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FOOD SAFETY

CONTENTS

EXE	CUTI	VE SUMMARY	v
1.	THE IMPORTANCE OF FOOD SAFETY: EXTENT AND MAGNITUDE OF FOODBORNE ILLNESS IN THE WORLD1		
	1.1	Introduction	1
	1.2	Increased trends in occurrence of foodborne diseases	2
	1.3	Categories of foodborne hazard	2
2.	NEW CHALLENGES		8
	2.1	Newly emerging and re-emerging foodborne pathogens	8
	2.2	New agreements in world trade	9
	2.3	New role for Codex Alimentarius	11
	2.4	The hazard analysis critical control point system: a preventive approach	11
	2.5	Risk analysis, a scientifically based process	
3.	HOW ARE THE COUNTRIES OF THE REGION PREPARED TO COPE		
	WIT	H THE NEW CHALLENGES?	13
	3.1	WTO membership	13
	3.2	Legislation	14
	3.3	National food safety coordinating committee	14
	3.4	Integration of HACCP into the food control system and legislative expression of HACCP	14
	35	Institutions involved in food safety	14
	3.6	Institutions involved in rood safety	
	3.0	Training of inspectorates	15
	3.8	Laboratory services	15
	3.0	Disease reporting mechanisms	15
	3.10	Consumer awareness and education	10
	2 11	Machanisms for improved food safety in selected countries outside	10
	5.11	the Eastern Mediterranean Region	16
4.	REGIONAL PLAN OF ACTION FOR ADDRESSING FOOD SAFETY		
	IN T	HE 21st CENTURY	16
	4.1	General requirements	16
	4.2	Specific concerns in present food control systems in the Eastern	
		Mediterranean Region	18
5.	PLAN OF ACTION AND RECOMMENDATIONS		19
	5.1	Region plan of action for addressing food safety in the 21st century in	
		the WHO Eastern Mediterranean Region	19
	5.2	Recommendations	20
5.	CON	CLUSION	24

EXECUTIVE SUMMARY

Since its inception, the World Health Organization (WHO) has been working towards the improvement of food safety through technical cooperation with Member States to strengthen national food safety programmes and by giving normative guidance in partnership with the Food and Agriculture Organization of the United Nations (FAO) in the Codex Alimentarius Commission and various expert bodies.

The Constitution of WHO in its Article 2, "Functions", makes specific reference to food and nutrition: "to promote, in co-operation with other specialized agencies where necessary, the improvement of nutrition, housing, sanitation, recreation, economic or working conditions and other aspects of environmental hygiene" and "to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products".

The Alma-Ata Declaration in 1978 recognized that the promotion of food supply and proper nutrition was an essential element of primary health care.

In 1990, the World Summit for Children identified the promotion of the health and nutrition of children as a high-priority issue; the need for adequate and safe diets was one of its important focus areas.

The 1992 United Nations Conference on Environment and Development adopted Agenda 21, which notes that human health needs to be promoted through, among others, the control of communicable diseases. Food is often the vehicle for transmission of organisms that cause such diseases. The management of toxic chemicals, many of which reach humans through food, was also highlighted.

The International Conference on Nutrition, held in December 1992, reaffirmed the statements, goals and targets of the World Summit for Children and Agenda 21. The Conference recognized that hundreds of millions of people worldwide are affected by diseases caused by contaminated food and water, and that the toll in terms of human life and suffering was enormous, particularly among infants and young children, the elderly and other vulnerable groups. Countries pledged to develop plans of action which would include the adoption of comprehensive measures to cover the control of food safety and quality with a view to protecting the health of consumers and ensuring sound food production, good manufacturing and fair trading practices. The World Declaration on Nutrition, which was endorsed by 159 countries, recognized the right of all people to safe and nutritious food.

In the developing countries, diarrhoea remains one of the most common illnesses of childhood and a major cause of infant and child mortality. Although major progress has been made in decreasing infant mortality worldwide, children under 5 years of age still suffer an estimated 1.5 billion annual episodes of diarrhoea which result in more than three million premature deaths.

The long-term consequences of repeated bouts of diarrhoea are malnutrition and an increased vulnerability to a wide range of diseases. Many infants do not survive under these circumstances; those who do may suffer from stunted physical and mental development, never reaching their full potential in society.

In the industrialized world, incidence of many diseases such as cholera has been sharply reduced as a result of better food safety education, improved standards of personal hygiene, improved water supplies and sanitation, and the application of safe food processing technologies. Many people enjoy safe water supplies and well regulated food products.

However, even in the developed countries, there is no room for complacency. The growing incidence of foodborne diseases annually affects between 5% and 10% of the population. Epidemics of emerging foodborne pathogens such as *Escherichia coli* O157 and *Campylobacter jejuni* in Australia, Japan, Europe and the United States of America have claimed thousands of victims and caused many deaths. New chemical hazards in foods that could affect human health are continuously being identified.

Strengthening food safety and quality control systems, promoting good manufacturing practices and educating food retailers and consumers about appropriate food handling are essential for health and good nutrition. In addition to consumer protection, proper food control measures reduce food losses and can stimulate world trade in food products, thus creating employment, increasing incomes and improving nutritional well-being.

As trade in food commodities expands internationally, food safety can no longer be considered only as a domestic issue. Since the establishment of the World Trade Organization (WTO), the standards, guidelines and recommendations of the joint FAO/WHO Codex Alimentarius Commission are regarded as the benchmarks for international harmonization. The new WTO rules also require the development of modern food control and safety programmes by national governments.

Ensuring food safety and quality so that the public can make a choice regarding a healthy diet requires comprehensive legislation and regulations, effective food control and safety programmes, as well as health education programmes.

In the countries of the WHO Eastern Mediterranean Region, food control systems do exist, but unfortunately, in most cases the current control systems are not able to cope with the new challenges. In many countries legislation is not up to date and is not flexible enough, standards are not in line with international and national needs, food inspection relies largely on end-product testing rather than on preventive systems of food safety promotion, and neither food-handlers nor consumers are aware of proper food-handling techniques to avoid crosscontamination and foodborne illnesses.

A regional plan of action for food safety in the 21st century is presented which advises in a coherent pro-active manner all steps that need to be taken by Member States in order to put in place strong food safety programmes that are efficient, effective and economic.

1. THE IMPORTANCE OF FOOD SAFETY: EXTENT AND MAGNITUDE OF FOODBORNE ILLNESS IN THE WORLD

1.1 Introduction

Food is a means to sustain and enjoy life but it is also a vehicle for transmitting hazards and causing disease and death. Illness due to contaminated food is perhaps the most widespread transmissible health problem in the world today and an important cause of reduced economic productivity.

The economic consequences of contaminated food are felt at different levels in society. At the individual and family level, illness caused by the consumption of unsafe food results in expenditure on care, be it institutionalized health care or self-care. Income is lost because of illness, which hits particularly hard if the affected are breadwinners. The burden of the worst consequence of foodborne illness—death—is severe and results in significant socioeconomic and psychological trauma.

The community that has to cope with a cumulative burden of foodborne illness and even death suffers economic and social losses, through expenditure on health care, time lost in seeking care and through lost income of the affected individuals and the caregivers; valuable resources are diverted.

Food manufacturers suffer economic losses in two respects when a product is found to be contaminated. First they suffer a direct loss through the costs involved in the recall of their products and possible payment of compensation. A more long-term, indirect economic loss is caused by the loss of credibility that the manufacturer may suffer and that may result in customer withdrawal from the implicated food and indeed the manufacturer itself.

The economic losses suffered by countries as a result of rejected food imports or exports are also considerable. These losses are difficult to quantify; they are highly dependent on the quality of the food safety assured by the manufacturing country, and on the mechanisms for import/export certification.

Adherence to Codex standards, use of HACCP (hazard analysis critical control point) methods in food manufacturing and scientific risk analysis, together with safe food handling and consumer education will go a long way to reducing the economic losses brought about by contaminated food.

With the paucity of data on the extent and magnitude of foodborne illnesses and death, and the lack of information on the costs of rejections in each country, it is difficult to arrive at general estimates of cost of foodborne illness. In the United States of America, seven pathogens found in animal foods (*Campylobacter jejuni*, *Clostridium perfringens*, *E. coli* O157, *Listeria monocytogenes*, salmonella, *Staphylococcus aureus* and *Toxoplasma gondii*) each year cause an estimated 3.3 to 12.3 million cases of foodborne illness and up to 3900 deaths. This costs the USA an estimated US\$ 6.5 to 35 billion a year.

page 2

1.2 Increased trends in occurrence of foodborne diseases

There are a number of reasons for the increased trends in occurrence of foodborne diseases.

- Population growth. Continued population growth entails more food production, more use of chemicals such as pesticides and veterinary drugs, and larger scale and more complex food production ("industrialization") and thus increased potential for contaminated food.
- Urbanization. Urbanization leads to a longer food chain—more and more complex steps between farm and fork. Consumers eat more meals away from home such as streetvended foods and catered and convenience foods. The result is increased opportunities for food contamination through the survival and growth of pathogens.
- International trade in food and feed is expanding rapidly, and so is international travel. People and food can move thousands of kilometres in a matter of hours, but the incubation periods of disease-causing organisms remain unchanged. International travellers can easily spread infection and illness.
- Technology has changed the way food is produced in many countries. Food is produced for more people in fewer manufacturing facilities. Thus, if there is a problem or microbiological contamination at a factory, more people are susceptible to becoming ill. Also, many manufacturers combine lots or batches of product, increasing the possibility of the final product being contaminated and making it more difficult to trace the original source of the problem. In addition, increased consumption of food of animal origin leads to "industrialization" of animal production, with possible introduction of subclinically infected animals and thus contaminated food.

1.3 Categories of foodborne hazard

Foodborne hazards can be grouped into two groups:

- (micro-) biological hazards: pathogenic bacteria, viruses and parasites
- chemical hazards: residues of pesticides and veterinary drugs, the use of hormones in beef cattle, unlawful food additives, mycotoxins, biotoxins and radionuclides.

Of these categories of hazard, microbiological contamination is by far the more important.

Microbiological hazards

Reliable information on the extent and magnitude of microbiological contamination is not available because of the absence of foodborne disease surveillance systems in many countries and weaknesses in existing programmes. Underreporting is common, and foodborne diseases are often perceived as mild, self-limiting diseases or as a normal occurrence. Also, some foodborne illnesses like diarrhoea and cholera are traditionally seen as water-borne diseases. WHO estimates that the reported incidence of foodborne diseases worldwide is only a very small proportion of the real incidence. Also, data from different parts of the world are not necessarily comparable, which makes a global estimate of the foodborne disease burden rather difficult.

Several worldwide surveys of foodborne disease reports from all over the world, including outbreak investigations, show that microbiological contamination is the major issue in all those countries conducting foodborne disease surveillance programmes.

The presence of foodborne pathogens in a country's food supply affects the health and well-being of the local population, and in addition presents a potential for spread to those who visit that country as well as for all those who consume food imported from that country.

In developing countries it is estimated that more than 1.5 billion episodes of diarrhoea occur per year in children under the age of 5 years, causing 3 million deaths per year.

In industrialized countries, infections with salmonella, campylobacter and enterohaemorrhagic *E. coli* show an increasing trend (Figure 1), and it is estimated that up to 10% of population in some countries suffer annually from foodborne diseases.



Figure 1. Number of reported cases of foodborne diseases in England and Wales, 1980–95

Food additives

A wide range of substances is added intentionally to food to improve its shelf-life, consistency, colour, odour or flavour or to give it some other specific property. Since such additives have usually been subjected to a thorough toxicological evaluation through international bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) prior to approval for use, the likelihood that they will give rise to adverse health effects when used according to established regulations is small. However, as with most chemicals, food additives might give rise to adverse reactions in certain hypersensitive individuals. Additives for which data on human dietary exposure are of particular interest include preservatives (sulfur dioxide, nitrite, nitrate, benzoic acid and its salts), antioxidants (butylated hydroxyanisol [BHA], butylated hydroxytoluene [BHT]), intense sweeteners (saccharin, sodium cyclamate, aspartame), sugar alcohols (sorbitol, etc.), colouring agents (tartrazine and other azo-colours, caramel colours, erythrosine), caffeine, quinine and mineral hydrocarbons. Further, there is a wide range of emulsifiers, stabilizers and thickeners, many of which are extracted from natural products, such as starch, cellulose or triglycerides. Flavouring agents and natural flavours comprise many different chemical entities, many of which have not been subjected to extensive toxicological testing. JECFA is the international reference for permitted food additives and their acceptable daily intake. Excessive or illegal use of such additives in many developing countries is responsible for many of the foodborne hazards attached to food additives.

Pesticide residues

Over 600 pesticides have been approved for use on food crops. The most commonly found pesticides in cereals and cereal products are malathion, inorganic bromide and pirimiphos-methyl. In most industrialized countries, the calculated intakes of residues of individual pesticides rarely exceed more that 1% of the acceptable daily intake (ADI), as proposed by the Joint WHO/FAO Meetings on Pesticide Residues (JMPR). However, since the consumer is simultaneously exposed to more than one pesticide, some of which have the same site for their toxic effect (e.g. organophosphorus insecticides), the possibility of additive effects or interactions should be borne in mind. Unless countries strictly control the use of pesticides in crop production, these substances will continue to pose a serious problem in many developing countries.

Veterinary drug residues

The administration of drugs to food-producing animals may result in the presence of drug residues in foods of animal origin, such as meat, milk, eggs and fish, especially if the prescribed withdrawal times are not observed or the dose given is higher than recommended. The most important groups of drugs as far as monitoring for residues is concerned are antibiotics and chemotherapeutic agents and antiparasitic drugs. The legal and controlled use of veterinary drugs is unlikely to result in the presence of residues that will have adverse health effects in humans.

The use of hormones in cattle

Hormones are fed to beef cattle to increase rate of weight gain and improve feed efficiency. Beef contains natural hormones whether treated or not. The increase in residue levels depends upon the preparation used and the sex of the animal, but in most cases the residue levels in treated animals fall within the natural levels of variation.

In 1987 and in February 1999, JECFA reviewed the use of hormones in beef cattle to increase rate of weight gain and improve feed efficiency.

Six hormones are commonly used as growth promoters in beef production. Three of them are natural (estradiol-17 β , progesterone and testosterone), while three of them are synthetic (trenbolone acetate, zeranol and melengestrol acetate). In 1987, the independent scientific experts convened by WHO and FAO concluded that there was a wide margin of safety for consumption of meat and meat products from animals treated with such hormones. JECFA further concluded that it was not necessary to establish acceptable daily intakes (ADIs) and acceptable residue levels for the natural hormones because they are produced endogenously at variable levels in human beings anyway, and that residues resulting from the use of these substances as growth promoters in accordance with good animal husbandry practice were unlikely to pose a hazard to human health. Numerical ADIs were established for trenbolone acetate and zeranol. The Codex Alimentarius Commission adopted these recommendations, and they are now Codex standards.

In 1998 JECFA and the Codex secretariats recognized that the evaluations were quite old and that significant new data had become available on them. JECFA therefore re-evaluated estradiol-17 β , progesterone and testosterone at its 52nd meeting in February 1999. Numerical ADIs were established for these three hormones and maximum residue limits (MRLs) "not specified" in edible tissues were recommended. MRL "not specified" means that, because the margin of safety for consumption of residues in food when the drug is used in line with good JECFA practice in the use of veterinary drugs is so large, numerical MRLs are not necessary.

A controversial substance is estradiol-17 β , which can cause cancer in hormonedependent tissues. Although there is some evidence that estradiol-17 β has genotoxic potential, JECFA concluded on the weight of the evidence that its effects, including carcinogenicity, are most probably a result of interaction with the tissues' hormonal receptors, and that a threshold exists for these effects.

Substances derived from materials in contact with food

Materials that come into contact with food during its production, handling or storage may contaminate it with toxic substances. Examples of such substances are monomers (e.g. vinyl chloride, styrene and acrylonitrile), which may be present in trace amount in polymers used as food packaging material, and plasticizers (e.g. adipates and phthalates) used in film for wrapping food or in flexible tubing in food processing equipment. Food in contact with ceramic food containers may become contaminated with lead or cadmium from the glazing,

and food coming into contact with solder in cans or processing equipment may become contaminated with lead.

Heavy metals

Extensive studies have been carried out to estimate the dietary intake of the heavy metals lead, cadmium and mercury. Although exposure to lead markedly decreased in the past decade in many European countries because of the phasing out of the use of leaded petrol and lead-soldered cans for food, lead exposure is still of considerable significance in countries of the Region. The fact that in those countries lead is commonly encountered in daily life means that many people may already have lead present in their bodies. In addition, exposure is high due to the continued use of leaded petrol and the presence of heavy industry in many cities. There are indications that the levels of cadmium in some basic foods, such as cereals, have increased markedly in the present century due, among other things, to the use of cadmium-contaminated phosphate fertilizer. Mercury, as methylmercury, is present at relatively high levels in some predatory fish, such as shark and swordfish. Other metals of current interest with respect to dietary exposure are arsenic and aluminium (Figure 2).

Persistent organic pollutants

Organohalogen compounds have long been the subject of considerable concern to the food toxicologist. Because of their persistence in the environment and their lipid solubility, they are often found as contaminants in fish and some other foods of animal origin. Examples





page 7

of such compounds are several pesticides (e.g. DDT and its metabolites. hexachlorocyclohexane isomers, hexachlorobenzene, dieldrin), polychlorinated biphenyls (PCBs). Although there is evidence that the levels of these compounds in some foods, such as fish and mother's milk, have decreased in recent decades, the calculated dietary intakes of these substances by breastfeeding infants and by persons consuming large amounts of fish from contaminated waters still gives cause for concern. Smoked and direct-dried foods and crops exposed to pollution from road traffic or other sources may become contaminated with carcinogenic polycyclic aromatic hydrocarbons.

Mycotoxins

Peanuts, tree nuts, maize and dried figs are examples of foods that have been regularly shown to be contaminated with carcinogenic aflatoxins, especially if they were harvested, transported or stored under conditions of high humidity. Aflatoxins are considered human liver carcinogens and seem to be potentiated by the presence of hepatitis B surface antigen, thus making a case for hepatitis B immunization to reduce the impact of consumption of aflatoxins. In the Codex system unsuccessful attempts have been made to reach international agreement on maximum limits for aflatoxins in a range of foods. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has made a quantitative estimate of the carcinogenic risk associated with different levels of aflatoxin intake, and noted in doing so that reductions in the intake of aflatoxins can be reached through avoidance measures such as improved farming and proper storage practices.

Radionuclides

After the 1986 accident at the nuclear power station at Chernobyl, Ukraine, large areas of northern Europe were contaminated by radioactive fall-out. The main remaining problems are contamination of sheep, reindeer, game and freshwater fish in the affected areas, particularly by caesium-137.

Biotechnology

Biotechnology is the application of biological systems in industrial processes. This may involve the use of a living organism or a biological agent derived from an organism such as an enzyme or hormone. Up to the present, WHO has been requested by its Member States only to evaluate the human food safety aspects of enzymes used in food processing. As such food products were found to be substantially equivalent to products produced by traditional methods, the health and safety testing requirements were the same as those applied to other agents proposed for use in food. The safety of biotechnology, like any new technology, is subject to uncertainty because of lack of experience. The focus of the safety evaluation has been to ensure that any changes introduced as a result of biotechnology are consistent with traditional methods and do not pose a public health concern.

Within its mandate of health, WHO has tried to assure that the real and significant benefits of this technology are not accompanied by unacceptable risks.

page 8

The direction and control of this technology must be decided by Member States and is one of the most important issues in the new millennium. Health is just one component of that debate which should include ethical, environmental, economic and cultural aspects.

Genetically modified plants, such as herbicide-resistant corn and soybeans, have not been evaluated by WHO and consequently, WHO cannot comment on the safety or otherwise of these products.

2. NEW CHALLENGES

2.1 Newly emerging and re-emerging foodborne pathogens

Recent years have seen the emergence of new and re-emerging foodborne pathogens such as enterohaemorrhagic *E. coli*, *Campylobacter* spp., *Listeria monocytogenes*, *Vibrio cholerae* and others, which are now seen in more and more countries, causing large outbreaks.

The situation is compounded by the increased consumption of raw and minimally processed foods and unhygienic food preparation practices by the food handler, including the consumer, such as insufficient cooking/reheating, improper storage, cross-contamination and poor personal hygiene.

Escherichia coli O157

In the early 1980s, an outbreak of foodborne disease caused by consumption of contaminated hamburgers was described in the USA, with bloody diarrhoea as its major symptom. The causative organism was a new strain of *E. coli*, which was subsequently named enterohaemorrhagic *E. coli* O157:H7. Since then, numerous outbreaks of *E. coli* O157 have been described, initially all from the USA and mostly due to contaminated hamburgers, or other meat products. The most well known outbreak in Europe was that in Scotland in 1996, traced to contaminated gravy prepared in a butcher's shop. In 1996, an unexpectedly large number of outbreaks occurred in Japan, where more than 5700 cases were reported. Almost half of the outbreaks in Japan occurred in schools and were traced to contaminated lunches provided by the schools. Although the exact vehicle was not clearly identified in all cases, contaminated radish sprouts were found in one central kitchen.

While the truth is not fully known about *E. coli* O157 it seems that the reservoir of this pathogen is mainly cattle, causing transmission through raw or undercooked meat products and raw milk. Contamination of water and other foods with manure from cattle, as well as cross-contamination during food preparation will also lead to infection.

Salmonella

Foodborne diseases caused by salmonella are an increasingly important health problem and economic burden in many parts of the world. Contributing factors seem to be microbial adaptation, increased global distribution of food and international travel (causing wider

dissemination of the pathogen), and increasingly susceptible populations. Lifestyle changes, such as increasing use of fast and frozen foods, combined with inadequate food handling measures, are also important factors.

Measures should be taken at all stages of the food chain to prevent the introduction of salmonella and its multiplication.

Foodborne listeriosis

This was a rare finding prior to 1960. Since then however, a tremendous increase in listeriosis cases has been reported. These trends reflect changes in social patterns and behaviour. Listeria grows well at low temperatures, and thus the widespread use of cold storage and the increasing demand for fresh-tasting, refrigerated or ready-to-eat foods has led to more frequent contamination with listeria. Many questions still remain about the etiology of this increasing listeriosis incidence, and no single factor can so far be implicated. The health status of the individual seems to be an important factor. Prevention and control of contamination and microbial growth, and protection of groups at higher risk are all important to prevent listeria infection.

Bovine spongiform encephalopathy (BSE)

Bovine spongiform encephalopathy (BSE), a transmissible spongiform encephalopathy (TSE) which affects cattle was reported in the United Kingdom in November 1986. Epidemiological studies suggested that the source of the disease was cattle feed prepared from carcasses of ruminants, and that changes in the process of preparing cattle feed introduced in 1981–82 may have been a contributing risk factor. By October 1996, BSE had been reported from 10 countries and areas outside the UK. In France, Portugal, Ireland and Switzerland, the disease occurred in native cattle, probably through importation of cattle feed from the UK. In Canada, Denmark, Falkland Islands, Germany, Italy and Oman, cases were identified only in cattle imported from the UK.

In March 1996 the occurrence in the UK of 10 cases of an apparently new form of a human TSE, Creutzfeldt–Jakob Disease, was announced. Evidence has suggested a causal link between this new variant of CJD and BSE.

Since 1991, WHO has convened seven scientific consultations to review the situation. Preventive measures have been identified and implemented as applicable. A workshop on CJD surveillance held in Cairo, Egypt, in February 1998 concluded that there is a need for national CJD surveillance, as well as dissemination of relevant information to health professionals. Effective risk communication is one of the pillars of a preventive strategy.

2.2 New agreements in world trade

Most if not all countries in the world are involved in international trade in food. Indeed, this international trade in food plays an important role in providing safe and nutritious diets for the world's population. Traditionally, international trade was subject to certain tariff and

page 10

non-tariff barriers at national borders, some of which were required to protect the health of the consumers and some of which were established to protect the domestic economy.

In 1962 the Joint FAO/WHO Codex Alimentarius Commission was established to protect the health of the consumer and at the same time, ensure fair practices in international trade. Codex has since then elaborated a large number of food standards, Codes of Practice, guidelines and recommendations. Until 1994, Codex texts were optional and were not directly linked to international trade requirements; the decision whether to implement Codex texts into national legislation was up to individual governments.

The World Trade Organization (WTO) was established in 1995 to govern international trade. The WTO does this through a number of agreements negotiated by WTO member countries.

Two important agreements were established, one relating mostly to safety aspects of food in trade, the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS agreement) and one covering all technical requirements and standards, such as labelling, not covered by the SPS agreement. This agreement is the Agreement on Technical Barriers to Trade, or TBT agreement. The main areas covered by the SPS and TBT agreements and their respective Codex references are shown in Figure 3.



Figure 3. Areas covered by the various WTO agreements

One of the main objectives of the SPS agreement is to protect human, animal and plant health in all WTO member countries. The SPS agreement recognizes the standards and related texts of the Codex Alimentarius Commission as international points of reference.

2.3 New role for Codex Alimentarius

Under the WTO agreements on SPS and TBT, the Codex Alimentarius standards, guidelines and recommendations have become the international reference. So far, over 230 food commodity standards and over 40 hygienic and technical practice codes have been elaborated by Codex. If local food industries in any country, with the support of the health sector, apply the Codex norms, the food they produce and process is safe for consumption and acceptable for export. Thus it is important that these standards reflect the concerns of as many countries as possible. Countries, especially developing ones, are strongly encouraged to participate in the work of Codex, in order to ensure that the standards, norms and guidelines it develops are consistent with their health and safety requirements and supportive of their food industry.

The Codex Alimentarius includes provisions for food hygiene, food additives, pesticide residues, contaminants, labelling and methods of analysis and sampling. As at 1 October 1998, the Codex Commission had 163 members, FAO Member Nations and WHO Member States.

The Codex Alimentarius Commission has an Executive Committee, a Secretariat and subsidiary bodies (Codex Committees). A Codex contact point has been established in each Codex member state, and countries are advised to establish national Codex committees. Guidelines for strengthening the work of Codex in countries elaborating the role of the Codex contact point and the national Codex committee have been developed by the Codex Committee for Asia. The Regional Office last year sent these guidelines to all countries of the Region. Information on all Codex meetings, and on all matters pertaining to Codex is sent by the Secretariat to all country contact points. This information can also be accessed through the Internet (http://www.fao.org/waicent/faoinfo/economic/esn/codex/Default.htm).

2.4 The hazard analysis critical control point system: a preventive approach to food safety

Traditionally, microbiological problems have been addressed by testing finished-product and in-process samples, and then rejecting produce that falls outside a given specification. This however is not effective in modern food production. For example, if 10% of meat carcasses contain pathogenic microorganisms, 10% of consumers may become ill. However, 9 times out of 10, sampling 10% of carcasses will not detect this level of contamination. Thus, testing food will not necessarily detect low levels of microbial contamination that might still pose a health risk.

The alternative is prevention. The aim is to find out what could go wrong and to stop it happening. That, in effect, is hazard analysis critical control point or HACCP—a scientific and systematic approach to assure food quality and safety.

page 12

HACCP has widespread applications, including biological and safety applications, control of chemical contamination, control of foreign bodies (physical hazards) and control of microbiological quality (microbiological spoilage). HACCP can be applied to raw materials, semi-finished products and finished products.

HACCP is defined as a series of observations and/or tests made to identify actual or potential hazards in food processes and to identify critical control points in a process. It also encompasses the design, implementation and monitoring of procedures at the critical control points to ensure that control is maintained.

HACCP can be described by the simple proposition that food for the customer should be safe to eat. HACCP is a logical method for helping this to happen. It is a critical analysis of three things:

- how food is produced and processed—to decide whether this is the best possible method;
- whether the existing method can be improved upon;
- how to find the best points in the process to make the improvements.

It is important to distinguish between good manufacturing practice (GMP) and HACCP, since GMP activities must be in place before a successful HACCP system can be installed. On the other hand, HACCP is a prerequisite for quality management systems, such as the ISO 9000 series.

WHO has recognized the importance of HACCP in the prevention of foodborne disease for over 20 years, playing an important role in its development and implementation. The Codex Alimentarius Commission has developed guidelines for the application of the hazard analysis critical control points system, which play an important role in facilitating international trade since the establishment of the WTO in 1995, and the application of its Sanitary and Phytosanitary Measures Agreement.

HACCP is an essential part of national food safety policies and programmes and an important component of a country's food safety action plan. All parties—government regulatory authorities, the food sector and consumers—should be involved in, and share responsibility for the development and implementation of national food safety programmes based on HACCP.

2.5 Risk analysis, a scientifically based process

National standards stricter than Codex standards should be scientifically justified through risk analysis, which is a scientifically based process. Risk analysis consists of three parts:

- *Risk assessment*, which involves the scientific evaluation of known or potential health effects resulting from human exposure to foodborne hazards with an emphasis on numerical expressions of risk. Risk assessment comprises four important steps: hazard identification, hazard characterization, exposure assessment and risk characterization;
- *Risk management*, which is the process of weighing policy alternatives to accept, minimize or reduce assessed risks and to select and implement appropriate options;
- *Risk communication*, which is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties.

In some cases, countries may have to introduce sanitary measures where international standards are nonexistent. Of course efforts should then be made to expedite Codex work in that area, but if this takes too long, a country itself should employ risk assessment when determining the content of such measures. FAO and WHO have already established several risk assessment mechanisms to assist countries in the area of food additives and pesticide residues. The Joint FAO/WHO Expert Committee on Food Additives and Contaminants and the Joint FAO/WHO Meetings on Pesticide Residues use risk assessment techniques, including toxicological evaluations, exposure assessment and other related methods.

In the area of microbiological risk assessment, no expert body currently exists. A recent FAO/WHO consultation held in Geneva in March 1999 recommended the establishment of such an expert body, in view of the major contribution of microbiological contamination to risk of unsafe food.

At the national level, epidemiological data on the incidence of foodborne diseases and information of the level of exposure of the population, and especially vulnerable groups, to foodborne hazards are essential prerequisites for any sound risk assessment.

3. HOW ARE THE COUNTRIES OF THE REGION PREPARED TO COPE WITH THE NEW CHALLENGES?

3.1 WTO membership

As of 1 July 1999, 10 countries in the Region are WTO members, while 4 more are observers, having applied for membership. Interestingly, one WTO member reported to WHO that it was not in fact a WTO member, while three countries, which are not members, reported to the contrary that they were. In addition, two observer-countries reported that they were non-members, while at that time they had already applied for membership. These discrepancies may be symptomatic of a lack of involvement of the ministry of health in matters of trade; however the ministry of health should be the ministry given full responsibility for matters of food safety, both nationally and with respect to WTO issues.

3.2 Legislation

In many countries of the Region, there is no separate food law, but food legislation is sometimes reflected in more general public health legislation. This is the case for example in Iraq, Jordan and Lebanon.

In some countries, such as Bahrain and Oman, there is extensive legislation on imported food, which may in some cases in fact be the only legislation relating to food in that country. The Islamic Republic of Iran requires food for export to be processed under HACCP. Some other countries, on the contrary, have a number of different laws, all somehow relating to food but, more often than not, not completely covering the field of food safety.

In several countries, the existing legislation, which may be a full food control act, dates from more than 25 years ago. Several of the countries in that position, such as Pakistan and Sudan, are therefore in the process of revising their legislation, in line with WTO requirements to minimize discriminatory and adverse effects of food legislation. Cyprus is revising its food legislation in view of its intention to join the European Union, while Palestine is still subjected to Israeli food legislation, as all its imported—and exported—food must pass through that country. Morocco reviewed its legislation two years ago and is one of the few countries of the Region regulating GMP and HACCP by law.

3.3 National food safety coordinating committee

A national food safety coordinating committee or similar body exists in a number of countries. In Bahrain such a committee brings together representatives from all concerned ministries and handles all food control and legislation issues. Cyprus also has a national food committee, which is charged with the revision of the legislation to harmonize it with European and WTO requirements.

Egypt, Islamic Republic Iran, Iraq, Jordan, Morocco, Saudi Arabia, Sudan and Syrian Arab Republic all report having national food coordination committees, which take care of laws and regulations, including their review. In some countries the national committee is also involved in standard setting; in other countries there is a separate body dealing with this.

3.4 Integration of HACCP into the food control system and legislative expression of HACCP

Although HACCP has been promoted by WHO, Codex Alimentarius and other bodies for several years, many countries report that HACCP has only very limited implementation. In several countries, including Bahrain, HACCP is applied by larger industries on a voluntary basis. The Islamic Republic of Iran has legislation requiring HACCP-certification for exported food items, while Egypt has issued a ministerial decree for voluntary application of HACCP in the food industry. In Cyprus also, the food industry in some cases applies HACCP on a voluntary basis.

As stated before, in Morocco there has been legislation on GMP and HACCP since 1990, and the law was reviewed in 1997. In Sudan, 40% of the national food industry reportedly uses HACCP, while in the Syrian Arab Republic, responsibility for auditing HACCP in industry is vested in the Ministry of Health and the Ministry of Supply. In Tunisia, HACCP is being piloted, and it is expected that legislation will soon be in place to promote it.

3.5 Institutions involved in food safety

The responsibility for food safety in most countries of the Region is complicated. Sixteen countries have multisectoral involvement, of at least two, more often four, and up to eight ministries, as well as departments from within these ministries. Only four countries have one ministry, the ministry of health, as the main responsible body for food safety; these are Bahrain, Libyan Arab Jamahiriya, Sudan and Tunisia.

3.6 Inspection

The inspection activities in the countries of the Region vary greatly in set-up and do not necessarily reflect all the institutions involved in food safety. In eight countries one institution is responsible for all inspection activities. In 11 countries either various institutions or various departments within the same institutions have the same or similar responsibilities regarding food inspection, with a minimum number of two and a maximum of four bodies involved. Two countries have inspection activities that focus solely on end-product testing. In one country, inspection activities are mainly reactive, following reported foodborne disease outbreaks.

3.7 Training of inspectorates

Most of the countries of the Region have attended one or more regional or international conferences on HACCP or food inspection, and actual local training in HACCP and new food inspection methods has been organized in recent years in a large number of countries. In Morocco, HACCP has been taught to inspectors, and is presently one of the subjects on the curricula of health institutes.

In Egypt a HACCP manual has been translated into Arabic, and in the Islamic Republic of Iran a number of WHO publications have been translated into Farsi and widely distributed.

3.8 Laboratory services

Of all the countries of the Region, only two—Cyprus and Morocco—stated in an EMRO survey that they had adequate laboratory services, in terms of both capacity and capability. All the other countries mentioned limited laboratory services, in that the number of tests that could be performed is not sufficient, or the extent and range of the tests was minimal. In most countries the need for a better food control system was expressed in the need for more and more elaborate laboratory services, without actually reviewing the national situation as a whole or proposing to introduce and enforce control mechanisms.

3.9 Disease reporting mechanisms

Most countries of the Region have no reporting mechanism in place for foodborne diseases, at least not one that communicates with the food safety authorities. Jordan, Kuwait, Oman and Saudi Arabia all have disease-reporting mechanisms in place that seem to function well. Jordan is at present developing a draft plan for specific foodborne disease surveillance.

3.10 Consumer awareness and education

Although in a number of the countries of the Region, consumer organizations and nongovernmental organizations are active regarding the issue of food safety, there seems to be little or no coordination in this field. Egypt mentions the development of four nongovernmental organizations to protect consumers against fraud. In Islamic Republic of Iran some educational material has been prepared, and a food safety project for primary health care has been planned. A first national conference on consumer protection was held in Jordan in September 1998.

3.11 Mechanisms for improved food safety in selected countries outside the Eastern Mediterranean Region

The problems and/or situations described above for the Eastern Mediterranean Region are not unique to the Region. In fact, increasing rates of foodborne illnesses and outbreaks and the problems and scandals plaguing many industrialized countries have led to refurbishment of the food control system in many of these countries. United States, Canada, United Kingdom, Ireland and Netherlands have all in recent years reviewed and revised their food control systems.

All these countries have developed models that have some main elements in common. Governments recognize the need for new food legislation and for the establishment of a central food control body; there is increasing acceptance of the role which preventative techniques play in the production of safe food; they are basing their programmes on HACCP principles; and they have acknowledged that risk analysis is one of the key concepts for maximizing dwindling food safety resources.

The need for new food legislation includes a reassessment of the structure of food administrations, agencies, departments and ministries, the development of relevant and enforceable food laws and the development of equivalence agreements with other countries.

4. REGIONAL PLAN OF ACTION FOR ADDRESSING FOOD SAFETY IN THE 21st CENTURY

4.1 General requirements

Effective food safety systems are essential in countries of the Region. The main and overriding reason for ensuring that food offered to the consumer is safe and wholesome is the

page 17

commitment of national governments to protecting the health of their people. In the area of international trade, food safety is a major issue which can make or break a country as a trade partner.

Countries in the Region which are members of WTO have very clear obligations to improve their food control systems as a whole and the food safety aspect in particular.

To ensure the safety of food, be it imported or domestically produced, an effective food safety structure within the national food control system is necessary. Ministers of health are the main actors in ensuring that food safety concerns are taken seriously by all players, and that food safety and food quality are both ensured.

A strong food safety programme is efficient, effective and economic.

An effective food safety system should:

- be science-based "science-based" implies a strong emphasis on risk analysis and prevention and the prioritization of resources to risks deemed to have the greatest potential impact
- be grounded in the law national laws should exist or be created that are clear, rational and scientific, based on risk analysis
- include comprehensive surveillance comprehensive surveillance and monitoring activities should serve as a basis for risk analysis
- rely on one central organization one central organization means one central voice at the national level responsible for food safety, which should have the authority and resources to implement science-based policy in all national activities related to food safety—an overlap of responsibilities in different government departments often leads to conflict of interest
- recognize the importance of nongovernmental partnerships the responsibilities and central role played by all partners in the food safety system, such as the state, local government, industry and consumers, must be clearly recognized
- be adequately funded.

Figure 4 illustrates the shared responsibility for safe food for all.



Figure 4. The shared responsibility for safe food for all

4.2 Specific concerns in present food control systems in the Eastern Mediterranean Region

All countries of the Region currently have food control systems, with legislation and standards. From the review of the regional situation in section 3 of this paper it has however become obvious that these food control systems are no longer relevant to the present situation in several aspects:

- food safety concerns are not a driving force behind most current food control systems;
- standards are often not in line with Codex standards and thus may constitute barriers to trade in terms of the WTO;
- the ministry of health is not a full partner in the development and implementation of food standards and regulations;
- most countries do not participate actively in the work of Codex Alimentarius, and even if they do, the ministry of health is rarely involved in such participation.

5. PLAN OF ACTION AND RECOMMENDATIONS

5.1 Region plan of action for addressing food safety in the 21st century in the WHO Eastern Mediterranean Region

Step 1. Preparation of a country profile based on country diagnosis

Countries need to assess their current food safety infrastructure and problems at a national level and prepare a national country profile

Mechanism for assessment and review:

- 1. Identify major problems
- 2. Systematically assess factors relevant to food safety at each stage of the food chain
- 3. Review health and socioeconomic issues
- 4. Identify functions of all sectors involved in food safety
- 5. Clearly identify strengths and weaknesses
- 6. Establish a mechanism for continuing review

Areas for review:

- Government organization
- Food production and consumption
- Food imports and exports
- Food legislation
- Epidemiological information
- · Human resources and training requirements
- Extension and advisory services
- Public education and participation

Step 2. Development and/or strengthening of the national food safety programme

Countries need to establish and/or strengthen a food safety control body which should be technically assisted by expert working groups

For establishing/strengthening food safety programme countries need to:

- 1. Develop and update food legislation
- 2. Strengthen their food control systems
- 3. Promote preventive food-safety management systems like HACCP
- Ensure effective education of food handlers and other workers in food safety matters
- 5. Carry out research and data collection, including food-borne disease surveillance

Step 3. Implementation of the national food safety programme

Countries need to operationalize the national food safety committee already established in Step 2

Step 4. Continuous monitoring and evaluation of all food safety activities

Countries must continue to regularly repeat the review of not only the programme but the food safety situation as a whole, as mentioned under Step 1

5.2 Recommendations

1. Member States need to assess their current food safety infrastructure and problems at national level and carry out a country diagnosis in order to prepare a country profile

Such a major comprehensive review of the current system is essential in order to identify the strengths and weaknesses of the current system and to build on the strengths. The country profile should:

- identify major problems
- systematically assess factors relevant to food safety at each stage of the food chain
- review health and socioeconomic issues
- identify functions of all sectors involved in food safety
- clearly identify strengths and weaknesses
- establish a mechanism for continuing review.

The areas where information needs to be collected include:

• Government organization

All departments involved in food safety—responsibilities and functions as well as the existing mechanisms for coordination—need to be described.

• Food production and consumption

Close collaboration between agricultural and nutrition and health departments, as well as academia, will assist in obtaining estimates of agricultural production, processing, food consumption, nutrient intakes and existing food quality and safety programmes in the food industry as well as food processing industries present in the country, their type, size and risk category.

• Food imports and exports Import/export trade statistics on quantity and value, food safety and quality problems are vital, as are import and export inspection and certification mechanisms.

• Food legislation

This important area should include a review of current food legislation, regulations and standards, as well as the year of their establishment; implementing authorities and enforcement procedures; systems of coordination between agencies; analysis of the food laws and regulations as they pertain to food adulteration and contamination; hygiene; additives; packaging; licensing; inspection; and analysis of foods. The consultation process with industry and consumer organizations also needs to be reviewed.

• Epidemiological information

Data to be collected should include prevalence and incidence of foodborne diseases, prevalence of micronutrient deficiencies, quality of data gathering, coverage estimates and coordination between agencies.

• Human resources and training requirements

Data to be collected should include numbers of staff in each category and agency, as well as their qualifications and evaluation of current staff training programmes.

• Extension and advisory services

Current government extension and advisory services to the food sector, nongovernmental organization involvement, if any, trade associations, education and research institutions should be reviewed.

• Public education and participation

Mechanisms should be in place for dissemination of information on food safety and prevention of foodborne diseases, participation of consumer groups, consumer complaint systems, incorporation of food safety in school curricula.

2. Member States need to develop and strengthen their national food safety programmes

Based on the review of the current system and the country profile prepared under Step 1 of the regional plan of action (see section 5.1), countries need to formulate a national food safety policy and plan of action. There are many different actors involved in food safety, with government agencies, industry and consumers all bearing responsibilities. Dialogue and collaboration between the various agencies and partners are essential to formulate and effective national food safety policy and ensure its implementation.

The best mechanism to ensure this is to *establish a national food safety committee* or similar body, which should be technically assisted by expert working groups. Such a food safety body should coordinate and facilitate the investigations as outlined in Recommendation 1, set up necessary liaison groups involving the food industry, research bodies and the consumer and provide guidance and support to ministers on food safety issues. The food safety body should be responsible for drafting a policy document on food safety and consumer protection defining the national strategy, goals and objectives for food safety. The same body or a subcommittee should also take upon itself the role of national Codex Alimentarius coordinating committee and act as enquiry point for WTO.

To establish an effective national food safety programme countries need to include the five essential pillars.

• Member States need to develop and update food legislation, so that it assures food safety and consumer protection

While food quality is seen more and more as a matter principally for the food industry, the role of national governments is evolving to one of inspecting and verifying that industry management systems for food safety assurance are working effectively.

page 22

National governments should establish flexible legislation and regulations in the everchanging evolving climate of food safety promotion. A framework food law is therefore suggested as the best option. Such a law will need clearly to identify and delineate the particular authorities and activities of government agencies, define methods to enforce legislation and set forth penalties for breaching the law, clearly identify the responsibilities of the food sector and all individuals and enterprises involved in the food chain, contain provisions to ensure food safety and consumer protection in matters other than those relating to health, such as fraud and deception, and finally, provide a mechanism for the introduction of subsidiary legislation and specific regulations such as codes of practice. Such subsidiary legislation and regulation will contain specific details on matters such as enforcement procedures, regulations on hygiene, use of food additives and labelling, licensing of food premises and import/export regulations. The importance of including these in subsidiary regulation is that such matters often need to be modified in light of the developments in the food sector and the global economy.

• Member States need to strengthen their food control systems

To provide consumer protection, and ensure that all foods during production, handling, storage, processing and distribution are safe, wholesome and fit for human use, an effective food control system should consist of three elements: an administration, an inspectorate and an analytical capability. National preference will determine at what level, centrally or locally, an administration will act, but coordination at top management level must be centralized. Food inspection must verify that all foods are produced, handled, processed, packed, stored and distributed in compliance with legislation and regulations. The central administration should develop a national policy and strategy for food inspection, in collaboration with the food sector and consumer The Codex Alimentarius Commission groups. standards. guidelines and recommendations are the model to follow to achieve international harmonization. A basic analytical capacity is necessary to monitor the quality and safety of a nation's food supply. Management structures and operational procedures of official food control laboratories should conform to the international guidelines such as ISO/IEC Guide 25, which details the general requirements for the competence of calibration and testing laboratories.

Training is an essential element of strengthening the national food inspection capacity, and training should certainly include the introduction of the HACCP system to chief food inspectors and senior industry managers, training of trainers in the principles and applications of the HACCP system, training of food inspectors in the principles of verification and auditing of industry-based HACCP management systems. Food control laboratory personnel should be trained in principles of laboratory management to comply with the ISO/IEC Guide 25, as well as in microbiological, chemical and physical analyses of foods.

• Member States need to promote preventive food-safety management systems based on HACCP

The HACCP strategy has now been generally accepted as the most useful preventive strategy for ensuring food safety, in the food processing and catering industry and even

at the small scale level, such as in street food vending. The role of government should be to provide leadership for the implementation of voluntary safety assurance systems based on HACCP. Food industry should ensure training of their food handlers on the principles of food hygiene and focus on the principles of good hygienic practices, good manufacturing practices and HACCP.

• Member States need to ensure effective education of food handlers and other workers in food safety matters

Food handlers may act as a source of food contamination through inadequate personal hygiene or through handling food when they are medically unfit. The traditional practice of periodic medical examination of food handlers is not an effective tool in preventing such contamination, on the contrary, it causes a false sense of security. The education of food handlers so that they adhere to good personal hygiene and to hygienic food handling practices is an essential component of a national food safety programme. Appropriate education of food handlers involves both professional food handlers in the food processing and catering industry and domestic food handlers, including the consumer. Appropriate education programmes are needed to ensure that domestic food preparation and storage do not reduce to nothing all the efforts of the government and the food industry to provide safe and wholesome food to its people.

• Member States need to carry out research and data collection, including foodborne disease surveillance to be able to cope with the new demands of risk analysis in ensuring food safety at all levels

As part of the national food safety programme, governments should develop mechanisms to collect and evaluate information on foodborne disease and hazards associated with the food chain.

3. Member States need to implement their newly developed or strengthened national food safety programmes effectively

As a first step, the food safety committee, assisted by expert working groups that will monitor and report on progress must be made operational. This implies consultation with all government departments involved in food safety, food control and public health functions and with industry, consumer groups, trade organizations, and collaboration and consultation with research institutes and academic bodies.

Countries must put in place an effective foodborne disease surveillance mechanism in line with the regional plan on emerging and re-emerging diseases, presented to the Forty-third Session of the Regional Committee, October 1996, and Regional Committee resolution EM/RC43/R.14.

4. Member States must continue to monitor and evaluate their food safety activities

An integral part of the development and strengthening of the national food safety programme is a management review process that includes an evaluation mechanism to ensure that the activities that are being undertaken are relevant, achieving substantial achievements and meeting goals and objectives. In essence, the evaluation of the national food safety programme should follow the same format as step 1 of the regional plan in its development and strengthening.

5. CONCLUSION

Food safety in the Eastern Mediterranean Region requires a strong impetus to enable countries to cope with the new challenges facing them. WHO and its sister agency FAO have established mechanisms to assist countries to effectively address food safety. Such mechanisms include the normative work at the global level, such as Codex Alimentarius Commission, JECFA, JMPR and the new initiatives on microbiological risk assessment. At the regional level, the WHO Regional Office for the Eastern Mediterranean has in recent years actively supported national efforts in the areas of review of national food safety programmes, including legislation and regulations, strengthening of the food inspection capability in all its aspects, strengthening the analytical capability of national and subnational food control laboratories and the establishment of sound preventive approaches such as HACCP. Support has been directly to individual countries and to groups of countries through regional workshops and consultations. This process must be accelerated in view of the new climate in world trade and the new challenges this implies, which makes a comprehensive review and overhaul of current national food control systems of paramount importance.

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