

MICROBIOLOGICAL RISK ASSESSMENT SERIES

Pre-publication version

Microbiological hazards in fresh fruits and vegetables

MEETING REPORT



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Acronyms used in the text

ERS	Economic Research Service [of the USDA]
USDA	United States Department of Agriculture
RASFF	Rapid Alert System for Food and Feed
GAP(s)	Good Agricultural Practice(s)
CCFH	Codex Committee on Food Hygiene
GMP(s)	Good Manufacturing Practice(s)

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Declarations of Interest

All participants completed a Declarations of Interest form in advance of the meeting. None of these were considered to present any potential conflict of interest.

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Summary

FAO and WHO convened an Expert Meeting on 19–21 October 2007 to consider how to adequately address the extensive request for scientific advice received from the 38th Session of the Codex Committee on Food Hygiene (CCFH) on the microbiological hazards associated with fresh produce (see Annex 1). Given the extent of that request, the primary purpose of the meeting was to use all available information—including that submitted by countries in response to a call for data and a circular letter distributed by Codex—to establish the priority commodities of concern and provide some guidance to FAO and WHO as to how these could be addressed.

The meeting agreed to a set of six criteria, which it used to rank the commodities of concern as identified by the last session of the CCFH and by member countries. The criteria were:

- Frequency and severity of disease.
- Size and scope of production.
- Diversity and complexity of the production chain and industry.
- Potential for amplification of foodborne pathogens through the food chain.
- Potential for control.
- Extent of international trade and economic impact.

The information available was reviewed in the light of these criteria, which enabled the identified commodities to be ranked into the following three priority groupings.

Level 1 Priorities – leafy green vegetables

Leafy greens were accorded the highest priority based on the ranking criteria. The available data varied in completeness, but the meeting concluded that there was sufficient information to indicate that, from a global perspective, leafy green vegetables currently presented the greatest concern in terms of microbiological hazards. Leafy greens are grown and exported in large volume, have been associated with multiple outbreaks with high numbers of illnesses in at least three regions of the world, and are grown and processed in diverse and complex ways, ranging from in-field packing to pre-cut and bagged product. Such post-harvest activities contribute to the possibility of amplification of foodborne pathogens.

Level 2 Priorities – berries, green onions, melons, sprouted seeds, tomatoes

These commodities were identified as being the second highest concern. Given the available knowledge, berries, green onions, melons and tomatoes were considered to be similarly problematic and it was not possible to rank them from a global perspective. However, it was clear that regional differences exist and therefore it would be easier to rank these commodities in order of priority from a regional perspective. Sprouted seeds were considered somewhat separately from the other four in this group as a Codex guideline for the hygienic production and packaging of sprouted seeds already exists. However, sprouted seeds continue to be implicated in outbreaks and therefore the meeting considered that the existing code should be reviewed in the light of the available information to determine if any revisions were necessary.

Level 3 priorities

This is the largest group and includes carrots, cucumbers, almonds, baby corn, sesame seeds, onions and garlic, mango, paw paw, celery and maimai. These were considered to be the lowest priority of the identified commodities of concern. While all these commodities have been implicated in cases or outbreaks of foodborne illness, the public health impact was considered to be low, based on information available to the meeting. Also, there are limited data available for most of these commodities, and in several cases the associated problems have been recognized only recently. However, these may be emerging problems and therefore the meeting recommended that problems linked to these commodities be noted and the commodities be monitored for further problems. As more information becomes available, the ranking of these commodities will need to be re-evaluated.

Recommendations

Based on the foregoing, the meeting made the following recommendations.

- Leafy green vegetables should be considered the highest priority in terms of fresh produce safety from a global perspective, and that FAO and WHO should focus their efforts to develop scientific advice on this commodity grouping.
- The 39th Session of the CCFH should take into account the outcome of the ranking exercise and the priority rankings assigned to the different commodities when selecting their work priorities.
- The annex to the Codex *Code of hygienic practice for fresh fruits and vegetables*, which addresses sprouted seeds, should be reviewed for adequacy.
- The ranking should be reviewed in the future and revised when substantial new information is available.

In addition, the meeting made a number of recommendations to FAO, WHO and Codex to be taken into consideration in the elaboration of scientific advice and risk management guidance, and to governments and institutions working on these issues.

1. Introduction

The role of fresh fruits and vegetables in nutrition and healthy diets is well recognized and in recent years many countries have undertaken various initiatives to encourage consumers to eat more of these products. This, together with increasing consumer demands for variety and availability, and the changing structure of global trade, and has led to an increase in international trade in these products. For many countries, particularly developing countries, such products have become valuable, making a substantial contribution to the economy as well as to the health of a country's population. However, recent food safety problems linked to these products threaten this. For nutritional, health and economic reasons, it is important that the consumption of fresh produce continues to increase. Therefore efforts at the international level to resolve food safety problems linked to fresh produce are essential and timely.

International standards play a critical role in protecting the health of consumers and facilitating international trade. The standard-setting process of Codex Alimentarius is well recognized as an inclusive, science-based, process involving all interested parties. While private standards for fresh produce are proliferating, these are not always accessible to all relevant parties and are not required under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. Therefore, the development of international food safety standards relevant to the current food safety issues remains an important task, and one for which the scientific advice developed by FAO and WHO based on information from all stakeholders provides a strong foundation.

1.1 Background

Problems linked with pathogens in fresh produce, including the associated public health and trade implications, have been reported in a number of countries worldwide. In noting this, the 38th Session of the Codex Committee on Food Hygiene (CCFH) requested FAO and WHO to provide scientific advice (CAC, 2006) to support the development of commodity-specific annexes for the Codex Alimentarius "Code of Hygienic Practice for Fresh Fruits and Vegetables" (CAC, 2003). Highlighting the need to address, in more detail, aspects related to the control of specific hazards of concern, in particular fruit and vegetable products, the committee provided terms of reference as guidance to the type of scientific advice needed (see Annex 1) (CAC, 2006).

The terms of reference for scientific advice was extensive, identifying the need for advice on eight types of products and eight different pathogens, and answers to approximately 40 questions spanning the whole food chain (see Annex 1). Given the need to provide advice in a timely manner (the request specified an 18-month timeframe), FAO and WHO decided it was necessary to address the various tasks in a prioritized manner, including the specific pathogen–commodity combinations identified.

Given the extensive range of fruits and vegetables marketed as fresh produce, FAO and WHO decided to apply a step-wise process to the provision of scientific advice on these products. The first step was to issue a call for data. This was issued in the form of a formal Codex Circular Letter (CL 2007/12-FH) to all Codex members, and was also circulated via other routes, such as the FAO and WHO Web pages, newsletters and food safety networks. A call for experts was issued at the same time. The second step was to implement a small Expert Meeting to review the available data and, in particular, to prioritize the issues to be addressed. The current report is the output of that meeting and serves to update the 39th Session of CCFH on the progress made by FAO and WHO in addressing the request of the 38th Session and allows CCFH the opportunity to provide feedback on the process thus far or provide other information to facilitate the elaboration of scientific advice. FAO and WHO will then proceed with developing scientific advice on the prioritized issues for presentation to the 40th Session of CCFH.

1.2 Objectives

FAO and WHO convened an Expert Meeting on 19–21 October 2007 in FAO Headquarters, Rome, to consider how to adequately address the extensive request for scientific advice received from the 38th Session of CCFH (see Annex 1). Thus, the purpose of the meeting was to advise FAO and WHO in this regard, as well as to provide advice to CCFH as to the fresh produce commodities of greatest

concern from a global perspective, and thus those areas that would benefit most from the development of specific management guidance. Specific objectives of the meeting were as follows:

- Review the available information on this topic, including that which was received by FAO and WHO in response to a call for data, in the context of the request from the CCFH.
- Develop criteria and use these to rank, in order of priority from the global perspective, the pathogen-product pairs that have been identified by countries.
- Provide advice and guidance to FAO and WHO on the work plan and approach to be taken to elaborate the requested scientific advice, specifically on those areas prioritized by the meeting.
- Prepare a short report of the meeting for presentation to the next (39th) Session of CCFH.

1.3 Scope

The scope of the work is microbial hazards in produce that is marketed fresh and often ready-to-eat. This may include produce that has been peeled, cut or otherwise physically altered from their original form, but remains in a fresh state and is intended for consumption raw.

The meeting considered the entire production-to-consumption continuum, including processing and marketing of fresh produce and the factors at the primary production level that contribute to the risk of foodborne disease, especially environmental hygiene, water for primary production and packing, and personnel health, personnel hygiene and sanitary facilities.

2. Overview of available information

FAO and WHO sought information from a number of sources as a basis for this meeting. As well as undertaking a literature review, a call for data was issued to all interested parties. In addition, a Circular Letter was issued to all Codex members, asking them respond to a series of questions regarding foodborne illness related to fresh fruits and vegetables, the extent of production in their countries, the hazards related to these products and the source of such hazards, the specific product-hazard combinations of greatest concern, and measures taken to address these hazards, including the implementation of existing guidelines.

FAO already has an extensive capacity building programme of activities to enhance the safety and quality of fresh fruits and vegetables. Therefore, information generated by these activities was also taken into consideration.

To facilitate the work of the meeting, these data were reviewed and summarized in advance and presented to the meeting in summary form. In addition, a number of the experts participating in the meeting provided additional information based on experiences in their countries.

2.1 Summary of replies to the call for data and the Codex Circular Letter

Codex Circular Letter CL 2007/12-FH called for the submission of scientific information about foodborne illnesses related to fresh fruit and vegetables during the period from 1996 to 2006, and to provide related information such as the implicated pathogen and food vehicle, the number of reported outbreaks and illnesses, whether the outbreaks were confirmed or suspected, and what follow-up actions were taken to prevent additional outbreaks. Twenty-two member countries; one member organization – the European Commission; observer organizations – the Institute of Food Technologists (IFT) and the Center for Science in the Public Interest (CSPI); and several independent institutions, companies and agencies submitted data.

Of those countries that ranked the products of concern, the majority identified leafy greens as the primary vehicle of concern, and either *Salmonella*, *Escherichia coli* O157:H7 or norovirus as the pathogens of concern. However, for some countries, melons and sprouted seeds were the products of primary concern. One country identified carrots as their biggest concern because in recent years it has been a vehicle for *Yersinia pseudotuberculosis*. However, only about half of the countries that responded provided a ranking.

A few countries asserted that produce safety is not a specific source of concern to them. This was often because they had no reported fresh-produce-related outbreaks. However, this often coincided with a limited, if any, disease surveillance system. One developing country pointed out that the burden of disease from outbreaks is likely to be large due to the lack of available clean water to grow and wash produce. Limited data are available to further support the assertion, but the burden of disease is presumed to be large for most developing countries.

Most responses recognized the potentially significant impact of microbiological hazards on the international trade of their fresh produce, but no country provided summary statistics about the actual impact of outbreaks on the imports or exports of most frequently traded commodities. The United States of America (USA) described the impact of the large spinach-*E. coli* O157:H7 outbreak of 2006 on the export of spinach to Canada, where spinach is sent in large volume. The outbreak led to Canadian trade restrictions on USA-grown spinach for several months, and a recall of imported spinach in Canada. As a condition for removing the trade restrictions, Canada now requires compliance with and certification by California growers that they are applying the “*Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens*” to their leafy green exports to Canada. The Economic Research Service (ERS) of the United States Department of Agriculture (USDA) submitted a case study of the spinach outbreak, which estimated that demand for spinach was still down by over 40% approximately one year after the event, demonstrating the harmful longer-term economic and health consequences from a nutritious but contaminated commodity. In Europe there have been numerous alerts sent via the Rapid Alert System for Food and Feed (RASFF) that highlight the detection of pathogens on fresh produce traded among European countries or imported from outside of the European Union. Although not always documented, this highlights that the implications for trade are not limited to North America.

Mexico identified several outbreaks that involved exports to the USA or Canada, or both; cantaloupes with *Salmonella* Poona, green onions with hepatitis A, and basil with *Cyclospora*. Some of the outbreaks included deaths, indicating the health impact of contaminated produce. Each outbreak also led to what has been described as “closed borders” with the USA and Canada, implying a large economic impact. Consequently, numerous Mexican states, with the help of the Mexican federal government, undertook an extensive effort to adopt a Good Agricultural Practice (GAP) programme and to train growers and distributors in compliance for certification. As a result, implementation of GAP programmes in the country has expanded from 1 state in 2001 to 22 states in 2005, and up to 32 by the end of 2007. Fresh produce commodities grown and distributed for export are often linked to marketing agreements that require compliance with GAPs and verification by third-party auditors.

Several countries stated that even though they did not require GAP application for their domestic consumption, growers and distributors—the industry itself—are or would begin following some type of voluntary GAP programmes for at least their exported fresh produce. Some countries noted pronounced differences between growers’ practices for domestic compared to export markets. Such voluntary steps by sectors of the industry indicates recognition of the health concerns and economic impact of contaminated products and the need to take steps to better ensure the quality and safety of fresh produce.

The responses received to the questions included in the call for data showed that outbreaks around the world are diverse, with a wide range of vehicles and hazardous agents. There was no clear pattern or dominant agent. Deaths linked to fresh produce have been identified. The USA reported 15 confirmed deaths from contaminated produce caused by *Salmonella*, hepatitis A and *E. coli* O157:H7. At least one death linked to lettuce has been reported in the United Kingdom (UK). Several countries highlighted the difficulties encountered in determining the aetiology of outbreaks, and in some data sets the food source was no more narrowly identified than “fruit” or “vegetable” or “mixed salad”, among other diverse characterizations.

Most countries—16 out of 22—indicated that they have an operational foodborne disease surveillance system in place. Among those that have one, most appear to be passive systems and it is not clear how effective they are. Fewer countries have adopted some kind of a GAP programme to date—only 10 out of 22 respondent countries. Table 1 provides an overview of the responses by country. The first column identifies the countries that submitted a response, and they are grouped by region. The second column summarizes whether the country has an operational foodborne disease surveillance system in place, and the third whether the country adopted and implemented the Codex “*Code of Hygienic Practice for Fresh Fruits and Vegetables*” or a similar GAP programme. The fourth and fifth columns identify the member country’s priority ranking of the food vehicle and pathogen(s) of concern. While more detailed information on various outbreaks, control measures and the actual situation in individual countries was also provided, it is not possible to summarize here. However, additional data was considered in the ranking exercise undertaken by this meeting and will be further used as work on this issue continues.

Table 1. Summary of country surveillance systems, GAP programmes, commodity and pathogen ranking based on response to Codex Circular Letter.*

Region and country	Current surveillance system	Current GAP programme	Commodity ranking	Pathogens of concern
Africa				
Ghana	Yes	No	Leafy greens and green onions	Many pathogens: <i>Salmonella</i> spp., <i>Shigella</i> spp., <i>E. coli</i> , <i>Campylobacter</i> , <i>Enterobacter sakazakii</i> , <i>E. cloacae</i> , <i>Entamoeba coli</i> , <i>Cryptosporidium</i> (other parasites, e.g. helminth eggs, <i>Ascaris lumvreciodes</i> and <i>Ancylostoma</i> spp., have been isolated from leafy green vegetables
Asia				
Japan	Yes	Yes (only for vegetables)	No ranking	Not indicated
The Philippines	No	Yes	Leafy greens	<i>Salmonella</i> and helminths
Europe				
France	Yes	Yes	No ranking	Not indicated
The Netherlands	Yes	Yes	Sprouted seeds as highest priority (did not rank others)	<i>Salmonella</i>
Sweden	Yes	No	Sprouted seeds	<i>Salmonella</i>
Finland	Yes	Yes	Carrots	<i>Yersinia pseudotuberculosis</i>
Poland	No information provided	No info. provided	No ranking	Not indicated
Hungary	Yes	No info. provided	No ranking	Not indicated
Ireland	No information provided	No info. provided	No ranking	Not indicated
United Kingdom	Yes	Yes	Leafy greens including herbs	<i>Salmonella</i> , <i>E. coli</i> O157: H7, norovirus
Latin America and the Caribbean				
Nicaragua	Yes	No	No ranking	<i>Salmonella</i> spp., <i>Shigella</i> , <i>E. coli</i> , faecal coliforms, <i>Vibrio cholerae</i> and <i>Giardia lamblia</i>
Panama	Yes	No	Leafy greens	None indicated
Peru	No	Yes	Leafy greens	<i>Salmonella</i> , enteropathogenic <i>E. coli</i> , <i>Shigella</i> , enteroparasites
Mexico	Yes	Yes	Melons	<i>Salmonella</i> , <i>E. coli</i> and faecal coliforms
Brazil	Yes	No	Leafy greens	<i>Salmonella</i>
Near East				
Egypt	No	No	Leafy greens	<i>E. coli</i> , <i>Shigilla</i> , parasites
Lebanon	Yes	Not indicated	Leafy greens	<i>E. coli</i> , faecal coliforms
Northern America				
U.S.A.	Yes	Yes	Leafy greens	<i>E. coli</i> O157:H7
Canada	Yes	Yes	All produce, except root vegetables	Not indicated
South West Pacific				
Australia	Yes	Yes	No ranking but highlighted that a number of products are of high concern	<i>Salmonella</i> , <i>Listeria monocytogenes</i> , <i>Bacillus cereus</i> , <i>Campylobacter</i> , <i>E. coli</i> O157:H7
New Zealand	Yes	Yes	No ranking (but risk profile has been undertaken)	Indicated range of potential hazards but none of specific concern

NOTES: * The data presented in this table is a summary of part of the information submitted by countries in response to Codex Circular Letter CL 2007-12-FH. This information was provided to facilitate the provision of scientific advice and should not be quoted as an official source of data for the abovementioned countries.

Table 2. Summary of the number of outbreaks, illnesses and deaths, the top two most frequently implicated commodity-pathogen pair between 1996 and 2006, as identified by countries in their response to CL 2007/12-FH.*

Region and country	Total outbreaks	Total reported illnesses (from all outbreaks)	Most frequently implicated commodity-pathogen pair	Next most frequently implicated commodity-pathogen pairs
Africa				
Ghana	Presumed many outbreaks but none reported	None reported	Leafy greens – no pathogens specifically paired	Carrots - no pathogens specifically paired Tomatoes - no pathogens specifically paired
Asia				
Japan	1	12	Sprouts-S. Montevideo	None
The Philippines	No reported outbreaks	None reported	None	None
Europe				
France	2	—	Raw watercress- <i>Fasciola hepatica</i>	Berries-norovirus
Netherlands	76	307	Sprouts-S. Enteritidis	—
Sweden	23	1037	Leafy greens- <i>E. coli</i> O157:H7	Sprouts- <i>Salmonella</i> and Berries-norovirus
Finland	40	5875	Berries-norovirus	Carrots- <i>Yersinia pseudotuberculosis</i> and leafy greens-various
Poland	33	584	—	—
Hungary	No reported outbreaks	None reported	None	None
Ireland	Not indicated	Not indicated	None	None
United Kingdom	88	>3435	Lettuce- <i>Salmonella</i>	Various
Latin America and the Caribbean				
Nicaragua	No reported outbreaks	None reported	None	None
Panama	No reported outbreaks	None reported	None	None
Peru	No reported outbreaks	None reported	None	None
Mexico	No reported outbreaks	None reported	None	None
Brazil	49	1036	Leafy greens- <i>Salmonella</i>	
Near East				
Egypt	Presumed many outbreaks but none reported	None reported	Leafy greens- <i>E. coli</i> , <i>Shigilla</i> , parasites	
Lebanon				
Northern America				
U.S.A.	98	10 367 (15 deaths)	Leafy greens- <i>E. coli</i> O157:H7	Tomatoes- <i>Salmonella</i> and Melons- <i>Salmonella</i>
Canada	25	2291	Sprouts- <i>Salmonella</i>	Various
South West Pacific				
Australia	25	782	Leafy greens-S. Typhimurium	Sprouts- <i>Salmonella</i> and Leafy greens-norovirus
New Zealand	13	189	Mixed salads-Campylobacter	Mixed berries-Hepatitis A

NOTES: * The data presented in this table is a summary of part of the information submitted by countries in response to Codex Circular Letter CL 2007-12-FH. This information was provided to facilitate the provision of scientific advice and should not be quoted as an official source of data for the abovementioned countries.

Table 2 summarizes the number of fresh produce outbreaks between 1996 and 2006, as identified by the response to the Call for Data and the Codex Circular Letter, including the total number of reported cases of illnesses, and deaths if any, the most frequently implicated food vehicle (commodity) and the pathogens most frequently either confirmed or suspected to have caused the outbreaks. Implicit in each of the responses is recognition of the difficulty of reporting the number of cases and the cause of the illness. Under-reporting of an unknown magnitude is an inescapable problem when working with the data. It should be noted that this table is not a complete list of all outbreaks and illnesses worldwide that have been linked to fresh produce.

2.2 Literature review

Extensive literature searches and reviews were also undertaken. A bibliography of published papers on the issue of microbiological hazards in leafy green vegetables, melons and tomatoes has been prepared. A further literature review on the hazards of concern in other commodities, production practices and control measures has also been undertaken.

2.3 Additional pertinent information

The discussion of available data and additional information brought to the meeting by the experts contributed to a clearer overview of the situation in many countries, and in particular developing countries. This also highlighted the challenges that exist in addressing problems posed by microbiological hazards in fresh produce, including:

- **Differences in production systems**

The production of fresh produce is increasing in many countries. However, as well as traditional crops, new crops are being introduced. For example, leafy green vegetables, particularly those eaten raw, are a relatively recent arrival in some countries, such as Ghana and China. The way in which crops are grown, harvested and marketed can vary substantially from one area to another, even within the same country. Differences exist between produce intended for export and for domestic consumption, particularly in developing countries, and between conventional and organic production systems. In some countries, a crop may be grown by many small producers who then supply a single processor or distributor, highlighting the difficulties of trace back.

- **Differences in post-harvest practices**

Such practices are again highly variable and may be related to the post-harvest distribution chain. Some developing countries have highlighted extensive post-harvest losses, often caused by lack of trained workers or limited, if any, access to a cold chain.

- **Water**

Seventy percent of fresh water use is for agricultural purposes. Many of the countries in the arid and semi-arid regions are already exploiting more than 40% of their renewable resources. Due to increasing demands, the search for alternative water sources is of paramount importance in water-stressed countries. In this context, wastewater re-use is becoming more valued as a reliable supply. The total land irrigated with raw or partially diluted wastewater is estimated at 20 million hectares in fifty countries, which is approximately 10% of total irrigated land. The proportion of that which is used in fresh produce production is difficult to estimate, but there is anecdotal evidence to suggest that both the demand for and supply of wastewater for irrigation is increasing in many areas. Demand is driven by the attractive returns farmers can earn from producing fruits and vegetables in urban and peri-urban settings. Demand also rises with increasing competition for limited water resources in deltaic areas and large-scale irrigation schemes. The supply of wastewater expands with population growth in large cities, towns and villages throughout the developing world. In many communities, the volume of wastewater has increased faster than the ability to build and operate treatment facilities, and as a result more wastewater is released into open ditches or discharged into agricultural drains.

FAO and WHO have jointly published new Health Guidelines for the Safe Use of Wastewater, Excreta and Greywater (WHO 2006a, b) to address health protection and risk management as the basis to setting health-based targets in pathogen removal in the context of technological feasibilities and socio-economic conditions.

Public concern regarding wastewater re-use varies with the type of water involved, treatment levels and information available. Effluent standards, taxes and tradable permits can motivate improvements in water management by households and industries discharging wastewater from point sources. Pertinent policies include effective water allocation and pricing, water rights, restrictions on groundwater pumping, full-cost energy pricing, and incentives for farm-level investments in water-saving irrigation methods.

- **Local environment**

The location and suitability of the land and the type of fertilizer used are also variable factors and can contribute to microbial contamination of fresh produce. With increasing populations and high demand for land, fresh produce is often grown in close proximity to urban areas or land used for other types of agriculture, such as livestock production. As mentioned above, this also means proximity to waste and run-off from both urban development and animal production. While some countries may have the infrastructure to deal with this, many countries do not, and it is released into local waterways and drainage ditches. However, even when the infrastructure is in place, events such as extensive rainfall or position of the growing fields in relation to the surrounding topography may mean that proximity to urban areas and livestock production remains an issue of concern. Other environmental aspects include the local wildlife or ecology and their role in environmental or produce contamination. These issues highlight the important role of the growing environment as a source of contamination in fresh produce production. Although not part of the local environment as such, tools and equipment used in horticulture may also be considered as potential sources of contamination, e.g. cross-contamination via the knives used in harvesting lettuce heads or spring onions.

- **Fertilizer from human and animal waste**

Fertilizer can be an expensive input to production. As wastewater can be a good source of nutrients for plants, it is often sought after. Similarly, other cheap sources of fertilizer, including animal and poultry manure, are widely used, often without appropriate composting, which means they are also a source of microbial hazards. However, apart from this use, organic waste is often applied to agriculture land as an economical means of treatment and re-use. While such land may not necessarily be used for horticulture, such activities still present an opportunity for the introduction of potential contaminants into the environment.

- **Worker health and hygiene**

Following some of the recent outbreaks linked to fresh produce, such as those caused by viruses in berries and green onions, the potential role of workers in contamination of fresh produce has been highlighted. Worker hygiene is affected by the availability and accessibility of wash and comfort stations on the farms. Another issue is the presence of sick workers or children in the fields or packing facilities, which is often linked to the economic needs, demographics or the culture of the workers. This again highlights the breadth of issues that need to be considered when addressing the problems linked to fresh produce, and hence the need to take a broad, multidisciplinary approach.

- **Consumption patterns and practices**

In recent years there has been an increase in the consumption of fresh produce. This is happening in both developed and developing countries. In addition, consumers are eating more raw products, and produce that was traditionally cooked before consumption is now being eaten raw. Differences also exist among regions in terms of preparation and consumption practices. For example, baby corn is cooked in Thailand but often eaten raw in many western countries. Baby spinach is a very popular raw salad vegetable in North America but is cooked before consumption in many other parts of the world.

The challenges identified above suggest that there will not be a unique solution to minimize the risks associated with microbiological hazards in fresh produce. Clearly, the whole food chain needs to be taken into consideration and the challenges at each step need to be addressed according to the characteristics of each product.

3. Ranking of priorities

3.1 Establishment of criteria

In order to prioritize the issues of concern, a set of criteria was established as follows:

- Frequency and severity of disease.
- Size and scope of production.
- Diversity and complexity of the production chain and industry.
- Potential for amplification of foodborne pathogens through the food chain.
- Potential for control.
- Extent of international trade and economic impact.

These six criteria were considered to encompass the main issues to be considered for ranking purposes, while allowing the experts to make optimal use of available data.

3.2 Ranking of issues of greatest concern

The above criteria were used to rank in order of priority the fresh fruits and vegetables of concern and the associated hazards. The meeting applied these criteria to the list of produce and associated hazards that had been identified in the request from the CCFH, as well as any additional produce and hazards identified in the replies provided by countries to the Circular Letter issued by Codex. Before embarking on this exercise, consideration was given as to whether issues should be identified on a produce-pathogen basis or a production system or process basis. It was agreed that the most appropriate approach was to rank the produce groups of greatest concern and identify the range of hazards associated with each produce group. While recognizing that certain aspects, such as the availability of safe water, would be applicable to all produce groups, it would not be possible for Codex to develop specific guidelines in this regard.

The criteria were applied to each of the identified produce categories using the information available and the expertise of the meeting participants. The available data relative to each of the six criteria varied significantly in terms of completeness for the different produce. Produce were ranked into three groups according to the degree to which they met the six criteria. The outcome of the ranking exercise is summarized in Table 3.

3.2.1 Level 1 priorities: Leafy green vegetables

Leafy green vegetables were identified as the commodity group of highest concern from a microbiological safety perspective. This commodity grouping was considered to include all vegetables of a leafy nature and of which the leaf is the intended for consumption such as lettuce (all varieties), spinach, cabbages, chicory, leafy fresh herbs (e.g. cilantro, basil, parsley) and watercress. This commodity group does not include green onions which differ in morphology from the above-mentioned vegetables.

Table 3. Summary of the outcome of the ranking exercise

Commodity	Hazards	Reasons for ranking
Level 1 Priorities		
Leafy green vegetables (spinach, cabbage, raw watercress, lettuce and salad leaves (all varieties), fresh herbs (cilantro, basil, parsley), chicory)	Enterohaemorrhagic <i>Escherichia coli</i> , <i>Salmonella enterica</i> <i>Campylobacter</i> <i>Shigella</i> spp. Hepatitis A virus, Noroviruses <i>Cyclospora cayatenensis</i> <i>Cryptosporidium</i> <i>Yersinia pseudotuberculosis</i> <i>Listeria monocytogenes</i>	<ol style="list-style-type: none"> Multiple outbreaks reported in at least 3 regions of the world – including illness and deaths. Grown in large production and wide and increasing consumption, especially in the pre-cut sector. Expanding in countries where not traditionally grown, for nutrition reasons and as convenience food Processed and distributed using very diverse systems, new to many countries. Potential for amplification exists, especially for fresh cut produce, both at individual scale and small wet-market scale. Complex production and distribution – multiple control points on farm to minimize potential for contamination and post-harvest to minimize cross contamination – multi-step approach needed. Extensive international trade.
Level 2 Priorities		
Berries	<i>Cyclospora cayatenensis</i> <i>Cryptosporidium parvum</i> Noroviruses (frozen berries) Hepatitis A	<ol style="list-style-type: none"> Outbreaks in several regions. Extensive production for some types of berries. Production varies according to berry type and includes wild berry collection. Limited if any amplification. Humans main source ... extensively handled products. International trade but certain berries frozen first (still have problems with those – viruses).
Green onions	Hepatitis A virus <i>Shigella</i> spp.	<ol style="list-style-type: none"> Outbreaks reported in one or two countries only. Smaller production but increasing. Widely consumed. Similar production systems in different countries, although size might vary. Pathogen may be in the leaf cavity where there is potential for amplification. Handling at harvest appears to be critical. Internationally traded.
Melons	<i>Salmonella enterica</i> Lower priority: Enterohaemorrhagic <i>Escherichia coli</i> Norovirus	<ol style="list-style-type: none"> Outbreaks in several regions of the world. Widespread production with year-round availability. Similar production techniques worldwide, but may be differences in the practices to keep growing melons off ground. Supports pathogen growth very well. Irrigation water, water used in packing houses – hydro cooling can be a source of contamination. Widespread international trade.
Sprouted seeds	<i>Salmonella enterica</i> Enterohaemorrhagic <i>Escherichia coli</i> (+ enterotoxigenic <i>E. coli</i>) <i>Bacillus cereus</i>	<ol style="list-style-type: none"> Outbreaks in a number of regions in the world. Regional differences, small production units. Depends on type of sprout. Ample opportunity for pathogen growth. Preventive controls such as pre-treatment of seeds, control of irrigation water, testing of water and seeds prior to sprouting. Sprout seeds widely traded, but not the sprouts due to short shelf-life.
Tomatoes	<i>Salmonella enterica</i> Hepatitis A	<ol style="list-style-type: none"> Numerous outbreaks but only reported in USA (outbreaks including numerous illnesses and 3 deaths). Very large and extensive production, but not all go to fresh consumption Diverse production – field vs. glasshouse, very short to long distribution chains, variation in post-harvest practices simple to complex, especially for pre-cut tomatoes, consumption of which is increasing in some regions, e.g. North America Lack of information about the source of contamination at primary production. At post-harvest, contamination probably related to cool water use. Widely traded produce.

Commodity	Hazards	Reasons for ranking
Level 3 priorities		
Carrots	<i>Yersinia pseudotuberculosis</i> <i>Shigella</i> spp. Enterotoxigenic <i>E. coli</i> Caliciviruses (cut carrots) Hepatitis A Parasites	1. Outbreaks in a couple of countries. 2. Little information on production but are increasingly being marketed as a convenience ready-to-eat raw food. 3. Little known. 4. In cut carrots, increased surface area, initial lethality but the effect does not seem to be long lived. 5. Depends on pathogen, handling of prepared carrots may be issue so controls exist. For <i>Yersinia</i> more information is needed to understand control options. 6. Little information but probably relatively small, although increase in value-added ready-to-eat product.
Cucumber	<i>Salmonella</i> <i>E. coli</i> <i>Campylobacter</i>	1. This group has had one or two isolated outbreaks associated with them, some of which are very recent. 2. Global production lower but may be very important produce in particular regions of the world.
Almonds	<i>Salmonella</i>	3. Very diverse group of produce—some such as seeds and nuts seeing an increase in raw consumption (may need to indicate to Codex to revise relevant codes of practice).
Baby corn	<i>Shigella</i>	
Sesame seeds	<i>Salmonella</i> <i>Bacillus</i>	4. Many of the produce provide good conditions for amplification. 5. Control measures depend on produce but feasible for many.
Onions and garlic	<i>E. coli</i> <i>Salmonella</i>	6. Traded internationally with global supply often originating from a few production areas.
Mango	<i>Salmonella</i>	
Paw paw	<i>Salmonella</i>	
Celery	Norovirus Hepatitis A	
Maimai	<i>Salmonella</i>	

NOTE: There may be other hazards that are present on the produce but not (as yet) linked to outbreaks. The presence of the listed hazards on fresh produce has been directly linked to illness and these were therefore considered as the hazards of greatest concern.

Frequency and severity of disease

Leafy green vegetables have been associated with multiple outbreaks of foodborne disease with high numbers of illnesses in at least three regions of the world. For example, there have been at least 30 outbreaks linked to these commodities in the USA and 5 in Sweden over the last 10 years. While reports of outbreaks come from developed countries in Europe, North America and the south-west Pacific, it was considered that this may be a reflection of the disease surveillance systems that exist in those regions. A recent outbreak associated with *Salmonella* in fresh basil grown in Israel led to illnesses in at least 4 countries and one reported death. Therefore, the meeting did not discount the possibility of illnesses linked to these commodities in other parts of the world. The severity of the disease is often linked to the implicated hazards, and the range of hazards that have been linked with this product group is extensive. For example, enterohaemorrhagic *Escherichia coli* in these products has caused severe illnesses and even deaths.

Size and scope of production of leafy green vegetables

It is difficult to quantify the size of production of these products on a global perspective. However, data from the FAO statistical database FAOSTAT indicate that developed countries produced over 9 million tonne of lettuce and chicory in 2006, while 14 million tonne of these two types of produce were produced in developing countries (FAOSTAT, 2007a). Interestingly, this represented a doubling of the production in developing countries since 1996. Production of spinach has also doubled in developing countries in the last 10 years (FAOSTAT, 2007a). In many countries, leafy green vegetables are now produced on an industrial scale, with production, harvesting and packing taking place practically on a 24-hour basis. There is an increasing demand for these commodities as a result of efforts to promote better nutrition and address the double burden of malnutrition. Some of the vegetables in this commodity group are also being introduced into countries where they were not

commonly grown or consumed previously, particularly developing countries, where they are often produced for export. The safety of leafy green vegetables has thus become an important issue worldwide.

Diversity and complexity of the production chain and industry

The production of these vegetables varies widely both within countries and between countries, ranging from large industrial producers to small farmers, who may also supply large processors and distributors. The leafy green vegetables may be marketed and consumed locally, nationally or internationally. The way in which the commodities are sold also differs. They are often sold as pre-cut packaged products and different commodities in this group may be combined and sold as mixed packages. This means that the commodities may only be subject to field packing before marketing or may go to packing houses or processing facilities for pre-cut packaged products. Other differences include the application of a cold-chain, which clearly varies from country to country. Within the commodity group there may also be differences in the way different vegetables are treated, e.g. leafy herbs may be subject to less washing due to their delicacy.

Potential for amplification of foodborne pathogens through the food chain

There is potential for introduction and amplification of the associated hazards as leafy green vegetables move through the food chain. While primary production is probably the main concern in terms of introduction of the hazard, there are also post-harvest opportunities during transport (e.g. open, unprotected transport), processing (mixing of different types of leafy greens), packing (contamination by handlers), distribution and market or retail (wet-markets). These steps may also provide the opportunity for any contaminating pathogens to increase in number. Also, there are opportunities for cross-contamination of product during processing, particularly in the case of pre-cut or mixed product.

Potential for control

Numerous opportunities to control the pathogens exist. However, there is no unique control point. Given the complexity and differences of the primary production, processing, packing and distribution systems, there are measures that need to be taken at all these steps to control hazards. This multi-step approach to hazard control is particularly important as the route of entry of these hazards is not always clear and may not even be identified in extensive investigations that follow an outbreak.

Extent of international trade and economic impact

Exact figures on the extent of international trade for a specific commodity group are not readily available; however, FAOSTAT data indicates that the export value of lettuce and chicory has doubled, and that of spinach quadrupled, over the last 10 years (FAOSTAT, 2007b). In addition, some of the recent contamination events and outbreaks linked to leafy greens have indicated that international trade in these products can be extensive and far reaching. For example, in the case of the outbreak linked to spinach in the USA in 2006, primary distribution of the product to three countries was confirmed with secondary distribution to at least one other country (INFOSAN, 2007). Also, many of the contamination events reported through the RASFF system in Europe have highlighted that the origin of these products often varies, with leafy green commodities being imported into Europe from around the world. The distribution pathways of these products are also often difficult to follow as the seasonality of these commodities results in seasonal changes as to whence they are sourced. The economic impact of an outbreak associated with leafy green vegetables can be extensive, as follow-up studies to the spinach outbreak in the USA have shown. Losses to farmers, processors and distributors occur as a result of recalled product, lost sales, cost of reviewing and implementing new practices, costs of increased testing and inspection, and lawsuits. Detection of contaminated products, without implicated illnesses, can also lead to product recalls and the closure of markets, particularly export markets, as has been the case for some Asian countries. It can also take time to restore consumer confidence in a product that has been implicated in an outbreak. For example, the demand for spinach in the USA was down by over 40% approximately one year after the outbreak (Calvin, 2007).

3.2.2 Level 2 priorities: berries, green onions, melons, sprouted seeds and tomatoes

The second level of priorities identified included berries, green onions, melons, sprouted seeds and tomatoes. Again, the available data varied in extent of completeness, but the meeting agreed that each of these commodities was important in terms of public health concern. However, in contrast to the leafy greens, the meeting considered that there was more variation in terms of the global impact of these produce. In some cases, the problem was linked to one region only, or the commodity may be produced to a lesser extent and therefore not as widely traded or consumed as the first group. The meeting considered that there was not adequate scientific information available to prioritize the commodities within this group. However, a distinction was made between sprouted seeds and the other four commodity groups, particularly because an international code of practice already exists for sprouted seeds.

Berries

This commodity group includes all soft berries that are consumed fresh, including blackberries, raspberries, strawberries and blueberries. Berries have been implicated in outbreaks in both North America and Europe, and have caused numerous serious illnesses. Imported berries were often implicated, indicating that this problem extends beyond those countries where there have been outbreaks. The size and scope of berry production varies according to berry type, with strawberries considered to be the most important in terms of production and trade. A unique characteristic of this group is that berries may be harvested from the wild as well as cultivated. Thus, the diversity of the production chain and industry can be extensive. Another important aspect of this commodity group is that harvesting is primarily undertaken by a large number of people, presenting a potential source of contamination. Also, the delicate nature of some of these fruits means that it is not possible to subject them to a wash step, as this would negatively affect quality. Also, while the main concern of this meeting was fresh products, the meeting highlighted that a number of outbreaks have been associated with frozen berries. In such cases, the hazard of concern has been viral. Freezing will maintain viral infectivity. As the source of such contamination may be during harvesting or the sprinkling of possibly contaminated water on the fruit before freezing, it was considered that efforts to minimize the hazard on fresh berries would also have a positive impact on the safety of frozen product.

The potential for amplification of foodborne pathogens on berries was considered to be small. Berries are typically acidic and so do not provide a suitable environment for microbial growth. Also, viruses and parasites, the hazards most frequently associated with berries, will not replicate outside their host; however, low numbers of some of these hazards can be adequate to cause illness. As berries are extensively handled, human hands are considered the primary source of contamination and therefore a critical point in terms of hazard control. Other potential areas of control include irrigation water, use of manure as fertilizer, and protection against birds.

International trade in berries is extensive, although the volumes may be small compared to other produce. For example, approximately half a million tonnes of strawberries and 120 000 tonne of raspberries and related berries were exported in 2005. Also, berries are often frozen before export, but, as noted above, this does not mean that the hazards have been eliminated. Outbreaks linked to berries have an economic impact, particularly on producer countries. For instance, an outbreak in North America linked to raspberries from Guatemala resulted in a loss of market for this Central American country (Calvin, Avendaño and Schwentesius, 2004).

Green onions

Green onions have been linked to three outbreaks in the USA, including 4 deaths and 1028 illnesses. While green or spring onions are widely used around the world, outbreaks from other parts of the world were not identified. However, the outbreaks in the USA were linked to imported green onions. Production of green onions was considered to be small compared to some of the other commodities considered here, but the product is widely used, often as a herb, garnish or minor component of a meal. Thus, a small volume of product may lead to exposure of a large number of people. The production systems around the world for green onions were considered to be similar, although the size of the farms and volume of production may vary.

The unique morphology of this product, with its moist hollow tube leaf, provides ample opportunity for amplification of microbial hazards. Also, if a pathogen is inside this tube, little can be done to remove it as it is protected from washing. Therefore, controls at primary production can be important in terms of preventing internalization of a hazard. However, the hazards associated with green onions to date are those known to be transmitted by human contact, i.e. hepatitis A and *Shigella*. Thus, handling is also a critical point in terms of control, particularly at harvest where these products are exposed to maximum handling.

Green onions are traded internationally. Production is labour intensive and often occurs in areas where labour costs are cheaper. The hepatitis A outbreak in the USA in 2003 led to a decrease in the market price of green onions, and a shut down of the American market for some Mexican producers. The food safety concerns led to a drop in demand for Mexican green onions and estimated losses of US\$ 10.5 million for Mexican growers in a two-week period in November 2003 (Calvin, Avendaño and Schwentesius, 2004). Although hepatitis A was not isolated from suspected farms in Mexico, practices that could contribute to contamination of the product were identified. This was an impetus for the implementation of GAPs among the producers and as a requirement for opening of export markets.

Melons

This commodity group includes honey dew, cantaloupe, sun melon, rock melon and watermelon. Melons have been linked to numerous outbreaks, primarily in North America and the south-west Pacific. However, melons are produced in several regions of the world and some of the outbreaks have been linked with imported produce. While melon production has been stable in the developed world over the last 10 years, watermelon production in developing countries has tripled, while production of other types of melons has doubled. The production systems for melon were not considered to vary much from one place to another. However, it was noted that different systems might be implemented to prevent contact between the growing melon and the ground.

The characteristics of the fruit itself are important aspects in terms of contamination and control. The rugged nature of the skin on many types of melon makes it difficult to remove any surface contamination. Also, cold water washes or hydro cooling have been identified as potential sources of contamination as freshly harvested, sun warmed melon may absorb the cold water and any contaminants therein. In such cases peeling of the melon before consumption will not remove the hazard. Another important consideration in relation to melons is changes in marketing practices, with an increase in pre-cut melon. The flesh of a melon provides an ideal environment for microbial multiplication. Thus, there is a high risk of amplification of foodborne bacterial pathogens that may be present. In terms of hazard control, the quality of the water used for irrigation, washing and the practice of hydro-cooling is critical. However, the difficulty of preventing soil and dust from getting onto the fruit and possibly contaminating it means that there is still a lack of knowledge as to how to minimize contamination at the farm level. Given that melon flesh is ideal to support microbial growth, refrigeration is critical for pre-cut melon.

Melons are produced in a number of regions in the world and are traded internationally. Some melon types are only available for harvest for a two-week period in any one area, which means that the source of melons on the international market changes regularly. Back-to-back outbreaks in North America linked to melons from Mexico had a large impact on producers in Mexico and resulted in the closure of market access to their biggest customer.

Tomatoes

Numerous outbreaks have been linked to tomatoes, but to date they have only been reported in the USA, where three deaths and 1840 illnesses have been linked to contaminated tomatoes. As these outbreaks have been linked to tomatoes from particular geographic regions in the USA, it is not clear whether this is a unique problem for this country or could be more widespread. Also, lack of clarity as to the source of the contamination (which may be birds, wildlife (e.g. lizards), or contaminated irrigation water) means that until more information is available it is difficult as yet to identify the global extent of this problem.

Tomatoes are a widely grown commodity, with production figures in 2005 reaching approximately 35 million tonne in developed countries and 90 million tonne in developing countries (FAOSTAT,

2007a). Production is, however, for both the fresh market as well as processing, and production systems may differ depending on the final use of the tomato. There is also great diversity of production systems among the tomatoes grown for the fresh market, with field and greenhouse production. There is an increase in the variety of tomatoes grown for the fresh market. The tomato variety often determines the post-harvest measures that can be taken. The length of the distribution chain also varies. The potential for amplification of the hazard may be dependent on the way in which the product is marketed. An increase in the marketing of pre-cut tomatoes, for example in North America, which, depending on variety and state of ripeness, can provide an environment more amenable to pathogen amplification, particularly salmonellae, which can adapt to low pH environments, may lead to increased problems. The limited information on the primary source of contamination means that our understanding of appropriate control is still inadequate. However, as with most commodities, the quality of the water used in irrigation and processing are important factors.

Tomatoes are a widely traded product internationally. Different varieties of tomatoes are often sourced from different parts of the world. They are a major contributor to the economy of some countries and the global export value of fresh tomatoes in 2005 was approximately US\$ 5000 million (FAOSTAT, 2007). Thus, they are an important commodity from an economic perspective.

Sprouted seeds

Sprouted seeds include alfalfa sprouts, mung bean sprouts, radish sprouts, sunflower sprouts and clover sprouts, among others. Outbreaks with this commodity have occurred in North America, Europe and Asia. The outbreaks in Japan in 1996, caused by *E. coli* O157:H7, led to 9451 illnesses and 12 deaths—all children—and worldwide attention to potential microbiological hazards in fresh produce (Michino *et al.*, 1999). This commodity is not universally produced or consumed and regional differences certainly exist. Sprouted seeds are a unique product in that they are essentially a factory crop produced under very controlled conditions. While production is considered to be low compared to some of the other commodities in this group, there have been a relatively high number of outbreaks and illnesses linked to the commodity.

Production varies according to the type of sprout: mung seeds and alfalfa seeds are sprouted in a liquid matrix, while radish, sunflower and clover are sprouted on a solid matrix. These conditions are very amenable to microbial growth. There are a number of control measures that have been identified and are being implemented. These include disinfection of the seeds and testing of the irrigation water. Codex has developed a code of practice for sprout production. Thus, while outbreaks linked to sprouts occur, there have been indications that at least in some cases they may be linked to a failure to implement the already identified measures. Preventive controls used in the USA, such as the pre-treatment of seeds, control of irrigation water and testing of water, are known to reduce the health risk to consumers. Preventive controls in other countries appear not to be as successful. The sprout industry has also indicated that it has some problems with the Codex code as it currently exists. Thus, the meeting considered that it would be appropriate to review the existing code in the light of some of the more recent information on outbreaks and control measures, in order to determine if the existing code is adequate.

Sprouted seeds are not an important commodity in international trade; however, the seeds themselves, which are often the source of contamination, are traded widely.

3.2.3 Level 3 priorities

This last group of commodities, which were considered to be the lowest priority of the commodities considered, is a mixed group, which includes both fruits and vegetables, namely carrots, cucumbers, almonds, baby corn, sesame seeds, onions and garlic, mango, paw paw, celery and maimai. They are included here as all have been linked to foodborne illness. However, compared to the produce previously addressed they have had a very limited public health impact to date. Information on these produce and the associated hazards and potential control measures is very limited, if it even exists. Nevertheless, the meeting considered that some of these may reflect emerging problems related to fresh produce. For example, the outbreaks linked to baby corn are very recent and little is yet known as to why this problem arose. Considering that much of the global supply of baby corn comes from one region, it may be important to monitor whether problems such as this develop further or have been

isolated events. Also, consumer use of some of the produce identified here is changing, with greater amounts being consumed raw, e.g. carrots, seeds and almonds. Thus, bringing attention to these products and the potential problems associated with them may serve to act as an early warning of the potentially emerging problems related to fresh produce.

4. Elaboration of scientific advice on fresh produce

The meeting identified some of the important aspects that need to be considered in the elaboration of scientific advice on fresh produce.

4.1 Primary production

The provision of scientific advice on fresh produce clearly needs a food-chain approach, taking into account all aspects from primary production to consumption. This includes consideration of the inputs to primary production, which include the farm environment (soil, wildlife, proximity to urban or industrial development, waterways, susceptibility to run-off), irrigation water source, manure, soil amendments, pesticides and even the seeds or plants themselves. In addition, the workers (growers, pickers) and transport (open transportation may provide contamination opportunities) from the field to the packing and processing houses are a consideration at this stage. All represent potential sources of contamination and their relevance to the particular commodity of concern may need to be assessed.

Consideration of the abovementioned aspects means that the elaboration of scientific advice to improve the safety of fresh produce must look to expertise outside of the traditional food safety experts. While the need for agriculture experts (practices, role of crop rotation in food safety) is clear, other types of expertise needed include hydrologists, ecologists (wildlife presence and behaviour) and sociologists (farm worker behaviour, awareness, education).

The range of potential hazards that can be introduced at primary production must be considered, as this can be extensive. Such hazards include pathogenic bacteria (*Salmonella*, enterohaemorrhagic *Escherichia coli*, *Campylobacter*, *Listeria*, *Shigella*, *Yersinia*), parasites (*Cryptosporidium*, *Cyclospora*, helminths) and viruses (hepatitis A, noroviruses).

Another aspect for consideration in relation to the inputs to primary production is the availability of data. Due to the relatively recent emergence of the problems related to fresh produce, there are many data gaps regarding the source of hazards and the role of various inputs in contamination of the fresh produce. This means that the identification of critical data gaps and research needs will also be a component of the process to provide scientific advice, as well as a caveat to any advice provided.

4.2 Packing and processing

The extent of post-harvest manipulation that fresh produce is subjected to will clearly vary according to commodity, as particular commodities may be packaged and processed in different ways. Lettuce, for example, may be packed directly in the field immediately after harvest with minor manipulation (perhaps removal of the outer leaves) before going to distribution; it may be transported to packing houses where it is also packaged whole, after removal of outer leaves and washing, with ice packing; or it may go to the pre-cut bagged sector, in which case it is cut, washed several times and may be mixed with other produce before being bagged or boxed. While there is still potential for contamination at this stage, for example with viruses or *Listeria*, these steps also provide the potential for a reduction or amplification of contaminants.

The type of expertise needed to address this step of the food chain is the more traditional food safety expert with practical experience of the hazards associated with packing and processing and the available control options.

4.3 Distribution

The distribution chains for fresh produce can be very varied, ranging from local to international. In addition, as the distribution chain gets longer there will be numerous intermediate distributors. Very limited information is available about the distribution chain for fresh produce, particularly in relation to time and temperature of storage and distribution. Such a data gap presents a problem in terms of trying to clarify the impact of this step on any contaminants on the fresh produce. As a chill chain may be necessary to maintain the quality of some fresh produce, particularly pre-cut packaged produce, it will probably be easier to get information on these products compared with fresh produce, which is less dependent on chill temperature to maintain quality and may also be minimally packaged. This is an area where additional expertise from food engineering would be of value.

4.4 Wholesale and retail

This sector is also one that can vary substantially in terms of fresh produce. Retail outlets can range from wet markets, where there is the potential of cross-contamination from other produce or non-produce commodities, to greengrocers, to supermarkets, where some produce may be cut and re-packaged. Handling can again become a source of contamination here, with the potential for the introduction of viruses and bacteria (*Salmonella*, enterohaemorrhagic *Escherichia coli*, *Shigella*).

4.5 Potential approaches to the elaboration of scientific advice

Qualitative analysis and in particular expert elicitation may be a relevant tool when elaborating scientific advice on fresh produce. Quantitative methods might not be feasible when data do not exist or are highly uncertain or variable, or because the overall problems are too complex for standard analytical techniques. In recent years, national agencies in some countries have used expert elicitation and guidelines to facilitate its application have been developed. A recent example is that conducted by the United States Food and Drug Administration to rank the most serious hazards and the most effective preventive controls found across the entire diverse processed food industry in the USA.

Quantitative risk assessment approaches to identify means of reducing the risks associated with fresh produce should also be feasible, at least to some extent. Work is already underway in several European countries and it is likely that such approaches are also being developed elsewhere. Quantitative data are one of the important inputs to this type of risk assessment. However, low levels of contamination are often associated with these products, and thus the extent of sampling and analysis necessary to acquire a dataset can be extensive and costly.

5. Conclusions and Recommendations

5.1 Conclusions

Following the review of the available information and the ranking exercise, the meeting reached the following conclusions.

The level of information available on the different commodities varies significantly. This, without doubt, had an impact on the ranking exercise, but could not be avoided. In many cases, our level of understanding of the hazards, the routes of contamination and the controls are limited. Nevertheless, there is a substantial body of data and information available that allows ranking of priority commodities of concern. Based on that information, it was concluded that leafy green vegetables were the commodity of greatest concern. The second group of priorities identified included berries, green onions, melons, sprouted seeds and tomatoes, and should be considered as second-level priorities. The meeting concluded that there was not adequate scientific information available to prioritize the commodities within this group. However, a distinction was made between sprouted seeds and the other four produce, particularly because an international code of practice already exists for sprouted seeds.

Many risk assessments to date have taken a pathogen-commodity approach. This was not considered optimal for fresh produce, where there are often several significant hazards associated with a single commodity. Thus, it was concluded that a commodity approach should be taken, and in each case the relevant hazards associated with that commodity be identified.

There are many variables to consider in the fresh produce sector, from the commodities themselves to the range of production systems, which vary within countries as well as among countries. It was therefore concluded that there would be no unique control measures that could be applied at one point of the food chain. Thus, in dealing with the food safety issues associated with fresh produce it is clear that a food chain approach is required. However, this case requires extending beyond the normal realms of food safety, and taking a truly multidisciplinary approach. In addition, any approach to elaborate scientific advice should include both fresh and fresh-cut produce, as these are practically impossible to distinguish in the early part of the food chain.

5.2 Recommendations

The meeting made the following recommendations.

- Leafy green vegetables should be considered the highest priority in terms of fresh produce safety from a global perspective, and that FAO and WHO should focus its efforts to develop scientific advice on this commodity grouping.
- The 39th Session of the CCFH should take into account the outcome of the ranking exercise and the priority rankings assigned to the different commodities when selecting their work priorities.
- The annex to the Codex code of hygienic practice for fresh practice for fresh fruits and vegetables, which addresses sprouted seeds, should be reviewed for adequacy.
- The ranking should be reviewed in the future and revised when substantial new information is available.

In the process to elaborate scientific advice and develop risk management guidance on the control of microbiological hazards in fresh produce, the meeting made the following recommendations to FAO, WHO and Codex.

- **Apply a systemic approach**

A broad systemic approach based on the link between related commodities and an array of known pathogens, rather than a narrow single product-pathogen pair approach, should be taken. Such a systemic or systems approach should incorporate comparable growing and harvesting practices across the food chain continuum with the array of pathogens that are known to have caused outbreaks—such as the meeting did for the broad category of leafy greens with its array of known pathogens. A broader systems approach captures a more comprehensive range and diversity of produce and pathogens.

- **Create an interdisciplinary team**

The expertise needed to develop the scientific advice and inform the elaboration of risk management guidance is diverse, and an interdisciplinary team will be needed to achieve a synergetic outcome. In addition to microbiologists, epidemiologists and food safety experts, the specialists could include water management experts, perhaps including engineers that deal in surface hydrology and water quality to address issues related to irrigation and provision of safe water; agriculture experts, including horticulturalists; wildlife management experts will be needed to address issues related to pests and wildlife and their control; ecologists and environmental engineers will be needed to address soil and environmental risks; and socialists to address some of the aspects related to worker behaviour and its impact on risk.

- **Evaluate training and education as a preventive control**

The training and education of growers and handlers along the entire food chain continuum should be considered as a primary preventive control. The proposed training requirement should address safe growing and handling practices, including general clean handling procedures, control of cross-contact, and personal hygiene. To have an effective training programme requires that growers and handlers have a level of consciousness about the potential hazards in their, often longstanding, practices. Additionally, consideration should be given to cultural and social aspects, including diverse local attitudes, working conditions and growing and distribution conditions, along with longstanding entrenched worker behaviours, attitudes and social taboos.

- **Evaluate differences between large- and small-scale production practices**

The differences in growing, handling and distribution practices may be significant between large- and small-scale production. Large-scale production achieves economies of scale and scope that enable the globalization of the sale of fresh produce, but in its very complexity and multiple control points carries the risk of amplification. Small-scale producers, which are often local growers and distributors, are subject to the variability of local conditions and often have limited potential for control. Different factors of production, like the availability of clean water sources, are often a function of scale of production, which therefore carries different consumer risks.

- **Assess new technologies, production processes and growing conditions**

New or potential technologies, production processes and growing conditions should be carefully examined. Some technologies enhance the safety in small-scale production, such as those that kill pathogens to reduce the risk from locally contaminated water sources. Some production processes and technologies that extend the shelf-life of fresh produce enhance the risk of extending the growing time of pathogens. New growing conditions, such as introducing fresh produce crops into tropical environments, increase the volume of nutritious foods that are sold, but also carry the risk of introducing new microbiological hazards.

- **Assess changes in consumption and production patterns**

Significant changes are occurring in both consumption and production patterns. Consumers that cooked produce in the past are now consuming produce raw as part of their regular diet, while more affluent consumers are increasingly demanding more types of fresh produce year round. In an ever-expanding volume of international trade, producers are increasingly supplying fresh produce year round from land that previously was not used to grow fresh produce. Producers are emerging in

regions that previously had not grown or distributed fresh produce. New technologies are also being adopted. The new patterns carry new or emerging risks that require periodic reassessment.

- **Use Risk Assessment approaches to characterize the risks and to assess the impact of controls**

Risk assessment approaches could contribute to both further ranking of the commodity and pathogens of concern and to evaluating the impact of prevention and controls measures across diverse regions and conditions. Quantitative risk assessment should be conducted when feasible, and qualitative risk assessment approaches should be used when quantitative methods are not feasible, or where data are significantly lacking and uncertain.

The meeting made additional recommendations to member countries and their national authorities and other institutions working in this area as follows:

- **Improve disease surveillance and data collection systems**

The burden of disease related to fresh produce, particularly in developing countries is not known. While it is assumed to be relatively high, there are few data available to assess the magnitude of the problem. In many parts of the world, operational foodborne disease surveillance systems need to be created or enhanced, while surveys of production and handling methods and population consumption patterns are needed to better understand the true risk to diverse populations and subpopulations worldwide. The development and implementation of trace-back systems were also considered important to facilitate outbreak investigations, identify sources of contamination and target control measures.

- **Increase awareness**

There is a need to create greater awareness among all those associated with fresh produce production, packing, processing, distribution, storage, retail and catering regarding the risks associated with contaminated fresh produce and the need for preventative control measures all along the food chain.

- **Improve interaction with other relevant sectors**

The problems related to fresh produce clearly cannot be addressed by looking at food safety and agriculture in isolation from other areas, such as water availability and quality, infrastructure, sanitation, proximity to urban and industrial areas and local ecology and environment.

- **Direct resources towards research and data generation on prioritized commodities**

While there are numerous data gaps related to microbiological hazards in fresh produce, prioritization of resource allocations would help ensure that limited resources are used to address the issues of greatest concern.

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Annex 1

TERMS OF REFERENCE FOR AN FAO/WHO EXPERT CONSULTATION TO SUPPORT THE DEVELOPMENT OF COMMODITY-SPECIFIC ANNEXES FOR THE CODEX ALIMENTARIUS “CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES” (ALINORM 07/30/13, Appendix VI)

BACKGROUND

Public health officials and consumers alike recognize that fresh fruits and vegetables play an important role in a healthy diet, providing important vitamins, minerals, and phyto-nutrients. As consumption of fresh fruits and vegetables increases, so has the incidence of fresh produce serving as a vehicle for foodborne illness. Most produce is grown in a natural environment, and is, therefore, vulnerable to contamination with pathogens from multiple sources, including agricultural and post-harvest water, ill workers, the presence of wild or domestic animals or animal waste, and unsanitary equipment and facilities. The safety of fresh produce is a global issue covering both the countries that import fresh fruits and vegetables and the countries that supply them. In many instances countries both export and import produce. For example, despite the United States of America being a major provider of fresh produce, approximately 35% of the fresh produce it consumes is imported. Given the role of fresh produce in a healthy diet, it is critical that these foods are as safe as possible.

In 2003, the CCFH elaborated a “Code of Hygienic Practice for Fresh Fruits and Vegetables” to address Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) to help control microbial hazards associated with all stages of the production of fresh fruits and vegetables from primary production to packing. The code provides a general framework of recommendations to allow uniform adoption by this sector, regardless of the diverse environmental conditions encountered or the commodities to which it might be applied. The code of practice is, of necessity, a flexible one to allow for different systems of control and prevention. This Code also recognizes that it should be a living document, foreseeing the need for revisions as science advances. Since this code of practice was established, experience in produce safety has grown exponentially. In implementing current GAP and GMP recommendations, it has become apparent that public health would benefit from the availability of more detailed, commodity-specific guidance. This need is being met, in part, through industry efforts. For example, several USA industry groups have developed commodity-specific supply-chain guidance documents. However, the global nature of produce production, processing and marketing requires an international perspective, and both public health and international trade in produce could be enhanced by the systematic development and elaboration of a series of commodity-specific annexes to the current “Code of Hygienic Practice for Fresh Fruits and Vegetables.” A prerequisite for consideration of the development of such guidance in a timely manner is a review of the available scientific and technological data. Furthermore, such a review would be beneficial to many, if not most member countries of CCFH. Accordingly, the 38th Session of CCFH requests that such scientific advice be provided by the FAO/WHO. The advice should be based on the solicitation of experts on the identification, impact and practical application of GAPs and GMPs on the safety of produce.

The expert consultation should focus on the specific commodities that have been associated with the highest incidence of foodborne outbreaks. The consultation should consider the entire farm-to-table continuum, including processing and marketing, and with a focus on the factors at primary production that contribute to the risk of foodborne disease, especially environmental hygiene, water for primary production, and personnel health, personnel hygiene and sanitary facilities. While the greatest information needs are associated with primary production, the expert consultation should also consider packing establishments, field packing operations, and other post-harvest handling facilities, particularly key aspects of hygiene control systems such as post-harvest water use, worker health and hygiene, cleaning and sanitizing of equipment and facilities, and the maintenance of the cold chain.

The selection of commodities should be based on their public health impact and should focus on the most significant pathogens associated with the commodity. An initial evaluation of available epidemiological data suggests that the commodities of primary concern would likely include (a) leafy green vegetables (enterohaemorrhagic *Escherichia coli*, *Salmonella enterica*, *Shigella* spp., *Yersinia pseudotuberculosis*, type A hepatitis virus, noroviruses); (b) tomatoes (*Salmonella enterica*);

(c) melons (*Salmonella enterica*); (d) green onions (type A hepatitis virus, norovirus, enterohaemorrhagic *Escherichia coli*); (e) sprouted seeds (*Salmonella enterica*, enterohaemorrhagic *Escherichia coli*); (f) herbs (*Salmonella enterica*, *Shigella* spp., *Cyclospora cayatenensis*); and (g) berries (*Cyclospora cayatenensis*, *Cryptosporidium parvuum*) and root vegetables (*Yersinia pseudotuberculosis*). Where possible, the expert consultation should rank the relative risk of product becoming contaminated by the risk factors above; and recommend quantitative criteria for implementing effective preventive controls. Where it is not possible to establish quantitative criteria, the expert panel should be asked to consider qualitative criteria for use by producers and packers to assist them in determining when and how to institute effective preventive controls. The expert consultation should also be asked to recommend practical procedures that could be used by competent authorities, producers, packers and other interested parties in verifying the effectiveness of mitigation strategies and other preventive controls in minimizing the incidence of microbial contamination of fresh produce.

QUESTIONS FOR CONSIDERATION

The following represent examples of the types of questions that will likely need to be addressed by the expert consultation on a commodity basis to elicit information and analyses that would be beneficial to CCFH and member countries.

Environmental hygiene

What is the role of wild animals, especially in high concentrations, as a potential source of contamination?

- What is the relative contribution from wild animals and other environmental reservoirs as a source of human pathogens in the production environment?
- What are the most important types of animals and pathogens that they may carry?
- Is there evidence of a population density above which risk of contamination of fresh produce and subsequent consumer illness is most likely to occur? (Could we apply an Integrated Pest Management approach where “surveys” are routinely conducted for pests in a field but no action is taken unless the population exceeds a given density for a given pest?)
- Are there specific times during the production cycle when exposure of the production environment to high densities of wild life produces the greatest risk that fresh produce will be contaminated?
- Are there specific mitigations (e.g. removing animal attractants and harbourage in the production environment) that can be used to minimize ingress of wild and domestic animals into growing areas while avoiding significant adverse impacts on native fauna and catchment conservation?
- Are there specific proximity and topographical features, weather events or other considerations that should be considered when assessing the potential for a production area to have a high risk of harvested produce being contaminated with foodborne pathogens?
- What is the relative importance of fields being in proximity of animal production facilities, urban and suburban environments, animal refuges, etc.?
- What are the primary vehicles and vectors for transmission of zoonotic, pathogenic micro-organisms from animal rearing facilities to produce production areas?
- Are buffer zones a viable risk mitigation strategy, and, if so, what size zone is required?
- Is periodic flooding of production areas of concern, and, if so, what time intervals are needed before the land is used for the production of different classes of fresh produce?
- Are there specific land uses that pose a risk to subsequent production of fresh produce and what strategies can be employed to mitigate those risks?
- What is the significance of detection of pathogens in the environment where produce is being grown. e.g. *E coli* O157:H7 in waterways, *Salmonella* in ponds and canals or ditches in close proximity to growing fields?

Soil amendments and fertilizers

Under what conditions can fertilizers derived from animal or human waste be safely employed for the production of fresh and fresh-cut produce?

- What criteria and testing requirements should be employed to verify that fertilizers derived from animal waste are free of potential pathogens?
- Does the use of “green” fertilizer (i.e. composted plant waste) represent any significant risk in relation to increasing the likelihood that pathogenic micro-organisms will be present on fresh or fresh-cut produce?
- Does the “ploughing under” of field waste represent any significant risk in relation to subsequent crops having an increased likelihood that pathogenic micro-organisms will be present on fresh and fresh-cut produce?

Water

What are the primary hazards associated with fresh produce for which water is an important source or vehicle?

What is the relative risk associated with different forms of irrigation and what are the conditions under which these forms of irrigation can be safely employed?

What are the relative risks associated with different sources of water used for irrigation?

- Does the distribution system substantially contribute to the risk of contamination?
- What are the practical, cost-effective strategies that can be employed to protect water supplies and their distribution systems and to minimize the potential for agricultural water to serve as a source of contamination of fresh produce or spreading contamination in the production environment?
- Is there evidence of a time interval between exposure of the crop to a given quality of water and harvest of fresh produce at which the risk is higher or lower?
- What national and international microbiological criteria currently exist for different agricultural water sources and how effective are these criteria for mitigating the risks associated with their use with fresh produce? Are there additional criteria that would be beneficial?
- Are there specific time intervals or events after which water sources should be tested?
- What are the relative risks associated with other uses of water in the primary production environment (e.g. pesticide applications, cleaning of equipment)?
- How effective are current criteria for the use of agricultural water sources for non-irrigation uses in mitigating the risks associated with their use with fresh produce?
- What are the relative risks associated with uses of water in the packing environment?
- How effective are current criteria for water uses in the produce packing environment?
- What is the potential for water used for transport of produce in the packing environment (e.g. fluming) to serve as a means of cross-contamination? What are the conditions of use that mitigate this potential?
- What are the conditions of water use that foster infiltration of pathogenic micro-organisms into fresh produce and how can this be avoided? What is the level of uptake of micro-organisms that can be expected in the absence of factors contributing to infiltration?
- What is the efficacy of water washes on the removal of pathogenic micro-organisms from fresh produce?

Personnel health, personnel hygiene and sanitary facilities.

What is the potential for farm workers to serve as a source of contamination for fresh and fresh-cut produce?

What is the potential for food workers in packaging, processing, distribution and marketing facilities to serve as a source of contamination for fresh and fresh-cut produce?

- Can public health data on the incidence and prevalence of enteric and parasitic disease among farm workers and food workers and characterization of carrier status provide useful information for hazard identification for different produce production areas? What are the disease surveillance systems that

need to be in place to collect such data?

- What mitigation strategies (e.g. improved health status, provision of toilet and hand-washing facilities, training and accountability, protective clothing) are available to reduce the risk of foodborne disease attributable to farm workers as a source of contamination, and what are the relative risk reductions that can be achieved by these mitigations?

Packing and post-harvest process operations

Does conducting post-harvest processes (e.g. removal of wrapper leaves, coring) in the field at the time of harvesting represent any increased risk of contamination of fresh or fresh-cut produce? Do current technologies and practices effectively eliminate any increased risk?

What washing and disinfection mitigation technologies are currently available, feasible and practical for reducing the levels of pathogenic micro-organisms on fresh and fresh-cut produce? What degree of risk reduction can be expected from these technologies?

Does infiltration of pathogenic micro-organisms into the interior of the produce play a significant role in reducing the effectiveness of washing and disinfection treatments designed to reduce contamination?

What additional technologies are available for reducing the levels of pathogenic micro-organisms on fresh and fresh-cut produce? What degree of risk reduction can be expected from these technologies? Are there any barriers to their application?

Maintenance of the cold chain

What portion of the risk of foodborne disease associated with fresh and fresh-cut produce is attributable to failure to maintain the cold chain?

Are there any practical technologies that are available that can be used by industry, competent authorities or consumers to verify that fresh and fresh-cut produce have been maintained under continual refrigeration?

Is there increased risk of foodborne disease associated with further extending the shelf-life of fresh and fresh-cut produce?

Utilization of existing information

Wherever feasible, the expert consultation should identify and make use of existing risk assessments or risk evaluations that have been performed by national governments or recognized scientific organizations.

Time frame

The results of the expert consultation would be most effective if completed within the next 18 months. This should include periodic reports to the CCFH and consultations with any working group established to amend the current code or develop annexes to the code.

