO Regional Conference on Food Safety for Asia and the Pacific was held at FAO Headquarters on 29 April 2003. The meeting was attended by all invited countries (those that have a representation in Rome) in the Asian and Pacific region other than Kazakhstan, Myanmar, New Zealand and Sri Lanka (see List of Participants in Annex 1\*). Mr Hartwig de Haen, Assistant Director-General, FAO Economic and Social Department, welcomed the delegates on behalf of FAO and WHO and emphasized the importance of sharing concerns and working together to improve food safety in the countries of the Asian and Pacific region.

Mr de Haen recalled the first Global Forum of Food Safety Regulators held in January 2002, the Pan-European Conference on Food Safety held in February 2002, and the upcoming second Global Forum to be held in 2004. The advice of the 123rd Session of the FAO Council on convening other regional food safety conferences, the recommendation of the 13th Codex Coordinating Committee for Asia, and the expression of interest from Malaysia in hosting a regional conference on food safety were also noted. In light of this background, FAO had convened this meeting to seek confirmation from the countries of the region of their interest in convening such a conference, receive guidance on the content and organizational aspects of the conference, and to discuss funding for the event. WHO will also be holding a similar meeting with the permanent missions to WHO in Geneva in May or early June 2003.

**Confirmation of interest in holding the Conference**

The delegates expressed general support to the proposal of convening a regional conference, welcomed the opportunity to discuss the matter, and expressed appreciation for the offer of the Government of Malaysia to host the proposed Conference. The meeting provided ideas to the Secretariat for containing the cost of such a Conference and offered in-kind and budgetary contributions to reduce the overall cost (see item 8 in this report and revised budget in Annex 4). The delegates expressed their desire to creatively overcome the remaining financial needs of the Conference. The countries will be notified by the time of the Codex Alimentarius Commission meeting in late June 2003 whether adequate funding for the Conference has been secured by the Secretariat.

**Discussion of working document***1) Objectives of the Conference*

The meeting emphasized the importance that the Conference takes into account the guidance of the FAO Council and yields practical results and capacity building actions that

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\* Annexes of both preparatory meeting reports are available from the Conference website at: [http://www.foodsafetyforum.org/asian/preparatory\\_en.asp](http://www.foodsafetyforum.org/asian/preparatory_en.asp)

governments can utilize, but not necessarily make policy recommendations, as this would duplicate the objectives of other fora such as the Codex Alimentarius Commission.

The objectives of the Conference were revised as indicated in Annex 2.

## 2) *Conference draft agenda and timetable*

The meeting discussed the proposed themes and offered suggestions for amendments and re-structuring. The revised themes are included in Annex 2. The meeting agreed that these revised themes should be re-circulated along with the report of the preparatory meeting to all governments of the region for comments. Once the list of themes is finalised, countries of the region will be consulted for the preparation of the relevant papers, on a voluntary basis. In addition, the secretariat will identify consultants to prepare some of the theme papers.

The meeting discussed the format of the Conference. The consensus was to have four plenary presentations by governments/consultants on four main themes including the listed sub-points under each theme. Any theme(s) included in the list but not addressed in the plenary sessions should be covered through information documents, including any related prior publications. Papers could be written jointly by more than one country and could also be contributed by NGOs.

Conference Room Documents (CRDs) addressing the national situation in relation to the themes of the Conference could be prepared by the countries of the region. These documents could be made available to participants prior to the Conference. Countries could also have side events or poster stands to present examples of programmes and actions implemented to address specific food safety issues. Informal meetings, not supported by the FAO/WHO secretariat, could be held before and/or after the three-day conference, if desired.

The meeting expressed general support to the proposal of convening two working groups. The two working groups could each cover two issues, one in each session. Accordingly, practical action points for all four main plenary themes could be developed in the working groups. Ideally, two representatives from each country would participate in the Conference so that all countries could contribute to the working group discussions.

In discussing the selection of themes for the working groups, the meeting agreed that such themes should provide opportunity for countries to establish concrete proposals for actions at the national and regional level to improve food safety. The meeting considered that these themes: “C) Prioritization and coordination of capacity building activities” and “D) Information exchange, education and communication” provided such opportunity.

The meeting considered that issues such as consumers’ rights, increased consumer awareness, and producer obligations need to be implicitly addressed in the themes.

## 3) *Participants*

The delegates attending the Conference should represent both the technical and policy aspects of national food safety systems. Representatives should be senior enough to influence policy decisions, yet still near to the practical application of food safety measures.

The meeting agreed to open the Conference to delegates from countries outside the region, as observers. Only FAO recognized (international) NGOs should be allowed to participate as observers, while national NGOs can participate as part of their country's delegation. ASEAN and other relevant regional inter-governmental organizations should be invited to the Conference as observers.

A limit of five delegates/country and two observers per observer country/organization was suggested. The total number of official participants at the conference should not exceed 200. For Malaysia, in addition to the five official delegates, some 100-150 persons would be able to attend as observers.

#### 4) *Languages of the Conference*

The meeting considered the cost reduction and logistical aspects of holding the Conference in English only. Some delegates highlighted the importance of enabling full participation of all countries of the region. The delegate from China indicated that he could not make any official comments on the issue of languages of the Conference at the meeting, and that he would contact his government for its instruction on this issue (no Chinese).

#### 5) *Documentation*

Australia is willing to contribute towards document preparation and speakers on the themes: A) Food safety legislation scientific, risk based approaches to harmonization and B) Application of risk analysis in food control challenges and benefits or E) Food borne disease monitoring and surveillance systems. Japan also expressed its willingness to contribute intellectually to the Conference preparation. The secretariat will approach all countries of the region to ask for their contribution of documentation.

#### 6) *Duration, date, and place of the Conference*

The meeting agreed that the Conference would be held in Malaysia. The specific responsibilities of the host country need to be clearly outlined in the "Memorandum of Responsibilities" which will be prepared by the Secretariat.

Malaysia proposed to hold the meeting in Kuala Lumpur from 25 to 27 May 2004 for a three-day conference, or from 24 to 27 May 2004 for a four-day conference. The fourth day could be necessary should the meeting be held in two languages which would require translation of the draft report.

#### 7) *Timetable of preparatory actions*

See Annex 3.

#### 8) *Support required*

Annex 4 provides a revised budget estimate which takes into account proposals made by the participants to contain the conference cost. The Secretariat will contact potential donors to seek their support to fund the Conference.

It was emphasized that in addition to direct financial support, countries could provide (i) temporary secondment of personnel to assist with conference preparation, (ii) support

through document writing, or (iii) direct support for the travel of delegates from low income countries.

Malaysia offered to provide for the printing of documents at the Conference (estimated cost US\$500) and the local expenses of meeting rooms, equipment, coffee breaks, hostesses, hospitality, local transportation (not accommodations) which is estimated to cost US\$65,000-70,000. Malaysia agreed to try to arrange for lower cost accommodations for Conference participants. Malaysia also offered to provide a liaison officer prior to and during the Conference, with the officer most likely located in Malaysia rather than Rome during the Conference preparations. Participants in the preparatory meeting expressed their appreciation of these offers by Malaysia.

Other countries also offered in-kind support for preparation of documentation for the Conference, as previously noted in the report.

It was recommended that middle income countries could support the travel of one or two delegates from at least one low income country of their choosing or through the arrangement of the Secretariat.

### **Other matters**

The meeting recognised the importance of prior preparation at the national level to enhance the quality of the participation of the countries at the Conference. To facilitate this, it was suggested that a circular letter be sent to FAORs/WHORs in the region to seek their active facilitation of the preparatory process (i.e. workshops/meetings). This should involve all government institutions and NGOs engaged in food safety at national level. To adequately prepare the delegates and identify Conference Room Documents that could be prepared by each country, these workshops/meetings would best be held approximately six months before the Conference, i.e. October - November 2003. FAO/WHO would likely not be able to fund such workshops/meetings; however, FAO/WHO officers travelling in the region could be encouraged to attend such events.

It was suggested that the next session of the Codex Alimentarius Commission (Rome, 30 June – 7 July 2003) and the preparatory meeting for the Second Global Forum (Rome, 8 July 2003) would provide a good opportunity for holding a second preparatory meeting with the permanent representatives and national food safety officials that will also be attending those meetings.

The meeting was closed at 16:40 hours on 29 April 2003.



## **FAO/WHO Regional Conference on Food Safety for Asia and the Pacific**

Report of the Second Preparatory Meeting  
FAO Headquarters Rome, Thursday, 3 July 2003  
14.30 hours, Malaysia Room (B-227)

### **Introduction**

The second preparatory meeting for the FAO/WHO Regional Conference on Food Safety for Asia and the Pacific was held at FAO Headquarters on 3 July 2003. The meeting was attended by 26 participants, representing 14 countries of the Asian and Pacific regions (see List of Participants in Annex 1). Mr. Hartwig de Haen, Assistant Director-General, FAO Economic and Social Department, welcomed the delegates on behalf of FAO and WHO.

Mr. de Haen recalled the advice of the 123<sup>rd</sup> and 124<sup>th</sup> Sessions of the FAO Council on convening regional food safety conferences and the expression of interest from Malaysia in hosting such Conference. The main outcomes of the first preparatory meeting were highlighted including: general support to convene the proposed Conference; appreciation for the offer of the Government of Malaysia to host it; ideas to contain the cost; and offers of in-kind and budgetary contributions to reduce the overall cost of such Conference. The recommendation of the 124<sup>th</sup> FAO Council to hold the proposed Conference in the official languages of the region (Chinese and English) was also noted.

### **Themes of the Conference**

The meeting emphasized the importance for the Conference to allow for the exchange of experiences and information among the countries of the region on tangible food safety issues and to lead to the development of a practical action plan for overcoming the actual difficulties and problems that countries of the region are facing in improving their food safety systems. Some delegates noted that themes which result in actions that can be more readily implemented at a lower cost, such as “(C) Prioritization and coordination of capacity building activities”; “(D) Information exchange, education and communication” and “(E) Food-borne disease monitoring and surveillance systems”, should be given higher priority than those of a more theoretical nature. It was noted that the envisaged outcomes of each Conference theme should be considered when preparing each paper. In order to contain Conference costs and foster a sense of regional ownership, it was agreed that the countries of the region, rather than outside consultants, should prepare the papers for the Conference. Countries of the region are encouraged to submit Conference Room Documents (CRDs) on specific issues of national interest (for instance the issue raised by the Iranian delegation on the impact of pesticide application equipment on the safety of food crops) that are related to the themes of the Conference. Countries are encouraged to offer to take the lead on document preparation or contribute to any of the themes which are not indicated to have a lead contributor.

It was agreed that issues of consumers’ rights, increased consumer awareness, and producer obligations should be explicitly addressed within all of the relevant themes.

#### **A) Food safety legislation- science and risk based approaches to harmonization**

Australia agreed to prepare this paper and will lead its presentation at the Conference. This paper will focus on sharing experiences of practical aspects of implementing and enforcing food safety legislation in order to assist other countries in building their own food safety laws. The paper will focus on the importance of harmonizing national legislation, which may eventually lead to regional harmonization and equivalence, all of which are important issues to the region. This paper should also include aspects of consumer’s rights and consumer participation. The inclusion of the risk-based aspects of food safety legislation

in this paper will complement, but not duplicate the separate paper on the application of risk analysis in food control.

This paper could offer a short review of the status of food safety legislation in other countries of the region, but should not be comprehensive of all national food laws. Countries would be encouraged to share their experiences in this regard through the submission of Conference Room Documents (CRDs).

The economic impact of food safety legislation will be covered briefly in the paper and can be presented in more detail in a separate background document. The Organization for Economic Cooperation and Development (OECD) has prepared numerous reports on this subject in recent years, some of which could be used for this purpose.

It was suggested that information on the legislation required for products at the food/drug interface could also be addressed in this theme. The Secretariat informed the meeting that pending the approval of the 26<sup>th</sup> Session of the Codex Alimentarius Commission (CAC), FAO/WHO are planning to hold an Expert Consultation on “Functional Foods”. The report of such Consultation, which is intended to include legislation aspects of “functional foods”, could be used as a background document for the Conference.

B) Application of risk analysis in food control - challenges and benefits

Australia agreed to prepare this paper and lead its presentation at the Conference. As the need for risk analysis is well known, this paper should instead focus on the practical actions needed to overcome the problems of applying risk analysis in less developed countries.

C) Prioritization and coordination of capacity building activities

India tentatively offered to take the lead in writing this paper, with support from the Conference secretariat. This paper should briefly refer to the benefits and drawbacks of each of the different aspects of food control systems and ways that countries can evaluate their own capacity building needs. FAO has issued a report on a survey conducted to assess countries' capacity building needs, which is included as an annex to paper CAC/26 INF/5. This report could be used as an aid in preparing documentation for this Conference theme. FAO and WHO are considering the convening of a technical consultation on capacity building in response to the request made by the CCASIA at its 13<sup>th</sup> Session. The results of this consultation could also be used as an input for this paper.

Some countries also mentioned specific aspects of capacity building, such as inspection/certification of fresh agricultural produce they would like to have addressed in this paper.

D) Information exchange, education and communication

The meeting noted that information exchange both within and between countries should be addressed in this paper. It was suggested that the paper should include practical examples of national success stories. The paper could also include practical information on successful education programmes such as food safety for small and medium scale producers and the street foods sector. It was suggested that, as part of the action plan for this Conference, the countries of the region could agree to establish a rapid alert system to notify other countries of food borne disease outbreaks.

While recognizing that Japan has not offered to prepare a paper, the Secretariat will communicate directly with Japan regarding the possibility that they would write this paper.

E) Food borne disease monitoring and surveillance systems

The meeting agreed that the WHO Western Pacific and South-East Asia regional offices could jointly prepare this paper with the input of the countries of the region. The paper could focus on the availability and/or the establishment of a regional food borne disease reporting and statistical information centre. As part of the Conference action plan, delegates could commit their countries to disease reporting in order to provide information on the nature and frequency of food borne disease outbreaks and facilitate control actions. Countries would need to come to the Conference with a commitment to contribute to the reporting efforts if this action item is to be successful. Public health preparedness, as well as surveillance was also noted as an important aspect of this theme.

The themes and sub-points of the Conference were revised as indicated in Annex 2.

### **Conference timetable and format**

The meeting agreed that the Conference should include five plenary presentations by governments on the five main themes including the listed sub-points under each theme. The meeting confirmed its support for convening two concurrent working groups, each with multi-disciplinary representation. In discussing the selection of themes for the working groups, the meeting agreed that such themes should provide opportunity for countries to establish concrete proposals for actions at the national and regional level to improve food safety. The meeting considered that these themes: “C) Prioritization and coordination of capacity building activities” and “D) Information exchange, education and communication” provided such opportunity. However, the themes to be discussed in the working group sessions can be finalized based on the discussions held in the plenary sessions.

The dates of the Conference were confirmed as 24 to 27 May 2004. Malaysia has offered to organize events on the third day of the Conference for those participants not involved in report writing.

Annex 3 provides a revised timetable for the Conference.

### **Budgetary matters**

Some countries indicated that it would be logistically difficult for them to support the travel of low income countries.

Malaysia agreed that it would pay up to \$5000 for printing costs, while the estimated budget for printing is \$500. The Secretariat will further discuss local expenses directly with Malaysia.

The costs of the Conference will be relatively low, especially because the countries will be providing the cost of document preparation. FAO/ WHO will provide for direct staffing costs through regular programme funds, but the other costs for an event such as this should be provided by extra-budgetary resources. The Conference Secretariat will determine by September whether adequate financial support has been secured to hold the Conference. Countries are encouraged to share ideas they have for donors as no offers of direct financial support have been made to date.

## **Other matters**

It was noted that Permanent Representatives with e-mail access would prefer to receive documents by e-mail rather than post to increase the speed at which countries receive documentation for the meetings.

The “Memorandum of Responsibilities” will be forwarded to Malaysia once it has been finalized within FAO, and will indicate that the commencement of the Conference is conditional upon receiving adequate funding for the Conference. The list of countries to be invited to the Conference, which will be included in the Memorandum of Responsibilities, was made available as an informative document at the meeting and is attached as Annex 4.

The meeting confirmed their willingness and political support for this Conference, although additional financial and in-kind support for the Conference is still required.

The meeting was closed at 16:40 hours on 3 July 2003.

**ANNEX 3**  
(CAP 04/1)**FAO/WHO Regional Conference on Food Safety for Asia and the Pacific**  
*Hotel Royal Adelphi, Seremban, Malaysia, 24-27 May 2004***Provisional Agenda**

<b>Agenda Item</b>	<b>Subject matter</b>	<b>Document Reference</b>
1.	Opening of the Conference	
2.	Election of Officers	
3.	Adoption of the Provisional Agenda and Timetable	CAP 04/1
4.	Keynote address	CRD
5.	Food safety legislation – science and risk-based approaches to harmonization	CAP 04/2
6.	Application of risk analysis in food control – challenges and benefits	CAP 04/3
7.	Prioritization and coordination of capacity building activities	CAP 04/4
8.	Information exchange, education and communication	CAP 04/5
9.	Food-borne disease monitoring and surveillance systems	CAP 04/6
10.	Other matters	
11.	Adoption of the Report	

**WELCOME REMARKS BY**

Dr Abd. Rahim bin Hj Mohamad, Director of the Food Quality Control Division, Malaysia  
on behalf of  
Y. Bhg. Dato' Dr Shafie B. Ooyub  
Deputy Director General (Public Health)  
Ministry of Health, Malaysia

*Distinguished delegates, ladies and gentlemen,*

First and foremost, on behalf of the Government of Malaysia and the Ministry of Health Malaysia, I would like to extend our warm welcome to all distinguished delegates. It is indeed a great honour for Malaysia to be selected as the host for this Regional Conference, which is part of a series of regional meetings that FAO and WHO is convening to meet the needs of member countries for policy guidance and capacity building. This Conference is in line with the recommendations of the "First FAO/WHO Global Forum of Food Safety Regulators" held in Morocco on 28-30 January 2002 and the 13<sup>th</sup>. Session of the Codex Coordinating Committee for Asia held in Kuala Lumpur on 17-20 September 2002.

*Ladies and gentlemen,*

We are all here today because we share the same goal, which is improving food safety and protecting public health. We are all working towards achieving the same objective, no matter how different is our thoughts or approaches. In this regards, I can safely say that we are all allies in this struggle and the enemy are the microorganisms and other food hazards.

*Ladies and gentlemen,*

I think most of us here today understand that "safety" does not mean "no risk". It is simply not feasible to identify every possible adverse effect of a food product. Analyzing safety often means the judicious weighing of the benefits as well as the risks. To do this we must identify and assess the risk associated with a food product, work to eliminate or minimize those risks and communicate risk information to all relevant stakeholders. This can be aptly summarized by the following saying/cliché "**All substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy**"

It must also be emphasized that the price of not taking adequate actions or any single mistake in ensuring safety can be catastrophic, as can be seen by recent incident of food contamination by dioxin and BSE. Every food borne outbreak can be an economic disaster not just to the company that produce the products associated with the outbreak but to the entire industry and affecting the whole country. This is because most of the public do not differentiate between lot numbers or even brands. With the stroke of a brush, the public will blacklist the entire industry and not just the brands or lot number.

*Ladies and gentlemen,*

As we are all aware, food safety is a global issue that demands a global response. Many of the food safety issues we faced domestically are also shared throughout the world. Diseases and pathogens do not respect national borders. As such, regional and international

collaboration is critical in developing effective solutions. Therefore in addition to our efforts to develop partnership within our domestic food chain, it is also important to establish a variety of working regional and international cooperation to exchange information and to learn from each other's experiences for the mutual benefits of all.

However, keeping up with such developments and adopting or adapting the new ways to prevent and to respond to new hazards require tremendous political commitment and effort from all stakeholders, especially developing countries that do not have adequate resources or capacity but depend on food export as a source of foreign earnings.

*Ladies and gentlemen,*

In this regard, this Regional Conference provides us with an appropriate forum and the opportunity to discuss food safety issues of common interest and promote the exchange of information and learn from each other experience to further improve food safety.

It is also important to note that such conference can provide the impetus for further collaborative effort in the area of food safety, especially in building alliances for capacity building and scientific cooperation. Such alliances, I am sure, will facilitate the pooling of resources and expertise to achieve results faster and greater than it could have been achieved alone. It will also allow expertise to be drawn internally, regionally and internationally

In closing, I would like to thank all of you for your interest in this important area of food safety and I look forward to an active and open discussion on all the themes of this conference with all of you in the next few days. Last but not least, I would also like to take this opportunity to wish all delegates an enjoyable stay in Malaysia.

**OPENING REMARKS BY**

Mr Hartwig de Haen  
Assistant Director-General, Economic and Social Department  
Food and Agriculture Organization of the United Nations

*Excellencies, honourable guests, distinguished delegates, ladies and gentlemen,*

It is my pleasure to welcome you on behalf of the Food and Agriculture Organization of the United Nations to the FAO/WHO Regional Conference on Food Safety for Asia and the Pacific. This Conference is part of a series of regional conferences that FAO and WHO are convening to provide a forum where food safety officials from the region can get together to share information and experiences on how the safety of foods may be improved.

The present Conference is being held in line with the recommendations of the First FAO/WHO Global Forum of Food Safety Regulators in Marrakech, Morocco in January 2002 and in preparation for the forthcoming Second Global Forum to be held in Bangkok, Thailand from 12 to 14 October 2004.

I would like to emphasize a few concepts that are fundamental to the success of this Conference: first, the critical importance of food safety; second, the challenges to improving food safety; and third, the practical actions that are being taken by FAO and other partner agencies to promote food safety.

**The importance of food safety**

- Ensuring safe and healthy food is an important precondition of food security. It is essential for improving human life in all countries, whether developed or developing.
- The World Food Summit, organized by FAO in 1996, recognized that access to safe food is in itself an element of food security. Rather than being a luxury of the rich, all people should have the right to an adequate supply of safe, nutritious food.
- The costs incurred in each outbreak of food borne illness include a number of direct and indirect costs. In developed countries, the average estimated cost is US\$100/person/year and the cost could be even greater in developing countries. The death toll of food borne illnesses is staggering: just diarrhoea caused by contaminated food and unclean water kills 1.8 million people per year.
- Practices aimed at improving food safety also reduce food losses, thus increasing food availability. A number of advanced technologies and practical control measures are available for countries to improve the safety of food, thus extending its usable life.
- Countries of the region are well aware of the importance of food safety for both exports and imports. For example, the detection of chloramphenicol residues in products shipped to the EU caused a recent ban on seafood and poultry imports into the EU, which cost one Asian country \$335 million of lost exports opportunities.



## Challenges to improving food safety

Despite these well-known and important reasons to improve food safety, the increased global knowledge and availability of advanced tools and technologies to improve food safety, many challenges remain. Let me mention just five:

- 1) Implementing standards often increases costs for food producers and processors and may force some suppliers out of business.
- 2) The benefits of aiming for completely safe food, i.e. food with “zero-risk”, should be balanced against the loss of competitiveness through the often high cost involved.
- 3) Individual countries are often unable to respond to food safety in emergency situations unless these are integrated in a regional cooperation network.
- 4) There is a widespread lack of consumer awareness for food safety which countries need to address through adequate communication and education policies.
- 5) The capacity of many countries to implement food safety measures and to monitor food borne diseases is inadequate.

There could not be a more timely confirmation of the relevance of concerted action, than the two events that hit the media headlines during the last two days. One is the Salmonella contamination of raw Almonds detected in California which resulted in the recall of large quantities from the market including quantities already exported into the Asian region. The other event is the death of 25 to 40 people in Kenya. Although we have no confirmation, the media report about the suspicion that these have been caused by consumption of Maize heavily contaminated by Aflatoxins.

This Conference is just one example of FAO’s efforts to improve the safety of our food throughout the world and specifically in the Asia and Pacific region. And there are good reasons for this region to address food safety risks particularly. Let me mention just three:

### 1) **Rapid urbanization**

With the rising number of people living in (mega) cities, people eat more processed food, marketing chains and shelf lives become longer, street food expands etc. All of this has implications for food safety.

### 2) **Trade**

The countries of the region are particularly involved in trade, both as exporters and importers. Hence, food quality and safety standards of trading partners must be respected.

### 3) **Livestock revolution**

By livestock revolution we mean the rapid expansion of consumption of animal products, particularly in this region where incomes have been growing rapidly. As a result, livestock production is growing and so are the risks of animal diseases. The vicinity of people and animals, in particular poultry, poses additional health risks.

### ***Practical actions by FAO and partners to promote food safety***

FAO is involved in many practical actions to promote food safety throughout the world. These include:

- 1) Provision of scientific advice on food safety risks by FAO and WHO to members of Codex Alimentarius.
- 2) Holding of expert consultations (often with WHO) on open issues. Recent examples include Microbial Risk Assessments, Acrylamide in foods, and the Safety Assessment of Genetically Modified foods.
- 3) FAO, WHO, OIE, WTO, and the World Bank have recently established a Standards and Trade Development Facility to coordinate the capacity building efforts of these organizations in the areas of food safety, plant, and animal health. An FAO/WHO project to assist the low income countries of Asia and the Pacific in Developing Food Standards within a Risk Analysis Framework has recently been approved for funding from this Facility and will be implemented in the upcoming months.
- 4) Manuals and Guidelines. For example FAO/WHO Guidelines for Strengthening National Food Control Systems were published in 2003. A Manual on Risk Analysis and a training package on Codex are under development.
- 5) FAO and WHO have implemented a Trust Fund for Participation in Codex to increase the participation of developing countries and countries in transition in the vital work of the Codex Alimentarius Commission.
- 6) Capacity and technical assistance. Examples include eight regional and sub-regional workshops on different food safety aspects in Asia and the Pacific in the past 3 years; and national technical assistance projects.
- 7) Food borne disease surveillance. We will discuss a new initiative for the region at this Conference. and hopefully agree on concrete steps.
- 8) Ensuring access to information. I am pleased to announce that FAO will also launch the International Portal on Food Safety, Animal and Plant Health during this Conference. This Portal will provide national governments and trading partners with access to official relevant information.
- 9) The World Health Assembly has just adopted a Global Strategy on DIET, PHYSICAL ACTIVITY AND HEALTH to address the rising burden non-communicable diseases by promoting healthy diets and lifestyles. FAO is determined to collaborate with WHO and member countries in the implementation of this global strategy which has indirect relevance for food safety.

### **Conclusion**

Countries in Asia and the Pacific have made remarkable progress in improving food security for their people and increasing the competitiveness of their food and agricultural products. These achievements need to be strengthened and expanded. Countries must also invest more in food safety, not only to enable the region to further improve its trading opportunities, but also to protect the health of their own consumers domestically.

Opportunities for regional cooperation and exchange of information at all levels must be improved. FAO and WHO have jointly convened this Regional Conference on Food Safety for Asia and the Pacific for exactly these purposes.

I want to thank you in advance for your efforts in addressing the many important issues you will face during the next four days. I wish you all the best in your deliberations and I look forward with anticipation to the results of those deliberations.

**OPENING REMARKS BY**

Dr Han Tieru  
WHO Representative for Brunei, Malaysia and Singapore  
World Health Organization

*Excellencies, honourable guests, distinguished delegates, ladies and gentlemen,*

On behalf of Dr JW Lee, Director-General of the World Health Organization, I would like to welcome you to the opening of this FAO/WHO Regional Conference on Food Safety for Asia and the Pacific and join my colleagues from the Food and Agriculture Organization of the United Nations (FAO) in thanking the Government of Malaysia for hosting us.

Food safety is of growing concern in all parts of the world, and recent events in Asia and the Pacific has shown us that our region is in no way immune from these concerns.

In all parts of the world, and certainly also in our region, a significant number of people die every year, including many children, as a result of infections they get from the food they eat.

Often in the past, these issues were only brought to the attention of the public when reports of spectacular outbreaks reached the press. This is still true to some extent, but we need to make sure that everybody understands that behind the press news on outbreaks there is a vast number of sporadic cases and small outbreaks which represent a real disease burden related to food. Many of these don't make it into reporting systems, and they certainly do not make the headlines.

In our region, WHO's general reporting system for causes of death shows that every year more than 700,000 people die from cases of food- and waterborne diarrhoea caused by microorganisms. In addition to diarrhoea, unsafe foods do also cause a number of other types of serious disease, including debilitating long-term effects of certain chemicals naturally occurring or added to foods through our agricultural production systems.

In addition, even though some of the recent public health emergencies in our region, such as Avian flu, Nipah virus and SARS are clearly not foodborne diseases, they are all in some way related to either the way food is produced or how food animals are handled.

Finally, food contamination also impacts on trade and national economies, given that trade barriers and food safety related bans result in major economic losses for exporting countries.

Therefore, there are many good reasons to look into the ways we protect public health through our food production systems and specifically our food safety systems. This Conference comes at an important point in time, and hopefully we can make a difference in moving this important issue forward also within the national priority setting.

As part of our future work, we need to make sure that the public can obtain answers to their questions about the foods they eat. The message that there is always a level of risk related to food sets the magnitude of the problem we need to tackle, but we also need to be

able to provide information about what the authorities are doing and what the public itself can do to reduce the possibility of being harmed.

We need to make sure the public understands that if you get a foodborne disease (which I believe most of us have experienced), and you are lucky, the episode may just result in some discomfort for a few days. However, this is not the sole possible consequence: you could also end up with absences from work and further incapacity, or, in a worst case situation, even death.

The outcome of foodborne disease also imposes strains on health systems and reduces economic productivity. Recent estimations from the USA suggest an annual health cost to that society of more than 6 billion dollars from foodborne disease. Such figures do not include further economic losses within production and trade systems.

WHO is the world's inter-governmental agency that specializes in human health. It helps governments, civil society, consumer groups, private entities, the media and other stakeholders, to access the best possible evidence about the possibility that foods can cause harm, and ways in which that harm can be minimized. This includes ensuring that policy responses are properly informed through surveillance systems and risk analysis, and helping to plan the right mix of information campaigns, legislation, or changes in the safety culture and systems within the food industries.

WHO adds value by helping to integrate different systems for surveillance of illnesses. Approaches to build and strengthen surveillance networks in our region will be discussed at this meeting and we hope that we will be able to move forward in these areas also.

WHO's mandate to ensure food safety calls for new, evidence-based, preventive strategies in order to lower the risk that food will cause harm. These strategies can be pursued throughout the whole "farm to table" food production chain. In other areas of the world it is getting longer than ever, while in many parts of our region the distance between production and consumption is very short: in our deliberations we should try to ensure that all our different food production systems are covered by future food safety initiatives.

This regional Conference on Food Safety is supported by WHO and FAO working together. Why? Because we need to look at the issues from a multi-disciplinary perspective! Many problems in the past stem from our inability to get all partners and government authorities with responsibility for the different parts of our food production chain to work together. We hope that the FAO/WHO link will also inspire collaboration at the national and international level between agriculture and health and other sectors.

Delegates, now is a good time to scale-up our collective efforts on food safety, initiating evidence collection and country-level surveillance and implementing effective responses, as well as ensuring that the issue is high on the political agenda. We need to share our experiences – good and bad – so that future food safety systems can improve and leap-frog over past mistakes.

I wish you a successful conference, and look forward to the outcome of your deliberations in this critical area of public health.

Thank you.

**OPENING SPEECH BY**

Honourable Datuk Abdul Latiff Ahmad  
Deputy Minister of Health  
Ministry of Health, Malaysia

*Distinguished delegates, ladies and gentlemen,*

First and foremost, let me bid all of you a warm welcome, “Selamat Datang” to Malaysia. On behalf of the Government of Malaysia and the Ministry of Health Malaysia, I would like to express my sincere thanks and gratitude to FAO/WHO for giving Malaysia the honour of hosting this Regional Conference to deliberate on this extremely important issue of ensuring food safety. It is also heartening to note the large number of delegates and countries participating in this conference, indicating the very high priority many countries, including FAO and WHO, placed on food safety

*Ladies and gentlemen,*

Today’s challenge with respect to food safety is complex and multi-dimensional. Government and public attention on food safety has increased, catalyzed by the recent events associated with food safety crisis like contamination of dioxin and mad cow disease. Globalization of food trade, rising level of economic interdependence and cultural exchanges between eastern and the western world has resulted in the gradual assimilation of taste and preferences. This has resulted in an influx of a wide variety of foods on the market. These foods are produced in high technology facilities, shipped over long distances, packaged and stored in new ways and handled at more steps, rendering more opportunities in the food chain for contamination. And Malaysia is no exception in going through such dynamic changes. Those of you who had the opportunity to visit some of our hypermarkets or supermarkets will notice you can obtain foods that are produced from many different parts of the world. In such situation, any contamination from a single source may be distributed to communities across the nation and even around the world, increasing the consequences or ramifications exponentially.

Though progress in food safety around the world over the last few decades has been phenomenal due to a large part to WHO and FAO providing the necessary leadership and guidance, I still believe **we can and we must do better**. There is still much more to be done. As the challenges to food safety continue to evolve, we have no alternative but to adapt our food safety system to meet these changing needs for the better protection of public health. And we must ensure that the food safety system is capable of responding to and preventing food borne illness and food hazards through the most effective means possible.

We must do everything we can, individually as a nation or through regional and international collaboration in developing effective solutions. Therefore in addition to our efforts to develop partnership within our domestic food chain, it is also important to establish a variety of working regional and international cooperation to exchange information and to learn from each other’s experiences for the mutual benefits of all. This I believe is especially important in assisting countries to continuously strengthen and periodically re-orientate their food safety programmes to keep-up with changes in knowledge and technology and to cope

with their new obligations and rights related to the safety and quality of food traded regionally and internationally.

*Ladies and gentlemen,*

I am sure that knowledge and experience in handling food safety issues including reducing the burden of food-borne diseases exist and should be shared, extended for the benefit of other countries or even applied globally if applicable.

Thus, it is a pleasure to note that the theme of this conference is “Practical Actions to Promote Food Safety”, aptly emphasizing the need to put in place actions that are practical and can be implemented as the best way forward in upgrading food safety. These actions must take into consideration the lessons learned from recent food safety crisis and outbreak of diseases such as bird flu and the food & mouth disease. This crisis exposes some of our weaknesses in our food safety system, both within individual country as well as between countries, helping us to determine where we should strengthen our preventive mechanisms. In other words, food safety crisis may not be all negative if we are able to learn and emerged stronger on how we can avoid any future crisis.

In this regard, conference like this provides an excellent platform/opportunity. I am also happy to see that the programme for this Conference includes the latest perspective on the following areas:-

- **Firstly, risk based approaches including the application of risk analysis**, which provides a new, science based and preventive basis for regulatory measures, both at national and international levels;
- **Secondly, food borne disease monitoring and surveillance system**, which is needed to provide reliable data on food borne diseases and linking them to food contamination, for evidence based interventions to lower their incidence;
- **Thirdly, prioritization and coordination of capacity building activities**, which is essential in strengthening food safety in the public health functions especially in developing countries; and
- **Finally, information exchange, education and communication**, which formed the basis for raising awareness, formulating strategies and building expertise necessary to improve food safety.

In conclusion, I hope delegates would be able to interact and get the best out of this conference. I would also encourage you to spend some time to enjoy and visit our beautiful country, known for its rich diversity of cultures, multiracial makeup and cuisine; and bring back pleasant memories of your stay in Malaysia.

On that note, it gives me great pleasure to officially open this “FAO/WHO Regional Conference on Food Safety for Asia and the Pacific – Practical Actions to Promote Food Safety”. I would like to wish all of you every success in your deliberations and I look forward to hearing your conclusions and recommendations on the ways by which we can collectively improve food safety in the Asia and Pacific region.

**“Practical Actions to Promote Food Safety”****KEYNOTE ADDRESS BY**

Dr Supachai Kunaratanapruk  
Secretary General, Food and Drug Administration, Thailand

Distinguished delegates, ladies and gentlemen,

I would like to thank the organizing committee for inviting me to participate in this important meeting that comes at an historic stage of food safety challenges around the world.

Undoubtedly, food safety is the prime concern of every country. More and more, the issue of food safety cannot be considered in isolation. It becomes an integral part of the development agenda. Food safety, health and economic prosperity should be recognized for their interconnection.

Outbreaks of bird flu and mad cow disease are just a few examples of the relationship between food safety and economics. Since the end of 2003, at least 100 million birds have been slaughtered to prevent the spread of the avian influenza virus. Before the avian flu, the world had experienced the outbreak of the mad cow disease. The economic loss was enough to affect GDP growth rate of the countries with these outbreaks. This kind of outbreak always gets much attention and an enormous budget to manage it.

On the other hand, some food safety issues have been under-monitored. While millions suffer from food shortages, billions suffer from microbiological and chemical food contamination having known and unknown long term health effects. The economic impact on this matter is unlikely to be calculated accurately, but think of the potential escalating number of cancer patients and the accompanied loss of productive lives. GMO foods, preservatives, colorants, flavouring agents and state-of-the-art food processing techniques are the inventions of food business that we should be proud of. However, are they definitely safe and should they require constant vigilance? I believe this Conference can help suggest future direction.

How and can issues of food safety foster health and economic development? I am an optimist; therefore, I believe the issues are not beyond our collective capability. This Conference is certainly a significant step. Nevertheless, to be realistic, there are conflicts of interest in the food safety arena that cause complications and need to be unraveled.

Food does not only feed people but is a gigantic industry too. There are countries having advantages and disadvantages from food production and trade. This fact is, thus, not supportive to promote co-ordination among countries.

Harmonization is a creative way to get countries to work together, hopefully to establish global standards for safety, food consumption and fair practice in food trade. Yet the good intentions have turned out to be technical trade barriers to those who are in the disadvantaged positions. Countries in the Asia region have faced the imposition of zero tolerance for nitrofurans and chloramphenicol. Meanwhile, beef related products from exporting countries with even one BSE case were universally barred from our countries. Do we really have enough scientific evidence that these are necessary measures to protect our



consumers' health? Such situations are not conducive for exchanging information and transparency requirement, which are the essence of good co-operation and mutual understanding among countries.

Would and could it be more fruitful and trustworthy to implement risk-based management approach? The concept does not focus merely on hazard identification, but includes exposure, tolerability and termination of the hazards. One good example is Aflatoxin. It is a known carcinogen, yet the Codex allows 15 micrograms per kilogram (ppb), given the fact that complete elimination of Aflatoxin from the food chain is impossible. I am certain that with the advanced research information we have had, it is possible to quantify the risk associated with food, and then decide. Unnecessary food safety restrictions certainly impede economic development of food exporting countries and the world as a whole, thus increasing poverty in this interdependent world.

In addition to the implementation of the risk-based approach, I would urge participating countries to share or develop an "Inter-country Alert System" besides the local alert system each country may already have had. Such system would be beneficial as a platform to prevent crisis at the possible earliest stage. Bird flu outbreak is a very good example of the important of good warning and surveillance systems. However, this can only be true when trust and fairness are well established.

There is one fundamental fact, food and water borne diseases are still prevalent in developed countries and even worse in developing countries. The poor is the most vulnerable group. Consequently, food safety should not be aimed only at exports. Each single citizen has the right to access and consume safe food. Therefore, safe food should be available to them. While the HACCP concept has been successfully implemented in factory-scale production, "Good Hygienic Practice" should be equally enforced (or implemented in parallel). In Thailand, village-scale food production accounts for at least 30% of the total production. It is the obligation of food regulatory agencies to assure the public that small-scale production is as safe as the large-scale one.

Adapting modern technologies to suit local production is what developing countries lack. Mobilizing evidence-based research and practice in the area of production should be one main issue of capacity building activities to be discussed at the Conference. We faced difficulties when the Thai government applied the "Dual Track" Policy – encouraging foreign investment while promoting small and medium enterprise that utilized embedded indigenous skills. Village-level food producers cannot meet the GMP or HACCP requirements without huge investment of high cost technology. If the gap did not exist, our Thai local food producers could contribute more to our economy. However, from that experience, we have come to realize that the most appropriate technologies are not necessarily the expensive ones. Hence, SME can also produce safe food at an affordable cost.

Food is basically an agricultural product. Therefore, improving the agricultural standard is a key to the success of food safety. The so-called "Farm-to-fork" or "Good Agricultural Practice" concepts should be extensively and rigorously implemented, provided that it is not "High-technology Agricultural Practice".

Effective consumer education on food safety is another important activity. I would like to emphasize. Food safety should not be considered on the supply side only, but simultaneously improving the demand side should also be targeted. Responsible authorities

cooperating with all related organizations in each country have a duty to improve consumers' knowledge on food safety.

In order to advise consumers on how to select and buy safe food for themselves and to increase consumer awareness on food consumption, information and education should be provided to the public through the different media such as, television, radio, leaflets, pamphlets, and newspapers. A lesson on food safety should also be incorporated into the curricula at every education level. Additionally, hygienic practice in food preparation processes should be also focused on consumers and poor consumption behaviours among those preferring to consume raw or undercooked food needs to be changed.

As a whole, capacity building for all personnel involved in each step of food processing plays an important role in food safety achievement. Unfortunately, we have gaps in bridging the theory, attitude and practice in all levels: officers, producers, distributors, retailers and consumers. This issue is worth considering for our way forward in actions and future collaboration.

Agencies responsible for food safety are in charge of sorting out optimum policy on food: legislation, control strategy, enforcement mechanism, private-public co-operation, research, education and public relation. Food safety policy should not be marginalized as "food only" issue. Food safety deserves the recognition of its health and economic consequences.

"Safe food for all" is the constitutive part of world development. The available resources countries now have could be more than enough if concerted attempts with an holistic approach could be established under a sincere atmosphere. I would like to pay tribute to the Food and Agriculture Organization of the United Nations and the World Health Organization for their relentless efforts to accomplish their missions.

Distinguished guests, ladies and gentlemen, I hope that this Conference is an auspicious starting point. I urge all participants to work together and bring about a better level of food safety in the countries of the Asian and Pacific region.

Thank you for your kind attention.

## ANNEX 9

**KEYNOTE ADDRESS BY**

Mr Neil Macleod  
Programme Manager, New Zealand Food Safety Authority

New Zealand has developed a new agency to regulate food safety, and new legislation to implement risk management in food production, processing and export. The Food Safety Authority commenced work on 1 July 2002, bringing together regulatory functions previously administered in the Ministry of Agriculture and Forestry (MAF) Regulatory Authority (later known as MAF Food Assurance Authority), and the food aspects from the public health area of the Ministry of Health.

This paper attempts to present some of the solutions New Zealand has developed and implemented to manage some of the issues and challenges which participants at this Conference are outlining in detail. This is done not to prescribe these elements as solutions for others, but to give the reasons and outcomes experienced in one of the region's member countries.

**The New Zealand angle**

New Zealand was asked to address issues from the perspective of a “developed” country. This may not be completely appropriate. New Zealand, like many represented at the Conference, has a heavy reliance on land-based production and fishing. It has a tiny population, and the main industry is primary production. It therefore shares many of the concerns of other agricultural or fishing economies from around the region.

Words heard frequently from New Zealand regulators in discussing food safety include:

- the need to manage risks, using only appropriate regulation (rather than applying measures without full justification);
- the separation of roles in the regulatory pyramid – regulator, auditor, and producer;
- recovering costs of regulation from those regulated – the food industry;
- performance- or outcome-based measures;
- links to foreign markets.

Legislation is designed specifically to ensure there is public confidence in a safe food supply, clear accountabilities for each of the players, and – unusually in food legislation – the need to ensure proper access to foreign markets, reflecting the fact that so much of the food produced in New Zealand is exported. Details on the NZFSA web-site ([www.nzfsa.govt.nz](http://www.nzfsa.govt.nz)) set out the regulatory relationships, and the roles of the government as standard-setter, a separate layer of audit, and the group with the prime role in ensuring food safety, the food industry itself.

**The external dimension**

As a food trading country, New Zealand has an interest knowing what a trade partner's food safety measures are designed to achieve: are they justified, and are they fairly applied? And do they achieve the stated purpose: protecting consumers' health? Because so

much of the food produced in New Zealand is exported, there is almost a double obligation on New Zealand regulators and industry. Consumers at home must be able to access safe food, but overseas consumers also have the power, through any rumour of problems, to shut down New Zealand food exports to that market, or even further afield. New Zealand's export food standards are high because food is pursued as a serious business for the whole country.

### **Managing risks: legislation**

A practical example of how New Zealand has implemented risk management is offered in the Animal Products Act, in force from 1 November 1999. Its objectives are clearly expressed: to manage the risks to human and animal health from animal material and products, and to facilitate market access. Its scope includes all animal material (except human), with milk and milk products to be included from later in 2004. There are similar programmes in the remaining parts of New Zealand legislation which cover the other food items, although some of these are still voluntary in application.

The risk management system comprises mandatory risk management programmes implemented at the company level, regulated control schemes to achieve consistency across a number of operations (such as the national chemical residues or microbiological survey programmes), official assurance provisions for certification, and clearly defined duties for all involved in food businesses including registration of exporters who may not be food producers themselves, and with high penalties for those who might operate outside the law. The risk management programmes are documented systems drawn up by the food business, independently evaluated and – if acceptable – registered by NZFSA. It has to show how all the known biological, chemical and physical hazards are identified and the associated risks are managed. It also extends beyond well-known hazard analysis and critical control point (HACCP) principles. This can include cover of issues of wholesomeness where the food has to meet consumer expectations or exhibit truth in its labeling. The desired outcome is that the product is fit for its intended purpose – which may not always be for human consumption, given the range of possible products derived from animals.

### **Issues in food safety regulation in New Zealand**

In an evaluation of the risk management programmes, it should be noted that they have only started with effect from 1 November 2000. While all new operations must be within the ambit of the 1999 Act, some previously existing businesses still apply transitional arrangements. There are indications that some of the more traditional operations have no great drive to use the new provisions; some prefer the old system where their activities were prescribed by central government. As the larger operators make the transition, there remain smaller operators who clearly have problems with the degree of documentation involved in the risk management programme style. For them, it may be necessary to make more use of templates to help guide their compliance with the Act. Undoubtedly those wanting to innovate find that the freedom to develop their own style of managing the risks peculiar to their operation or product line make good use of the flexibility which the Animal Products Act offers. NZFSA is still to some extent guided by the concern that if too much is done for the operators, they lose their incentive to think through for themselves what food safety objectives their business is trying to attain, and are less likely to comply with the law.

With so much of New Zealand food's traded, the issues that become evident in relationships with overseas counterparts are quite starkly evident. NZFSA, while welcoming visits from overseas counterparts to see that the food safety system which NZFSA implements

actually functions as intended, is less sure that a useful purpose is served by overseas agencies which appear to think they need to visit New Zealand factories and approve them as suitable to export. NZFSA sees this as an appropriate role for New Zealand, and feels that an overseas “snap shot” impression from a one-day visit might well not be the best basis to assess ongoing management of food safety.

Another issue that is of concern is fraud involving fake New Zealand certificates or product labels. Among the measures developed to help counter this is a system (in which Australia is now also active) of establishing secure electronic certification for exported food products.

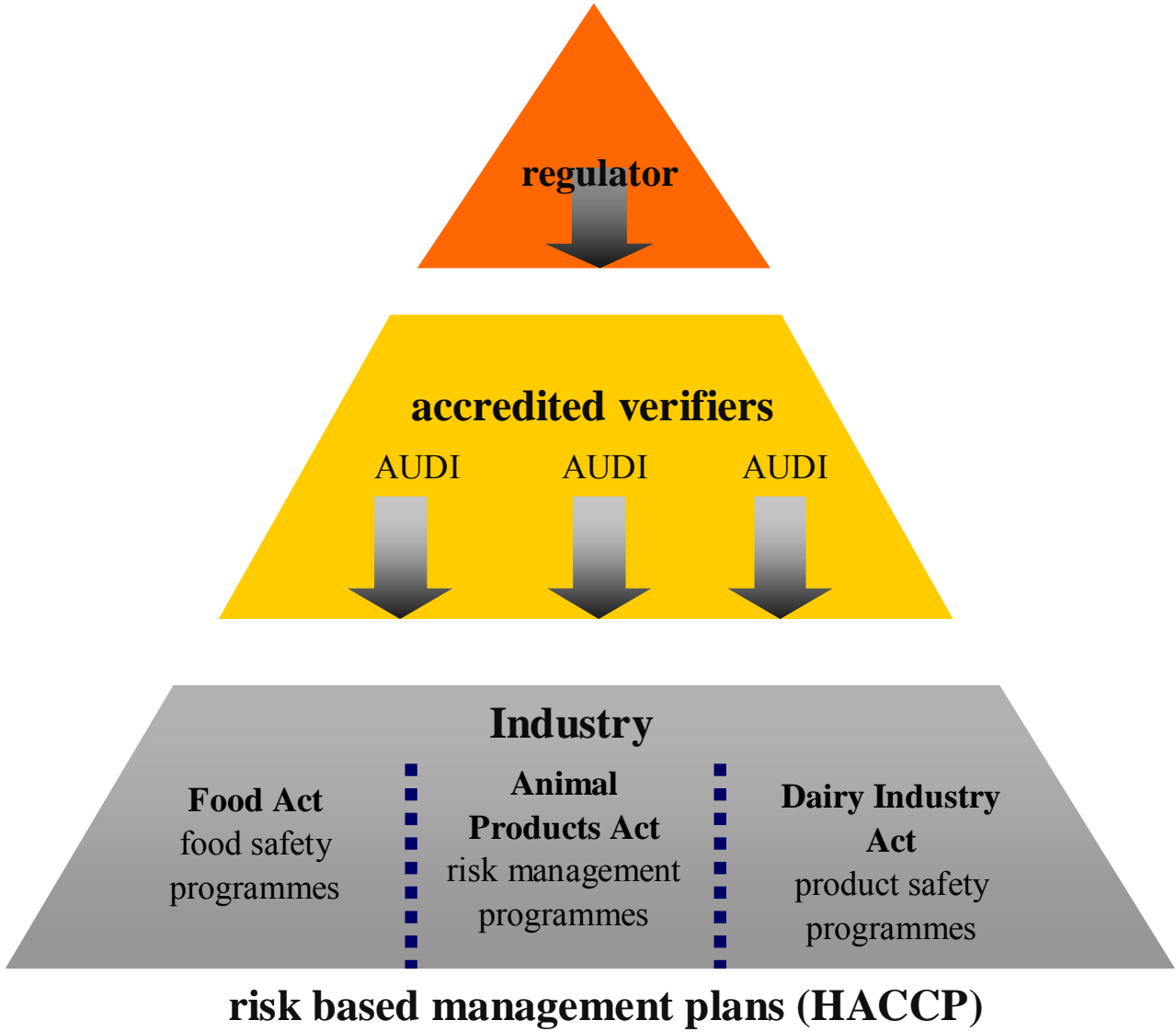
In common with other countries, there are still occasions when the number of various agencies NZFSA has to deal with in a particular trade partner can hinder smooth resolution of any issues. But New Zealand too has biosecurity authorities to handle animal and plant health concerns and NZFSA for the human health components of imported food. Consistency in application of SPS measures by overseas counterparts is not always evident. There is sometimes no apparent reference to international standards (or justification of divergence from these), nor even to previous decisions made on similar import proposals. The conclusion can be drawn that reasons such as farmer or local production are enjoying protection, rather than the expected focus for food safety measures: human health.

Experience in food trade leads NZFSA to suggest that there may be some simple tools which overseas regulators could apply when risk analysis principles would normally be called for. There can be qualitative assessments made. For instance, does the exporting country already send similar products into the market with no food safety issues? Are there exports to other “benchmark” markets with suitably rigorous import regimes (eg like the EU or US)? Is the product being exported from eg a different species of animal but subject to the same regulatory system in the exporting country?

Some trade partners argue that they must apply the same measure to all exporters equally, but this ignores the WTO SPS Agreement provisions for recognising that two countries can conclude that measures in place are equivalent without necessarily following every detail of the other’s legislation, and still achieving the desired food safety outcome. It can also be claimed that there has to be reciprocity in these “special” deals. That is not usually the case. In many instances the trade in food will be one way, and the balance comes from the fact of the trade itself: one partner wants to sell, and the other wants to buy.

In all these regulatory relations, whatever form is chosen, there can be no assurance of food safety unless there is a basis of trust: that the industry has in its best interests to produce safe food; that the exporting authority has proper confidence; and that its assurances of compliance can be believed. No food safety system can exist or survive without this trust and confidence. In New Zealand’s case, NZFSA is the (Codex-defined) competent authority. NZFSA believes that the assurances it delivers are trustworthy and hopes that trade partners accept that too. If there are problems with New Zealand food, NZFSA will want to know – please.

**The food regulatory model applied in New Zealand**



**ANNEX 10****LIST OF CONFERENCE DISCUSSION PAPERS**

<b>Document Reference</b>	<b>Title</b>
CAP 04/2	Food safety legislation; the use of science and risk-based approaches to harmonization
CAP 04/3	Application of risk analysis in food control – challenges and benefits
CAP 04/4	Prioritization and coordination of capacity building activities
CAP 04/5	Information exchange, education and communication
CAP 04/6	Food-borne disease monitoring and surveillance systems

**FAO/WHO Regional Conference on Food Safety for Asia and Pacific**  
*Seremban, Malaysia, 24-27 May 2004*

**Food safety legislation; the use of science and risk-based approaches to harmonization**  
(Paper prepared by Australia)

**1. Summary**

Numerous challenges and opportunities exist for harmonizing food safety legislation both at the national and international level. This paper discusses key risk-based principles and processes – such as *risk analysis*, and the use of ‘farm to table’ approaches and HACCP (Hazard Analysis and Critical Control Point) process control systems – that are increasingly being elaborated to support harmonized and transparent food safety regulations. Risk communication is particularly difficult for countries and the importance of ensuring all stakeholders are involved in the regulatory process is also discussed. The importance of giving priority to public health in implementing food safety legislation, while at the same time taking into consideration socio-economic implications through regulatory impact assessments, is also discussed. Finally, challenges and opportunities facing the international harmonization of food safety legislation are considered, in particular the influence of international trade and trade agreements, and the use of Codex Alimentarius Commission (Codex) norms. International linkages, such as regional alliances, information exchange networks and technical cooperation, are touched on as means to assist international harmonization of food safety regulations and to enhance global public health and trade. Recommended approaches for the implementation of consistent national and international risk-based food safety regulatory strategies are outlined.

**2. Challenges and opportunities for harmonizing national food safety regulation**

Food law in many countries has traditionally consisted of legal definitions of unsafe food, and the prescription of enforcement tools for removing such food from markets and penalizing responsible parties post market. Food laws generally do not, however, provide food control agencies with a clear mandate and authority to *prevent* food safety problems. The result is that many countries have food regulatory systems that are reactive and focus on the enforcement of legislation rather than directing and encouraging the use of preventive and holistic approaches to reducing the risk of food borne illness.

While many countries have recognised that food regulatory systems need to be under-pinned by systematic and objective food regulatory principles, with clear food safety objectives in mind, a number of countries have struggled to recognise the value of these approaches. As a consequence, food safety regulations in these countries continue to incorporate a patchwork of provisions that do not conform to science-based food safety objectives. These regulatory systems often fail to be fully effective in protecting public health, and can compromise domestic food markets and trade capacity.

Proactive approaches to food safety control and regulatory systems have been driven over recent times as a consequence of a number of factors including:



- a greater scientific understanding of food safety risks and means to assess their impact on public health (including emerging food pathogens);
- new food production technologies and food safety control/management systems;
- increased food trade and obligations under trade agreements;
- increased consumer/market interest in food safety; and
- development of international food standards by Codex.

In order to assist member states consolidate and better coordinate food regulatory systems, international agencies such as the United Nations Food and Agriculture Organization (FAO), the World Health Organization (WHO)<sup>1</sup> and Codex, have acted in the face of these (at times competing) factors by elaborating objective risk-based decision-making criteria for establishing food safety regulations that are transparent and proactive in scope. The key to these initiatives is the development and use of risk analysis principles.

## 2.1 Risk Analysis

Objective justification of food safety regulations is being increasingly undertaken internationally by demonstrating that the need for public health and safety measures are in balance with socio-economic considerations<sup>2</sup>. In order to achieve this balance a number of countries and international organizations are increasingly using risk analysis systems to characterize risks (both in terms of food safety and economic impacts), devise acceptable risk management options, and communicate with all relevant stakeholders in these processes.

Risk analysis consists of three inter-related components; risk assessment, risk management and risk communication. Each component is discussed in Conference Theme B – *The Application of Risk Analysis in Food Control – challenges and benefits* that includes how risk analysis frameworks are being elaborated by international agencies, and specific case studies undertaken by Food Standards Australia New Zealand (FSANZ).

Risk analysis has been incorporated into a structured approach by many countries in the setting of food safety regulations and been elaborated by the Codex as the basis of many of its norms. Codex is a joint body of the FAO and WHO that is charged with developing international food norms (such as standards, guidelines and codes of practice) to enhance global public health and assist in the harmonization of standards to facilitate international trade. Codex has recognised the importance of adopting risk-based principles by introducing *Working Principles for Risk Analysis* into the Codex Procedural Manual<sup>3</sup> by which all Codex committees operate.

Whilst the basic principles and benefits of risk analysis are widely recognised and increasingly applied internationally, variation remains in the manner in which different countries apply it and the degree to which it is formalized within domestic regulatory processes.

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<sup>1</sup> See Joint FAO/WHO Publication *Assuring Food Safety and Quality: Guidelines for strengthening national food control systems*. <http://www.fao.org/DOCREP/006/Y8705E/Y8705E00.HTM>

<sup>2</sup> *Food safety regulation: an overview of contemporary issues*. S. Henson and J. Caswell. Food Policy 24: 589-603. 1999

<sup>3</sup> [www.codexalimentarius.net/procedural\\_manual.stm](http://www.codexalimentarius.net/procedural_manual.stm)

Key issues of contention include the manner in which scientific uncertainty (where scientific evidence is insufficient) is factored into risk analysis; equivalence criteria (where risk-analyses performed on similar products by differing agencies or different countries result in dissimilar risk management approaches); and the manner and extent to which 'other legitimate' factors are taken into consideration in establishing food safety regulations. These issues are currently the subjects of ongoing international debate.

To assist governments of the region institute effective and transparent risk analysis frameworks that are in line with Codex and international trade agreements, FAO and WHO, in collaboration with the International Life Sciences Institute (ILSI) and the Industry Council for Development (ICD), are developing a range of tools including a risk analysis manual<sup>4</sup> and providing regional workshops on risk analysis.

- ❖ *Risk analysis principles as elaborated and adopted by Codex should be the foundation on which food regulatory decisions in all countries should be based. Governments should take advantage of the risk analysis tools of FAO/WHO in developing their own food control and regulatory systems.*

## **2.2 Risk Assessment**

Risk assessment is the primary step of risk analysis and is based on (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterizations (see Theme B paper).

While not all countries have sufficient scientific resources, capabilities, or data to carry out risk assessments, it may not be necessary in all cases to have integrated systems for this purpose. Greater resources for risk assessments are being applied at the national, regional and international level and governments should take advantage of these assessments when developing domestic regulations. For example, risk assessments developed by joint FAO/WHO expert committees such as the Joint Expert Committee on Food Additives and Contaminants (JECFA), the Joint Expert Meeting of Pesticide Residues (JMPR) and the Joint Expert Meetings on Microbial Risk Assessments (JEMRA) are applicable internationally.

FAO have recently reviewed data on food borne illness across a number of developing countries and evaluated the use of such data in assisting risk assessments and in determining risk management options (including means to assess the economic impact of such decisions)<sup>5</sup>. Related issues are discussed in Conference Theme E – *Food borne disease monitoring and surveillance systems*.

- ❖ *Countries should, as much as possible and practical, develop the capacity to utilize and assess international risk assessments, especially those undertaken by Codex and subsidiary/related bodies. In addition, to facilitate development of domestic food safety regulations that are both nationally (e.g. with local dietary patterns and conditions) and internationally consistent, data from other countries with similar environmental and socio-economic status should also be used.*

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<sup>4</sup> [http://www.fao.org/es/ESN/food/capacity\\_tools\\_ramanual\\_en.stm](http://www.fao.org/es/ESN/food/capacity_tools_ramanual_en.stm)

<sup>5</sup> *The Economics of Food Safety in Developing Countries*. S. Henson. FAO. ESA Working Paper 03-19. 2003

### 2.3 Risk Management and Regulatory Impact Assessment (RIA)

Risk management is a distinct step from risk assessment and consists of weighing identified regulatory alternatives in consultation with all interested stakeholders. This includes considering the outcomes of risk assessments and other relevant factors such as cost effectiveness, including the impact on industry and enforcement agencies, and the types of potential regulatory intervention (e.g. code of practice versus a mandatory standard).

In general terms, risk management should be established through a transparent national food policy involving formal procedures of stakeholder consultation. Establishment of the acceptable risk level is an inherently political decision considering a broad variety of public health, socio-economic and environmental factors. However, in reaching these decisions, governments need to consider whether the desired level of protection is no more trade restrictive than necessary to comply with obligations under international agreements. Greater balance in risk management is being attained in many countries by the adoption of transparent regulatory impact assessments (RIA). The RIA is a method of systematically and consistently examining and consulting on the potential impacts arising from government decisions, and communicating the outcomes to decision-makers. Food RIAs attempt to develop and assess different regulatory options in order to balance competing public health and socio-economic interests.

A number of national legislative models exist in the development of transparent risk management and RIA frameworks for food safety. For example, FSANZ has incorporated risk management transparency and RIA requirements established by the Council of Australian Governments in its development of standards (see FSANZ *Guide to Applications and Proposals*<sup>6</sup>). The Organization for Economic Co-operation and Development (OECD) has also established a guide to regulatory impact analysis in the *Recommendation of the Council of the OECD on Improving the Quality of Government Regulation*<sup>7</sup>.

An example of the use of a food regulatory RIA is one conducted in 1999 for the introduction of mandatory food safety programmes in Australia by the then Australia New Zealand Food Authority (now Food Standards Australia New Zealand). RIAs are required in Australia (and many other countries) under federal obligations for all proposed regulations. Four safety standards were adopted in Australia: three mandatory standards that variously defined food safety, acceptable food safety practices, and food premises and equipment. A fourth voluntary standard recommends that food businesses develop certifiable food safety programmes where hazards are identified in food handling operations (note this voluntary standard is being implemented as a mandatory standard in some Australian states).

The cost benefit study predicted that ongoing cost for businesses for implementing these safety standards would be approximately A\$1,000 per business; 35% lower than for pre-existing regulations that incorporated a patchwork of legislation. Indirect benefits included that the new standards allowed for greater industry flexibility in food safety control systems and innovation in food production. Costs to government of implementing administrative and auditing systems to enforce the new standards were determined to be almost 50% higher (approximately A\$48m) with local governments bearing much of this cost. The study inferred that a 20% reduction in food borne illness would result from the adoption of the standards that was equated to a saving of A\$500m in productivity and health costs.

<sup>6</sup> [http://www.foodstandards.gov.au/\\_srcfiles/revised\\_Guide\\_Props\\_Appls\\_July02.pdf](http://www.foodstandards.gov.au/_srcfiles/revised_Guide_Props_Appls_July02.pdf)

<sup>7</sup> <http://193.51.65.78/puma/regref/pubs/rco95/foreword.htm>

On this basis, Australian governments determined that the food safety standards represent a tangible means of achieving highly significant savings that would benefit the entire Australian community and adopted the majority of the standards into the Food Standards Code. The effectiveness of the standards is to be assessed ten years. Note these food safety standards were not included in New Zealand due to different policy approaches to food safety regulations and perceived equivalence in the effectiveness of existing national food safety measures in New Zealand.

- ❖ *Governments should take advantage of risk management and regulatory impact assessment models developed by international agencies such as the OECD and establish mechanisms for sharing such information to ensure transparency in decision-making and to harmonize food regulatory processes.*

## **2.4 Risk Communication and Regulatory Transparency**

Effective communication of information and opinion on risks associated with real or perceived hazards in food is an essential and integral component of risk analysis, whether it is related to immediate food safety crises or as a component of food legislation development.

Risk communication makes stakeholders aware of the process at each stage of risk assessment. This helps to ensure that the logic, outcomes, significance, and limitations of the analysis are clearly understood by all the stakeholders. Information pertinent to the assessment may be available from many stakeholders. Industry stakeholders may, for example, have unpublished data crucial to the risk assessment that may influence risk management options and decisions. To the extent that it is practical and reasonable, interested parties should be involved in identifying management options, developing the criteria for selecting those options and providing input to the implementation and evaluation strategy.

Risk communication may originate from official sources at international, national or local levels. It may also be from other sources such as industry, trade, consumers and other interested parties.

When a final risk management decision has been reached, it is important that the basis for the decision be clearly communicated to all interested parties. Effective risk communication should have goals that build and maintain trust and confidence. It should facilitate a high degree of consensus and support by all interested parties for the risk management option(s) being proposed.

The report of a joint FAO/WHO Expert Consultation - *The Application of Risk Communication to Food Standards and Safety Matters*<sup>8</sup> elaborates principles and guidelines for risk communication that should be used by all governments to underpin transparency and inclusiveness in food regulatory matters.

- ❖ *Governments should increase risk communication efforts to convey key food safety messages and involve a wide set of stakeholders in both national risk assessment and management processes (such efforts are equally pertinent to setting national positions in Codex).*

- ❖ *The guidance and recommendations of the joint FAO/WHO Expert Consultation on Risk Communication should be adopted within risk analysis frameworks of all governments and be incorporated into risk analysis capacity building efforts.*

### **3. 'Farm to table' and performance-based approaches to food safety regulation – the role of HACCP**

The scope of food safety regulation has expanded in recent years to the entire food supply chain – from primary production through to consumption. This 'farm to table' approach aims to identify the multiple points along the food supply chain that can compromise food safety, and the coordinated interventions required to assure food safety. This approach to food safety arises from a desire to *prevent* risks rather than detecting them in the final product and places a particular emphasis on on-farm management and production practices.

A progressive evolution of food legislation has also occurred in many countries away from detailed specification or product standards toward horizontal outcome-based performance standards. Performance-based standards specify *what* food safety objective has to be achieved rather than defining *how* it is to be achieved, and are becoming prevalent in countries where common elements exist in the focus and nature of food safety and regulatory systems.

Performance standards depend on food producers maintaining process controls that demonstrate, through verifiable documentation, that a food safety objective is being met. Performance standards thus allow suppliers to take greater responsibility for producing safe food, providing flexibility for processing innovation. However, for high-risk foods, precise and specific product and processing regulations may still be applied.

Performance standards allow producers to be proactive in adopting voluntary food safety controls including codes of good hygienic practice and process-control systems such as HACCP (Hazard Analysis and Critical Control Point). HACCP-based food safety standards adhere to science-based food safety assessment and management principles within a defined risk analysis framework and can be applied at various levels across the food chain.

Performance-based standards and HACCP systems are being increasingly adopted in a number of countries for high-risk food products. For example, Australian food standards require HACCP systems to be applied to the production of minced fermented meat products. New Zealand dairy regulations require the application of HACCP in the manufacture of milk and dairy products. Mandatory food safety programmes employing HACCP principles are being introduced to other high-risk food businesses in Australia over the next few years. Similar generic provisions for the application of HACCP in food production are in place in the EU and are mandated in the United States for seafood, meat, poultry, and fruit juice.

As the introduction of HACCP-based systems may be difficult in small and medium-sized food businesses with limited capacity and knowledge, its implementation is best achieved by collaboration within the food industry, and by the involvement of training and regulatory agencies at the national and international level (see below).

Another outcome of the commercial and regulatory introduction of HACCP is that developing countries wishing to trade in developed markets have increasingly needed to adopt HACCP systems. For example, in Malaysia, the Ministry of Health operates a voluntary HACCP certification programme in response to the EU requirements for HACCP in fish

processing plants. Over 40 food processing plants were certified under the programme at the end of 2001 and, as a consequence, a key priority of food hygiene regulations will be the implementation of Codex-based HACCP systems in other export-oriented sectors.

The growing use of HACCP as a science-based industry and regulatory food safety system has also influenced Codex to adopt and develop guidelines for HACCP<sup>9</sup>. Codex is in the process of incorporating HACCP into codes of hygienic practice under development in the Codex Committee for Food Hygiene. HACCP systems are thus becoming benchmarks for international food safety standards and trade and should be made the mainstay of all national food safety regulations.

Various international agencies have developed tools and programmes to assist the adoption and integration of HACCP process controls into food production. This includes FAO/WHO *HACCP Principles; a Practical Teacher's Handbook*<sup>10</sup>. FAO has also instituted training projects targeting food processing plants in various countries<sup>11</sup> that need to upgrade their technical skills to improve the quality of their products and meet the requirements for export. The United Nations Industrial Development Organization (UNIDO) has also instituted a number of HACCP-based capacity building efforts in a variety of developing countries<sup>12</sup>.

- ❖ *In developing and reviewing food safety regulatory measures, governments should consider a 'farm to table' and preventative approach to food safety management and incorporate performance based food safety standards. HACCP-based food safety control systems should be considered mandatory for all high-risk foods.*
- ❖ *Governments should take advantage of the HACCP guidelines and capacity building efforts of FAO, UNIDO, WHO and other international organizations.*

#### **4. International harmonization of food safety regulations**

International trade in bulk foods commodities and processed foods has undergone a significant expansion over recent decades, driven by the demands of rising populations and expanding income growth in most countries and increased export opportunities.

The expansion in global food trade has brought into sharp focus differences in the food safety control systems (both private and public) and regulatory approaches adopted by various countries. The diverse emphases and efforts various countries have on food safety are highlighted in international fora. Moreover, these differences can influence international disputes that can impede food trade. Differences in food safety legislation occur even between nations that have established scientific risk-based frameworks for national food safety standards.

The diversity in food safety regulations between countries has a number of origins including:

- Different inherent and unique food safety risks in the food supply (including differences in production practices, plant and livestock pathogens, and/or climatic conditions);

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<sup>9</sup> Recommended International Code of Practice – General Principles of Food Hygiene. Codex 1999.

<sup>10</sup> [http://www.who.int/foodsafety/publications/fs\\_management/haccp\\_teachers/en/](http://www.who.int/foodsafety/publications/fs_management/haccp_teachers/en/)

<sup>11</sup> [http://www.fao.org/es/ESN/food/capacity\\_projects\\_africa\\_en.stm](http://www.fao.org/es/ESN/food/capacity_projects_africa_en.stm)

<sup>12</sup> [http://www.enyox.com/dev/unido-tcb/index.php?ccpage=projects\\_list&set\\_z\\_sidenav=0](http://www.enyox.com/dev/unido-tcb/index.php?ccpage=projects_list&set_z_sidenav=0)

- Different principles and protocols for assessing and managing food borne risks;
- Differing capacities to develop and implement regulatory programmes and infrastructure to control food safety risks and assure enforcement of legislation;
- A country's cultural preferences and the level of protection deemed acceptable to address food safety risks (e.g. EU permits use of unpasteurized milk in some instance whereas its use and sale is banned in Australia);
- Domestic regulatory systems being a mix of old and new policies and standards that are frequently inconsistent across products or countries;
- Food safety regulations being used as a technical barrier to trade to protect domestic industries from foreign competition.

#### **4.1 Alignment of food safety regulations**

Countries can, and do, align food safety regulations either through bilateral or multilateral agreements in order to facilitate trade. Bilateral agreements are generally developed between major trading partners in order to facilitate trade. For example, Australia and New Zealand decided in 1996 to work towards unilaterally harmonizing many food standards in order to reduce regulatory trade barriers and industry costs. In 1998, the United States and Canada signed an agreement under which agricultural trade in many sectors would be facilitated – including the harmonization of certain food safety standards.

The most comprehensive multilateral agreement that aims to minimize the impact on trade of inconsistent and occasionally incompatible food, health and environmental regulatory measures is the Sanitary and Phytosanitary (SPS) Agreement of the WTO. Standards set by other international organizations, such as the World Organization for Animal Health (OIE) and the International Plant Protection Convention (IPPC) also attempt to harmonize regulations in the animal and plant sector, respectively. While not directed at food safety regulations, the Technical Barrier to Trade Agreement (TBT) of the WTO also requires that technical regulations on traditional quality factors, fraudulent practices, packaging, labelling etc. imposed by countries should not be more restrictive on imported products than they are on domestically produced products. The TBT Agreement also encourages the adoption of international standards.

The SPS Agreement confirms the right of WTO member countries to apply measures to protect human, animal and plant life and health. The Agreement covers all relevant laws, decrees, regulations; testing, inspection, certification and approval procedures; and packaging and labelling requirements directly related to food safety. Member states are asked to apply only measures that are based on scientific principles – principally risk assessment and only to the extent necessary according to their determined appropriate level of protection, and not in a manner that may constitute a disguised restriction on international trade.

Justification of food safety regulations under the SPS Agreement can be achieved in different ways. Principally:

- by the adoption of international standards, or
- through a science-based risk analysis of the proposed food safety regulatory measure.

The SPS Agreement presumes Codex norms (including those related to food additives, veterinary drugs and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practices) are consistent with provisions of SPS. Thus, Codex standards serve as a benchmark for comparison of national sanitary measures. While it is not compulsory for member states to apply Codex standards, it is in their best interests under the SPS Agreement to harmonize national food standards with those elaborated by Codex.

The justification of food regulatory measures can also be established under the SPS Agreement through a risk analysis of the regulatory measure as described previously and in Conference Theme B.

- ❖ To enhance public health and facilitate trade, governments should establish mechanisms to conform food safety regulations to WTO Agreements to which they are signatory. This includes aligning to or adopting, food safety standards and guidelines set by Codex.

#### **4.2 Codex norms as benchmarks for regulatory alignment**

Food safety norms developed by Codex provide a basis for food safety harmonization because they reflect sound, contemporary, internationally recognised science and, increasingly, the application of risk analysis.

They also reflect a broad international consensus on the methodology for developing food safety standards on the basis of scientific data and other technical information (e.g. how to take account of differences in dietary patterns between countries). Moreover, Codex standards are developed through a consensus-seeking process and in almost every case are adopted by consensus.

Although comprehensive data are not available, it is known that Codex norms have been widely adopted by many countries as the basis for their food standards. For example, in 2001 the Codex Coordinating Committee for Africa noted that a number of member states of the Economic Community of West African States (ECOWAS) free trade zone decided to adopt Codex standards in order to harmonize regional food standards.

As Codex norms are increasingly referenced or adopted, it is important that they are technically sound and fully address contemporary food safety risks using consistent risk based principles. Codex norms need also to be credible to industry and consumers and trading partners and applicable to both developed and developing countries.

- ❖ Governments should recognise the importance of active participation in Codex.

#### **4.3 Equivalence<sup>13</sup>**

It is often the case that importing and exporting countries operate different food inspection and certification systems. The reasons for such differences include different prevalence of particular food safety hazards, differing national choice in the management of food safety risks, and differences in the historical development of food control systems.

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<sup>13</sup> Guidelines on the judgment of equivalence of sanitary measures associated with food inspection and certification systems ALINORM 03/30A, Appendix II, adopted by the 26<sup>th</sup> Session of the Codex Alimentarius Commission, July 2003.



In such circumstances, and in order to facilitate trade while protecting public health, exporting and an importing country may work together to consider the effectiveness of sanitary measures of the exporting country to meet the appropriate level of sanitary protection of the importing country. Application of the principle of equivalence has mutual benefits for both exporting and importing countries. While protecting the health of consumers, it serves to facilitate trade and minimize the costs of regulation to governments, industry, producers, and consumers by allowing the exporting country to employ the most convenient means in its circumstances to achieve the appropriate level of protection of the importing country. Importing countries may be able to reduce the frequency and extent of verification measures following a judgment of equivalence of measures applied in the exporting country.

Codex has also developed practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements.<sup>14</sup>

- ❖ Governments should work with trading partners to assess and harmonize regulatory approaches to facilitate trade in safe food using the practical guidance of Codex.

#### **4.4 Technical assistance and the SPS Agreement**

The SPS Agreement encourages the provision of technical assistance to member states, especially developing countries, through either bilateral agreements or through international organizations (e.g. the FAO/WHO Trust Fund for Participation in Codex that provides funds to enhance developing nation attendance and engagement in Codex standard setting). These SPS Articles referring to capacity building have had only limited impact in fostering the regulatory capacity of developing countries due to limitations in funding or lack of recognition of these rights by developing countries. Substantial coordinated investment among developed country members and appropriate international organizations, international banks and non-government organization/industry partners will be needed if the real food safety regulatory challenges faced by developing countries are to be addressed.

The Standards and Trade Development Facility (STDF) is one example of a partnership that aims to strengthen donor coordination in standard setting related to food safety, the SPS Agreement, and plant and animal health in developing countries. The STDF is a joint initiative of the World Bank, FAO, OIE, WHO, and WTO which operates by (a) provision of small grants for pilot projects that build capacity in standards setting and development in developing countries, (b) assistance to government and private sector in meeting international standards, such as those referenced in the WTO Agreements, and (c) strengthened inter-agency coordination and donor collaboration in the delivery of technical assistance in standards. The STDF will also implement a database of capacity building projects in the areas of food safety, plant, and animal health conducted by all the agencies involved in the STDF, which will allow for increased coordination of capacity building efforts.

The success of the SPS Agreement in accomplishing both enhanced international trade and food safety will ultimately be determined by the degree to which all countries are able to institute comprehensive and effective food control systems. As Codex and domestic regulatory standards will influence each other, it is likely that food safety standards will become increasingly harmonized especially in terms of criteria used to develop standards and systems introduced to ensure their effectiveness.

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<sup>14</sup> Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems (CAC/GL 34-1999)

- ❖ *Both donor and recipient governments should recognise the importance of food regulatory capacity building efforts, including through relevant international agencies and bilateral channels, in order to facilitate harmonized food safety regulations.*

## **5. Regional strategies for the harmonization of food safety regulations**

Many countries, especially the least developed, have neither the capacity nor the resources to fully address the challenges or take opportunities arising from the introduction of risk-based food safety legislation. Strengthening and building food safety regulatory systems in these countries will improve food security and public health, and lead to improved international trade opportunities.

Capacity building should be tackled on a regional basis. Whenever needs common to countries in a particular region can be identified, governments of the region should collaborate to exchange information and share technical assistance resources to meet these needs.

These issues are more fully explored in Conference Theme C – *Prioritization and co-ordination of capacity building activities.*

FAO, WHO and Codex<sup>15</sup> have identified capacity building to enhance national food safety regulatory systems, and regional alliances, as key food safety priorities. These were key themes at the FAO/WHO *Global Forum of Food Safety Regulators*<sup>16</sup> in 2002. A second Global Forum will be held in Bangkok, Thailand, from 12 to 14 October 2004, with the theme *Building Effective Food Safety Systems*. Two main areas for discussion will be:

- Strengthening official food control services; and
- Surveillance of food borne diseases and food safety rapid alert systems (this is more fully explored in Conference Theme E – *Food borne disease monitoring and surveillance systems*)

International organizations such as FAO and WHO are well positioned to take leadership in building alliances, establishing frameworks for exchange of information, and coordinating capacity building activities related to food safety. Such coordination avoids duplication and overlap of work, allows proper sequencing of technical assistance to specific countries, captures lessons learned from related countries, and enhances ownership. It also provides a system for transparent and regular review and evaluation of capacity building initiatives in order to ensure they are successful and sustainable.

One of the first steps in building alliances is the establishment of clear and integrated communication between regional government agencies to provide regular exchange of information related to food safety activities. These issues are more fully explored in Conference Theme D – *Information exchange, education and communication.*

To facilitate information exchange on food legislation, FAO, along with the SPS-standard setting organizations and WTO have developed an International Portal on Food Safety, Animal and Plant Health<sup>17</sup> to provide a single access point to international standards,

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<sup>15</sup> <http://www.fao.org/DOCREP/MEETING/006/y9805e.htm>

<sup>16</sup> <http://www.foodsafetyforum.org/>

<sup>17</sup> IPFSAPH Concept paper, (*INF/6, 26th Session of CAC, July, 2003*) :

notifications, and related texts, and national legislations and regulations. This portal will also be launched during this Conference.

Examples of regional communication networks include the Association of South East Asian Nations (ASEAN) nations who have shown their commitment to better coordinate food safety efforts through the ASEAN Food Safety Network. A key plank of the South-East Asian region of the WHO (WHO/SEARO) food safety strategy also includes the need for governments of the region to ensure food safety legislation is regularly revised and evaluated, especially in the light of Codex standards.

Another aspect fundamental to national and international food regulatory harmonization efforts is the need to assess the capability and constraints of individual food control systems through a country needs assessment (see also Conference Theme C discussion).

The needs assessment process is assisted by development of a country profile that includes a review of existing legislation and regulations, food inspection activities, laboratory capacities, public health concerns, priorities for export access, etc. The purpose of the country profile is to provide an overall appreciation of the needs for capacity building and technical cooperation including technical assistance and human and institutional capacity building, both in the immediate and longer term.

The result of the needs assessment provides useful information to design a coherent and integrated approach for internal actions and external assistance to meet the specific needs of individual countries. The assistance provided should be coordinated by the international agencies and other parties involved, taking into consideration the agencies' respective mandates, resources and expertise.

Regional needs assessments are being addressed, for example, by the Western Pacific Regional Office of the WHO (WPRO) that has been active in implementing a strategy<sup>18</sup> through the WHO Pacific Food Safety Initiative to enhance food safety-related information sharing amongst Pacific Island countries. This includes an online database of country-specific information about food importation and food legislation.

FSANZ has also been active in conjunction with WPRO and other international agencies in assisting countries in South-East Asia, including Vietnam, Indonesia and South Pacific countries to review food legislative structures to facilitate the introduction of transparent risk-based food safety regulations that are aligned with international trade requirements (see Theme B paper).

- ❖ *FAO and WHO should continue to lead the coordination of global capacity building efforts for food safety control systems and work with other international organizations, such as WTO, World Bank, non-government organizations and Member States, to build alliances, establish frameworks for exchange of information, and implement technical assistance related to food safety.*

- ❖ *Governments of the region and associations should continue collaborative efforts to address common food safety control issues in order to gain collectively in terms of both public health outcomes and trade opportunities.*

Agenda Item 6

CAP 04/3

**FAO/WHO Regional Conference on Food Safety for Asia and Pacific**  
Seremban, Malaysia, 24-27 May 2004**The application of risk analysis in food control**  
**- challenges and benefits**

(Prepared by Food Standards Australia New Zealand, Canberra, Australia)

**1. Introduction**

As its name states, Food Standards Australia New Zealand (FSANZ) sets food standards for both Australia and New Zealand. However, in this paper, the role of FSANZ is confined to the Australian context only. As part of the food regulatory system in Australia, FSANZ applies risk analysis to underpin its decision-making process. FSANZ has developed a scientifically rigorous and transparent process for setting food standards and is happy to be sharing its experience with colleagues in this Conference.

Risk analysis is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate the risks and measures applied to stakeholders. In order to operate effectively, the various activities associated with risk analysis must also be supported by an infrastructure, including legislation, testing laboratories, enforcement systems, coordination between jurisdictions and clear lines of responsibilities. Further information on FSANZ's activities may be obtained from FSANZ's website<sup>1</sup>.

In this paper the general framework of risk analysis and Australia's experience in its application in order to maintain and enhance the safety of the food supply are presented. The paper focuses on the challenges and benefits in applying risk analysis and uses specific case studies to illustrate key points.

**2. Risk Analysis****2.1 Risk Analysis: General Framework**

There is now wide international agreement on the framework for Risk Analysis as it is applied in the regulatory context of food and human health and safety in order to facilitate a risk and evidence based approach to decision making<sup>2</sup>. The framework has three major components: risk assessment, risk management; and risk communication. In developing food standards within this framework, the primary consideration is the impact on human health and safety. However, when developing risk management options there are often a number of other considerations, such as economic impact and feasibility of implementation, that are taken into account in order to select the most appropriate option.

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<sup>1</sup> <http://www.foodstandards.gov.au/>

<sup>2</sup> Report of the Joint Expert FAO/WHO Consultation on Application of Risk Analysis to Food Standards Issues. 13-17 March 1995; Report of a Joint FAO/WHO Consultation on Risk Management and Food Safety. 27-31 January 1997; FAO/WHO Expert Consultation on Application of the Risk Communication to Food Standards and Safety Matters. 2-6 February 1998.

Risk Assessment: The objective of risk assessment is to determine the degree of risk associated with the food under consideration by answering three questions: What can go wrong (scenario)? How likely is that to happen (likelihood)? If it happens, what are the consequences (magnitude)? The process of risk assessment can be divided into four distinct steps - hazard identification, hazard characterization, exposure assessment and risk characterization. The integrated information from these steps provides an estimate of the health and safety risk based on the likelihood of the occurrence of an adverse event and the magnitude of the consequences.

Risk Management: The objective of this stage is to establish if and what food regulatory measures are required to mitigate the risk to a level that is acceptable to the community. Risk management options are developed and assessed for their effectiveness in dealing with the health and safety risks while considering the impact of each option on relevant stakeholders such as primary producers, food manufacturers, retailers, consumers, and government.

Risk Communication: Risk communication, including community consultation, is an essential element in the risk analysis process. It is useful to have risk communication activities at various stages of the process to allow appropriate involvement of stakeholders. Effective risk communication benefits all participants by ensuring a rigorous and transparent risk analysis process, adequately informed stakeholders and a high level of community confidence in the regulatory system.

Below is a graphical representation of the risk analysis framework.

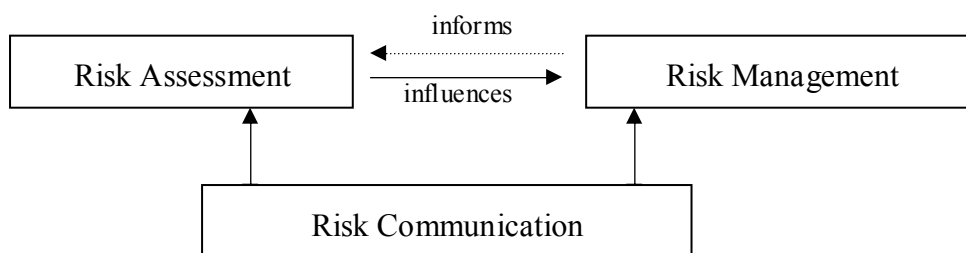


Figure 1. The Risk Analysis Framework consisting of the three elements of risk assessment, risk management and risk communication.

## 2.2 *The International Environment*

The application of risk analysis to the development of food regulation is a key element in ensuring that a country fulfils its rights and obligations under the World Trade Organization (WTO) trade agreements. In the context of this paper, the WTO agreement of most relevance to food regulation is the Agreement on the Application of Sanitary and Phytosanitary Measures<sup>3</sup> (the SPS Agreement). The SPS Agreement requires that regulatory measures adopted by a member country must be based on scientific principles and not maintained without sufficient scientific evidence. Member countries are required to base their measures on an assessment of the risks to human life and health. Risk assessments performed at the national level should take into account risk assessment methodologies

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<sup>3</sup> [http://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm)

developed by the relevant international organizations and be appropriate to the circumstances. In the case of food safety, the relevant international standards setting body is the Codex Alimentarius Commission (CAC). The CAC and its various committees and other bodies are generically referred to as 'Codex'.

Codex standards are the benchmarks against which national food measures and regulations are evaluated. Member countries can introduce measures which achieve a higher level of protection than that achieved by a Codex standard, but only if there is a scientific justification, or as a consequence of setting a higher appropriate level of protection (ALOP). In determining ALOP, countries must take into account the objective of minimizing negative trade effects.

There are a number of principles that underpin the SPS agreement that are of importance, including:

- harmonization of safety measures as far as possible between member countries, thereby avoiding unnecessary obstacles to trade;
- acceptance of 'equivalent' measures from an exporting country, when it can be ascertained that the measures taken, albeit different from those of the importing country, achieve the same level of safety protection; and
- transparency – provision of information and notification of changes in food safety and trade measures.

### **2.3 Application of Risk Analysis in Codex**

The risk analysis framework provides for the evaluation of existing knowledge around food borne hazards or potential hazards, and assists in determining the best ways of managing those hazards in order to mitigate the risk of disease or other adverse health effects. Risk analysis also takes into account the need to communicate with affected parties and interested stakeholders such as potential consumers, other risk assessors, public health professionals, and other government agencies. In other words - undertaking risk analysis entails a process of:

- assessing food borne risks;
- determining and implementing ways of most effectively managing those risks; and
- communicating both aspects to all affected parties in a meaningful and timely manner.

Codex has defined the three components of risk analysis and in mid 2003 Codex finalized and adopted its Working Principles for Risk Analysis by incorporating it into the Codex Procedural Manual<sup>4</sup> These principles provide an approach and guidance in developing Codex standards and related texts, based on risk analysis. Codex is currently working to develop a guidance document on risk analysis for use by member governments (Proposed Draft Working Principles for Risk Analysis for Food Safety), which was discussed at the May 2004 meeting of the Codex Committee on General Principles.

The working principles state that risk analysis used in Codex should be:

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<sup>4</sup> [http://www.codexalimentarius.net/procedural\\_manual.stm](http://www.codexalimentarius.net/procedural_manual.stm)

- applied consistently;
- open, transparent and documented;
- conducted in accordance with both the *Statement of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Statement of Principle Relating to the Role of Food Safety Risk Assessment*<sup>A</sup>; and
- evaluated and reviewed as appropriate in light of newly generated data.

Further principles are elaborated to the effect that the risk analysis should be structured around its three components and there should be a functional separation of risk assessment and risk management in order to avoid any confusion regarding functions, to avoid conflicts of interest, and to ensure the scientific integrity of the risk assessment.

Finally, because of the many uncertainties that may exist in the process of risk assessment and risk management, any risk management options that are selected should take account of the level of certainty and the characteristics of the hazard.

## **2.5 Application of Risk Analysis at the National Level**

Australia has fully integrated the principles and processes of risk analysis into its food regulatory system. Risk analysis is applied both in the development of food standards, as well as to address food emergencies that result from emerging hazards or breakdowns in control systems.

In Australia, FSANZ operates as the risk assessor on food safety issues. Within Ministerial guidance and subject to ultimate Ministerial responsibility, it also operates as the risk manager, particularly in food safety emergency situations, such as the examples outlined below. Finally, as the food regulator, FSANZ undertakes most, although not all, of the risk communication. Depending on the issue, colleagues in health and agriculture may also have a role in this area.

It is also recognised that the depth and breadth of the risk analysis will be proportionate to the urgency and complexity of the issues to be addressed. In normal circumstances it is usually possible to allocate sufficient time to perform all the risk analysis steps comprehensively. However, in an emergency situation it may be necessary to make a decision within a short period of time. In such circumstances, it is important that the risk analysis framework is preserved as much as possible to ensure that decisions are based on rational considerations. Provisional risk management measures that may be applied in an emergency situation must be revised within a reasonable time as new information becomes available.

In the Australian context, risk analysis is applied to the full range of hazards that may be associated with food and impact on human health. These include chemical hazards, infectious agents (such as microbial hazards and prions), nutrients (both in terms of deficiencies and excesses), and whole foods (such as genetically modified, irradiated and other novel foods).

The risk assessment methodology applied to each type of hazard may vary depending on the available methodology and information. For example, a fully quantitative methodology is generally used with chemical hazards while a qualitative or semi-quantitative approach is



used to address microbiological hazards. Risk management measures may take the form of food standards, including prohibitions, restrictions, maximum limits on contamination and/or labelling requirements. Other risk management measures may include advice to specific at-risk populations, co-regulatory measures with industry such as guidelines and codes of practice and general advice to the community.

Over the past several years, Australia has taken significant steps to increase the effectiveness of its risk communication activities. For many years, Australia has made public its rationale underpinning decisions on food regulatory measures and the documentation is now available electronically. In addition, Australia develops information about regulatory measures that aim to be easy to understand and actively communicated in a broad range of community, industry and professional events.

## **2.5 Challenges and Benefits**

There are a number of challenges and benefits in the application of risk analysis at the national level. Some of these are listed below:

### **2.5.1 Challenges:**

- The availability of data at the national level. Australia has invested quite heavily in systems to obtain and analyse data relating to both food consumption and food contamination. However, difficulties are still sometimes encountered in obtaining sufficient high quality quantitative information for risk analyses that are specific to Australia's food supply and community. This point is closely linked with infrastructure issues such as laboratory capabilities. Outside the national infrastructure, there are additional sources of data to draw on, including international expert bodies (e.g., JECFA, JMPR and JEMRA), assessments undertaken by other countries, and regional diets developed by the WHO. These can all be utilized by countries in the region.
- Availability of adequately trained staff – competencies in a broad range of scientific and other professional skills are required to effectively apply risk analysis in a food safety context. The scientific skills required include microbiology, toxicology, food technology, nutrition, immunology and molecular genetics. Other professional skills such as legal, economic and communications are also required. FSANZ currently offers a training programme in scientific risk assessment and risk management to government officials applying risk analysis techniques in the region.
- Difficulty in communicating complex concepts, especially scientific and technical concepts, to the broader community restrict effective risk communication. FSANZ is currently developing training in risk communication which can be utilized by government officials in the region.

### **2.5.2 Benefits**

- Better identification and targeting of public health problems ultimately facilitate improvements in managing food safety.
- Better utilization of resources by focussing on addressing the highest food safety risks.
- Trade opportunities – risk analysis provides a solid basis for negotiating access to other countries by objectively demonstrating the absence of hazards or the effective control of hazards to produce a safe food.

- A community better informed about food safety issues, leading to improving production, manufacturing and trading practices.

### **3. Applications/Case Studies**

Four case studies are discussed below, based on Australian experiences, to illustrate the application of risk analysis principles in the context of food safety issues.

#### **3.1 Case study 1: Chloropropanols in soy and oyster sauces**

##### **3.1.1 The Problem**

In recent years there has been increasing scientific interest in a class of chemicals known as chloropropanols. The major chloropropanols are 3-chloro-1,2-propanediol (3-MCPD) and 1,3-dichloro-2-propanol (1,3-DCP), both of which can be found in a number of foods. Whilst it has been known for several years that chloropropanols can occur in soy and oyster sauces made from hydrolyzing vegetable proteins, a UK survey of soy and oyster sauces released in 2001 indicated the presence of high levels of 3-MCPD in some products.

Subsequently, FSANZ initiated its own food safety risk assessment and an analytical survey of soy and oyster sauces available at Australian retail outlets to ascertain the level of risk from chloropropanols in the Australian food supply.

##### **3.1.2 The Risk Analysis**

Initially the dietary exposure assessment component of this national risk assessment utilized the frequency and levels of contamination in samples from the UK survey, together with Australian food consumption data. However, as Australian test data became available, these were used in the dietary exposure assessment. The hazard identification and characterization components of the Australian risk assessment relied heavily on the work of the 57th meeting of the JECFA<sup>5</sup> held in 2001.

The national risk assessment concluded that the higher levels of chloropropanols in soy and oyster sauces posed an unacceptable food safety risk to consumers. Risk management decisions were taken in three areas:

1. Retailers and manufacturers of a number of soy and oyster sauce products that contained unacceptably high levels of 3-MCPD undertook a recall of these products.
2. A maximum limit of 0.2 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP, for soy and oyster sauces calculated on 40% dry matter content, was incorporated into the *Food Standards Code*. These standards ensured that the contaminants were at safe levels but also included the application of the ‘*as low as reasonably achievable*’ principle and were the levels that industry advised could be achieved using good manufacturing practice. The maximum limit of 0.005 mg/kg for 1,3-DCP was the limit of reporting for this substance using accredited analytical methods.

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<sup>5</sup> Joint FAO/WHO Expert Committee on Food Additives

3. Import testing for soy and oyster sauce products was introduced to prevent the importation of soy and oyster sauces containing unacceptably levels of chloropropanols.

Throughout the consideration of this issue, there was close communication between agencies and the relevant industry bodies. As soon as it was identified that certain products posed an unacceptable food safety risk, consumers were alerted by internet notices and newspaper advertisements and the affected individual products were recalled. Subsequently the full Australian risk assessment (Chloropropanols in food - an analysis of public health risks-technical series report number 15) has been published on the FSANZ website.<sup>6</sup>

### 3.1.3 The Issues

The formation of chloropropanols in food is still not fully understood, and Australian government agencies continue to liaise with relevant industry sectors to determine the source of chloropropanols in food, as well as monitoring the international literature. Initially there was very little data on chloropropanols in the Australian food supply and the data could be collected only after a testing capability was established. In the interim, Australia was able to draw on the work of the international expert bodies and other regulators to facilitate risk management decisions.

## 3.2 *Case study 2: Residues of nitrofurans in prawns*

### 3.2.1 The Problem

Nitrofurans are synthetic broad-spectrum antimicrobial agents used in some countries in human and veterinary medicine. There are four main nitrofuran chemicals referred to in the scientific literature, namely, furazolidone, furaltadone, nitrofurantoin and nitrofurazone.

In 1993, JECFA withdrew the health standard (ie. acceptable daily intake) for these nitrofurans due to the incomplete nature of the toxicological database and concerns about carcinogenicity in animal studies. As a result, many countries, including Australia, subsequently restricted, or prohibited, the use of nitrofurans in food-producing animals and subsequently, detectable residues in food products were not permitted.

In October 2003, data became available indicating that very low levels of a furazolidone metabolite, 3-amino-oxazolidinone, had been found in certain imported prawns. Where residues had been detected, they were only at a few parts per billion (ug/kg). However, in the absence of a specific maximum residue level (MRL) in the *Food Standards Code*, these residues were not permitted.

### 3.2.2 The Risk Analysis

As a result of these test findings, FSANZ undertook a risk assessment to establish the level of food safety risk to consumers from the levels of residue being detected in prawns. The risk assessment was undertaken to help inform enforcement agencies as to whether any risk managements actions should be taken to protect consumer health, such as testing of

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<sup>6</sup> [http://www.foodstandards.gov.au/media\\_releases\\_publications/technicalreportseries/technicalreportserie2094.cfm](http://www.foodstandards.gov.au/media_releases_publications/technicalreportseries/technicalreportserie2094.cfm)

prawns and/or recalls of batches of prawns containing detectable residues. The dietary exposure assessment component of the risk assessment utilized the residue concentrations found in an industry survey, and the hazard identification and characterization was based on a re-evaluation of the data summarized in the JECFA monographs.

The risk assessment indicated that the risk arising from these trace residues in prawns was very low and that the prawns were safe to eat. It was not considered necessary to recall prawns that had entered into distribution within Australia. However, given that these residues were not compliant with the *Food Standards Code*, the enforcement authorities were advised to introduce import testing of prawns for nitrofurans. A relatively low frequency of testing has been implemented, commensurate with the level of food safety risk to the consumer.

### 3.2.3 The Issues

The issue of nitrofurans residues in imported prawns has received considerable media attention within Australia and FSANZ and other government agencies have stressed that these prawns are safe to eat. However, the paucity of toxicological data and the absence of an acceptable daily intake posed a particular challenge to the risk assessment. These residues had been detected in other countries but Australia was unable to confirm their presence until a testing methodology was established. This also made the communication of the level of risk to the community more difficult, particularly in the light of sensational media reporting. FSANZ plans to publish its risk assessment on its website.

## 3.3 ***Case study 3: Listeria monocytogenes in cooked crustacea***

### 3.3.1 The Problem

*Listeria monocytogenes* in certain food categories poses a potential public health and safety problem, especially for vulnerable sub-populations such as pregnant women, the immunocompromised and the elderly. While the incidence of systemic infection caused by *L. monocytogenes* in food is low, the consequences can be severe and include death. In 2002, FSANZ performed a microbiological risk assessment to estimate the public health risk posed to Australian and New Zealand consumers from the consumption of cooked crustacea contaminated with *L. monocytogenes*.

### 3.3.2 The Risk Analysis

The risk assessment utilized data derived from a survey of *L. monocytogenes* in cooked prawns undertaken by FSANZ in 2002<sup>7</sup>, and from public health information on the frequency of Listeriosis. This survey was undertaken because of a lack of national information on the level of *Listeria* contamination of this food in Australia. Probabilistic modelling undertaken as part of the risk assessment estimated that, if there was no growth of the organism during domestic storage, one case of listeriosis every 1,600 years may arise from the consumption of contaminated crustacea in Australia. Modelling of a worst-case scenario, which assumed that cooked prawns would be stored in a domestic refrigerator for a maximum of three days after purchase (allowing growth of *L. monocytogenes*), indicated that there could be one case of listeriosis caused by cooked crustacea every 2.5 years in Australia.

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<sup>7</sup> FSANZ Survey of *Listeria monocytogenes* in Cooked Prawns, 2002.

The risk assessment concluded that the risk of contracting Listeriosis from this commodity is very low. This was based on:

- the findings of the probabilistic modelling;
- the infrequent contamination of cooked crustacea with *L. monocytogenes* (~ 3 %) and at low levels (< 50 cfu per gram<sup>8</sup>);
- the production process includes a kill step (cooking), and
- the shelf life of the product is short, thereby restricting the opportunity for growth of the pathogen present in the food due to post processing contamination.

As a result of the risk assessment, the low risk to the general population posed by *L. monocytogenes* in cooked crustacea did not warrant a microbiological limit. However, it was recognized that the risk may be higher for certain subpopulations and that alternate risk management measure were needed.

### 3.3.3 The Issues

Additional advice for susceptible populations (in the form of an advisory fact sheet) was considered the most appropriate risk management strategy. FSANZ has previously developed such advisory material and is currently revising its fact sheet for persons at risk.

A copy of the full microbiological risk assessment is available from FSANZ website<sup>9</sup>.

## 3.4 **Case study 4: Risk analysis of foods derived from biotechnology**

### 3.4.1 The Problem

How to firstly ensure that foods derived from genetically modified (GM) crops and other GM organisms could be demonstrated to be as safe as their conventional counterparts, and secondly, to ensure that consumers have information about the food they purchase through appropriate labelling.

### 3.4.2 The Risk Analysis

In Australia food produced using gene technology is subject to a scientific safety assessment before it may enter the food supply. The mandatory pre-market approval process applies to all GM foods whether grown domestically, or in other countries. There are similar procedures for the assessment of GM foods in other countries such as Canada, Japan, the United States, the United Kingdom and other parts of Europe. In addition, the FSANZ safety assessment process for GM foods is consistent with the approach developed by the Codex Alimentarius Commission.

FSANZ undertakes the safety assessment of GM food according to five key principles:

1. *Safety assessments use scientific, risk-based methods:* Scientific data for safety assessments are obtained from a variety of sources (primarily from the applicant but also from the scientific literature, general technical information, independent

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<sup>8</sup> The limit of detection for the enumeration method used

<sup>9</sup> <http://www.foodstandards.gov.au/srcfiles/P239listeriaFAR.pdf>

scientists, other regulatory agencies and international bodies, and the general community) and assessed using internationally recognized scientific, risk-based methods.

2. *Safety assessments are conducted on a case-by-case basis:* The safety of GM foods cannot be assessed as a single class because the safety concerns depend on the type of food and the nature of the genetic modification. Safety assessments are done on the fractions or components of individual GM varieties that are used as food or in food preparation. For example, food derived from soybeans that have been genetically modified in different ways would be assessed separately.
3. *New genetic material, new proteins and other characteristics of the GM food are considered:* FSANZ considers the safety of new components (new genetic material/ DNA, and proteins which are coded by the DNA) in the GM food are considered separately and completely. Other characteristics of the food, such as the levels of nutrients and naturally occurring allergens, toxins and anti-nutrients, are also considered in detail because they could be indirectly affected by the genetic modification.
4. *Both the intended and unintended effects of genetic modification are considered:* The intended effect (direct effect) of the introduction of the new gene is the production of the new protein that confers the desired trait. The direct consequences of the genetic modification, for example the potential toxicity/allergenicity of any novel protein, potential for horizontal DNA transfer of an antibiotic resistance gene or the nutritional consequences of any intended compositional change, are thoroughly assessed as part of the safety assessment process. Unintended (indirect) effects, such as changed composition, e.g. significant changes to the fatty acid profile, the potential creation of a new toxin or allergen, significantly changed vitamins and minerals etc, need to also be considered in detail. These may vary depending on the nature of the genetic modification.
5. *Where appropriate, comparisons are made to conventionally produced foods:* The new food is compared to its conventionally produced equivalent. A GM food can be compared with its conventionally produced equivalent provided the latter has a history of safe use. The comparison is used to identify whether the GM food has different levels of allergens, toxins, nutrients or anti-nutrients that are naturally present in the conventional food. Any significant differences between the GM food and the conventional food are assessed for potential adverse health effects. It is important to note that, although a GM food may be found to be different in composition to the traditional food, this in itself does not necessarily mean that the food is unsafe or nutritionally inadequate. Each GM food needs to be evaluated on an individual basis.

### 3.4.3 The Issue

The risk analysis framework established for the regulation of GM foods in Australia and New Zealand is arguably one of the most scientifically robust, consultative and transparent in the world today. Valuable experience gained by FSANZ is being used to improve the regulatory system for GM plant-derived foods and assist the development of guidelines for the future regulation GM foods derived from microorganisms, animals and fish, and foods produced using novel production techniques or containing novel ingredients.

#### **4a. Practical actions which have been taken by Australia**

Each country will meet the challenges of food regulation in its own way and which suit its particular circumstances. Some examples of how Australia has contributed to an international and regional response are given below.

##### ***International contributions to risk analysis activities***

With the expertise FSANZ has in food regulation and in the application of risk analysis to address food safety issues, it regularly contributes to regional and global dialogue on food safety issues and specifically risk analysis. FSANZ contributes to the international dialogue on food safety issues through Codex meetings, expert panels, and at international consultations in the World Health Organisation (WHO). For example, FSANZ contributes to the work of joint FAO/WHO Expert Committee on Food Additives (JECFA), Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and the joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA), and provides expert advice and data to FAO/WHO expert consultation meetings.

##### ***Capacity building in risk analysis***

FSANZ is also involved in technical assistance programmes with neighbouring regional countries. Technical assistance is usually provided via collaborative projects with support from agencies such as AusAID, APEC, FAO, WHO, the Organization for Economic Co-operation and Development (OECD), and MFAT (the New Zealand Ministry of Foreign Affairs and Trade). These programmes seek to:

- increase trade in safe food by improving the consistency and transparency of food regulatory systems in developing countries;
- develop means for facilitating the harmonization of food standards in the Asia Pacific region;
- improve the scientific and technical capacity of developing countries, particularly in respect to their participation in the work of Codex;
- build on and strengthen the technical and scientific credibility of the developing countries; and
- assist in the development of strategic partnerships between APEC/ASEAN countries, particularly in Codex matters.

The form of international capacity building is varied and includes the following:

- exchange of information on food standards, standards development, survey design and implementation, and risk assessment methodology;
- collaboration and exchange of information on research and scientific risk assessments;
- exchange of views on the work of international food safety and food standards bodies and the development of a shared vision in food safety; and
- visits by experts and management personnel.

Examples of the types of programmes undertaken in recent years include:

Activity	Country	Collaborating Agency
Food recall programme	Fiji	WHO
Training workshop on safety and risk assessment of agriculture-related GMOs	ASEAN countries	ASEAN/ILSI
Food recall programme	Vanuatu	WHO
User guide for food labelling and compositional standards	Indonesia	AusAID
Risk assessment training (2 programmes: chemical and microbiological risk assessment)	12 regional economies	APEC/AusAID
Food safety training programme development	Viet Nam	WHO
Development of food legislation	Viet Nam	WHO
Safety assessment of genetically modified food	Regional economies	APEC

In the last six months, FSANZ has undertaken a major review of its contribution to capacity building in the region. It has restructured its offerings and now offers a comprehensive training programme. Details can be found on the FSANZ website.

### ***Developing Strategic Alliances***

In order to improve food safety generally, FSANZ has sought the creation of linkages and alliances with regional and international organizations. Such alliances have enhanced the capacity of FSANZ to access external funding in order to be able to deliver technical assistance projects. Alliances have been developed with:

(a) *World Health Organization (WHO) Western Pacific Regional Office*

There has been very significant activity with WHO's Western Pacific Regional Office. A major focus for FSANZ has been its training activity in Vietnam. In addition to its interest in this particular activity, WHO WPRO has indicated that it wishes to discuss collaboration in delivering the FSANZ- developed training programmes on risk assessment and standards development to other countries in the Asia Pacific region, in particular in the South Pacific.

(b) *International Life Sciences Institute (ILSI)*

FSANZ has had discussions with ILSI on joint work on food safety, genetically modified foods and in the area of food/drug interface products. FSANZ and ILSI (South East Asia) are developing a draft protocol/agreement concerning such collaboration.

(c) *Bilateral Links*

FSANZ also provides professional advice and guidance on risk analysis to individual countries on a bilateral basis. A recent initiative involved a strategic assessment of the food safety system for the Government of Brunei in 2003.

### ***Case Study: Training in risk assessment in support of food safety measures***

FSANZ, through funding support from APEC and AusAID, was able to deliver two training programmes designed to improve the capacity of developing member economies to undertake risk assessments.

The training consisted of two, two-week courses. The first course (Hanoi, July 2002) concentrated on the risk assessment of contaminants, natural toxicants and pesticide residues



in food. The second course examined microbiological risk assessment and was held in Ho Chi Minh City in October 2003.

Participants were drawn from a number of countries in the region, including: Brunei Darussalam, China, Chinese Taipei, Hong Kong, Indonesia, Lao People's Democratic Republic, Malaysia, Papua New Guinea, Philippines, Republic of Korea, Singapore, Thailand, South Korea and Viet Nam. Participants were provided with comprehensive training materials and during the intensive hands-on programme were instructed in how to undertake a risk assessment, and in the roles and responsibilities of risk assessors.

A recently completed programme involved training in the safety assessment of genetically modified (GM) foods. FSANZ, with funding support from APEC, conducted a one-week training programme in the safety assessment of GM foods. The course focussed on international perspectives for safety assessments of GM foods, including examination of approaches and guidelines established by Codex and FAO/WHO, a review of international approval systems, and an overview of current methodology.

#### **4b. Conclusions**

Firstly, countries should apply risk analysis principles in the management of food safety risks. This is both a requirement of the WTO (the SPS Agreement in particular), but is also a useful tool for the efficient identification of risks and the devising of appropriate risk management strategies.

The most effective food regulatory system, in the view of FSANZ, is one in which countries have clearly defined the responsibilities of food regulatory agencies in managing food safety issues. As a country that has a more complex food regulatory system than most, the importance of this is well known. Food safety emergencies are not the ideal time to be deciding who has responsibility for a particular issue.

Food safety emergencies are the best test of the quality of a food regulatory system. They are usually characterized by incomplete data, public concern and a lack of time to make a full risk assessment. In such circumstances, countries should undertake a provisional risk assessment, which must be revised as additional scientific data becomes available. The technical, scientific and management skills that are required to operate an effective food safety system in the 21<sup>st</sup> century are not easily come by. Developed countries have an obligation to ensure that their expertise is shared, both by information sharing and the provision of technical assistance (particularly training) to developing countries.

As part of the information sharing, countries can exchange documented risk assessments relating to food safety hazards to facilitate consistency and a common understanding of food hazards. FSANZ has found that placing technical reports and risk assessments on its website to be an excellent mechanism for encouraging this type of exchange.

Finally, the best risk assessment techniques and superlative risk management strategies are useless if there is poor communication of these aspects to stakeholders, particularly consumers. The 1990s were characterized by a loss of faith in a number of countries in the ability of the food regulators to protect public health and safety in those countries, not least because of poor communication. The level of public trust is closely related to the openness and transparency of the regulator. As new food safety risks emerge,

food regulators need to ensure that there is a clear and consistent message about those risks which is continuously communicated to industry and consumers, and that in turn, the regulator listens carefully to what those industry and consumer voices are saying. Food safety is a shared responsibility and everyone must feel that they have a role to play in delivering a safer future.

Agenda Item 7

CAP 04/4

**FAO/WHO Regional Conference on Food Safety for Asia and Pacific**  
Seremban, Malaysia, 24-27 May 2004**Prioritization and Coordination of Capacity Building Activities**  
(Paper prepared by India)**1. INTRODUCTION**

With globalization, the Uruguay Round of Multilateral Trade Negotiations and subsequent World Trade Organization (WTO) Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT), food quality and safety issues have become significant in the context of food security, public health protection and international food trade. The need to improve food quality and safety, and accordingly the need for capacity building in this area, is well acknowledged, not only in developing but also many developed nations with a view to make them WTO-compatible.

Article 9 of the SPS Agreement and Article 12 of the TBT Agreement emphasize the need for 'Technical Assistance' to developing country members, in particular, to meet the SPS measures of the developed importing countries to facilitate market access for developing members. The Agreement further provides that the technical assistance may cover creation of infrastructure, research activities and processing technologies. It provides not only for technical expertise and training to the developing members but also the hardware necessary to achieve the appropriate levels of sanitary and phytosanitary protection needed in their export markets.

Accordingly, there has been an increase in food safety capacity building activities internationally. Some of these activities under the aegis of Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) which have taken place in the recent past are available as an informational document for the 26<sup>th</sup> Session of the Codex Alimentarius Commission (Codex) (<http://www.fao.org/DOCREP/MEETING/006/y9805e.htm>).

This paper addresses the need for national identification and prioritization of specific, urgent and important capacity building needs, coordination of capacity building activities, the long term sustainability of the capacity building activities.

**2. NATIONAL IDENTIFICATION OF SPECIFIC URGENT AND IMPORTANT CAPACITY BUILDING NEEDS**

The capacity building process must begin with an honest assessment by that country, involving all stakeholders, to identify the specific urgent and important needs of that country. The needs assessment process requires the review of the existing structure including legislation, agencies involved, existing capabilities, and priorities. The assistance needs would broadly include various aspects of human and institutional capacity building. FAO is in the process of developing guidelines for assessing food safety capacity building needs which includes assessment tools for different components of food control systems to assist countries in determining what these needs are for that particular country in each area.

In 2002-2003, the Food Quality and Standards Service of FAO developed, administered and compiled questionnaires for capacity building in food safety. Based on responses from at least 48 countries in Africa, Asia, Latin America, the South-west Pacific and the Near East, areas were identified which needed strengthening. The report of these questionnaires can be found at: [ftp://ftp.fao.org/es/esn/food/CB\\_questionnaire.doc](ftp://ftp.fao.org/es/esn/food/CB_questionnaire.doc).

In 2003 FAO and WHO jointly published *Assuring Food Safety and Quality - Guidelines for Strengthening National Food Control Systems* to enable national authorities, particularly in developing countries, to improve their food control systems. The guidelines outline the strengths and weaknesses of the elements of various food control systems and seek to provide advice on strategies to strengthen food control systems to protect public health, prevent fraud and deception, avoid food adulteration and facilitate trade. In addition to national authorities, the guidelines are also useful in providing assistance to a range of other stakeholders including consumer groups, industry and trade organizations, farmer groups and any other groups or associations that influence national policy in food safety and quality.

### **3. COORDINATION OF CAPACITY BUILDING ACTIVITIES**

Although there have been various capacity building and technical assistance activities implemented in individual countries which have resulted in strengthening of specific elements of food safety and quality control, these have not always been coordinated or placed in the context of an overall food safety and quality strategy or development plan. As a result, many of these have been ineffective or inadequate in achieving optimal or sustainable results. It is therefore necessary to improve the collaboration and coordination amongst various agencies involved in food safety capacity building, whether within a specific country, regionally, or internationally.

#### **3.1 Regional approaches**

Many capacity building activities do not adequately address the regional needs or address areas of common concern. Areas for regional cooperation should be identified so that appropriate assistance can be developed, thus leading to strengthening of the capacities of the entire region. Furthermore, the strengths of each country need to be identified and a system developed for providing technical assistance to other countries in the region. Some of the areas identified could include testing, inspection and certification including export certification.

##### *3.1.1 Joint participation in international standards formulation*

With greater acceptance of Codex standards, there has been an increased interest by member countries in the activities of the Codex Alimentarius Commission. The SPS Agreement also clearly emphasizes that countries should participate in international standards work.

Participation by individual countries in the work of international standards setting organizations is very difficult due to cost and capacity constraints. Making known the view point of a developing country can require a great deal of effort. Regional capacity building efforts which would foster more regional cohesiveness would enable all the countries of the region to have a more effective voice in the Codex process. Countries also need assistance to provide relevant data to the Codex system and to take part fully in the standard setting process, including physical attendance at Codex meetings.

### 3.1.2 *Safety management systems approach*

The HACCP-based approach is being incorporated into the new hygienic codes under development by Codex, as well as the regulatory requirements of many countries including Australia, Canada, USA, members of the European Union, and others, especially for more risk-prone products such as marine, meat, poultry and dairy products.

To develop the industries and control authorities in the region, regional programmes can be arranged on a rotational basis to cover the following aspects:

- i) Study the HACCP systems being implemented in the developed countries;
- ii) Develop HACCP modules for various important sectors which would assist the industry;
- iii) Arrange training for industry and for competent authorities on all aspects of HACCP, including auditing.

### 3.1.3 *Establishment of a regional centre for human resource development in food safety and quality*

Training has been identified as an important activity to develop and upgrade human resource skills and to implement food quality and safety programmes as per international requirements. Efforts should be made to establish a regional centre for human resource development in food safety and quality to address the training needs of the region in areas such as food inspection, laboratory analysis, the application of HACCP, etc. Required funding could be sought from potential donors. This would address the needs of all countries in the region.

### 3.1.4 *Equivalence*

The concept of equivalence has been recognized in the SPS Agreement and is also being encouraged at the international level by Codex with a view to using pooled resources more effectively, avoiding duplication of inspection and testing, and ensuring that health and safety requirements are met effectively. These also serve as an important means of facilitating trade by recognition of the standards and certification systems of the exporting country to provide for an equivalent level of protection against health risks as those of the importing countries and also lead to reduced rejection rates and provide for reduced inspection of export products in overseas markets.

Such equivalence agreements are normally signed between the importing and exporting countries individually. However, if such agreements are developed regionally – a form of regional agreement for recognition of the equivalence of specified SPS measures of all countries in the region, it would not only benefit trade within the region but also give strength for negotiating equivalence agreements with third-party countries on regional basis. Such agreements would also help reduce the financial burden for each member.

### 3.1.5 *Risk-based approach and harmonization at regional level*

Risk to consumers resulting from hazards in foods has been identified as a significant concern at the international level. Article 5 of the SPS Agreement provides that sanitary and phytosanitary measures should be based on risk assessments, taking into account an appropriate assessment of the actual risk involved, and, if requested by the exporting country,

make known details of this assessment. Codex is also promoting the application of risk analysis principles throughout all Codex Committees in establishing and adopting standards. It becomes necessary, at times, to carry out risk assessments before fixing standards for domestic use, especially when these relate to indigenous products or are different to international standards due to local or regional conditions. It is proposed that such standards are formulated at the regional level, based on joint risk assessment studies which are conducted by utilizing the strengths of respective countries. This may also require harmonization of standards within the region.

#### 3.1.6 *Laboratory networking*

Increasing sophistication of laboratory instrumentation and methods of food analysis has handicapped many developing countries. Accordingly, strengthening the equipment, manpower and infrastructure of laboratories has been identified as an important area. A system of networking of laboratories within the region may be useful in order that the facilities in one country could be utilized by other countries so that facilities are not unnecessarily duplicated, while at the same time are available to all countries of the region. Accreditation of these laboratories on common international criteria would be a prerequisite.

Joint training programmes for laboratory personnel may also be organized. It may also be useful to have a system of specific laboratories given the responsibility of development and maintenance of standard methods and sharing of the same. Inter-laboratory calibration tests could also be organized within the region. This would also facilitate sharing of analytical test data for decision-making as well as standards development.

#### 3.1.7 *Certification*

Facilities for certification in different areas, such as export certification, HACCP, ISO 9000, etc. should be recognized within the region, irrespective of the country of operation. A country which has additional experience in one area could assist the countries of the region without existing systems in that area until they are able to establish their own system.

#### 3.1.8 *Regional committee on safety and quality*

It is proposed to set up a regional committee to deal with all food safety and quality issues in the context of WTO, which should have members from all countries in the region and meet quarterly to discuss the areas of joint cooperation and collaboration in the above areas, identify assistance needs etc. The chair could be decided by rotation and meetings also held in countries on rotational basis.

### 3.2 International level

There is a need to coordinate food safety capacity building activities at the international level, including activities such as those given below:

- Arranging regional or global food safety events to discuss and share experiences on food safety issues of global concern;
- Organizing workshops on the application of HACCP in the prevention and control of contaminants, toxins etc;
- Formulation and implementation of projects on food safety in which different countries may take part and thus improve the quality of the trade intensive

products common to each other. These projects might also include trans-boundary movement and prevention of animal and plant diseases;

- Implementing an integrated international programme on biotechnology and food safety and quality to build up human resources and sanitary and phytosanitary measures.

#### **4. LONG-TERM SUSTAINABILITY OF THE RESULTS OF CAPACITY BUILDING ACTIVITIES**

In order for technical co-operation activities to be effective and sustainable in the long term, all stakeholders should be involved in addition to professional capacity building. Special emphasis should be given to appropriate sensitization of key persons, such as policy makers, and to the development of public education programmes related to food safety, such as inclusion of quality and safety aspects in educational curriculum. Food control systems must be strengthened by implementation of international systems standards such as Codex, ISO 17020, ISO 17025, ISO/IEC Guide 62 and 65 and seeking accreditation to ensure continued implementation of international norms.

#### **5. CONCLUSION**

Capacity building must reflect the needs, priorities and conditions of developing countries. Although there have been activities related to capacity building, efforts have been sporadic and critical mass and multiplier effects have not been achieved. Most of the capacity building activities have been focused on training and seminars, while infrastructure development, such as equipment for laboratories, has been limited. Capacity building must be addressed in an integrated manner with a national, regional and international perspective.

**FAO/WHO Regional Conference on Food Safety for Asia and Pacific**  
Seremban, Malaysia, 24-27 May 2004

**Communication, Information Exchange and Education  
Related to Food Safety**

(Paper prepared by the Government of Japan)

**1. Introduction**

Today's global society demands that all stakeholders along the food chain, including government bodies, research and academic institutions, the food production and processing sector and consumers, improve their information exchange, education, and risk communication. This increased transparency should improve food safety and strengthen consumer confidence. Important lessons learned by one country in these areas should be shared with other countries, which should lead to improved regional collaboration in improving food safety.

**2. Risk Communication - Examples from Japan**

Recently Japan has experienced a number of incidents that led to the loss of consumer confidence in the safety of food. A large-scale food poisoning caused by milk products produced in a HACCP<sup>1</sup>-certified factory in June 2000 and the detection of the first Bovine Spongiform Encephalopathy (BSE)-infected cow in September 2001 are among a sequence of such incidents. In April 2002, the Government of Japan established the "Ministerial Council on the Administration of Food Safety" to consider and propose modalities for a new administrative organization necessary for ensuring food safety. The Ministerial Council consists of the Ministers of Public Management, Home Affairs, Post and Telecommunications; Health, Labour and Welfare; and Agriculture, Forestry and Fisheries; and the Chief Cabinet Secretary. The Ministerial Council, utilizing the report of the Advisory Committee on the Investigation of BSE Problems and information from other sources, decided that: (1) with a view to protecting the health of consumers as the highest priority, risk analysis should be implemented by the government to deal with food safety issues and a new body, the Food Safety Commission, should be established to conduct risk assessments; and (2) a new comprehensive law, the Basic Law on Food Safety (provisional name), should be elaborated to ensure food safety with an objective to protect consumers. Consequently, the Basic Law on Food Safety was enacted in May 2003, and the Food Safety Commission was established in July 2003 as a subsidiary body of the Cabinet Office. The Commission is independent from the risk management bodies of the Ministries of Health, Labour and Welfare (MHLW) and of Agriculture, Forestry and Fisheries (MAFF).

The above-mentioned decisions and activities of the Government of Japan show that in order for consumer concerns about BSE in Japan to subside, not only successful risk communication, but also significant changes in the government system were necessary. These changes include the introduction of risk management measures, the enactment of the

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<sup>1</sup> Hazard analysis and critical control point.



comprehensive law, and the establishment of the risk assessment body, all of which the Government hoped would restore consumer confidence.

## **2.1 Risk communication examples before the implementation of risk analysis**

### **2.1.1 Food Poisoning caused by milk products**

This first case, also reported in the *Lancet* medical journal (page 573; Vol. 356, 12 August 2000), is an example of problems caused by inappropriate company management.

Food poisoning caused by the consumption of milk products, including "low fat milk", produced in the Osaka factory of the Snow Brand Company, affected 14,780 persons (the number of those who showed symptoms since the first report on 27 June 2000), making this an unprecedentedly large-scale food poisoning. It became clear during the investigation that there were many problems that triggered the outbreak, all of which contributed to the great loss of consumer trust in the manufacturer. These problems include: the delay in reporting the incident to the authorities, which increased the number of persons affected; inappropriate hygienic practices despite the fact that the factory had been HACCP-certified by the MHLW under Article 13 of the Food Sanitation Law; improper implementation of the HACCP plan; multiple occasions where the contents of press releases regarding the intermediate reports of the outbreak investigation both from regulatory authorities and the company were released prematurely; the continuation of the sale of other products which might contain the staphylococcus toxin; insufficient manufacturing record keeping and others.

In this case, the lack of information disclosure by the company, defective food safety controls, a lack of a sense of crisis, and inappropriate communication with consumers were identified as major problems.

### **2.1.2 BSE-infected cows in Japan**

This case contains examples of problems that were worsened by the inappropriate safety controls and crisis communication of the Government.

On 10 September 2001, MAFF officially announced that a dairy cow brought to a slaughterhouse in Chiba Prefecture was unable to stand up and was suspected to be infected with BSE. This announcement drove the whole nation into a state of panic.

The government explained to the public immediately after the first BSE case that the number of BSE cases would be very low in Japan. However, consumers erroneously perceived the threat of BSE cases to be very large rather than listening to the government's statements and began to distrust and become discontented with the Government.

The MHLW and the MAFF undertook a series of measures to ensure the safety of beef in the market, including the following:

- Discontinuation of the sale of beef from the farm where the suspected cow was raised (11 September);
- Suspension of the shipment of any cows at or above 30 months of age in the entire nation (19 September);
- Removal and incineration of the specified risk materials (SRM) from cows at or above 12 months of age (27 September);

- Removal of the SRM and the implementation of screening tests of all cows of all ages (18 October); and so on.

As the Government implemented such measures to ensure the safety of beef and informed the general public about these measures, consumers' concerns gradually subsided.

## **2.2. Examples after the implementation of risk analysis**

Since July 2003, the Japanese Government has actively conducted risk communication within the framework of risk analysis. For example, 34 meetings of stakeholders, such as administrators, consumers, producers, and food safety experts were held to exchange opinions in different areas of Japan between July 2003 and March 2004. The purpose of these meetings is to listen to the opinions of stakeholders and reflect those opinions in risk management measures. Some of the experiences occurring under this new framework are detailed below.

### **2.2.1 BSE-infected cows in Canada and the United States of America**

A BSE-infected cow was found in Canada in May 2003 and another in the USA in December 2003. Immediate suspension of beef imports from these countries; disposal of beef contaminated with SRM; rapid announcements of the identification of BSE-infected cows in Canada and the US; and effective control measures taken by the Japanese government all resulted in insignificant changes in the purchasing and dietary behaviours of Japanese consumers.

### **2.2.2 Avian Influenza cases in Japan**

In the case of Avian Influenza (AI), despite banning poultry imports from the affected areas as soon as information about the outbreaks was obtained, some cases have unfortunately been found in Japan. It is considered, however, that these cases were caused by migratory birds rather than related to international food trade.

The first outbreak in Yamaguchi Prefecture, reported on 16 January 2004, and another in Oita Prefecture, reported on 16 February 2004, did not significantly change the purchase or dietary behaviours of consumers.

However, the AI case in Kyoto, first reported on 26 February, resulted in a drastic reduction of the sales of chicken and eggs. No report had been made to the animal health authority in the Prefecture before that day, even though a huge number of chickens died and the number of deaths had increased every day for the last 6 days. These signs should have led the farm to suspect Avian Influenza or other disorders. Despite the large number of deaths, the farm sent chickens to two chicken processing establishments, one in Hyogo Prefecture and the other in Aichi Prefecture on 25 and 26 February. Some meat entered the food chain despite the efforts to recall all the products originating from that farm. Because consumers considered the actions of the farm to be immoral, the communication between different prefectural governments was insufficient, and the recall situation report from the Hyogo Prefecture government was revised and consumer confidence was lost.

Immediately after the AI outbreak in the Yamaguchi Prefecture, the Government began to disseminate information through the Internet and other means to promote good understanding by the general public. Since national concerns grew sharply after the outbreak

in Kyoto, on 9 March the Government of Japan began a campaign to provide the people of Japan with the correct knowledge about Avian Influenza. Moreover, a meeting of the executive officials and relevant AI experts was held in Kyoto on 22 March along with an opinion exchange meeting with local stakeholders, thus deepening mutual understanding.

An Internet survey was conducted on 7 and 8 March 2004 by a company named "OISIX", which sells vegetables and other foods to the readers of their mail magazines. The results showed that although 84% of the respondents knew that there was no epidemiological information to suggest that the disease can be transmitted through contaminated chickens and eggs, 44% of the respondents refrained from their purchase, which indicates that knowing that something is safe does not cause someone to purchase it. These results illustrate the difficulty of risk communication.

With regard to Avian Influenza, it is estimated that consumers' concern is proportional to the amount of reports about it in the press, although inadequate handling of the problem by the farm is obviously the critical factor for the increased concern.

### **3. Strengthening Information Collection and Exchange Activities Related to Food Safety**

Information must be accurately collected and effectively exchanged between and among research institutes, government bodies, the food production and food processing industries and consumers in order to improve transparency, and in an effort to improve food safety.

Triggered by the BSE cases, the system to address food safety has been strengthened in Japan, especially information collection and exchange activities.

#### **3.1 Information collection and exchange within Japan**

One element of the food poisoning control measures based on Article 58 of the Food Sanitation Law in Japan is an information collection system. Any physicians that diagnose a food borne disease must report the case to the government through the health centre in the area.

This system has proved to function effectively in large-scale food poisoning cases, such as the Snow Brand case. Hospitals and other medical institutions care for patients suffering from vomiting, diarrhea and other food poisoning symptoms, and therefore can identify signs of the occurrence of food poisoning. In the Snow Brand case, such hospitals and other medical institutions reported the occurrence of food borne disease to their respective health centre on the same day as seeing the patients. After obtaining this information from the health centres, city officials performed an emergency investigation of the factory on the following day and reported the results to the MHLW.

Information collected through food poisoning reports has also been utilized for identifying increased risk associated with specific food/pathogen combinations, developing risk profiles, and making risk management decisions to control the specific hazards in the food.

### **3.2 Information collection and exchange with other countries**

After the first BSE cases in Japan, it was recognized that collection and analysis of food safety information from abroad was insufficient, and needed to be strengthened. Following these cases, the mechanism to collect information from international organizations and overseas countries in a more timely and efficient manner has been enhanced.

It is extremely important for Japan to be able to obtain food safety- related information from other countries as early as possible because imported foods occupy about 60% of the total food supply in Japan. Furthermore, the concept of the global spread of emerging hazards is not yet common in the country as Japan is geographically isolated by the seas, which made the intrusion of foreign hazards unlikely until recent decades.

The control of other diseases such as SARS emphasizes the importance of information collection and its timely exchange. For example, Japan could successfully prevent the occurrence of SARS because of adequate information collection and counter-measures.

## **4. Education on Food Safety**

Education in food safety is essential, at all levels, with all stakeholders, and utilizing all types of educational methods. Through effective education and communication, a culture of food safety should be fostered in each country. Several activities in this regard already exist in many countries of the region. In Japan, the system for educating small-scale food producers/processors and food vendors in food hygiene and other areas of food safety has been developed over many years and has contributed to the improvement of food hygienic conditions in Japan.

The Food Sanitation Law of Japan was established in 1947. Food manufacturers, producers, processors and vendors, subject to regulation by the Food Sanitation Law, are obliged to comply with this Law. In 1948, the Japan Food Hygiene Association, comprised of food manufacturers, producers, processors and vendors, was founded. The objective of this Association is to prevent food borne illness, food poisoning and any other problems related to food and beverages through increasing food hygiene awareness among its members and through the implementation of their voluntary food control systems.

In Japan, food sanitation inspectors belonging to the health centres of each local government conduct food inspections and provide guidance in accordance with the Food Sanitation Law. The above-mentioned Food Hygiene Association works in this area in collaboration with health centres in local governments and the national government.

Each time when a food safety- related law or rule is amended, the national government and health centres organize meetings to explain the amendment(s) to food manufacturers, producers, processors and vendors. The activities of the Food Hygiene Association in this area include: assigning August as a nation-wide “Month of Food Hygiene”; organizing briefing meetings and training courses for food manufacturers, producers, processors and vendors and consumers; providing food sanitation instructors’ guidance on food safety; and giving advice to newly- opened restaurants. These activities provide more specific guidance and advice in the area of food safety than those by the governments and are more focused on small-scale food manufacturers, producers, processors and vendors.

While the responsibilities borne by food manufacturers, producers, processors and vendors in relation to food safety have increased, there has been little change in the food safety- related education system for several years, except that the government now puts more emphasis on consumer education.

## **5. Conclusions**

It appears that the concept of risk analysis in food safety has not been well understood by the public in Japan although the Government has been actively involved in risk communication since July 2003. Therefore, the Government should strive for both the promotion of the concept of risk analysis and enhancing risk communication for sometime to come. The Japanese in general respect harmony, but expressing one's own opinions in front of many other people or debating is not in the national tradition. It is the Government's duty to make risk communication more useful and effective under the internationally- agreed risk analysis framework, taking into consideration the tradition, culture, and characteristics of the Japanese people.

It is essential to collect and exchange food safety related information within Japan as well as with other countries. Since global food trade is increasing, food safety problems in exporting countries should be carefully monitored. Information from the all other countries should be collected and carefully analyzed in order to make better risk management decisions based on scientific information.

## **6. Recommendations**

When performing risk communication, it is important to offer exact information as early as possible. Since zero-risk in food safety issues cannot be achieved, in order to decide and implement risk management options for minimizing the risk in practical way, risk communication among all stakeholders, especially those who might suffer any negative affects, is extremely important to achieve consensus to implement the risk management strategy.

The rapid globalization of food production and trade has increased the potential likelihood of international incidents involving food contaminated with microbial or chemical hazards. This is important for exchanging routine information on food safety issues and to have rapid access to information in case of food safety emergencies. In order to manage food safety risks appropriately in a timely manner, it is important to establish a mechanism to promote the exchange of food safety information and to improve collaboration among food safety authorities at national and international levels. In this regard, Japan would like to encourage the development of a new International Food Safety Authorities Network (INFOSAN), which has recently been proposed by the Food Safety Department (FOS) of WHO.

In order to reduce the burden of food borne illness, it is important to provide relevant food safety education and information to a large audience across the food chain, including small-scale businesses and street vendors, and to ensure consistency in food safety messages that are being disseminated. In this regard, scientifically- sound food safety information should be accessible globally from FAO and WHO.

**FAO/WHO Regional Conference on Food Safety for Asia and Pacific**  
Seremban, Malaysia, 24-27 May 2004

**FOODBORNE DISEASE MONITORING AND SURVEILLANCE SYSTEMS**  
(Paper prepared by the Government of Malaysia)

**1. INTRODUCTION**

Food borne diseases are usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food. They have a significant impact on people's health, along with economic consequences, and represent a growing public health problem. Outbreaks of food borne disease attract media attention and raise consumer concern in developing as well as developed countries.

The global incidence of food borne diseases is difficult to estimate although many people fall ill and die as a result of eating unsafe food. In industrialized countries, 30% of the people are affected by food borne diseases annually, and the problem is likely to be even more widespread in developing countries. WHO reported that in 2000, 2.1 million people died from diarrhoeal diseases, most of whom were children in the less developed countries. For example, in the United States of America (USA), 76 million cases of food borne diseases resulting in 325, 000 hospitalizations and 5,000 deaths were estimated to occur each year, while medical costs and loss of productivity were estimated as USD 35 billion (1997). The cholera outbreak in Peru in 1991 resulted in the loss of USD 500 million in fish and fishery export for that year while in Japan an outbreak of *Escherichia coli* O157:H7, an emerging food borne pathogen which presents itself as acute bloody diarrhoea and renal failure, had affected over 6,300 school children and resulted in 2 deaths in 1996.

In Malaysia the incidence of notifiable food borne diseases, namely cholera, typhoid, food poisoning, hepatitis A and dysentery is less than 5/100,000 population, sporadic in nature and outbreaks are confined to certain areas only.

The increased incidence of food borne diseases with widespread outbreaks, the emergence of new food borne pathogens and the development of antimicrobial resistance were recognized as threats to our food safety agenda. The factors contributing to the above were globalization of the food supply, advances in food production and processing technologies, changes in agricultural and animal husbandry practices, demographic changes and changes in lifestyle.

The true dimension of the burden of food borne diseases is still unknown as a result of poor documentation and absence of reliable data, thus limiting our understanding of its public health importance and impeding our efforts to secure the resources and support necessary for effective control of food borne diseases.

Improving surveillance on human food borne disease and monitoring of food contaminants will help greatly in establishing and evaluating priorities in the prevention and control of food borne diseases and reduce uncertainties in its mitigation strategies. The 53rd

World Health Assembly (WHA) in the year 2000 adopted a resolution to recognize food safety as an essential public health function and called for the development of a Global Strategy for reduction of the burden of food borne diseases. The resolution WHA 53.15 encouraged member states 'to implement and keep national, and when appropriate, regional mechanisms for food borne diseases surveillance'. In 2002, WHO published a document 'WHO Global Strategy for Food Safety: safer food for better health' to address this issue. The overall objective of strengthening surveillance of food borne disease is to provide member states with the necessary data to reduce the burden of food borne disease by improving their food safety system.

Innovative strategies and methods are needed for surveying food borne disease and food contamination. Development of a strategy to reduce food-related risks requires knowledge about the current situation of food borne diseases at all levels and must be based on best scientific evidence on food borne hazards and the incidence of food borne disease.

Under the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), WTO Member Countries should ensure that their sanitary or phytosanitary measures are based on a scientific risk assessment, taking into account the risk assessment techniques developed by the relevant international organizations. In this respect, Codex, which is the international reference for food safety under the SPS Agreement, has adopted the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, whilst Codex is also developing working principles on risk analysis intended for application by governments. Risk analysis is comprised of risk assessment, risk management and risk communication. Surveillance data is of paramount importance for conducting a risk assessment and eventually for formulating risk management options and implementing risk communication.

## **2. FOODBORNE DISEASE SURVEILLANCE**

Food borne disease surveillance assists in the assessment of the burden of food borne diseases, identification of public health priorities, setting of policies, evaluating program performance and the prevention, detection and control of outbreaks and in the process stimulating research. It may also identify emerging food safety issues.

All countries have different public health systems, giving rise to a wide variation in surveillance systems, with each having a different focus within the realm of food borne diseases. In the year 2002, a WHO consultation on methods for food borne disease surveillance in selected sites had reviewed and grouped the existing food borne disease surveillance systems into 4 categories according to their capacity to generate information (refer to ANNEX 1). It varied from one with no formal surveillance to that of an integrated food chain surveillance system. A country may be primarily within one category but may have surveillance elements from more than one category. Surveillance of food borne diseases may also be part of a national notifiable communicable disease system. However as there is no clear 'best-methods' of surveillance at the moment, the WHO consultative meeting recommended 5 actions to be taken to strengthen the food borne disease surveillance system. (Refer to ANNEX 2).

In Malaysia the current mandatory notification of certain priority food borne diseases has been useful for surveillance, but is inadequate in the event of new emerging food borne diseases. The current surveillance data collected is mainly through physician-based surveillance and outbreak investigations as there is no mandatory requirement for notification

from laboratories. Through this system, notification is received from government health facilities consisting of health centers, outpatient departments and hospitals and also from the private hospitals and general medical practitioners. The food borne diseases included in this list are cholera, typhoid and paratyphoid fevers, viral hepatitis A, food poisoning and dysentery.

A systematic approach for the early detection of unknown aetiological agents and notification is therefore needed. The Ministry of Health, Malaysia has produced a manual on a syndromic approach to infectious disease notification and laboratory investigation which complements the other existing specific disease notifications and is useful for rapid response to newly emerging and reemerging diseases. Here the notification is based on a syndrome, not on a specific disease, and the one related to food borne diseases is the “National Acute Gastroenteritis Surveillance”. The Ministry of Health also conducts laboratory- based surveillance of specific infectious diseases and includes food borne diseases due to *Salmonella spp.*, *Shigella spp.*, *Salmonella typhi* and *Vibrio spp.*.

In Malaysia the facilities of Pulse Field Gel Electrophoresis (PFGE) DNA fingerprinting and gel documentation are already available in the public health and university research laboratories. However, some of the problems and challenges associated with PFGE are the standardization of protocols, reagents, chemicals, electrophoretic conditions, cost and lack of sufficient trained personnel. The realization of a national PulseNet Malaysia will require training of personnel in the use of the standardized protocols so that DNA fingerprints are comparable between laboratories and between countries for rapid identification of clusters of food borne pathogens in case of disease outbreaks. PulseNet is not just about PFGE, but rather a communication network for personnel from the laboratories, surveillance, and epidemiological units to rapidly recognize an imminent food borne disease outbreak.

Improper food handling and unhygienic practices among food handlers have contributed to food poisoning episodes. The Ministry of Health, Malaysia has facilitated a basic training programme on food hygiene and sanitation that food handlers could undergo. Currently the Code of Practice for Food Hygiene and By-Laws of the Local Authority provide general and specific hygienic requirements for food premises. The proposed Food Hygiene Regulations, which is in the process of gazettment, requires that all food handlers be trained by institutes accredited by the Ministry of Health. The Ministry of Health also promotes the use of food safety assurance systems such as HACCP, GMP, and GHP in food industries. The implementation of food safety measures, for example hazard analysis and critical control point systems (HACCP), from farm to table, along with certification of food/farm service outlets using national standards for food safety and introduction of continuous employee training on safe food preparation would greatly reduce contamination of food.

In Malaysia, the Department of Veterinary Services (DVS) conducts a national surveillance program for food borne pathogens associated with livestock products, namely *Salmonella*, *E.coli O157*, *Campylobacter*, *Yersinia* and Vancomycin-resistant *Enterococci* (VRE). The Epidemiology and Veterinary Medicine Division, DVS has formulated several diseases surveillance, control, monitoring and eradication programs/protocols of livestock /zoonotic diseases such as for *Salmonella*, Avian Influenza, VRE, *Brucella*, Tuberculosis, Johne’s Disease, Nipah Virus and Bovine Spongiform Encephalopathy (BSE).

Besides disease control, eradication and disease free zone programs/protocols, a Livestock Farm Accreditation Scheme has also been implemented. The criteria of the scheme includes an infrastructure protocol, biosecurity protocol, Flock/Herd Health Program, Good



Animal Husbandry Practices, control of drug usage, labeling and trace back system and quality system. The implementation of the scheme will ensure a safe food supply.

Sources of surveillance data for food borne diseases include disease notifications, laboratory reports, environmental indices (food establishment inspection sources; agriculture, veterinary and food analyses), outbreak investigation reports, research studies, morbidity reports, case investigations, sentinel reports, surveys, census and media reports. A considerable amount of information on causative agents, disease characteristics and vehicles of transmission collected by several agencies could be successfully used to decrease the incidence of food borne disease.

Malaysia convened a workshop on this subject from 7-9 July 2003, with the discussion centering on the setting up of a regional laboratory network. The following strategies were agreed upon:

- Determine existing laboratory infrastructure, technical expertise and testing capabilities of each member country.
- Establish a mechanism to achieve information collection, collation, dissemination and regular updates
- Establish a laboratory contact point in each country
- Establish linkages with international agencies

In the Philippines, a project to improve laboratory-based surveillance for food borne pathogens has been started in conjunction with existing surveillance programs. The systems are independent of each other and, as of now, data is not systematically integrated. The project aims to integrate these systems to create a Food borne disease surveillance system that will include antimicrobial resistance data. Microbiologists recently received training in *Salmonella* serotyping and anti-sera for performing this and forwarding all isolates to the Research Institute of Tropical Medicine.

Viet Nam is currently conducting a study to enhance the capacity to conduct food borne disease surveillance and determine the burden of food borne diseases. The executing agency is the Viet Nam Ministry of Health with supervision from CDC and guidance from WHO's Western Pacific Regional Office. This project comprises four studies:

- (1) Active surveillance - conducted at four sentinel hospitals to determine prevalence of diarrhoeal illness, including culture confirmed infections;
- (2) Case-control study - to determine risk factors for acquiring diarrhoeal illness by interviewing culture confirmed cases and for each case, two matched controls by age and sex;
- (3) Laboratory survey - a postal survey of 126 clinical laboratories to determine laboratory capacity; and
- (4) Population survey - an interview survey of 3,000 persons to determine the prevalence of diarrhoeal illness four weeks prior to the interview.

Fiji, in collaboration with Fiji Ministry of Health, the Fiji School of Medicine, the Western Pacific Regional Office of the World Health Organization, and the Centers for Disease Control and Prevention, has recently developed a national collaborative non-Typhi *Salmonella* surveillance and laboratory support program. It is designed to provide technical and procedural information for all relevant public health personnel on the surveillance of

patients found to have non-Typhi *Salmonella* and includes specific procedures that need to be carried out to determine the source of infection and associated risk factors.

The USA, the United Kingdom, Australia and the Netherlands have developed an active national surveillance of food borne diseases. In the USA, the Food borne Disease Surveillance Network (US FoodNet) is a collaborative project between the Centers for Disease Control and Prevention (CDC), US Department of Agriculture (USDA) and US Food and Drug Administration (FDA) and was set up in 1996. It is a network of nine sentinel sites conducting active surveillance for a number of food borne pathogens and it measures the burden of illness, determines the source of infection through large case-control studies of sporadic cases and also evaluates the impact of control measures on these infections. Australia established OzFoodNet in 2000 as a collaborative project with the state and territorial health authorities to provide better understanding of the causes and incidence of food borne diseases in the community and to provide an evidence base for policy formulation.

The surveillance capacity to detect widespread outbreaks in the USA has dramatically improved in recent years with PulseNet USA, a national molecular sub-typing network of food borne pathogens. PulseNet is able to compare online results from different laboratories with each other and with a nationwide database. When a cluster is flagged, a detailed epidemiological investigation can often determine the source. PulseNet has gone 'international' with extension to other countries, namely PulseNet Canada, PulseNet Europe, PulseNet New Zealand and most recently, PulseNet Asia Pacific.

At the ASEAN level, pursuant to the ASEAN Leaders Meeting on SARS held on 29 April 2003 and ASEAN+3 Health Ministers Meeting on SARS held from 10-11 June 2003, efforts are being undertaken to strengthen collaboration and networking in the surveillance of infectious diseases in this region. Three health projects were identified for strengthening regional cooperation. Thailand was nominated to coordinate the strengthening of disease surveillance, Indonesia to strengthen the ASEAN disease surveillance Net and Malaysia to coordinate the strengthening of laboratory capacity and quality assurance for infectious disease surveillance among ASEAN+3 countries.

At the international level, the WHO Global Salmonella Surveillance Network (WHO Global Salm-Surv) was initiated in the year 2000 to enhance the capacity and quality of *Salmonella* isolation, identification, serotyping and antimicrobial resistance testing throughout the world. The network consists of institutions and individuals in human health (epidemiologists and microbiologists), veterinary and food-related disciplines. Activities include regional training for microbiologists, external quality assurance and reference testing, a moderated electronic discussion group and a web-based databank containing an annual summary of laboratory results of salmonella serotypes.

WHO Global Salm-Surv has also conducted training courses for microbiologists in China and will be conducting a third course in 2004 for epidemiologists. There are also plans to develop a burden of illness study, similar to that being performed in Viet Nam. This should be coordinated with any action by WHO and the World Bank.

In the era of information and communication technology (ICT), exchange of information is easier and faster. The utilization of ICT will enhance the surveillance system to be more efficient and effective. Networking, network of networks, on-line reporting, and electronic discussions, to name a few, are ways for various agencies to utilize this technology to the benefit of food borne disease surveillance at various levels.

Effective and efficient food borne disease surveillance will help ensure the quality and safety of food consumed. It should have a global approach in order to enhance the detection and response of food borne illness and act as an early warning system for any outbreak or crisis which may occur at any level, i.e. national, regional or international. Therefore the system should be comprehensive and integrated with food monitoring data along the entire feed-food chain. This would result in robust surveillance and allow appropriate priority setting and public health intervention. Currently, several agencies and stakeholders from multiple disciplines at various levels are involved in the surveillance of food borne diseases, namely Ministries of Health, Veterinary Services, Agriculture and Fisheries, Food industries, Universities, laboratories. While most of the agencies work independently of each other, there should be attempts to collaborate and coordinate the related activities of these agencies so that a unified surveillance system can emerge.

### **3. NEXT STEPS**

To strengthen and enhance the existing food borne disease surveillance systems, WHO should play the leadership role in guiding member countries with a clear vision and mission. The objectives and strategies established should be acceptable to all member countries, facilitating their implementation of the strategies and their commitment. It has been observed that political commitment from member countries is vital in ensuring the success and sustainability of health programmes implemented, due to the complexity of the interactions involved.

For our existing food borne disease surveillance system to be strengthened, coordinated activities among all sectors dealing with food borne disease surveillance and food safety are of paramount importance. Recognized and standardized methods of surveillance, with epidemiologically- sound and suitable technology will be needed to ensure a functional system. The usage of ICT networking for efficient and effective communication will further enhance and sustain a successful surveillance system. Coordinating centers should be selected based on the level of epidemiological and laboratory facilities and technical expertise available. The centers should be made responsible for conducting training and research in epidemiology as well as laboratory methodology and surveillance.

Innovative strategies and methods are needed for surveying food borne disease and food contamination. Studies linking pathogens in food to the disease in humans would help quantify the risk of food borne diseases. Collaboration among all sectors dealing with food borne disease surveillance and food safety is essential for a meaningful risk analysis outcome. In addition, a laboratory- based surveillance system having networking facilities at the regional and international levels could be utilized in providing food borne disease surveillance information on new emerging pathogens using the modern framework of risk analysis.

In the lesser developed and developing countries where the surveillance system of food borne diseases may be non- existent or not systematic, resources for setting up or strengthening of these surveillance systems should be considered. The issue of manpower, technical expertise, laboratories and technological infrastructure as well as cost effectiveness of the system should be given due emphasis.

The capacity building component in surveillance of food borne diseases in these countries may need to be considered, not only at the national level but also extended to regional and international levels. Capacity building with sufficient resources for infrastructure improvements and development of technical expertise should be considered, especially in the

underdeveloped and developing countries. Efforts should also be taken to facilitate the sharing of knowledge, skill and technical expertise related to food borne disease surveillance. Financial constraints posed in measuring the true burden of food borne diseases could be overcome with the establishment of sentinel sites.

Last but not least, food borne diseases should be integrated into the revision of International Health Regulations. The development and enforcement of such legislation will also need the coordination and cooperation among different governmental agencies such as agriculture, fisheries, veterinary services and health.

#### **4. CONCLUSION**

Food borne diseases are an important public health problem as it not only affects human health, but also has a significant impact on economic and trade issues. The global changes affecting population growth, lifestyle, international food trade, food production and processing, agricultural and animal husbandry practices and antimicrobial resistance have posed a threat to the emergence of food borne diseases. As most of the food borne diseases are not reported, the true dimension of the problem is unknown. The added absence of reliable data on the burden of food borne diseases impedes understanding of its public health importance, although recently publicized outbreaks of food borne diseases have attracted the attention of consumers and policy makers to food safety issues.

Surveillance of food borne diseases provides valuable information in the estimation of the burden of food borne diseases and in the rapid detection and response to outbreaks. For it to be effective, surveillance of food borne diseases has to be integrated with food monitoring data along the entire food chain from farm to table, thus improving the ability to link the pathogen in food to the disease in humans. It must be emphasized that strong leadership with political commitment and collaboration and coordination of activities of the related agencies at the national, regional and global levels are of paramount importance in strengthening and enhancing the existing surveillance systems and in the process, lowering the risk of food borne diseases.

#### **5. RECOMMENDATIONS**

Countries of the region should:

1. Strengthen their capacity for surveillance of food borne diseases to facilitate the timely recognition of emerging food borne diseases through national, regional and international surveillance networking, as evidenced in the recent SARS and Avian Flu outbreaks.
2. Improve food borne disease surveillance and food contaminants data collection by the relevant agencies, to enable proper documentation and evaluation of the burden of food borne diseases.
3. Establish sentinel sites for the surveillance of food borne diseases to allow access to data, measurement of the burden of food borne diseases and to appropriately priorities areas of concern in the prevention and control of food borne diseases.
4. Study the various systems of food borne disease surveillance in different countries in an effort to harmonies regionally and internationally.

5. Improve the ability to link pathogens in food to disease in humans through the enhancement of surveillance, not only of human disease, but also of pathogens throughout the food production chain using systematic microbiological risk assessment techniques.
6. Strengthen national capacity and infrastructure for laboratory- based surveillance of priority food borne diseases and also strengthen national capacity to detect, monitor and respond to the emergence of antimicrobial- resistant food borne pathogens.
7. Develop training and capacity building programmes with sufficient resources for infrastructure improvements and for development of technical expertise

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**CATEGORIES OF FOODBORNE DISEASE SURVEILLANCE**  
**(WHO/CDS/CSR/EPH/2002.22: Methods for Food borne disease surveillance**  
**in selected sites:**  
 Report of a WHO consultation)

**Category 1                    No formal surveillance**

*Description of system*

This situation typically exists in countries with political instability, recent history of war, or extreme poverty. The public health system is very low priority or non-existent. Some elements of surveillance may be undertaken by outside agencies.

*Data elements*

None.

*Information expected*

Large or unusual outbreaks may be detected and investigated by an outside agency (e.g., non-governmental organizations).

**Category 2                    Syndromic surveillance**

*Description of system*

Syndromic surveillance is the collection, analysis and interpretation of syndromic data (e.g., diarrhea or food poisoning) from at least selected sites. The surveillance system should use standard case definitions for classifying syndromes. Data should be routinely reported, collated at a central level and promptly disseminated to the public health community. These systems may function with or without laboratory capacity (ministry of health or hospital) but there is no formal laboratory-based surveillance system.

*Data elements*

Case counts (e.g., see WHO cholera guidelines).

*Information expected*

Trends over time, seasonal variation.

Define at-risk and high-risk populations.

Recognition of point source outbreaks at the local level.

Recognition of large or unusual outbreaks at the national level.

**Category 3                    Laboratory-based surveillance**

*Description of system*

Laboratory-based surveillance is the collection, analysis and interpretation of laboratory data from at least selected sites. The surveillance system should use standard case definitions for classifying diseases. Laboratories should use standardized methods for pathogen identification with recognized international quality assurance systems. Data should be routinely reported, collated at a central level and promptly disseminated to the public health community. Laboratory-based surveillance provides higher quality data than syndromic surveillance; countries should strive to develop this type of surveillance system.

*Data elements*

Etiologic identification

Etiologic agent-specific case counts

Pathogen characterization (e.g., serotyping, antibiogram, etc.)

*Information expected*

Etiologic agent-specific trends over time, seasonal variation  
Define at-risk and high-risk populations  
Recognition of point source at the local and diffuse outbreaks at the national level

#### **Category 4                    Integrated food-chain surveillance**

##### *Description of system*

Integrated food-chain surveillance (IFCS) is the collection, analysis, and interpretation of data from animals, food, and humans. The surveillance system should use standard case definitions for classifying diseases. Data should be routinely reported, collated at a central level and promptly disseminated to the public health community. IFCS allows the attribution of burden of illness to specific food categories through the use of detailed information from monitoring food and animals.

##### *Data elements*

Etiologic identification  
Etiologic agent-specific case counts in the population  
Etiologic agent-specific prevalence in animals and foods  
Pathogen characterization (e.g., serotyping, antibiogram, etc.)  
Community-level case counts

##### *Information expected*

Etiologic agent-specific trends over time, seasonal variation  
Reliable incidence rates  
Define at-risk and high-risk populations  
Recognition of point source at the local and diffuse outbreaks at the national level  
Ability to use food and/or animal data to generate hypotheses for human disease outbreaks  
Comprehensive estimates of burden of food borne disease  
Ability to assess the effectiveness of food safety policy interventions  
Ability to attribute burden of food borne disease by food category  
Ability to detect and control hazards in food  
Ability to recognize emerging pathogens in animal

**FINAL GENERAL RECOMMENDATIONS**  
**(WHO/CDS/CSR/EPH/2002.22 : Methods for Food borne disease surveillance in**  
**selected sites:**

Report of a WHO consultation)

- WHO should encourage development of an inventory of existing studies on burden of food borne disease and a comparison of their results;
- WHO should encourage Member States to conduct studies to determine the burden of food borne disease and provide technical support to these countries;
- WHO should select countries using the criteria identified in this report and identify resources to support burden of illness studies;
- WHO should seek resources to enhance laboratory-based surveillance and outbreak detection and response for food borne disease;
- Member States should seek to improve their existing food borne disease surveillance system.



## ANNEX 11

## LIST OF CONFERENCE ROOM DOCUMENTS

<b>Country/Organization</b>	<b>Conference Room Document Reference</b>
Keynote speeches	Annexes 8 and 9 (CRD 1)
Programme for Consumers International side event	CRD 2
Programme for ILSI side event	CRD 3
Information document for Portal launch	CRD 4
Malaysia - 1	CRD 5
Malaysia - 2	CRD 6
Malaysia - 3	CRD 7
Malaysia - 4	CRD 8
Thailand - 1	CRD 9
Thailand - 2	CRD 10
Korea	CRD 11
Philippines -1	CRD 12
Philippines -2	CRD 13
ILSI Informative document	CRD 14
Bangladesh	CRD 15
Japan	CRD 16
ASEAN	CRD 17
PDR Laos	CRD 18
Cambodia	CRD 19
ICD	CRD 20
Tropical Fruit Network	CRD 21
New Zealand	CRD 22
China - 1	CRD 23*
Indonesia	CRD 24
Pakistan	CRD 25*
Sri Lanka	CRD 26
Myanmar	CRD 27
Singapore	CRD 28
China – 2	CRD 29

All Conference Room Documents except those marked with an asterisk (\*) are available electronically from the Conference website: [www.foodsafetyforum.org/asian](http://www.foodsafetyforum.org/asian).

## Executive Summary

Seminar on *Enterobacter sakazakii* in Powdered Infant Formula  
26 May 2004, Seremban, Malaysia

A seminar on ***Enterobacter sakazakii* in Powdered Infant Formula** was held on May 26, 2004 in Seremban, Malaysia, as a satellite event at the FAO/WHO Regional Conference on Food Safety for Asia and the Pacific. The meeting is of due importance following the joint FAO/WHO workshop on *Enterobacter sakazakii* and other microorganisms in powdered infant formula, held in Geneva, Switzerland in February 2004. The workshop recognized the need for increased understanding and awareness of *E. sakazakii* and its consequences.

The overall objectives of the seminar on ***Enterobacter sakazakii* in Powdered Infant Formula** was to increase the awareness of *E. sakazakii* by facilitating the exchange of science-based information, to increase the capacity building efforts related to microbial risk assessment, to share information on current studies and to identify data for future research.

Scientists from industry, academics, and international organizations were invited to give presentations at the seminar. A total of 100 participants from regulatory agencies and health ministries from the Asia Pacific attended the half-day event. The topics discussed include current knowledge and issues on *E. sakazakii* contamination in infant foods, the minimizing of *E. sakazakii* contamination in the manufacture of infant formula, prevention of cross-contamination of *E. sakazakii* during infant formula preparation and present work as well as future research needs on *E. sakazakii*.

### ***Introduction to Enterobacter sakazakii***

**Dr Sally Hasell** of New Zealand Milk, New Zealand, opened the seminar with an overview of the microbes' characteristics. It is known that *E. sakazakii* is considered as an opportunistic pathogen and can cause disease in all age groups. Infections are uncommon in healthy adults and children, although low birth weight, premature and immuno-compromised infants are more susceptible to *E. sakazakii*-related infection.

*E. sakazakii* can be widely found in the environment and foods, and it is probable that soil, water, and vegetables are the principle sources of the bacteria when it is found in food. It is difficult to differentiate *E. sakazakii* from other closely related bacteria that are often present in the food. Currently there are no internationally validated methods to detect *E. sakazakii*. The most commonly used methods are those documented by ISO and FDA.

The bacteria can grow at a temperature between 6–47°C. A new research shows that inactivation of the bacteria occurs quickly at temperatures above 70°C. A study has also shown that the bacteria can survive in a dry environment quite well.

Recent outbreaks of severe diseases-like meningitis in at-risk infants have been linked to infant formula consumption, even though the products were generally in conformance with microbiological requirements of the current Codex Code of Hygienic Practices of Foods for Infants and Children.

### ***Current Knowledge and Issues in Enterobacter sakazakii Contamination in Infant Foods***

Contamination of powdered infant formula with *E. sakazakii* and *Salmonella* are linked to severe illness in infants, which includes serious developmental sequelae and death. **Dr Peter Ben Embarek**, World Health Organization (WHO), Switzerland, stated that neonates, especially pre-term infants, low-birth weight infants and immunocompromised infants are at the greatest risk of *E. sakazakii* infection.

The current Codex criteria was established many years ago and it needs to be reviewed in view of new developments and knowledge. It is recommended that revision to the current Codex guidelines include replacing coliforms with *Enterobacteriaceae* as indicators, tightening the limits for *Enterobacteriaceae*, and adopting different levels according to the age groups.

Low levels of *E. sakazakii* contamination in powdered infant formula are considered to be a significant risk factor. However, based on a preliminary risk assessment, the inclusion of a pathogenic lethal step at the point of preparation and a decrease in the holding and feeding times would effectively reduce risk.

The food industry is encouraged to take appropriate steps to minimize the concentration and prevalence of *E. sakazakii* in the manufacturing environment, as well as in the powdered infant formula. It was also recommended that a greater range of commercially sterile alternative formula products be available from the industry for high risk infants.

### ***Minimizing Enterobacter sakazakii Contamination in the Manufacture of Infant Formula – a Perspective from Industry***

**Dr Anthony Huggett** of Nestle, Switzerland, stated that the industry's experience in eliminating *Salmonella* from infant formula has provided insights into managing *E. sakazakii*. Though it is not currently possible to completely eliminate *Enterobacteriaceae* from manufacturing environments, it is possible to achieve a substantial reduction in the level of *Enterobacteriaceae*, including *E. sakazakii*, in infant formula.

As the manufacturing of infant formula included the wet and dry steps, it has been noted that addition of ingredients after heat treatment is a possible source of contamination. It is important that these ingredients must be sterilized prior to addition into the product. Dry cleaning of manufacturing plants has also shown positive results in reducing the presence of *E. sakazakii* and other bacteria in the final products.

The risks from *E. sakazakii* can only be mitigated effectively through the implementation of a combination of complementary preventive measures, including limiting the presence of the bacteria in the infant formula and ensuring that the products are used in a way that prevents the introduction or growth of *E. sakazakii* in the formula prior to infant feeding. This can be achieved by providing clear instructions on the use and preparation of infant formula and providing means for education of caregivers.

## ***Preventing Cross-contamination of Enterobacter sakazakii during Infant Formula Preparation***

In April 2001, a premature infant death in a neonatal intensive care unit in Tennessee, USA was linked to *E. sakazakii*. This led to an investigation by the Centres for Disease Control and Prevention (CDC), which resulted in policy changes at the hospital in the preparation, storage and administration of infant formula.

**Mr Michael Stein** of Mead Johnson Nutritionals, Thailand, stated that as of now, there are no internationally-available guidelines concerning infant formula feeding. Recommendations by the CDC are to select formula products based on nutritional needs, and use alternatives to powdered infant products whenever possible. Trained personnel should also prepare powdered infant formula using aseptic techniques in a designated preparation room. The manufacturer's instructions should be followed and the product should be refrigerated immediately or discarded if not used within 24 hours after preparation. Lastly, the administration or "hang time" for continuous enteral feeding should not exceed 4 hours.

Reference documents were also made available to health care providers, to increase their awareness.

## ***Present Work and Future Research Needs on Enterobacter sakazakii***

**Dr Sri Estuningsih** of Bogor Agricultural University, Indonesia, shared the fact that currently, little is known about the ecology, virulence factors, pathogenicity, and prevalence of *E. sakazakii* in powdered infant formula. There are also no available data about the prevalence of the bacteria in powdered infant formula available in developing countries.

It is important to determine the prevalence of *E. sakazakii* in infant foods in developing countries through proper reporting and investigation of the sources and vehicles of infections. At the same time, research on pathogenicity and virulence factors of *E. sakazakii* should be conducted to increase the knowledge of these bacteria, especially in the infant formula. Development of specific and rapid microbiological and molecular detection methods and their respective validation studies should take into consideration, the current situation in developing countries.

The seminar concluded with a discussion session where the participants shared the countries technical constraints and resource limitations in conducting data collection and testing for *E. sakazakii*. Collaboration between academia and industry scientists to conduct surveys and checks of microbial contamination of commercial infant food products may be explored. A study on hygienic practices and the impact on *E. sakazakii* in children hospitals may also be a topic to be considered. Public education for mothers and other caregivers having direct contact with infants on the preparation, use and handling of infant formula are also important to reduce *E. sakazakii*-related infections.

## ANNEX 13

**Side Event on the Safety of Street Vended Foods**  
organized by Consumers International Asia Pacific Office  
at the FAO/WHO Regional Conference on Food Safety for Asia and the Pacific  
*09:00–12:30 hours, 26 May 2004, Seremban, Malaysia*

In support of the Conference's goal to identify practical actions and capacity building recommendations promoting food safety in the Asia Pacific region, a Side Event was organised by Consumers International (CI) Asia Pacific Office on the Safety of Street Vended Foods. Some 100 government officials from countries in Asia and the Pacific attended the half-day event.

**Dr Sothi Rachagan**, Regional Director of Consumers International Asia Pacific Office, Malaysia, in his opening remarks, provided a brief overview of CI's work in the food programme, and in particular the project on the Safety of Street Vended Foods. Dr. Sothi highlighted the centrality of street food to food security and employment in urban areas, particularly for the urban poor. The role of street food in preserving and promoting local and traditional foods was also mentioned. He also outlined consumer concerns with respect to health risks associated with street vended food.

**Ms Kavitha Anand**, Researcher from Citizen, Consumer and Civic Action Group (CAG), Chennai, India, outlined CAG's future intervention plans. The plan included the lobbying of municipal councillors for the integration of street food vending in local urban planning and the establishment of model vending facilities and training of food handlers.

**Dr Sonia de Leon**, President of the Foundation for the Advancement of Food Science and Technology (FAFST), Philippines, described the work of local organisations involved in the street food sector. The examples she gave included the: Food Safety Training Institute, which offers training and intervention programmes to food handlers and practitioners; Wintex Technologies, which provides inventions and utility models in food safety; Food Training Institute, which offers consultancy and courses in food safety, quality and processing.

**Dr Ngo Thi Phi Yen**, a medical doctor representing the Ho Chi Minh City Nutrition Centre, Vietnam, described the proposed plan for improving the food safety situation of street food vending in Ho Chi Minh City. The first step of the plan involves choosing a site and designing a model for street food vending. Step two focuses on enhancing the food safety knowledge of consumers, vendors, and managers (government), and implementing a sound management system. Step three consists of an evaluation of the model to determine whether it should be replicated in other areas.

**Ms Londa VanderWal**, Associate Professional Officer of the United Nation's Food and Agriculture Organization (FAO) outlined FAO/WHO's proposed future initiatives for improving street food safety. These include the: improvement of the conditions under which street food is prepared and sold in collaboration with municipal authorities; strengthening of food quality control capabilities to improve overall quality of raw and processed foods used by vendors; training of food handlers and education of consumers.

For more information, please contact [alice@ciroap.org](mailto:alice@ciroap.org) or visit: <http://www.consumersinternational.org/roap>.