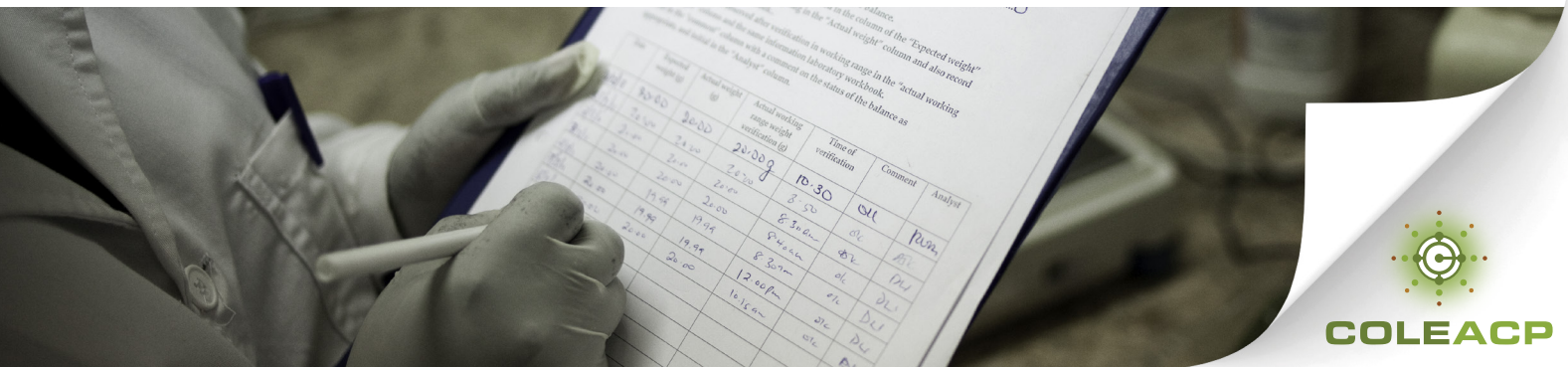
TRAINING MANUAL

- FOOD SAFETY -

NATIONAL HEALTH CARE MANAGEMENT SYSTEMS



COLEACP

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NATIONAL HEALTH CARE MANAGEMENT SYSTEMS

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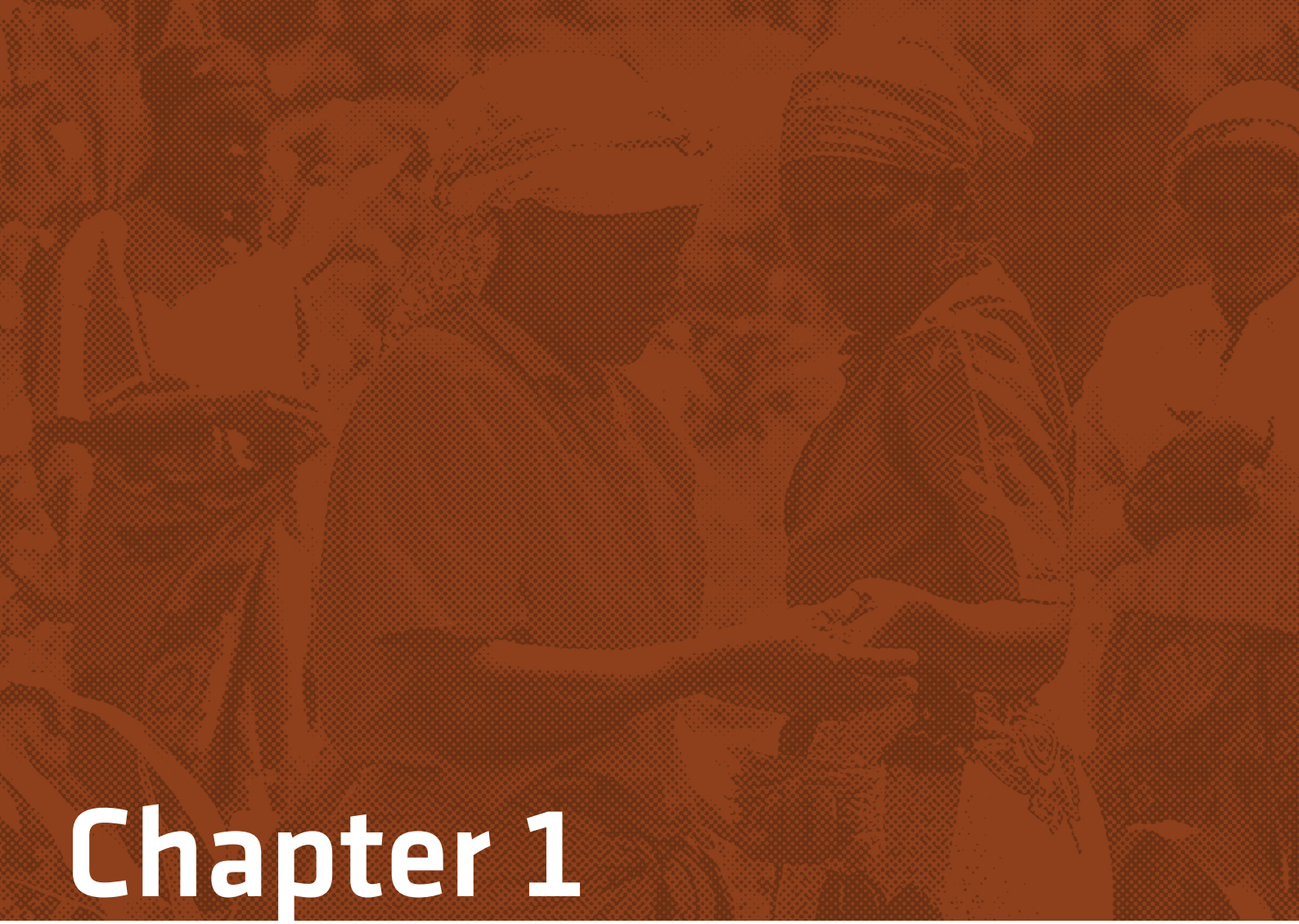

Chapter 1

SPS Agreements and international standards (OIE, IPPC and Codex Alimentarius)

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1.1. Introduction

1.1.1. Background

Foodborne diseases (FBD) are a major cause of morbidity and mortality. They are a prevalent and growing public health problem worldwide. In industrialized countries, the proportion of people suffering each year from foodborne diseases may be as high as 30%. While less well documented, developing countries bear the brunt of the problem. Although most foodborne diseases are sporadic and often go unreported, they can spark outbreaks that assume massive proportions.

Foodborne diseases, which are infectious or toxic by nature, **are the result of the ingestion of foodstuffs contaminated by biological** (bacteria, viruses, pests, prions, etc.) **or chemical pathogens** (chemical products and biological toxicants). Contamination can occur at any stage, from production to final consumption. Contaminated food causes acute and chronic diseases of varying degrees of severity, from mild symptoms and self-limiting infection (nausea, vomiting and diarrhea) to very severe conditions, which may be life-threatening (kidney or liver failure, neurological problems, paralysis and cancers).

Against the current backdrop of globalized trade, **international trade in food increases every year, adding to the risk of rapid propagation of pathogens and foodborne diseases beyond national borders**.

In response to the food crises of the past twenty years (mad-cow disease, dioxins, bird flu, etc.), and the growing demand from consumers, particularly in developed countries, for safe, high-quality products, **food safety** has become a major concern for governments and all the players in the agri-food industry. It is a **public health imperative**, as acknowledged by the adoption of the World Health Organization (WHO) Resolution by its members in 2000 and a **prerequisite for the development of national and international trade in foods**.

Food safety

The assurance that foods will not cause harm to consumers when they are prepared and/or consumed in accordance with their intended use.

This covers all measures aimed at providing foods that are as safe as possible in order to protect consumer health. This must be guaranteed from end to end of the food chain, at national and international level, by measures based on reliable scientific data.

Quality refers to all the other characteristics that determine the value of a product for the **consumer**.

At an international level, the World Trade Organization (**WTO**), which deals with the global rules of trade between nations, is **not directly responsible** for food safety. Nevertheless, the rules it has adopted provide an effective framework for applying food safety measures to international trade.

The WTO has 155 member countries, which account for around 95% of world trade. Some thirty other countries are currently negotiating their accession to the organization. The WTO's main function is to ensure that **trade flows as smoothly, predictably and freely as possible**. The World Trade Organization came into being in 1995 as the successor to the General Agreement on Tariffs and Trade (GATT), established in 1947, to gradually reduce barriers to trade (tariff and non-tariff barriers) and anti-competitive practices (dumping, subsidies, etc.). The GATT has contributed to the establishment of a multilateral trading system that has developed over the years through a series of trade negotiations, or so-called rounds.

The last and most important round – the **Uruguay Round** (1986–1994) – led to the **creation of the WTO**, with the signing of the Marrakesh Agreement and in-depth reform of the system through the adoption of a series of new agreements, the WTO Agreements. These agreements, the basic structure of which is set out in Table 1, constitute the legal rules on which international trade is based, and spell out the rights and obligations of WTO member countries.

These agreements focus on liberalizing and expanding world trade, while ensuring equal treatment for all.

Developing countries participated in all aspects of the Uruguay Round negotiations to an unprecedented extent.

Basic structure of the WTO Agreements
Source: www.wto.org/english/thewto_e/whatis_e/tif_e/agrm1_e.htm

Framework	**Agreement establishing the WTO**		
Trade	***Goods***	***Services***	***Intellectual property***
Fundamental principles	**GATT**	**GATS** (General Agreement on Trade in Services)	**ADPIC** Agreement on Trade-Related Aspects of Intellectual Property Rights)
Additional details	Other agreements and annexes concerning goods, **including the SPS Agreement and the TBT Agreement**	Annexes relating to services	
Market access commitments	List of members' commitments	List of members' commitments (and MFN* exemptions)	

Dispute settlement	**Dispute settlement****
Transparency	**Trade policy reviews**

** MFN: Most favored nation*
***Dispute settlement is the cornerstone of the multilateral trading system and is the WTO's contribution to the stability of the global economy. Without a way to settle differences, a system based on rules would be of no use since the rules could not be applied.*

The Uruguay Round was the first to deal with the liberalization of international trade in agricultural products and agri-food, and the negotiations resulted in a reduction in non-tariff barriers to trade in these products. This Round led to two specific binding agreements, which came into force in January 1995:

- **Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)**;
- **Agreement on Technical Barriers to Trade (TBT Agreement)**.

These two agreements lay down **rules governing the drawing up, adoption and application** by WTO member countries of:

- **sanitary measures to ensure food safety and animal health and phytosanitary measures for plant protection** (the SPS Agreement);
- **technical regulations, standards and conformity assessment procedures, other than measures covered by the SPS Agreement** (the TBT Agreement), that have a direct or indirect impact on international trade, in order to avoid unjustified non-tariff barriers and to ensure the supremacy of free trade is not undermined.

The fact is that SPS and TBT measures can be used to **restrict trade** and shield national producers from economic competition, particularly since the Uruguay Round Agreements lowered other trade barriers. A restriction that is not truly required for legitimate objectives can be a very effective protectionist device and, because of its technical complexity, can be a **particularly deceptive and difficult barrier** to challenge.

In other words, the SPS and TBT Agreements set out and clarify the rights and obligations of the WTO member countries wanting to introduce SPS and TBT measures. The agreements therefore **establish a legal framework to bolster measures taken by States to ensure the quality and safety of foods, while guaranteeing that such measures do not constitute barriers to international trade**.

The SPS and TBT Agreements recognize the importance of **harmonizing international SPS and TBT measures** in order to reduce to the minimum, if not eliminate, the risk that they become obstacles to trade. To this end, the agreements encourage WTO member countries to base their SPS and TBT measures on international standards, guidelines and recommendations, where they exist.

While the TBT Agreement makes no explicit reference to international standardizing bodies, the SPS Agreement acknowledges three organizations involved in drawing up sanitary and phytosanitary standards:

- the ***Codex Alimentarius*** **Commission** (**CAC**) for food safety;

- the **World Organization for Animal Health** (**OIE**, formerly the International Office of Epizootics) for animal health and zoonoses;
- the **International Plant Protection Convention** (**IPPC**) for plant protection.

While the standards established by these organizations are not mandatory, they are, nevertheless, authoritative and based on sound scientific data. The WTO has incorporated these standards into its own trade rules and uses them as **a benchmark to facilitate international trade and settle trade disputes**.

There are also internationally agreed commercial quality standards for agricultural produce, drawn up by the United Nations Economic Commission for Europe (UNECE) and the Organization for Economic Cooperation and Development (OECD).

This document sets out the objectives and key elements of the SPS and TBT Agreements, while pinpointing the differences between the two, and the importance and advantages of the SPS Agreement for international trade in foodstuffs, animals and plants. It also presents the principal international sanitary and phytosanitary benchmark standards drawn up by the CAC, OIE and IPPC, as well as the internationally agreed commercial quality standards.

1.2. The SPS and TBT Agreements

1.2.1. Definitions, field of application and legitimate objectives

The scope and legitimate objectives of the SPS and TBT Agreements are set out in Table 2.

❑ **A few definitions**

➢ ***SPS measures***

Measure designed to protect human and animal life and health (sanitary measures) and plants (phytosanitary measures) against the risks arising from:

- additives, contaminants, toxicants or disease-causing organisms in foods, beverages or feedstuffs (**food safe for human and animal health**);
- diseases carried by animals, plants or their products, or caused by the entry, establishment or spread of pests (**human health**);
- the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms (**animal and plant health**).

➢ ***Technical regulation and standard***

A document that lays down:

- the characteristics of a product (descriptive characteristics, design, functions and performance criteria) including its quality;
- the production processes and methods for a product if they affect any of those characteristics;
- the terminology, symbols and instructions for packaging, marking and labelling for a given product or production process or method.

Difference with regard to the obligation to comply, with implications for international trade:

- **Technical regulation:** compliance is **mandatory** in placing a product on the market.
- **Standard: approved by a recognized body** and compliance is **voluntary**. An imported product that does not comply with standards may come onto the market, but its sale may be affected if consumers prefer products that meet local standards.

➢ ***Conformity assessment procedure***

A procedure used, directly or indirectly, to **determine that the requirements in technical regulations or standards are fulfilled**.

This includes, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

❑ **The SPS and TBT Agreements: field of application and legitimate objectives (Table 2)**

	SPS Agreement	TBT Agreement
Field of application	**All SPS measures** relating **to agricultural and foods:** animals, plants, foods and beverages, feedstuffs. From a legal viewpoint, these measures may take the form of **laws, decrees, regulations, requirements or other legal procedures** relating to: - end-product criteria; - production processes and methods; - testing, inspection, certification and approval procedures; - phytosanitary and zoosanitary quarantine systems; - transport of animals or plants or the materials necessary for their survival during transport; - statistical methods; - sampling procedures; - risk assessment methods; - packaging and labelling requirements directly related to food safety.	**All technical regulations, standards and conformity assessment procedures (CAP) relating to all –** industrial and agricultural – **products, with the exception of measures covered by the SPS Agreement. The following discussion refers to them as TBT measures.** Examples of products: - machines and equipment for medical purposes or for food processing, etc. - consumer items: foods, medicines, cosmetics, household appliances, cars, toys, clothing, etc. - agricultural inputs: fertilizers, insecticides, etc. For **foods,** the TBT Agreement concerns **requirements, not directly linked to safety**, that relate to **composition, nutritional value, quality, packaging and labelling**.
	The SPS and TBT measures apply equally to **national products and imported products**.	
Legitimate objectives	Protection of human, animal and plant health	- Protection of human, animal and plant health - National security - Prevention of deceptive or fraudulent trade practices - Environmental protection

SPS measures may take many forms. Countries may, for example, impose a requirement for:

- products to come from a disease-free area;
- products to be inspected;
- products to undergo specific treatment or processing;
- allowable maximum levels to be set for contaminants and residues of pesticides or veterinary medicines;

- only certain food additives to be used.

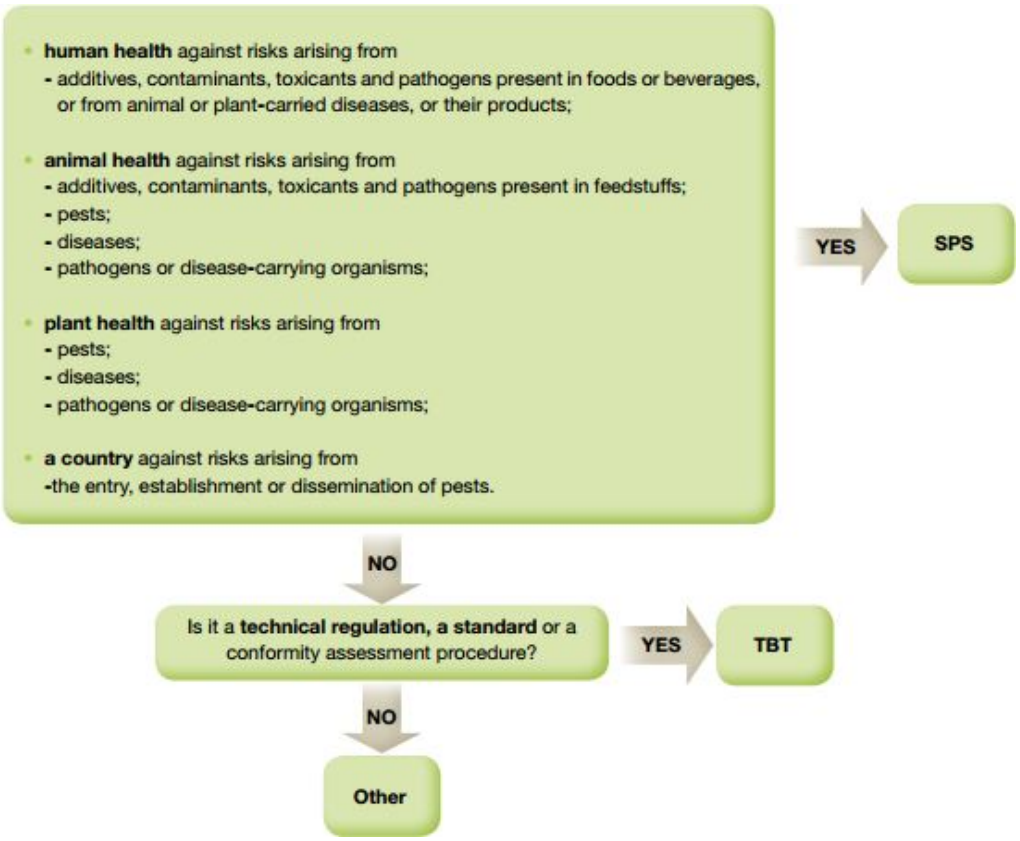
TBT measures generally relate to:

- the labelling of foods, beverages and medicines;
- instructions on the calibration and quality of foods;
- instructions relating to the packaging of foods;
- the packaging and labelling of hazardous chemicals and toxic substances;
- regulations on electric appliances;
- regulations on mobile telephones, radio equipment, etc.;
- the labelling of textiles and clothing;
- tests of vehicles and accessories;
- regulations on ships and their equipment;
- regulations on toy safety;
- Regulations on recycling of paper and plastic materials or on vehicle emissions levels;
- etc.

To which agreement does a given measure relate? SPS or TBT?
This distinction is important because although the two Agreements have several common elements, the substantive rules are different.

It is the type of measure that determines whether it is covered by the TBT Agreement. It is the purpose of the measure that determines whether it is subject to the SPS Agreement.

Does the measure relate to a food, beverage or feedstuff and with the aim of protecting?



1.2.2. The SPS and TBT Agreements: key features and differences

Table 3 summarizes the key features of the SPS and TBT Agreements. These features are similar in many ways, but there are four major differences between the rules laid down in the SPS Agreement and those contained in the TBT Agreement.

❑ Importance given to scientific evidence in drawing up measures

In the case of the SPS Agreement, there is an unequivocal obligation to base any measures on scientific evidence. In contrast, the TBT Agreement considers that the use of scientific factors depends on the objectives for which the measures were adopted. These factors are not necessarily relevant to measures targeting national security or the prevention of deceptive or fraudulent trade practices.

❑ Application of the precautionary principle

The SPS Agreement authorizes countries to provisionally adopt SPS measures, as a precaution, if there is an immediate health risk but the scientific evidence is insufficient. The TBT Agreement contains no such provision.

❑ Application of the MFN (most-favored-nation) principle

TBT measures must be applied on the MFN basis (equal treatment) to all imports of any origin.

In contrast, SPS measures may deviate from the MFN principle and be applied more or less rigorously to imported products depending on their region of origin, differences in the SPS characteristics and, in particular, the degrees of prevalence of certain pest or diseases which exist between regions of origin. The SPS Agreement, however, checks unjustified discrimination in the use of SPS measures, whether in favor of domestic producers or among foreign suppliers.

❑ Application of the international standards

The TBT Agreement makes no explicit reference to international standardizing bodies and states that countries are not obliged to use international standards if those standards are ineffective or inappropriate for achieving the legitimate objectives sought.

In contrast, the SPS Agreement refers to three international standardizing bodies, and gives countries the right to establish SPS measures which result in a higher level of protection than is achieved by international standards:

- if there is scientific justification; or,
- if, based on a risk assessment, the country concerned considers that a higher level of SPS protection is required.

➢ *The SPS and TBT Agreements: key elements*

	SPS Agreement	**TBT Agreement**
Administration	SPS Committee	TBT Committee
	The SPS and TBT Committees are open to all WTO member countries. They provide a forum for consultation between those countries on any issue relating to the implementation and operation of the SPS and TBT Agreements.	
No protectionist measures	SPS and TBT measures **must not constitute unnecessary** obstacles **or disguised restrictions on international trade**.	
Necessity test and minimum restriction of trade	They must be **necessary to achieve a legitimate objective**, at a level the Members consider to be appropriate and **must not be more trade-restrictive than required** to achieve that level, taking into account the risks non-fulfilment would create and the technical and economic feasibility. Consequently, if several measures would make it possible to achieve the same legitimate objective, **that which is the least restrictive for trade must be adopted**.	

	When determining the appropriate level, members must take into account the objective of minimizing negative trade effects. The **control, inspection and approval procedures** to verify and ensure the conformity of SPS measures and **conformity assessment procedures** must be **undertaken and completed as quickly as possible and without undue delay**.	
Non-discrimination	The SPS and TBT measures **must not arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail**, including between their own territory and that of other members.	**Application on a non-discriminatory basis to all imported products:** Products imported must not be accorded treatment no less favorable than that accorded to like products of national origin (**principle of national treatment**) and to like products originating in any other country (**MFN principle**).
Adaptation to regional conditions	SPS measures must be **adapted to the SPS characteristics of the product's region of origin and destination**, whether this relates to all or parts of one country or several countries, **allowing for and recognizing, in particular, exempt areas or areas with a low prevalence of pests or diseases**. **Exporter member countries** claiming that areas in their territory are exempt or have a low prevalence of pests and diseases must **provide the necessary evidence thereof and provide reasonable access, on request, to the importing Member** for inspection, testing and other relevant procedures.	
Scientific justification **Risk assessment**	SPS measures must be **based on scientific principles** and, as much as possible, on **analysis and evaluation of**	TBT measures must be **based on an assessment of the risks associated with the legitimate objective**

	objective and accurate scientific data. They **cannot be retained without sufficient scientific evidence**. They must be **based on assessment of the actual risks involved, using internationally accepted methods**. Member countries must, on request, **indicate the risk assessment procedures used, the factors taken into account and how the level of SPS protection they believe is appropriate is determined** (the level of risk deemed to be acceptable). **The precautionary principle** If the scientific proof is insufficient but there is an imminent food safety risk, SPS measures may be adopted provisionally. The Members must then seek to obtain the additional information necessary for a more objective assessment of the risk and must review the SPS measure in the light of this within a reasonable period of time.	targeted, taking into account, *inter alia*: • the scientific and technical data available; • the related processing techniques; • the final use intended for the product. **The measures shall not be retained if the circumstances or objectives which led to their adoption have ceased to exist or have changed** so that they can be met in a way that is less restrictive for trade.
Code of good practice for the preparation, adoption and application of standards		**The member countries shall ensure that the standardization bodies for their territory accept and comply with this Code**. Under this Code the principles and rules are similar to those for technical regulations (necessity test, application of the principles of national and MFN treatment, international harmonization and transparency). Standardization bodies that have accepted or withdrawn from the Code must notify this to the ISO/IEC (International Organization for

<table>
<tr><td></td><td></td><td>Standardization/International Electrotechnical Commission) Information Centre.</td></tr>
<tr><td rowspan="3">International harmonization</td><td colspan="2">Member countries are encouraged to use international standards, guidelines and recommendations, where they exist, in drawing up national SPS and TBT measures. SPS and TBT measures conforming to international standards are presumed not to create unnecessary obstacles to trade. International standards are not, however, mandatory and do not constitute a minimum or maximum level.
The SPS and TBT Agreements expressly authorize member countries to opt not to use international standards.</td></tr>
<tr><td>Members may adopt SPS measures that entail a higher level of protection than under international standards if there is scientific justification based on a risk assessment or if this is the consequence of a level of protection which a member country believes to be appropriate.

The SPS Agreement makes explicit reference to three international standards bodies:
• the Codex Alimentarius Commission (CAC) for food safety;
• the World Organization for Animal Health (OIE) for animal health and zoonoses;
• the International Plant Protection Convention (IPPC) for plant protection.</td><td>Member countries may decide not to use international standards if those standards are ineffective or inappropriate for achieving the legitimate objectives sought, e.g. due to an inadequate level of protection, fundamental climatic or geographic factors or fundamental technological problems.

The TBT Agreement does not specify the international standardizing bodies.

With regard to foods, the standards established by the Codex Alimentarius Commission (on the composition, nutritional value, packaging and labelling), not directly linked to safety, fall within the scope of the TBT Agreement.</td></tr>
<tr><td colspan="2">Member countries participate, within the limits of their resources, in the activities of international bodies in the development and periodic review of international standards, guidelines and recommendations with respect to all aspects of SPS and TBT measures.</td></tr>
</table>

Principle of equivalence	Members must accept the SPS measures and technical regulations, standards and findings of the conformity assessment procedures of other Members as equivalent, even if these measures differ from their own, provided the exporting Member objectively demonstrates, to the importing Member, that its measures fulfil the importing Member's objectives. For this purpose, reasonable access must be given, on request, to the importing Member for inspection, testing and other relevant procedures. Members are encouraged to conclude **agreements on mutual recognition of SPS measures and the findings of conformity assessment procedures**.	
Transparency	Members must **notify all new projects or amendments to SPS or TBT measures that do not conform to international standards and that could affect international trade if they were implemented**. A reasonable interval must be allowed before measures are adopted to enable other Members to make comments. This deadline may be shortened in urgent circumstances. The comments of the other Members must be taken into account in drawing up the final documents. Once adopted, the SPS and TBT measures must be published promptly and, except in cases of urgency, Members must allow a reasonable interval between publication of the measures and their entry into force, in order to allow time for exporting Members to adapt their products and production methods to the requirements of the importing Member. **Establishment of national enquiry points on SPS and TBT measures.**	
Technical assistance	Especially for developing and least-developed countries. Either bilaterally or through the appropriate international organizations to enable them to reinforce their SPS and TBT systems.	
Special and differential treatment	With a view to ensuring that Members are able to comply with the SPS and TBT Agreements, time-limited exceptions may be granted, on request, from obligations, in whole or in part, under these Agreements, taking into account Members' financial, trade and development needs.	
		Developing countries may adopt technical regulations, standards and conformity assessment procedures designed to preserve national techniques and production methods and procedures compatible with their development needs. They may also ask international standardizing bodies to examine the possibility of drawing up international

		standards on products of special interest to their trade.

1.2.3. The advantages of the SPS Agreement

❑ **For consumers in all countries**

- The SPS Agreement helps to ensure, and in many cases improve, **food safety** given that it encourages the systematic use of scientific information in this regard, thus reducing the scope for arbitrary and unjustified decisions in this area.
- **More information becomes available** to consumers as a result of greater transparency in governmental procedures and on the basis of their food safety and animal and plant health decisions.
- The elimination of unnecessary trade barriers allows consumers to benefit from a **greater choice of safe foods** and from healthy international competition among producers. SPS requirements are most frequently applied on a bilateral basis between trading countries.

❑ **For developing countries**

- Developing countries benefit from the SPS Agreement as it provides an **international framework for SPS arrangements among countries**, irrespective of their political and economic strength or technological capacity. Without such an agreement, developing countries could be at a disadvantage when challenging unjustified trade restrictions.
- Governments must **accept imported products that meet their safety requirements**, whether these products are the result of simpler, less sophisticated methods or the most modern technology.
- **Increased technical assistance** to help developing countries in the area of food safety and animal and plant health, whether bilateral or through international organizations, is also an element of the SPS Agreement.

❑ **For exporters of agricultural products in all countries**

Exporters **benefit from the elimination of unjustified barriers to their products.** The SPS Agreement reduces uncertainty about the conditions for selling to a specific market. Efforts to produce safe food for another market should not be thwarted by regulations imposed for protectionist purposes under the guise of health measures.

❑ **For importers of food and other agricultural products**

Importers also benefit from the **greater certainty regarding border measures**. The basis for SPS measures that restrict trade is made clearer by the SPS Agreement, as well as the basis for challenging requirements that may be unjustified. This also benefits the many processors and commercial users of food and animal or plant products.

1.3. *Codex Alimentarius* standards

1.3.1. The *Codex Alimentarius*

The ***Codex Alimentarius*** (food code)**,** abbreviated to **Codex,** is a **collection of international food safety standards, codes of practice, guidelines and other recommendations on food quality and safety.**

Codex standards are **drawn up and adopted, then revised and updated by the *Codex Alimentarius* Commission** and its secondary bodies under the Joint FAO (Food and Agricultural Organization of the United Nations)/WHO (World Health Organization) Food Standards Programme. The objectives of this Programme are to **protect the health of consumers** and **ensure fair practices in the food trade**, but also to promote the coordination of all food standards work undertaken by international governmental and non-governmental organizations (NGOs).

The *Codex* standards (totalling 326 August 2012) are available on the *Codex* Website at www.codexalimentarius.org/standards/list-of-standards/en/?no_cache=1. They include 212 standards, 46 codes of practice and 65 guidelines, and establish maximum residue limits (MRLs) for residues of contaminants, pesticides, veterinary drugs and food additives. Some of them have been compiled by thematic area (see www.codexalimentarius.org/normes-officielles/thematic-publications/en).

Codex standards are **not mandatory** and are not, therefore, binding on Member States. Being **based**, however, **on objective scientific evidence and risk analysis**, they serve in many cases as a basis for national legislation and have become **international references** for consumers, food producers and processors, national food control agencies and the international food trade.

Explicitly acknowledged in the SPS Agreement and **used by the TBT Agreement**, even if not officially mentioned therein, *Codex* standards are reference points against which national standards can be tested to determine that they are justified, not arbitrary, and provide an appropriate level of protection which is not in violation of the SPS and TBT requirements. **The WTO uses *Codex* standards in dispute resolution proceedings between countries** to settle disputes relating to food. The WTO can sanction trade penalties against a country that cannot justify a more stringent trade-restrictive requirement than that specified in Codex standards.

Reference is made to the *Codex Alimentarius* in many bilateral and plurilateral trade agreements in addition to those quoted above. European Union directives also frequently refer to the *Codex Alimentarius* as the basis for their requirements.

The *Codex Alimentarius* system presents a unique opportunity for all countries to join the international community in formulating and harmonizing food standards and ensuring their global implementation.

❑ The *Codex Alimentarius* Commission

Established in 1963 by **FAO** and **WHO**, both of which deal with food safety from their respective and complementary viewpoints (food production and human health), the ***Codex Alimentarius* Commission (CAC)** is an intergovernmental body with 185 member countries. International governmental organizations and NGOs can become accredited *Codex* observers to provide expert information, advice and assistance to the Commission.

The CAC draws on the expertise of its subsidiary bodies for the preparation of projects and coordination of its food standard activities at regional level:

- ***Codex* committees dealing with general subjects,** such as contaminants, food additives, pesticide residues, veterinary drug residues, food hygiene, labelling, analysis and sampling methods, etc.;
- ***Codex* committees dealing with products** such as fish and fisheries products, fresh fruits and vegetables, fats and oils, sugars, etc.;
- ***Ad hoc* intergovernmental task forces** with a limited mandate established for a given period (e.g., on feedstuffs or food derived from biotechnology);
- **Regional coordinating committees** (six in total: Africa, Asia, Europe, etc.).

It may create new subsidiary bodies or phase out those whose mission has come to an end.

The list of all the committees and *ad hoc* intergovernmental task forces, including those which are active, can be found on the Codex Website at www.codexalimentarius.org/committees-and-task-forces/en.

The specific recognition of *Codex* standards and the importance they have assumed in the SPS Agreement have stimulated considerable interest in the CAC's activities. Consequently, attendance at *Codex* meetings, especially by developing countries, has markedly increased. This is a welcome development, particularly as both Agreements ask members, within the limits of their resources, to play a full part in the work of international standards organizations and their subsidiary bodies.

❑ *Codex* standards

Codex standards, bearing the reference **CODEX STAN n year**, usually relate to food product characteristics. They fall into two categories: general standards, and standards for specific products.

General standards relate to:

- food hygiene;
- pesticide and veterinary drug residues;
- food additives;
- contaminants;
- labelling;
- sampling and analysis methods;
- import and export inspection and certification systems;
- nutrition and special dietary foods.

Standards for specific products relate to individual foods or groups of foods. They contain information on:

- the scope of the standard and the description of the product(s);
- the factors essential for their composition and quality;
- food additives and contaminants;
- food hygiene;
- weights and measures;
- labelling;
- sampling and analysis methods.

The content of the standards, in particular product standards, shows clearly that the Codex has given top priority to the protection and interests of consumers by ensuring that they have **safe products that are not a danger to health and that are reliable and of acceptable minimum quality**.

Provisions contained in product standards	**Objectives targeted**
• Scope of standard and description of product(s) • Weights and measures • Labelling	Ensure that the consumer is not misled and that the product purchase corresponds to what is indicated on the label.
Factors essential to their composition and quality	Factors essential to their composition and quality
Food additives, contaminants and hygiene	Protect consumer health

❑ ***Codex* codes of practice**

***Codex* codes of practice**, bearing the reference **CAC-RCP no. year,** set out practices for the production, processing, manufacturing, storage, packaging and transport of foods or groups of foods, which are deemed to be essential to ensure they are safe to eat and edible.

They include **codes of practice on hygiene** and **on the prevention and reduction of contaminants** in products for human and/or animal consumption.

❑ ***Codex* guidelines**

***Codex* guidelines**, bearing the reference **CAC/GL no. year**, fall into two categories:

- ***Codex* principles**, setting out general policies in certain key areas;
- **Interpretative *Codex* guidelines** for the interpretation of these principles or for the interpretation of other *Codex* standards.

❑ **The role of food standards**

Governments have an obligation to protect the health of their citizens, and this includes protection against foodborne diseases for which publicly-set standards are necessary. However, standards do not protect consumers unless they are enforced through a properly functioning food control system. This calls for many elements – comprehensive and current legislation, food monitoring and foodborne disease surveillance, licensing and

inspection (which in turn requires educated and trained staff and good laboratory facilities), not to mention political and institutional support and stability, lack of corruption, etc. In these respects, responsibility rests squarely with individual countries.

There are, however, costs related to the improvement of governance and manpower training, and **investments** in the public and private sector infrastructures are needed to implement standards. The cost implications of implementing standards are particularly important in developing countries, and such countries may need financial assistance and training. Moreover, the Codex principles and procedures are of benefit for recognition of the equivalence of food control systems.

In addition to protecting consumers' health, food standards also **reduce the cost** of doing business (e.g. the risk of fraud, and costs of finding reliable trading partners). To be useful, they must be meaningful to consumers and thus **reduce consumers' risks** (of inadvertently buying food of inferior quality or possibly unsafe). In providing benefits to both producers and consumers, standards promote **economic welfare**, thus they are considered by many economists to be a prerequisite for the operation of a well-functioning market. If standards are harmonized (within or between countries), they naturally facilitate trade (domestic and international), and trade itself is generally seen to promote economic development.

As an international standard-setting body, one of the difficulties the *Codex* faces is **balancing** the different needs of consumers in developed and developing countries. Balancing the costs and benefits of incremental increases in food safety and quality is part of the process of risk management.

1.3.2. Scientific basis for *Codex* standards

Codex standards are **based on sound scientific data and principles**, and, in the case of food safety, **on risk assessment**.

Risk assessment

A scientifically based process consisting of the following four steps:

i) **hazard identification;**
ii) **hazard characterization;**
iii) **exposure assessment;**
iv) **risk characterization**.

The risk assessment process is a means to provide an **estimate of the probability and severity of adverse health effects attributable to the presence of a hazard**.

Hazard

A biological, chemical or physical agent in, or condition of, food or feedstuff, with the potential to cause an adverse health effect.

Risk assessment information is useful in determining which hazards are of a nature to require their prevention, elimination or reduction to acceptable levels. This information is also useful in determining the most effective intervention strategies.

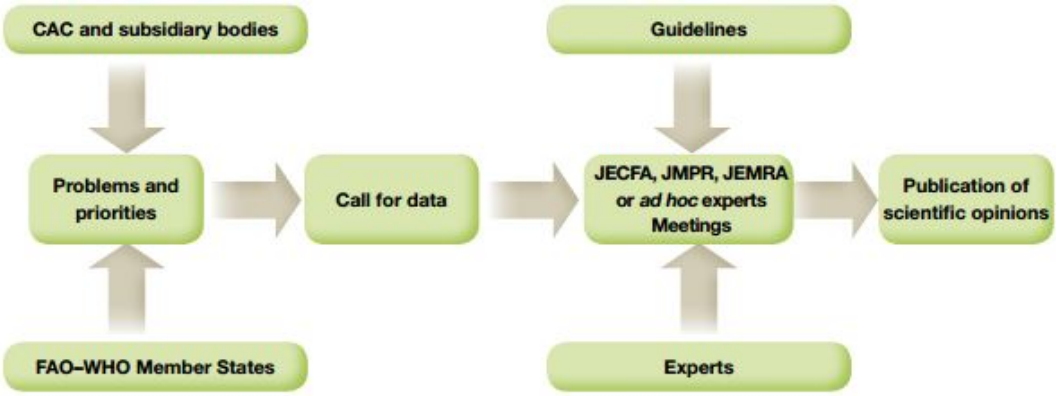
Since there is no such thing as "zero risk", Codex standards are based on the concept of "no appreciable risk" over a human lifetime, with very conservative safety margins applied to ensure that scientific data provide assurance of protection for all consumers.

Codex standards are drafted calling on the opinions of independent scientific experts expressed at meetings of joint FAO/WHO standing committees:

- **the Joint FAO/WHO Expert Committee on Food Additives (JECFA)**;
- **the Joint FAO/WHO Meetings on Pesticide Residues (JMPR)**;
- **the FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA)**.

Information on these committees is available on the FAO and WHO Websites.

The FAO and WHO also frequently organize ***ad hoc* expert consultations** (scheduled or in cases of emergency) **to respond to specific questions** raised by the CAC or member countries in the area of food quality and safety that do not fall within the remit of these three standing committees.



❑ Joint FAO/WHO Expert Committee on Food Additives (JECFA)

The JECFA has been meeting since 1956. It was initially responsible for evaluating the **risks linked to food additives**, but it now also evaluates **contaminants, naturally occurring toxicants and veterinary drug residues** in food. The JECFA has evaluated over 2500 food additives, approximately 40 contaminants and naturally occurring toxicants, and the residues of approximately 90 veterinary drugs.

In particular, it conducts toxicological evaluations and establishes:

- the **acceptable daily intake (ADI) for food additives**;
- the **ADI** and **maximum residue limits (MRL) for veterinary drugs**, in accordance with good practice for the use of these drugs. MRLs are intended to provide assurance that when the drug has been used properly, the intake of residues of the drug present in food is unlikely to exceed the ADI.
- **for contaminants and naturally occurring toxicants,** levels corresponding to 'tolerable' intakes, such as **the provisional maximum tolerable daily intake**

(PMTDI) or provisional tolerable weekly intake (PTWI), when there is an identifiable no-observed-effect level. When that level cannot be identified, the JECFA provides other advice depending on the circumstances and on the data available.

Acceptable daily intake (ADI)

The amount of a substance that can be ingested daily over a lifetime without an appreciable health risk for consumers. It is expressed in mg/kg of body weight.

Maximum residue level (MRL)

The maximum concentration of residue (expressed as mg/kg) recommended by the CAC to be legally permitted in or on foods and animal feeds. MRLs are based on data relating to good agricultural practices (GAPs), and foods derived from commodities that comply with the respective MRLs are presumed to be toxicologically acceptable.

Provisional maximum tolerable daily intake (PMTDI)

The ceiling used for contaminants with no cumulative properties. Its value represents the permissible human exposure as a result of the natural occurrence of the substance in food and in drinking water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI.

Provisional tolerable weekly intake (PTWI)

The ceiling used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods.

For food additives, contaminants and naturally occurring toxicants, the JECFA also evaluates the **characteristics, quality and validity of the analysis methods**. **Specifications for the identity and purity of food additives are also developed** to ensure that the commercial product is of appropriate quality, can be manufactured consistently, and is equivalent to the material that was subjected to toxicological testing.

For veterinary drugs, the JECFA determines **appropriate criteria for, and evaluates methods of, analysis for detecting and/or quantifying residues** in food.

Finally the JECFA has **developed and regularly updates principles for the safety assessment of chemicals in food** that are consistent with current thinking on risk assessment and take account of recent developments in toxicology and other relevant scientific areas.

❑ **Joint FAO/WHO Meetings on Pesticide Residues (JMPR)**

The JMPR has convened annually since 1963 to conduct evaluations of the risks of pesticide residues in food. The meetings are composed of the FAO Panel of Experts on Pesticide Residues in Food and the Environment, and the WHO Core Assessment Group on Pesticide Residues.

The JMPR conducts toxicological evaluations and determines ADIs, acute reference doses (ARfDs) and MRLs for pesticides. MRLs are based primarily on the residue levels estimated in supervised field trials when the pesticide is used according to Good Agricultural Practices (GAPs).

Acute reference dose (ARfD) :

The maximum amount of active substance (expressed as mg/kg of body weight) that can be ingested by a consumer over a short period (i.e. for a day or less) without any adverse health effect.

Like the JECFA, the JMPR develops and regularly updates general principles for assessing food safety and the risks of chemicals in food that are consistent with current scientific knowledge.

❑ **Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA)**

The JEMRA began in 2000 in response to growing demand for risk-based scientific advice on **microbiological food safety issues**.

The JEMRA terms of reference are to:

- assess the risks of microbiological hazards in foods (studies of combinations of pathogens and food products);
- draw up guidelines and tools for conduction and using microbiological risk assessments;
- assess the likely impact of different risk management options on the reduction or control of specific microbiological risks in foods.

JEMRA's activities are aimed at developing and optimizing the utility of microbiological risk assessment as a tool to inform actions and decisions aimed at improving food safety, and to make that tool equally available to both developing and developed countries.

1.3.3. *Codex* standards on food hygiene

Food hygiene is of major concern in ensuring food safety. It **begins at the very start of the food chain with hygiene rules for professionals** and extends to **domestic hygiene advice** with the aim of **controlling the risks of food contamination** (biological, physical and chemical).

Professionals are encouraged to use **guides to Good Hygiene Practice (GHPs)** as tools for controlling risk within a process.

Food hygiene

All conditions and measures necessary to ensure safety and food safety at all stages of the food chain.

The basic *Codex* texts on food hygiene can be found under the thematic area "food hygiene" at ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene_2009e.pdf.

The CAC has adopted **codes of practice on food hygiene**, using as the basic document the code of practice on the **Principles of Food Hygiene (CAC/RCP 1-1969)**, which:

- identifies the essential principles of **food hygiene** applicable **throughout the food chain** (including primary production through to the final consumer) to achieve the goal of ensuring that food is safe and suitable for human consumption;
- recommends an **HACCP (Hazard Analysis and Critical Control Point)-based approach** as a means to enhance food safety;
- indicates how to implement those principles;
- provides **guidance for specific codes** that may be needed for sectors of the food chain, processes, or commodities to amplify the hygiene requirements specific to those areas.

The seven principles of the HACCP method

1. Identify any hazards that must be prevented, eliminated or reduced to acceptable levels.
2. Identify the critical control points (CCPs) at the step or steps at which control is essential.
3. Establish critical limits at CCPs beyond which action is needed.
4. Establish and implement effective monitoring procedures at CCPs.
5. Establish corrective actions when monitoring indicates that a CCP is not under control.
6. Establish self-assessment procedures to verify that the measures taken are working effectively.
   Establish records to demonstrate the effective application of the measures and facilitate official checks by the competent authority.

Code of practice CAC/RCP 1-1969 addresses governments, industry and consumers alike. Its provisions relate to:

- the establishment: design, facilities, maintenance and sanitation;
- primary production;
- control of operations;
- personal hygiene;
- food transport;
- product information and consumer awareness;
- training of food business operators.

These **general food hygiene principles** lay a firm foundation for ensuring food hygiene and should be **used in conjunction with any specific codes and guidelines on hygiene and guidelines on microbiological criteria**, a partial list of which is given in the compilation of basic texts on "Food hygiene" and to which can be added:

- Regional Guidelines for the Design of **Control Measures for Street-Vended Foods (Africa)** (CAC/GL 22R-1997). These guidelines specify the general hygienic requirements and practices to be recommended for inclusion in codes of practice for the preparation and sale of street foods;
- Guidelines on the application of the general principles of food hygiene to the **control of pathogenic *Vibrio* species in seafood** (CAC/GL 73-2010).

1.3.4. *Codex* standards on monitoring criteria

❑ **Contaminants**

Any biological or chemical agent, foreign matter, or other substances added to food, which may compromise food safety or suitability:

- **Microbial contaminants:** bacteria, viruses, parasites, moulds and algal toxicants;
- **Toxicants naturally present in food:** alkaloids, cyanogenic glycosides, etc.;
- **Chemical contaminants:** heavy metals, persistent organic pollutants (POPs), acrylamide, polycyclic aromatic hydrocarbons (PAHs), pesticide and veterinary drug residues, etc.

There is a **general *Codex* standard for Contaminants and Toxins in Food and Feed** (CODEX STAN 193-1995).

This Standard contains the **main principles** recommended by the *Codex Alimentarius* **in dealing with contaminants and toxins** in food and feed, and lists the **maximum levels and associated sampling plans** for contaminants and natural toxicants in food and feed that are recommended by the CAC to be applied to commodities moving in international trade.

This Standard includes only maximum levels of contaminants and natural toxicants in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health.

Contaminant

Any substance not intentionally added to food, which is however present in food as a **result** of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport and distribution, and storage of food or as a result of environmental contamination.

The term **does not include** insect fragments, rodent hairs and other **extraneous matter**.

This standard applies to any substance that meets the terms of the Codex definition for a contaminant, except:

- contaminants having only food and feed quality significance (e.g., copper), but no public health significance;
- micro-organisms and bacterial toxicants;
- pesticide residues;
- residues of veterinary drugs;
- residues of processing aids.

It implicitly includes naturally occurring toxicants, including those produced by moulds (mycotoxins) and algae (phycotoxins). However, endogenous natural toxicants that are implicit constituents of food and feed are not generally considered within the scope of this standard.

Standard CODEX STAN 193-1995 establishes the maximum limits for the following contaminants based on the foods concerned:

- **Mycotoxins:** total aflatoxins, aflatoxin M1, ochratoxin A, patulin;
- **Heavy metals**: arsenic, cadmium, lead, mercury, methylmercury, tin;
- **Radionuclides**;
- **Others:** acrylonitrile, chloropropanols, melanine, vinylchloride monomer.

For each contaminant, it refers to the corresponding code(s) of practice for prevention and reduction. In addition, it establishes sampling plans for total aflatoxins.

All the codes of practice for the prevention and reduction of contaminants (*i.e.* mycotoxins, heavy metals and chemical substances) in food and/or feeds adopted by the CAC until 2011 are published in a specific volume, ***Prevention and Reduction of Food and Feed Contamination***, available at: ftp.fao.org/codex/Publications/Booklets/Contaminants/CCCF_2012_EN.pdf.

There are, in addition to standard CODEX STAN 193-1995:

- **specific product standards that also deal with contaminants** and that refer to standard CODEX STAN 193-1995;
- standard CODEX STAN 228-2001, which establishes **methods of analysis for certain heavy metals** (lead, cadmium, copper, iron, zinc).

With regard to **microbiological criteria**, there are **principles governing the establishment and application of such criteria for food (CAC/GL 21-1997)**, as well as principles and guidelines for the conduct of microbiological risk management (CAC/GL 63-2007), but no *Codex* document establishing microbiological limits.

Codex standards dealing with the residues of pesticides, veterinary drugs and processing aids are set out in the paragraphs below.

❑ Pesticide residues

The CAC has adopted maximum residue limits (MRLs) (as defined above), as well as extraneous maximum residue limits (EMRLs) for pesticides in food and feed.

Extraneous maximum residue limits (EMRLs)

The maximum concentration (expressed in mg/kg) of a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses), other than the use of a pesticide or contaminant substance directly or indirectly on the commodity. The maximum concentration recommended by the CAC to be legally permitted or recognized as acceptable in or on a food, agricultural commodity, or animal feed.

Information about the MRLs and EMRLs for one or more pesticides, and for a product or group of products, are available in the **Codex Pesticides Residues in Food Online Database**: www.fao.org/fao-who-codexalimentarius/standards/pestres/en.

Names and definitions of commodities are found in the Codex Classification of Foods and Animal Feeds (CAC/MISC 4-1993).

The foods listed shall not contain more than the MRL or EMRL of the pesticide residue (indicated, in each individual case, in the definition of the residue) at the point of entry into a country or at the point of entry into trade channels within a country. This maximum limit must not be exceeded at any time thereafter.

The MRLs and EMRLs apply to the residue content of the final sample representative of the lot and of the portion of commodities that is analyzed.

Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs are laid out in CAC/GL 33-1999.

The objective of these sampling procedures is to enable a representative sample to be obtained from a lot for analysis to determine compliance with Codex MRLs for pesticides.

In addition to these recommendations, other relevant Codex guidelines are relevant in the application of LMRs, including:

- Guidelines on **good laboratory practice in pesticide residue analysis** (CAC/GL 40-1993);
- **Portion of Commodities to which Codex Maximum Residue Limits apply** and which is analyzed (CAC/GL 41-1993).

❑ Residues of veterinary drugs

The CAC has adopted maximum residue limits for veterinary drugs (MRLVDs).

Maximum residue limit for veterinary drugs (MRLVD)

The maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the CAC as being legally permitted or recognized as acceptable in or on a food.

Information about MRLs for veterinary drugs and for a species or a tissue are available in the ***Codex* Veterinary Drug Residue in Food Online Database:** www.fao.org/fao-who-codexalimentarius/standards/vetdrugs/en.

❑ Food additives

Food additive

Any substance not normally consumed as food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, **for a technological (or organoleptic) purpose** in the manufacture, processing, preparation, treatment, packing, packaging, transportation or holding of such food, results, or may be expected to result, (directly or indirectly) in this food, or to its by-products, becoming a component of or otherwise affecting the characteristics of such foods.

The term does not apply to contaminants or substances added to food for maintaining or improving nutritional qualities.

The ***Codex* General Standard for Food Additives** (**GSFA, CODEX STAN 192-1995**) sets out the **conditions under which permitted food additives may be used in all foods**, whether or not they have been previously standardized by *Codex*.

Only food additives listed in the above standard are recognized as suitable for use in food, in other words, only those that have been assigned an ADI or determined, on the basis of other criteria, to be safe by the JECFA and have been allocated an International Numbering System (INS) designation by Codex.

The use of additives in foods standardized by *Codex* is subject to the conditions of use established by the Codex commodity standards and this General Standard for Food Additives.

The General Standard also establishes **maximum use levels for food additives in various food groups** to ensure that the intake of an additive, from all its uses, does not exceed its ADI.

All the provisions on food additives adopted by the CAC are available on the **Codex General Standard for Food Additives Online Database**: www.fao.org/fao-who-codexalimentarius/standards/gsfa/en.

These provisions can be consulted by food additive (name, synonym, INS number), by functional category and by food category.

Other relevant *Codex* documents in the area of food additives include:

- **Class names and the International Numbering System for food additives** (CAC/GL 36-1989);
- **General Methods of Analysis for Food Additives** (CODEX STAN 239-2003).

The provisions on food additives in the General Standard for Food Additives do not include uses of substances as processing aids. The CAC has adopted **Guidelines on**

Substances used as Processing Aids (CAC/GL 75-2010), which aim to provide information for the safe use of substances used as processing aids and the safety of their residues in the preparation of foods and food ingredients.

1.3.5. *Codex* standards on food labelling

Food labelling is the primary means of communication between the producer and seller of food on one hand, and the purchaser and consumer on the other. The *Codex* standards and guidelines on food labelling are published in a specific volume, ***Food Labelling***, available at ftp.fao.org/codex/Publications/Booklets/Labelling/Labelling_2007_EN.pdf.

The General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) applies to the labelling of all prepackaged foods to be **offered as such to the consumer or for catering purposes**, and to certain aspects relating to their presentation.

Specific *Codex* product standards also deal with labelling and refer to standard CODEX STAN 1-1985. They set out specific provisions relating to the name of the product and the labelling of containers not for sale by retail.

CODEX STAN 1-1985

❑ **General principles**

The label on prepackaged food must not:

- **describe or present the food in a manner that is false, misleading or deceptive** or is likely to create an erroneous impression regarding its true nature in any respect;
- **refer to or be suggestive**, either directly or indirectly, **of any other product with which such food might be confused**, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

❑ **Mandatory labelling information**

CODEX STAN 1-1985 specifies the information that must appear on the label of all prepackaged foods as applicable to the food being labelled, except if otherwise specified in an individual *Codex* standard:

- Name of the food indicating its true nature.
- Full list of ingredients, indicating:
  - the allergens:
    - cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
    - crustacea and products of these;
    - eggs and egg products;
    - fish and fish products;
    - peanuts, soybeans and products of these;
    - milk and milk products (lactose included);
    - tree nuts and nut products;

  - sulphite in concentrations of 10 mg/kg or more;
- the specific name or SIN number and functional classes of food additives authorized in food by *Codex*.

- net contents and drained weight;
- the name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food;
- country of origin ;
- lot identification ;
- date marking and storage instructions: in addition to the date of minimum durability, any special conditions for storage of the food must be declared on the label if the validity of the date depends on it;
- instructions of use ;
- irradiated foods – the label of a food (or ingredient) which has been treated with ionizing radiation must carry a written statement indicating that treatment in close proximity to the name of the food or ingredient.

Furthermore, it requires labels on prepackaged foods to be applied in such a manner that they will not become separated from the container and that the statements required to appear on the label be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use.

In addition to the general recommendations of CODEX STAN 1-1985, other *Codex* standards and guidelines set out policies on certain claims often made on the market in order to provide consumers with clear information:

- General standard for the labelling of and claims for **prepackaged foods for special dietary uses** (CODEX STAN 146-1985);
- Codex standard for the labelling of and claims for **foods for special medical purposes** (CODEX STAN 180-1991);
- Guidelines on **nutritional labelling** (CAC/GL 2-1985);
- **General guidelines on claims** (CAC/GL 1-1979);
- Guidelines for the use of **nutritional and health claims** (CAC/GL 23-1997);
- General guidelines for the **use of the term "halal"** (CAC/GL 24-1997).

Claim

Any representation which states, suggests or implies that a food has particular qualities relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

1.3.6. *Codex* standards on organically produced foods

In general, organic agriculture is a means of production governed by rules that **foster biological and physical methods** rather than the **use of synthetic products (fertilizers, pesticides, etc.)**.

Organic agriculture

Organic agriculture is a holistic production management system which promotes and enhances agro-ecosystem health, including biodiversity, biological cycles and soil biological activity.

Organic agriculture **practices include**:

- crop rotation, the very foundation for effective use of soil resources;
- stringent limits on the use of phytopharmaceutical products, synthetic fertilizers, antibiotics, additives, processing aids and other inputs;
- prohibition of genetically modified organisms;
- use of the farm's resources: for example, manure as a fertilizer or livestock feed produced on site;
- selection of disease-resistant vegetable and animal species adapted to local conditions;
- rearing in the open air and with a free range, feeding of livestock with feed of organic origin and animal husbandry practices appropriate to the requirements of each species.

The CAC has adopted **guidelines for the production, processing, labelling and marketing of organically produced foods** (**GL 32-1999**) to increase production and international trade in organically produced foods with a view to facilitating trade and preventing misleading claims. These guidelines are intended to facilitate the harmonization of requirements for organic products at international level, and may also provide assistance to governments wishing to establish national regulations in this area.

The aims of these guidelines are to:

- **protect consumers** against deception and fraud in the marketplace and against unsubstantiated product claims;
- **protect producers of organic produce against misrepresentation of other agricultural produce** as being organic;
- **ensure that all stages** of production, preparation, storage, transport and marketing are subject to inspection and comply with these guidelines;
- **harmonize provisions** for the production, certification, identification and labelling of organically grown produce;
- **provide international guidelines for organic food control systems** in order to facilitate recognition of national systems as equivalent for the purposes of imports;
- **maintain and enhance organic agricultural systems in each country** so as to contribute to local and global preservation.

These guidelines apply to the following products which carry, or are intended to carry, descriptive labelling referring to organic production methods:

a) **unprocessed plants, plant products, livestock and livestock products**;
b) **processed agricultural crop and livestock products** (intended for human consumption derived from (a) above).

They do not apply to materials and/or the products produced from genetically engineered/modified organisms (GEO/GMO).

The guidelines cover the following areas:

- **Labelling and claims:**
  - general provisions referring to the CODEX STAN 1-1985 standard;
  - labelling of products of farms in transition to organic production methods;
  - labelling of non-retail containers.
- **Rules and principles of organic production** at the level of the farm, storage, transport, processing and packaging of products.

  Guidelines are also established for substances authorized for use to fertilize and condition the soil, combat pests and plant diseases, and as food additives and processing aids.
- **Inspection and certification systems**
- **Imports**
- In particular, products which are imported may be marketed only where the competent authority or designated body in the exporting country has issued a certificate of inspection stating that the lot designated in the certificate was obtained within a system of organic production.

1.3.7. *Codex* standards on food import/export controls

Food controls are the **responsibility of the exporting country or the exporter itself**, which must provide assurance that its products comply with international standards and regulations on food quality and safety. It is the **responsibility of the importing country** to ensure that food imported into its territory complies with its standards, legislation and regulations.

For developing countries, it is more advantageous to adopt ***Codex* standards** rather than beginning the long and costly task of drawing up their own standards.

However, products intended for an EU Member State must also comply with **stringent European legislation and regulations on the quality and safety of food from third-party countries**.

Adopting *Codex* norms helps to establish a soundly based inspection system. These standards are of considerable benefit to national food control bodies since they help them to **reinforce their programmes, re-examine their priorities and train their control officers**.

The *Codex* standards and guidelines on inspection and certification systems for food imports and exports are published in its ***Food import and export inspection and certification systems***:
ftp.fao.org/codex/Publications/Booklets/Inspection/CCFICS_2012_EN.pdf.

In addition, the CAC has adopted the **Code of ethics for international trade in food**, including concessional and food aid transactions **(CAC/RCP 20-1979**). The objective of

this Code is to establish principles for the ethical conduct of international trade in food, in order to protect the health of consumers and ensure fair practices in the food trade.

❑ **Principles for food import and export inspection and certification (CAC/GL 20-1995)**

Inspection

The **examination of food or systems for the control of food**, raw materials, processing, and distribution, including in-process and finished product testing, in order to **verify that they conform to requirements**.

Certification

The procedure by which **official certification bodies** or **officially recognized certification bodies** provide written or equivalent **assurance that foods or food control systems conform to requirements**. Certification of food may be, as appropriate, based on a range of inspection activities, which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

Food inspection and certification systems should ensure that foods, and their production systems, meet the requirements laid down in order to protect consumer health and to facilitate **fair practices in the food trade** while ensuring that they do not give rise to unjustified technical barriers to trade.

This document sets out the key principles of the SPS and TBT Agreements: risk assessment, non-discrimination, international harmonization, equivalence, transparency, and special and differential treatment. It also involves assurance that the food inspection and certification systems, together with the control procedures and the validity of certification, are fully effective and fit for purpose.

❑ **Guidelines for food import control systems (CAC/GL 47-2003)**

This document provides a framework for the **development and operation of an import control system** complying with the principles of Codex CAC/GL 20-1995 and supplementing the guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997).

It establishes the general characteristics and conditions for implementation of food import control systems. Operational procedures should be developed and implemented to minimize undue delay at the point or points of entry without jeopardizing the effectiveness of the controls to meet requirements. Implementation should encompass the following elements:

- points of control;
- information about the food to be imported;
- frequency of inspection and testing of imported food;
- sampling and analysis conducted in official or licensed laboratories;

- criteria for decisions on the clearance of food imports;
- dealing with emergency situations (suspect products);
- recognition of exporting country control systems/certification agreements;
- information exchange between the competent authorities for exporting and importing countries;
- documenting the system;
- trained inspectorate.

The CAC has also adopted guidelines on:

- **determination of the equivalence** of food import and export inspection and/or certification systems and the **development of equivalence agreements**;
- design, production, issuance and use of **official certificates** to attest that food presented for international trade has met the importing country requirements relating to food safety, and/or ensuring fair practices in the food trade;
- **exchange of information between countries** on food control in emergency situations and on rejections of imported foods;
- **traceability of products** as a tool within a food inspection and certification system;
- **evaluation of the competence of testing laboratories** involved in the import and export control of foods.

1.4. World Organization for Animal Health standards

1.4.1. World Organization for Animal Health (OIE)

The need to fight animal diseases at the global level led to the creation of the Office International des Epizooties in 1924.It became the World Organization for Animal Health in 2003 but kept its historical acronym, OIE.

The OIE is the intergovernmental organization **responsible for improving animal health worldwide**. It has a total of 178 member countries and maintains permanent relations with 45 other international and regional organizations. It also has regional and sub-regional offices on every continent.

The OIE **draws up and adopts standards to ensure the sanitary safety of international trade in animals and animal products**, under the mandate conferred on it under the WTO SPS Agreement. The World Trade Organization **recognizes these standards, used as international reference rules**, in particular for settling trade disputes. They are compiled into two codes and two manuals:

- *The **Terrestrial Animal Health Code*** and the ***Aquatic Animal Health Code***, aimed at ensuring safe international trade in terrestrial and aquatic animals and their products. The Codes deal with the OIE's traditional spheres of responsibility, notably **animal health** and **zoonoses**. Over the past few years, its responsibilities have, however, extended to **animal welfare** and **food safety**.

- The ***Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*** and the ***Manual of Diagnostic Tests for Aquatic Animals***, which provide a **harmonized approach to the diagnosis of diseases** by describing the techniques recognized at international level.

The OIE also has as its mission:

- To **collect**, **analyses and disseminate** to the member countries **information** about the occurrence and development of **animal diseases and zoonoses throughout the world** and **ways of combating them**. This information is circulated through:
  - the World Animal Health Information Database (WAHID): www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home/indexcontent/newlang/en;
  - works and periodicals published by the OIE;
  - a system of emergency alerts (electronic distribution list).

  It provides member countries with the key elements for launching national programmes to combat diseases and to regulate animal health for the purposes of international trade.

- To **improve the safety of food of animal origin** by developing synergies with the activities of the CAC. The OIE normative activities in this area complement those of the CAC and focus on preventing dangers present before animals are slaughtered or their products are first processed (meats, milk, eggs, etc.), and that subsequently are likely to create risks for consumers.

- To **contribute its expertise and encourage international solidarity** to control animal diseases and zoonoses. The OIE provides technical support to member countries – in particular the poorest – requesting assistance with animal disease control and eradication operations, including diseases transmissible to humans.

- To **coordinate international studies** devoted to monitoring and combating animal diseases.

1.4.2. The sanitary safety Codes for terrestrial and aquatic animals

The terrestrial and aquatic Codes are available on the OIE Website at:
www.oie.int/en/international-standard-setting/terrestrial-code/access-online
www.oie.int/en/international-standard-setting/aquatic-code/access-online

These are **reference works** essential to **veterinary and competent authorities, import and export services, epidemiologists** and all **operators concerted by international trade** in terrestrial and aquatic **animals** and the products derived from them.

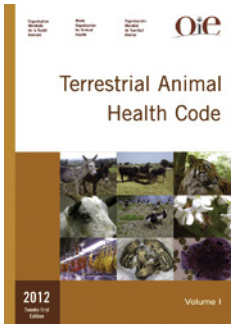
The sanitary measures deriving from the two Codes must be **applied by the veterinary authorities of importing and exporting countries** to provide for early detection, reporting and control of pathogenic agents and to prevent their transfer and dissemination to land and aquatic animals and to humans, while avoiding unjustified sanitary barriers to trade.

❑ **The Terrestrial Animal Health Code**

Scope

The standards compiled in the **Terrestrial Code** are intended to **improve animal health and welfare** as well as veterinary public health worldwide. To this end, the work contains normative texts to ensure **the safe international trade** in terrestrial animals (**mammals, birds and bees**) and their **derivative products**.

The Terrestrial Code, formerly called the “International Zoosanitary Code”, consists of two volumes.



The first volume sets out general provisions on:

- animal disease diagnosis, surveillance and notification;
- import risk analysis;
- quality of veterinary services;
- general recommendations on disease prevention and control;
- trade measures, import and export procedures and veterinary certification;
- veterinary public health;
- animal welfare.

The second volume is devoted to recommendations applicable to specific diseases of importance for international trade.

❑ **The Aquatic animal Health Code**

Scope

The standards compiled in the **Aquatic Code** are intended to **improve aquatic animal health and welfare** as well as veterinary public health worldwide. To this end, the work contains normative texts to ensure **the safe international trade** in aquatic animals (**amphibians, crustaceans, molluscs and fish**) and their **derivative products**.

The first part of the Aquatic Code lays down:

- provisions relating to the diagnosis, monitoring and notification of aquatic animal diseases, risk analysis and the quality of services responsible for aquatic animal health;
- general recommendations on disease prevention and control;
- trade measures, import and export procedures and health certification;
- guidelines for veterinary public health and the welfare of farmed fish.

A second part is devoted to recommendations on specific diseases. These recommendations are designed, on the basis of the nature of the goods marketed and the sanitary situation in the exporting country, to prevent the introduction into the importing country of the disease to which the recommendations relate. This means that, if correctly applied, they confer on the planned import an optimum level of sanitary safety based on the latest scientific knowledge and techniques available.

1.4.3. The Manuals of Diagnostic Tests and Vaccines for Terrestrial and Aquatic Animals

The *Terrestrial and Aquatic Manuals* are available on the OIE website at:
www.oie.int/en/international-standard-setting/terrestrial-manual/access-online
www.oie.int/en/international-standard-setting/aquatic-manual/access-online

❑ ***Manual of Diagnostic Tests and Vaccines for Terrestrial Animals***

Scope

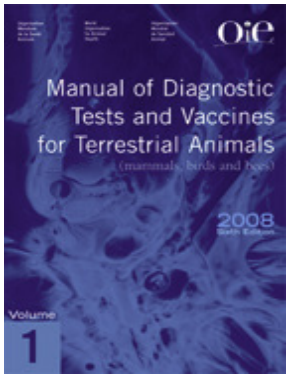
The objective of the ***Terrestrial Manual*** is to facilitate **international harmonization of methods for monitoring and controlling** the principal animal diseases.

It sets out the **approved standards for laboratory diagnostic tests** and for the **production** and **control** of veterinary biological products, primarily **vaccines**, used worldwide.

It deals with all the diseases listed by the OIE and associated diseases that may affect trade.

The *Terrestrial Manual* consists of two volumes.

The first volume relates to general standards on:



- sampling methods;
- quality management in veterinary testing laboratories;
- principles of veterinary vaccine production;
- biotechnology;
- validation of assays;
- tests for sterility;
- laboratory safety;
- the role of international institutions in regulating international veterinary biologicals;
- antimicrobial susceptibility testing.

The second volume includes chapters dealing with specific diseases. These chapters begin with a general overview of the diagnostic tests and vaccines available for the disease in question. This is followed by a case study intended for laboratory officers, which provides detailed information on the diagnostic tests and the recommended standards, if any, for vaccines and other biologicals. Bibliographic references are provided at the end of each chapter.

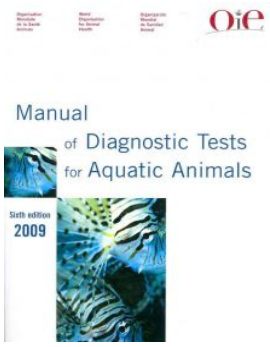
❑ ***Manual of Diagnostic Tests for Aquatic Animals***

Scope

The objective of the **Aquatic Manual** is to propose a **uniform approach for the diagnosis of the diseases** listed in the Aquatic Code so that the requirements for health certification in connection with trade in aquatic animals and aquatic animal products can be met.

The *Aquatic Manual* is a reference work describing the diagnostic techniques applicable to the diseases on the OIE list. It is intended for aquatic animal pathology laboratories

worldwide, and is designed to enhance their efficiency and promote developments in the field of global aquatic animal health.



The first part deals with:

- quality management in veterinary testing laboratories;
- principles and methods of validation of diagnostic assays for infectious diseases;
- methods for disinfection of aquaculture establishments.

The second part relates to recommendations applicable to specific diseases (diseases of amphibians, crustaceans, fish and molluscs).

1.5. International Plant Protection Convention standards

1.5.1. International Plant Protection Convention (IPPC)

The International Plant Protection Convention (IPPC) is a multilateral treaty (177 signatories) that aims to facilitate international cooperation to **control pests affecting plants and plant products** in order to prevent their spread worldwide, and particularly their introduction into endangered areas.

Adopted by the FAO in 1951 and revised in 1997 to comply with the SPS Agreement, this Convention **provides for the implementation of phytosanitary measures by governments to protect their plant resources** (cultivated and wild plants), while ensuring that these measures are justified and are not used as unjustified barriers to international trade.

The IPPC enables countries to analyses risks to their national plant resources and to use science-based measures to safeguard them.

The SPS Agreement strengthens the role of the IPPC with regard to trade, in particular by recognizing it as the organization responsible for drawing up and setting International Standards for Phytosanitary Measures (ISPMs). These standards constitute an important reference point for the WTO dispute-settlement mechanism.

In addition to setting ISPMs, the IPPC's activities include:

- reviewing the global status of plant protection and identifying measures to prevent the spread of posts to new areas;
- exchanging phytosanitary information (regulations and legislation, official pest reporting, pest-free areas, etc.) between contracting countries through the IPPC Website (International Phytosanitary Portal – IPP);
- providing technical assistance and capacity development, notably for developing countries, to assist with implementation of the Convention and the ISPMs;
- dispute settlement;
- cooperation with regional plant protection organizations (RPPOs) and certain international organizations, such as the WTO and the Convention on Biological Diversity (CBD), national and provincial governments, as well as with local authorities through national plant protection organizations (NPPOs). An RPPO is an intergovernmental organization that plays the role of a coordinating body at regional level for NPPOs. There are nine RPPOs.

1.5.2. International Standards for Phytosanitary Measures (ISPMs)

ISPMs are standards, guidelines and recommendations recognized as the basis for phytosanitary measures applied by WTO members under the SPS Agreement.

They are adopted by IPPC contracting parties through the Commission on Phytosanitary Measures (CPM), the IPPC governing body that contributes to the implementation of its objectives. IPPC non-signatory parties are encouraged to comply with these standards.

Any changes to import and export requirements must be communicated to the NPPOs.

The ISPMs relate to:

- procedures and references;
- pest surveillance, survey and monitoring;
- import regulations and pest risk analysis;
- compliance procedures and phytosanitary inspection methodologies;
- pest management;
- post-entry quarantine;
- exotic pest emergency response, control and eradication;
- export certification.

Thirty-six ISPMs have been adopted and are available on the IPPC Website: www.fao.org/docrep/010/a0785e/a0785e00.htm.

1.6. Internationally agreed commercial quality standards for agricultural produce

1.6.1. UNECE standards

The United Nations Economic Commission for Europe (**UNECE**) is one of five regional commissions of the United Nations. It is composed of 56 members, including Canada and the USA. It was set up in 1947 to develop economic activity and **strengthen economic relations** within the UNECE region and between this region and the rest of the world.

UNECE provides a regional forum for governments to develop conventions, norms and standards with the aim of **harmonizing** action and **facilitating** exchanges between member States. As such, UNECE provides consumer guarantees of safety and quality, helps protect the environment, and facilitates trade and the greater integration of member States at the regional level and also with the global economy.

The Committee on Trade (CT) works to develop closer economic relations among member States, as well as to better integrate their economies into the world economy. It makes policy recommendations, develops standards for use in trade and assists member States in implementing them. It also suggests ways and means of creating legal and administrative frameworks to foster trade, investment and the development of companies.

UNECE, through its Working Party on Agricultural Quality Standards, which reports to the Committee on Trade, **develops and promotes international commercial quality standards** for agricultural produce, covering a wide spectrum of agricultural products: **fresh fruit and vegetables** (including early and ware potatoes), **dry and dried products**, **potato plants, meat, eggs and egg-based products**, as well as **cut flowers**. These standards are used by governments, producers, importers, exporters and international organizations. They aim to:

- facilitate fair trade, preventing technical barriers to trade and providing a common trading language;
- promote sustainable production of quality agricultural produce;
- define minimum quality to keep unsatisfactory produce out of the market;
- establish transparent trade for the benefit of producers, traders and consumers.

UNECE quality standards for agricultural produce are structured as follows:

- **definition of produce**;
- provisions concerning **quality**:
  - minimum requirements: this relates to the appearance, whether it is sound, clean, affected by humidity, without odor and/or foreign taste, state of development and maturity; the development and condition of the produce

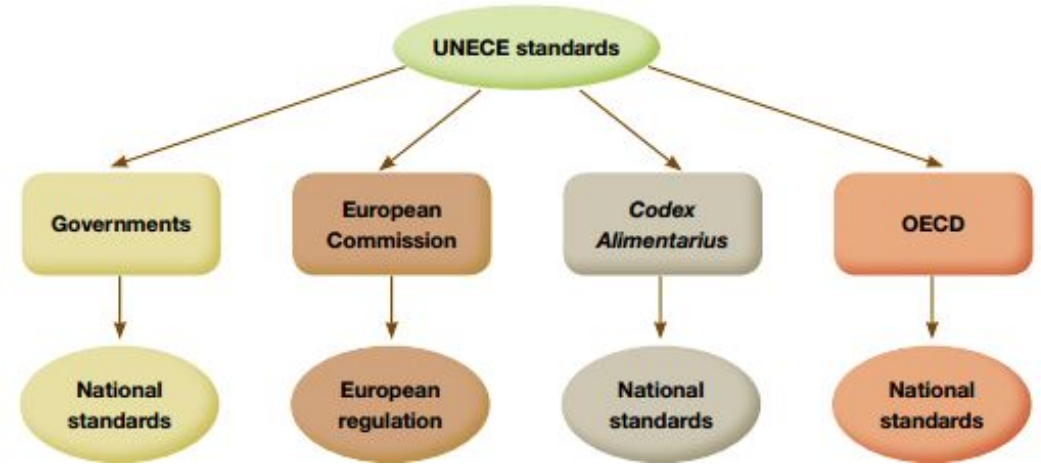
must be such as to enable it to withstand transportation and handling, and to arrive in satisfactory condition at the place of destination;

- classification in classes “Extra”, “I” and “II”, defined on the basis of the produce quality and the extent to which certain defects are present;

- provisions concerning **sizing**;
- provisions concerning **tolerances in respect of quality and size**;
- provisions concerning **presentation** (uniformity and packaging);
- provisions concerning **marking** (identification, nature of the produce, origin of the produce, commercial specifications and official control mark).

These standards are available on the UNECE Website:
www.unece.org/trade/agr/welcome.html

The procedure for implementation is as follows:



1.6.2. OECD standards

The Organization for Economic Co-operation and Development (OECD), established in 1960, provides a forum within which the governments of 34 countries can work together to **seek solutions** to economic, social and environmental problems posed by globalization. The Commission of the EU takes part in the OECD’s work.

The OECD has a **Scheme for the Application of International Standards for Fruit and Vegetables**, open to any member country of the United Nations or one of its Specialized Agencies, or of the World Trade Organization, that wants to take part in relation to all or some of the produce concerned. Twenty-three countries currently participate in the Scheme; intergovernmental organizations and NGOs also take part as observers.

The principal objectives of the OECD Scheme are to:

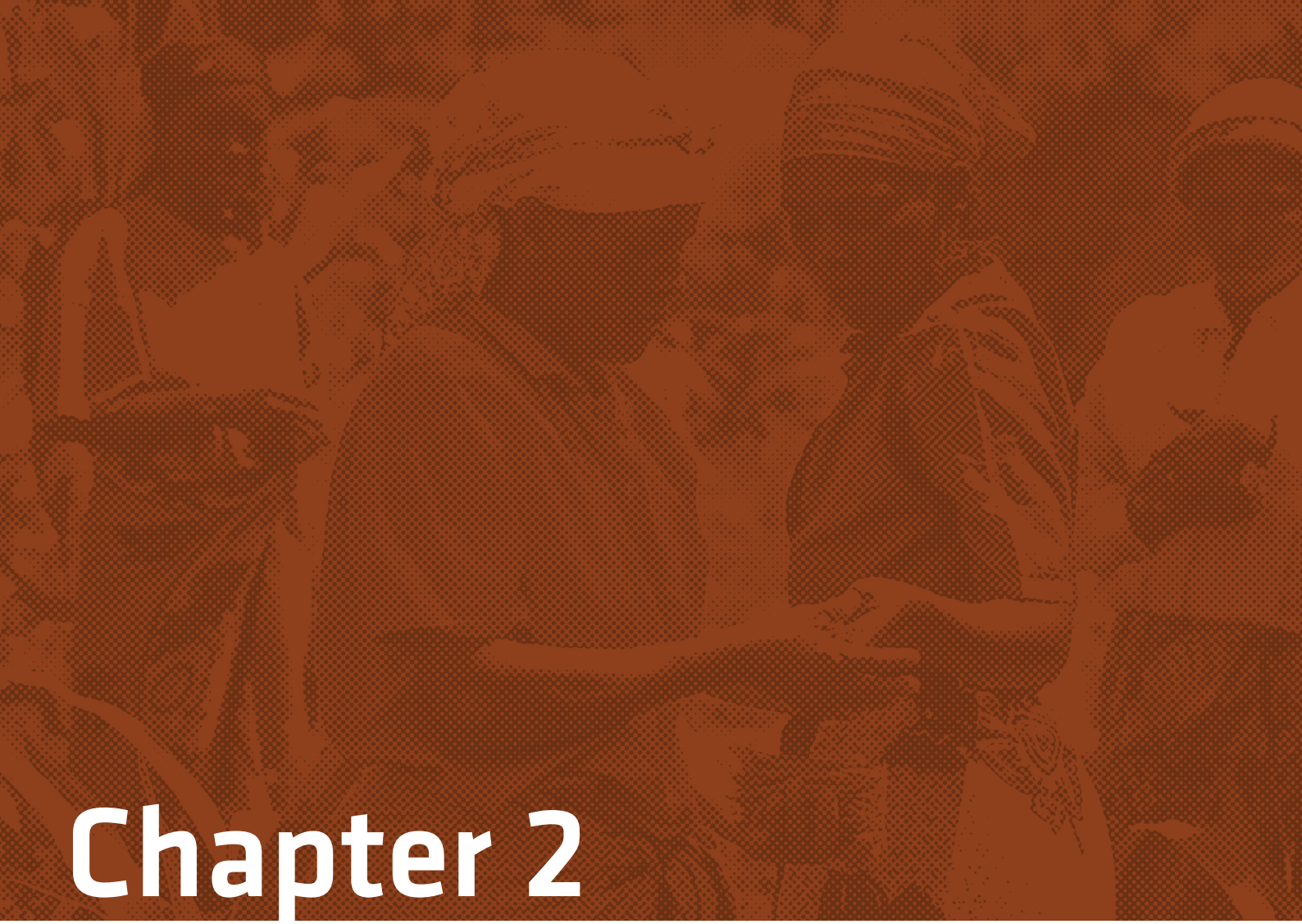
- facilitate the **adaptation of quality standards to present production, marketing and export conditions**;

- promote **uniform quality control procedures** and disseminate quality assurance guidelines;
- promote the use of an **internationally recognized control certificate**;
- improve the conditions for **maintaining the quality of produce during transport and handling**;
- promote international standardization of packaging and labelling;
- improve **conditions and quality assurance operations**.

The activities of the Scheme help producers, traders and quality inspectors by:

- developing and revising **standards** in cooperation with UNECE;
- developing **explanatory brochures for standards with photos**;
- developing **tools for gauging the skin color of various products**;
- providing **guidance** for the application of **quality assurance and inspection systems**.

OECD standards are **identical to UNECE standards** and have the **same structure**. **OECD standards for 50 fruits and vegetables** are available on the UNECE website: www.oecd.org/agriculture/code/fruitandvegetables.htm.



Chapter 2

Guidelines for strengthening national food control systems

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Developing a national food control strategy 52
Building blocks of a national food control system 55
Strengthening institutions responsible for national food control systems 63
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2.1. The need for national food control systems

2.1.1. Introduction

There is a need to review and strengthen the food control systems of many countries in order to make improvements to national food safety. In addition, the increasing global trade in food imposes certain responsibilities and obligations on both importing and exporting countries. Their systems must now be based on risk assessment and a preventative approach. The commonly accepted Food and Agricultural Organization (FAO) definition of food control is given below.

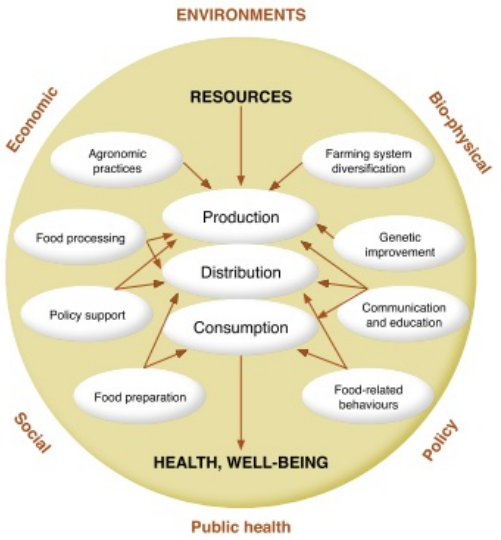
❑ **What is food control?**

"A mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labelled as prescribed by law".

❑ **The concept of 'system'**

"A group of interacting, interrelated, or interdependent elements forming a complex whole and designed to work as a coherent entity.

Food safety must be conceived as an "organized system" with the aim of meeting the regulatory objective of producing safe and suitable food".



Exports of food products by some ACP countries to Europe are an important component of their economy. The introduction in 2006 of EU regulation 882/2004 on (Sanitary and Phytosanitary, SPS) food and feed official controls requires third countries to have SPS food control systems that are equivalent to European Standards. Many businesses, particularly small producers who make up a large proportion of ACP suppliers, are finding it very difficult to implement some of these SPS requirements.

Dangerous pathogens and contaminants in food are on the increase as travel and tourism is growing. Foodborne diarrheal diseases, for example, reportedly kill over 2 million people globally every year. A significant number of these deaths occurs in poor countries, jeopardizing international development efforts. These occurrences however are not confined to developing countries. In 2007 it was reported that in the United States, foodborne diseases result in 37.2 million illnesses, 228,744 hospitalizations, and 2,612 deaths annually.[1] This initiative has generated a priority list of causal agents which is the focus for deriving global disease estimates.[2] Another part of the initiative will focus on studies at country level, with results expected in 2012.

Table 1: List of causative agents from which global disease estimates are to be derived according to WHO Task Force

Parasites	Enteric Pathogen	Chemicals and Toxins
Ancylostoma duodenale	Adenovirus	**Elementals contaminants**
Angiostrongylus cantonensis	*Aeromonas spp.*	Lead, mercury, cadmium, manganese, arsenic
Angiostrongylus costaricensis	Astrovirus	
Anisakis simplex	Bacterial toxins *(B. cerus)*	**Mycotoxins**
Ascaris lumbricoides	Bacterial toxins *(C. perfringens)*	Aflatoxins, ochratoxin, fumonisin, trichothocenes
Blastocystis hominis	Bacterial toxins *(S. aureus)*	
Capillaria philippinensis	*Brucella sp.*	**Food additives**
Clonorchis sinensis	*Campylobacter sp.*	Sulphites, nitrites/nitrates, benzoic acid
Cryptosporidium spp.	*Clostridium botulinum*	
Cyclospora spp.	*Enteroaggerative E. coli* (EAggEC) Entero-	**Pesticides**
Dicrocoelium dendriticum	pathogenic *E. coli* (EPEC)	Organophosphates, carbamates, DDT, pyrethrins
Dientamoeba fragilis	Entero-toxigenic *E. coli* (ETEC)	
Diphyllobothrium latum	Enterovirus	**Organic industrial contaminants**
Echinococcus spp.	*Helicobacter pylori*	Persistent organic pollutants
Echinostoma spp.	Hepatitis A virus	
Entamoeba histolytica	Hepatitis E virus	**Veterinary drugs/residues**
Fasciola spp.	*Listeria monocytogenes*	Antibiotics, hormones – but not antimicrobial residues
Fasciolopsis buski	*Mycobacterium bovis*	
Gastrodiscoides hominis	*Leptospira sp.*	**Seafood toxins**
Giardia intestinalis	Non cholera Vibrios	Tetrodotoxin, ciguatera, shellfish toxins, DSPs, PSPs, histamines
Gnathostoma spinigerum	Norovirus Prions Rotavirus	
Heterophyes heterophyes	*Salmonella* (non-typhoidal) *sp.*	
Hymenolepis nana	*Salmonella* (typhoid) *sp.*	
Isospora belli	Shigatoxin producing E. coli (STEC)	
Linguatula serata	*Shigella sp.*	
Metagonimus yokogawai	*Vibrio cholerae 01/0139*	
Nanophytes salmincola	*Yersinia sp.*	
Opisthorchis felineus		
Opisthorchis viverrini		
Paragonimus spp.		

[1] Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.-A., Roy, S.L., Jones, J.L. and Griffin, P.M., "Foodborne illnesses acquired in the United States– major pathogens", *Emerg. Infect Dis*., No. 17, 2011, pp. 7-15.

[2] WHO Initiative to Estimate the Global Burden of Foodborne Diseases, First formal meeting of the Foodborne Disease Burden Epidemiology Reference Group (FERG), Geneva, 26-28 November 2007.

Sarcocystis hominis *Taenia saginata* *Taenia saginata* *Taenia solium* *Toxocara spp.* *Toxoplasma gondii* *Trichinella spp.* *Trichostrongylus spp* *Trichuris trichiura*		**Process contaminants** Acrylamide, PAHs, choropropanol **Allergens** Peanuts **Natural toxicants** Cyanide in cassava, aminoglycosides **Radionuclides and depleted uranium**

Most countries have a food control system at some level or other, implying that food legislation relating to consumer protection must exist. One may then ask why significant numbers of people in developing countries in particular still suffer from food safety issues and why there are huge losses in food export trade.

There are several causes of food safety problems which are highlighted throughout this chapter. This information has been sourced from several reports available in the public domain. Most of the content of this booklet is adapted from the FAO publication guidelines **Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems**,[3] prepared to enable national authorities, particularly in developing countries, to improve their food control systems. The FAO and the World Health Organization (WHO) have a very strong interest in promoting national food control systems that are covering all sectors of the food chain and which are based on scientific principles.

The scope and requirements of food safety, including SPS measures (such as traceability, pesticide maximum residue levels, recalls etc.), are increasingly replacing tariff barriers as the main concern of African, Caribbean and Pacific (ACP) countries seeking to export to the European Union (EU).

SPS measures deal with food safety and animal and plant health standards and provide a fundamental element of the negotiations on economic partnership agreements (EPAs) foreseen under the Cotonou Agreement between the ACP groupings and the EU, as it directly affects ACP exporters' ability to benefit from opportunities that may arise (Scallan *et al.*, 2011).

The World Trade Organization (WTO) SPS Agreement encourages member countries to use standards set by international organizations (e.g. Codex Alimentarius; International Office of Epizooties, OIE; and International Plant Protection Convention, IPPC), but also allows members to set their own standards.

[3] www.fao.org/docrep/006/y8705e/y8705e00.htm.

2.1.2. How can the world's food supply be made safer and what are the particular problems faced by some developing countries?

❑ **Food systems**

The risk of exposing food to unhygienic conditions, contamination and adulteration increases as increasing amounts of food are handled by numerous food system operators. Problems occur as a result of poor postharvest handling, processing and storage of food and also due to inadequate facilities and infrastructure such as the absence or shortage of safe water supply, electricity, storage facilities including cold stores, good roads and transport facilities and road networks. Some of these are depicted below.

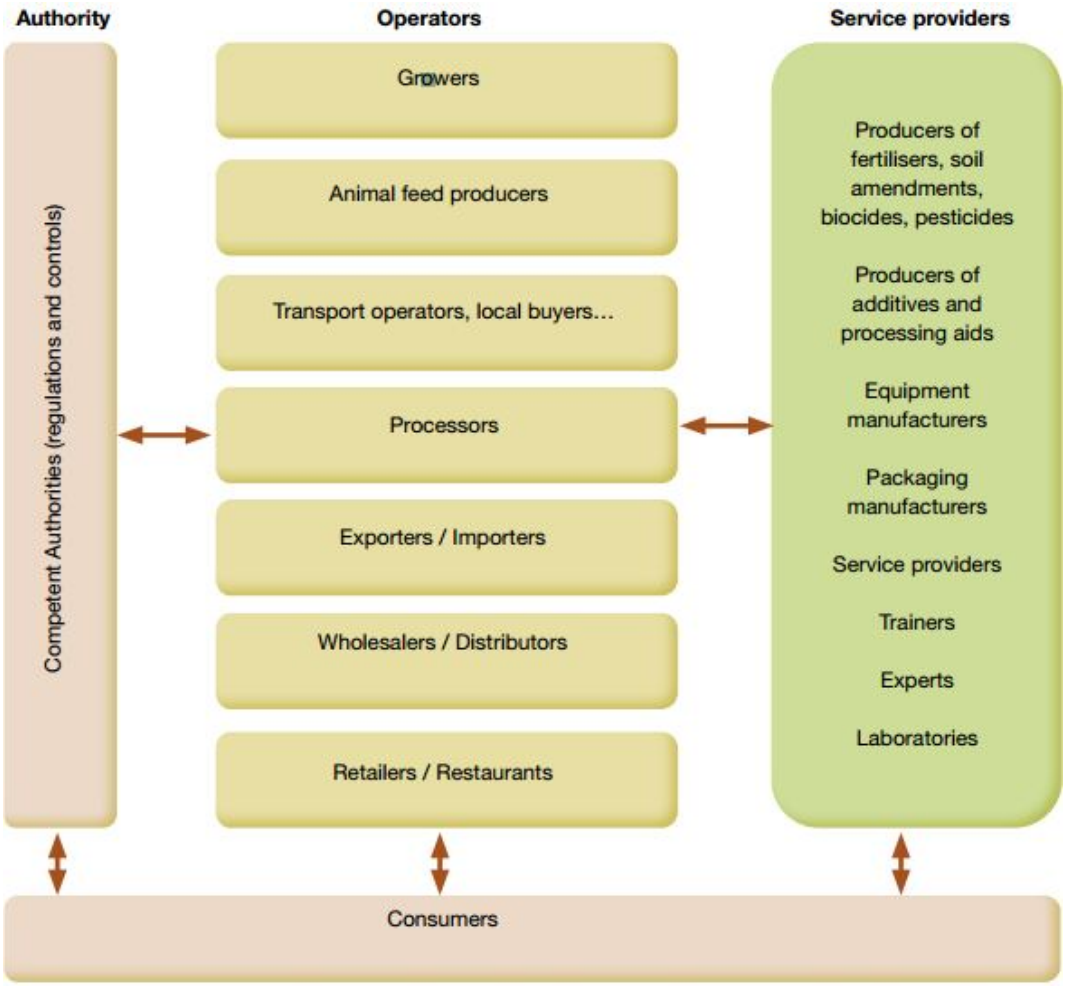
Poor roads

Simple storage

Modern cold store

The diagram below shows the actors in typical national, regional or global food systems, and the network of information flows.

Basic Food Safety Concepts



Source: Manual COLEACP, "Principles of hygiene and food safety management"

❑ Processing industries

The food processing industry in developing countries ranges from state-of-the-art facilities to small artisanal operations within the local community. With the latter, these premises are not equipped to address food safety and quality in a scientific and sustained way.

Food processors in developing countries also face problems with the delivery of raw materials, either with respect to quality reliability or timeliness of delivery. This necessitates greater vigilance by food business operators and adherence to food control activities through all stages along the farm to fork continuum.

❑ Street foods

Increasing urbanization is giving rise to an increased consumption of foods outside the home. Furthermore, some segments of the population depend entirely on street foods, having no access to their own cooking facilities. The safety of street foods is a cause for

concern, as they are often prepared and held under poor hygiene practices.

(*Source: mira terra images)*

(Source: Thrift Trip)

❑ **Particular problems faced by global food systems and rebuilding confidence**

Europe has witnessed a number of food health scares in the last few years. Some of these are highlighted below:

- 1997: **Numerous cases of BSE (mad cow disease)**

(Source: Health Picture)

- 1999: **Listeria – Illegal dioxin levels in chickens**
- 2001-2002: **Foot and Mouth disease, Genetically Modified Organisms, various meat origin frauds**
- 2003: **Sudan red dye**
- 2004: **Avian (bird) flu**
- 2006: **BTV – Catarrhal fever (blue tongue virus)**
- 2008: **Melamine-tainted milk powder**

Six babies died and 300,000 were ill (Source: Le Nouvel Observateur*)*

The Sudan red dye contamination of chilli powder stemming from India came about through traders (who had never before set eyes on the product) giving no consideration to its safety. The incident involved over 200 companies and over 700 product batch recalls in many countries. With the melamine example, 47 countries had imported

products contaminated with melamine, making the incident one of the largest deliberate food contamination incidents. Unsurprisingly, consumers still worry about food safety and quality issues and are increasingly seeking to be better informed.

In many countries, effective food control is undermined by fragmented legislation, multiple jurisdictions, weak surveillance, monitoring and enforcement.

These guidelines seek to provide advice to national authorities on strategies to strengthen food control systems to protect public health, prevent fraud and deception, avoid food adulteration and facilitate trade.

2.2. Developing a national food control strategy

2.2.1. Elements of a national food control system

Meeting the objectives of a national food control system needs a good understanding of the present situation, and the development of a national food control strategy. The Codex Alimentarius Commission (CAC), established by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), provides several guidelines and standards for food and agricultural products which have become virtually mandatory, as WTO also endorses these CAC standards through SPS and TBT agreements. Under these agreements, WTO member countries are encouraged to adopt internationally recognized standards whenever they exist. An important preventative approach that may be applied at all stages in the production, processing and handling of food products involves the Hazard Analysis and Critical Control Point (HACCP) system. The principles of HACCP have been formalized by the Codex Committee on Food Hygiene, and provide a systematic approach to the identification and control of foodborne hazards.

Governments should recognize the application of a HACCP approach by the food industry as a fundamental tool for improving the safety of food.

Success in the development and operation of food control can be achieved through a well-conceived national food control strategy developed with the support of all relevant stakeholders.

Agendas devised to achieve food control system objectives should be country specific. Whilst developing a national strategy, particular attention needs to be paid to international perceptions of food risks, socioeconomic factors, international standards, emerging food safety and quality issues, and any international commitments in the food safety area.

It would be difficult to meet food safety objectives without the cooperation of producers, traders, scientific community, industry and government. Since many consumers in developing countries have very low levels of confidence in official regulatory institutions they have had to develop and share localized knowledge about the quality and safety of the various foods to which they can have access. Therefore integrating information on these informal systems and local knowledge is extremely important.

The strategy will need to make sure adequate human resources and funds are available and well-coordinated. The strategy also establishes mechanisms for collaboration across all stakeholders, highlighting the role of governmental agencies, including provision for managing emerging health and economic challenges.

2.2.2. Collection of information

This is achieved through the collection and collation of relevant data in the form of a Country Profile. These data underpin:

- strategy development, with stakeholders reaching consensus on objectives;
- priorities;
- policies;
- roles of different ministries/agencies;
- industry responsibilities;
- timeframe for implementation.

In particular, major problems associated with the control and prevention of foodborne diseases are identified so that effective strategies for the resolution of these problems can be implemented.

The profile should permit a review of health and socioeconomic issues impacting on foodborne hazards, consumers' concerns, and the growth of industry and trade, as well as identification of the functions of all sectors which are directly and indirectly involved in ensuring food safety and quality and consumer protection.

The collection of epidemiological data on foodborne illness is an indispensable component of a country profile and should be done whenever possible

2.2.3. Development of a strategy

The preparation of a national food control strategy enables the country to develop an integrated, coherent, effective and dynamic food control system, and to determine priorities, which ensure consumer protection and promote the country's economic development. Such a strategy should provide better coherence in situations where there are several food control agencies involved with no existing national policy or overall coordinating mechanism. In such cases, it prevents confusion, duplication of effort, inefficiencies in performance, and wastage of resources.

The strategy should:

- be based on multi-sectoral inputs;
- focus on the need for food security;
- focus on the need for consumer protection from unsafe adulterated or misbranded food;
- take into consideration the economic interests of the country in regard to export/import trade;
- consider the development of the food industry;
- consider the interests of farmers and food producers;
- use a risk based approach to determine priorities for action.

Areas for voluntary compliance and mandatory action should be clearly identified, and timeframes determined. The need for human resource development and strengthening of infrastructure such as laboratories should be also considered.

Certain types of food control interventions require large fixed capital investments in equipment and increased investment in human resources. While it is easier to justify these costs for larger enterprises, imposing such costs on smaller firms who may coexist with larger enterprises may not be appropriate. Therefore the gradual phasing in of such interventions is desirable.

For example, countries may allow small enterprises longer periods of time to introduce HACCP based systems.

The strategy will be influenced by the country's stage of development, the size of its economy, and the level of sophistication of its food industry. The final strategy should include:

- a national strategy for food control with defined objectives, a plan of action for its implementation, and milestones;
- development of appropriate food legislation, or revision of the existing legislation to achieve the objectives defined by the national strategy;
- development or revision of food regulations, standards and codes of practice as well as harmonizing these with international requirements;
- a programme for strengthening food surveillance and control systems;
- promotion of systems for improving food safety and quality along the food chain, *i.e*. introduction of HACCP-based food control programmes;
- development and organization of training programmes for food handlers and processors, food inspectors, and analysts;
- enhanced inputs into research, foodborne disease surveillance, and data collection, as well as creating increased scientific capacity within the system;
- promotion of consumer education and other community outreach initiatives.

2.2.4. Organizational structure

It is important to consider the type and size of the organization necessary to implement the strategy during the preparation of a national food control strategy. Owing to existing well-established agency structures, it may not be possible to join them together. In such cases, it is necessary for the national food control strategy to clearly identify, and if necessary review, the role of each agency to avoid duplication of effort and to bring about coordination, identifying segments of the food chain which need additional resources for strengthening.

2.3. Building blocks of a national food control system

2.3.1. Introduction

Through national food control systems, **governments should provide a supporting infrastructure and assume an advisory and regulatory role**.

When seeking to establish, update, strengthen or otherwise revise food control systems, national authorities must take into consideration a number of principles and values that underpin food control activities.

Food control systems should cover all food produced, processed and marketed within the country, including imported food.

2.3.2. Integrated farm-to-fork concept

The objective of reduced risk can be achieved most effectively by the principle of prevention throughout the production, processing and marketing chain. To achieve maximum consumer protection it is essential that safety and quality be built into food products from production through to consumption.

This calls for a comprehensive and integrated farm-to-fork approach in which the producer, trader, processor, transporter, vendor, and consumer all play a vital role in ensuring food safety and quality.

It is impossible to provide adequate protection to the consumer by merely sampling and analyzing the final product.

The introduction of preventive measures at all stages of the food production and distribution chain, rather than only inspection and rejection at the final stage, makes better economic sense, because unsuitable products can be identified earlier along the chain. Many but not all potential food hazards can be controlled along the food chain through the application of good practices, *i.e.* Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP).

❑ **Control of food safety is based on a number of principles**

The Precautionary Principle

The precautionary principle states that: where there is evidence to indicate presence of an unacceptable risk to consumer safety, action shall be taken to minimize that risk and protect consumer health, even if the supporting scientific evidence required for a

comprehensive risk assessment has yet to be gathered. Such actions or measures shall be temporary until such time that the scientific evidence is obtained and a risk assessment conducted.

This principle forms the foundation of food safety in EU legislation (EU Regulation 178/2002 Article 7), although not yet included in the *Codex* global standards.

Principles of Risk Analysis

European food law, and its implementation, is based on the principles of risk analysis, using available scientific evidence undertaken in an independent, objective and transparent manner (EU Regulation 178/2002, Article 6).

Codex has defined risk analysis as a process that is composed of risk assessment, risk management and risk communication.

Principle of Due Diligence

With respect to the supply of food, due diligence is the requirement that those responsible are able to demonstrate with objective evidence that all reasonable precautions have been taken to ensure the safety of food; the objective evidence being the documented procedures and records.

Equivalence Principle

Access to EU markets by third countries is dependent on both the food safety control systems implemented throughout the supply chain, and the controlling authority being in a position to guarantee 'equivalence' with the requirements set out in EU legislation (EU Regulation 178/2002, Article 11). Where 'equivalence' is defined as capability of different systems or measures to meet the same objectives, the term 'equivalent' means different systems or measures capable of meeting the same objectives. The ability of a third country's control systems to meet equivalent objectives is subject to scrutiny by the European Commission's Food and Veterinary Office, FVO (Scallan *et al.*, 2011), the inspection wing of the Health and Consumers Directorate-General (DG SANCO). The FVO is also responsible for assessing the guarantees on paper given by all third countries in the context of their residue control plans.

Approved residue control plans are a pre-requisite for any third country wishing to export food of animal origin to the EU.

2.3.3. Food Law and Regulations

The development of relevant and enforceable food laws and regulations is an essential component of a modern food control system. **Many countries have inadequate food legislation and this will impact on the effectiveness of all food control activities carried out in the country.** Food law has traditionally consisted of legal definitions of unsafe food, and the prescription of enforcement tools for removing unsafe food from

commerce and punishing responsible parties after the fact. It has generally not provided food control agencies with a clear mandate and authority to prevent food safety problems. The result has been **food safety programmes that are reactive and enforcement oriented rather than preventive and holistic** in their approach to reducing the risk of foodborne illness. To the extent possible, modern food laws not only contain the necessary legal powers and prescriptions to ensure food safety, but also allow the competent food authority or authorities to build preventive approaches into the system.

Source: ec.europa.eu)

In addition to legislation, governments need updated food standards.

The establishment of formal food safety regulations and standards in developing countries, of the sort used in industrialized countries, has often depended on the requirements of urban and international sales.

For example, shrimp farmers in Thailand only started treating their stock with antibiotics to comply with the microbiological requirements for imports into industrial countries, and to match the performance of competitors in Brazil and Vietnam (Holmes *et al*., 2006). International trade may have a greater impact on formal food safety systems in developing countries than domestic trade. When outbreaks of Rift Valley Fever (RVF) in East African livestock are reported for example, exports to Arabian markets are blocked, which weakens the predicament of African pastoralists and livestock keepers but their food and veterinary safety governance regimes have not yet helped eradicate or control RVF (OIE, 2009).

In preparing food regulations and standards, countries should consult Codex standards and food safety lessons learned in other countries. Taking into account the experiences in other countries while tailoring the information, concepts and requirements to the national context is the best way to develop a modern regulatory framework that will both satisfy national needs and meet the demands of the SPS Agreement and trading partners.

The performance of the relevant competent authority in the overall operation of a national control system, especially its ability to transpose, implement and enforce EU legislative standards effectively, is now the focus of importing countries.

The way in which government policy and institutions respond to the issues arising from unsafe foods varies among the developing and more advanced countries. The foremost responsibility of food control is to enforce the food laws protecting the consumer against unsafe, adulterated and unauthentic food by prohibiting the sale of food not of the nature and or quality demanded by the purchaser.

Regulation (EC) 178/20024[4] (General Food Law) clearly defines the responsibilities of the various authorities and food business operators (Poudelet, 2010):

Operators must

- Ensure that food hygiene conditions are met at every stage of production
- Place on the market products that comply with standards
- Ensure the traceability of processes and products
- Be able to withdraw non-compliant products immediately and to warn customers.
- Keep the authorities informed and cooperate with them

Competent Authorities must

- Establish the regulations and standards applicable to the products
- Evaluate sanitary and phytosanitary risks transparently and independently
- Define a food safety policy (objectives)
- Draw up a programme for official controls and set up these controls
- Communicate information on food safety and risks

The Feed and Food Controls Regulation 882/04 has been introduced to complement the umbrella Regulation 178/2002 which sets out the basic principles of food safety within the EU. Regulation 882/04 establishes how these basic principles will be interpreted, implemented and enforced in a harmonized manner by the EU and Member States' authorities through official controls of both EU produced and imported feed and foods.

Improving food safety in informal supply chains raises questions at both the technical and organizational levels. These are areas where there are no ready-made solutions, either because knowledge is lacking on the incidence and characteristics of hazards, or because the nature of the supply chain is such that imported solutions are not entirely suitable without modification – for instance, the need to allow for scattered actors, for the lack of integration of the chain, for rudimentary processing technologies, etc. In such situations, it has become popular to look for 'HACCP-type' approaches to quality management. The aim is not to introduce programmes involving the full HACCP system (complete with documentation, recordkeeping, and internal audits), but rather to use the HACCP approach as a guide to determining problems and solutions.

2.3.4. Transparency

A food control system must be developed and implemented with transparency. The confidence of consumers in the safety and quality of the food supply depends on their perception of the integrity and effectiveness of food control systems. Therefore it is important that all decision-making processes are made open and transparent and ensure active participation of all stakeholders in the food chain.

Food control authorities should also examine the way they inform the public of food safety information. This may comprise scientific opinion on food safety, overviews of inspection activity, and findings on foods implicated in foodborne illnesses, food poisoning episodes, or gross adulteration. This constitutes part of risk communication to enable consumers to

[4] Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *OJEU*, L31/1 of 1 February 2002.

better understand the risks and their responsibilities for minimizing the impact of foodborne hazards.

2.3.5. Inspection services

The administration and implementation of food laws require a qualified, trained, efficient and honest food inspection service.

The food inspector is the key functionary who has day-to-day contact with the food industry, trade and often the public.

The responsibilities of the inspection services include:

- inspecting premises and processes for compliance with hygienic and other requirements of standards and regulations;
- evaluating HACCP plans and their implementation;
- sampling food during harvest, processing, storage, transport, or sale to establish compliance, to contribute data for risk assessments and to identify offenders;
- recognizing different forms of food decomposition by organoleptic assessment; identifying food which is unfit for human consumption; or food which is otherwise deceptively sold to the consumer; and taking the necessary remedial action;
- recognizing, collecting and transmitting evidence when breaches of law occur, and appearing in court to assist prosecution;
- encouraging voluntary compliance in particular by means of quality assurance procedures;
- carrying out inspection, sampling and certification of food for import/export inspection purposes when so required;
- in establishments working under safety assurance programmes such as HACCP, conduct risk-based audits.

Proper training of food inspectors is a prerequisite for an efficient food control system.

The food inspector must:

- be trained in food science and technology to understand the industrial processes, identify potential safety and quality problems;
- have the skill and experience to inspect the premises, collect food samples and carry out an overall evaluation;
- have a good understanding of the relevant food laws and regulations, their powers under those laws, and the obligations such laws impose on the food sector;
- be conversant with procedures for collecting evidence, writing inspection reports, collecting samples and sending them to a laboratory for analysis;
- be trained to handle HACCP audit responsibilities.

There is continuous need for training and upgrading the skills of existing inspection staff with a policy for human resource development. As human resources in some food control agencies in developing countries may be limited, environmental health inspectors are often also asked to work as food inspectors. This is not ideal as they may lack the

skills and knowledge to effectively evaluate and inspect food operations. If environmental health inspectors must be used, then they should be carefully supervised and provided with on-the-job training.

2.3.6. Laboratory Services: Food Monitoring and Epidemiological Data

Due to the globalization of animal, food trade, and increased tourism, national food safety issues can have global implications. Laboratory-based surveillance of animals, food and humans is important, both to detect and prevent foodborne pathogens from entering or spreading through the food chain, as well as to identify foodborne disease outbreaks so that appropriate control measures can be taken.

(Source: DERONI)

Many countries still lack the necessary surveillance capacity for foodborne disease outbreak detection and response.

In addition, many foodborne disease outbreaks go undetected, in part due to lack of communication between the human, veterinary, and food sectors. An important element of a national food control system is its integration in a national food safety system so that links between food contamination and foodborne diseases can be established and analyzed.

Access to reliable and current intelligence on the incidence of foodborne illness is critical. The laboratory facilities for this type of activity are generally situated outside the food control agencies. It is essential that effective linkages are established between food control agencies and the public health system including epidemiologists and microbiologists. In this way information on foodborne diseases may be linked with food monitoring data, and lead to appropriate risk-based food control policies. This information includes:

- annual incidence trends;
- identification of susceptible population groups;
- identification of hazardous foods;
- identification and tracing of causes of foodborne diseases;
- the development of early warning systems for outbreaks and food contamination.

In response to the impact of foodborne and other infectious enteric diseases, WHO, in collaboration with other partners created The Global Foodborne Infections Network (GFN). GFN is part of WHO's endeavors to strengthen the capacities of its Member States in the surveillance and control of major foodborne diseases and to contribute to the global effort of containment of antimicrobial resistance in foodborne pathogens (Scallan *et al*., 2011).

Laboratories are an essential component of a food control system. The establishment of laboratories requires considerable capital investment and they are

expensive to maintain and operate. Therefore careful planning is necessary to achieve optimum results. The number and location of the laboratories should be determined in relation to the objectives of the system and the volume of work. If more than one laboratory is required, consideration should be given to apportioning the analytical work to achieve the most effective coverage of the food analyses to be performed and also to having a central reference laboratory equipped for sophisticated and reference analyses.

All food analysis laboratories may not be under the control of a single agency or ministry, and a number could be under the jurisdiction of the states, provinces and local authorities. The Food Control Management should, however, lay down the norms for food control laboratories and monitor their performance.

The laboratories should have adequate facilities for physical, microbiological and chemical analyses. In addition to simple routine analysis, the laboratories can be equipped with more sophisticated instruments, apparatus and library facilities as required.

It is not only the type of equipment that determines the accuracy and reliability of analytical results but also the qualification and skill of the analyst and the reliability of the method used. The analytical results of a food control laboratory are often used as evidence in a court of law to determine compliance with regulations or standards of the country. It is therefore necessary that utmost care be taken to ensure the efficient and effective performance of the laboratory.

The introduction of analytical quality assurance programmes and accreditation of the laboratory by an appropriate accreditation agency within the country or from outside, enables the laboratory to improve its performance and to ensure reliability, accuracy and repeatability of its results. Prescription of official methods of sampling and analysis also support this effort.

2.3.7. Information, Education, Communication and Training

An increasingly important role for food control systems is the delivery of information, education and advice to stakeholders across the farm-to-fork continuum. These activities include the provision of balanced factual information to consumers; the provision of information packages and educational programmes for key officials and workers in the food industry; development of train-the-trainer programmes; and provision of reference literature to extension workers in the agriculture and health sectors.

(Source: Dadamac)

Food control agencies should address the specific training needs of their laboratory analysts as a high priority. These activities provide an important means of building food control expertise and skills in all interested parties, and thereby serve an essential preventive function.

2.3.8. SPS-related assistance

The international standard-setting bodies have substantial programmes related to SPS capacity building. Some of these include the International Office of Epizooties (OIE); International Plant Protection Convention (IPPC) (see www.ippc.int); World Bank; The Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA); Inter-American Institute for Cooperation on Agriculture (IICA); United Nations Industrial Development Organization (UNIDO); The United Nations Conference on Trade and Development, (UNCTAD); Standards and Trade Development Facility (STDF); and EU technical assistance programmes targeted at helping ACP countries.

2.4. Strengthening institutions responsible for national food control systems

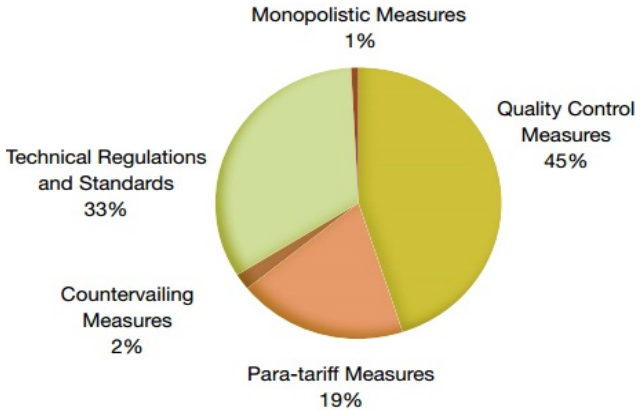
2.4.1. Introduction

As highlighted in the previous unit, many countries have inadequate food legislation and this will impact on the effectiveness of all food control activities. Institutional obstacles to reforms can be considerable and can create disincentives for development of industry, causing significant damage to national economy.

2.4.2. Food legislation

In many countries, existing food legislation is outdated and needs reviewing. The FAO/WHO Model Food Law can provide guidance but with local conditions taken into account. The 'Model Food Law'[5] lays down general principles, basic definitions, responsibilities for implementation, inspection and analytical requirements, penalties, and powers. The model food law suggests a central advisory committee, which will adopt a co-ordination role, with inputs from industry and consumers, making recommendations on food standards and other regulations. It is therefore recommended that governments also set up National Codex Committees if they have not already done so. According to an FAO report on non-tariff measures and agricultural trade, differing standards between trading partners have increased the number of notifications of technical measures to WTO (Figure 2), with over two-thirds of SPS notifications from OECD countries and more than half related to food safety.[6]

Non-tariff measure in the agro-food sector by type of measure



[5] Vapnek, M. and Spreij, J., *Perspectives and guidelines on food legislation, with a new model food law*, Rome, FAO, 2005.

[6] "Non-tariff measures in agricultural trade", FAO, 2005, www.fao.org/docrep/005/y4852e/y4852e14.htm.

2.4.3. Compliance

A compliance policy is an official statement or group of statements that establish specific or general limits to which products; processes or conditions must comply and be, in accordance with relevant laws and regulations. **Such compliance policies are again seriously lacking in many developing countries.** The policy serves the purpose of helping in administering, interpreting and assisting in implementing the law and leads to uniform application of the law, transparency, provides specific instructions and guidance for the agency staff and on compliance matters to the industry.

Development of a compliance policy necessitates a legal authority, resources, scientific expertise, community support, and a periodic review process. Effective application of the policy must also however be addressed as this can be an issue across many countries. In a study undertaken in 2006 on small to medium-sized food enterprises (SMEs) in the UK,[7] a significant number of food SMEs stated that Environmental Health Practitioners (EHP) for example had inconsistent approaches towards compliance, undermining the perceived food safety importance of the non-compliance.

In the same study, many SMEs still appeared to rely on the EHP to advise them of non-compliant areas within the premises, and were not proactive. The monitoring of food safety requirements was not common owing to the SMEs' lack of management systems. This especially related to activities such as temperature control. And until a formal EHP inspection was undertaken, this went undetected. It was suggested that in order for SMEs to address non-compliances, the perception that action would be taken by authorities was required.

❑ The role for Government in promoting food safety

In addition to the lack of institutional infrastructure at the regional and local levels, and lack of information regarding various standards applicable to their products in different countries, SMEs have identified a number of key constraints. These include frequent changes in packaging, labelling, and other product-quality norms in other countries; lack of availability of efficient and economical technology at the local level for achieving the desired level of quality; and lack of skilled personnel for quality processing; lack of incentive to invest costlier technology when there is a huge domestic market for which the prescribed level of minimum quality is much lower than in international markets. Industry must play its role in assuring food quality and safety through the application of quality assurance and risk-based food safety systems utilizing current scientific knowledge.

The implementation of such controls throughout production, handling, processing and marketing leads to improved food quality and safety, increased competitiveness; and, reduction in cost of production and wastage. Thus, government have a role to play in supporting SMEs.

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[7] Yapp, C. and Fairman, R., "Factors affecting food safety compliance within small and medium-sized enterprises: implications for regulatory and enforcement strategies", *Food Control*, No. 17, 2006, pp. 42-51.

The presence of national standard-setting organizations, testing and training centers, and other supporting organizations at the local and regional levels – especially near the major clusters of food and agricultural firms – can act as catalysts in increasing the demand for higher quality in developing countries.[8]

With regards to the interface between the public sector and the public at large, if consumers are to be able to play a more effective role in protecting themselves from foodborne diseases, health education is essential.

Another area for public sector action is research. The research needs of developing countries in the food safety area are multiple, and cover the entire range of risk assessment and quality assurance activities. **In many supply chains there is a need for better understanding hazards** – their characterization and their incidence – and how to control them. Low-cost methods are needed both for hazard detection and remediation. These are areas where the private sector is unlikely to have the resources to do or fund the work on its own. Public private collaboration is needed for research on hazard management; so is collaboration with teams from countries with greater experience in these areas, including other developing countries. Many workshop participants in the study above (Yapp and Fairman, 2006) stressed the key role that could be played by regional networks to address the particular challenge of laboratory quality in this work. The other part of the risk assessment equation relates to the epidemiological aspects: **exposure rates of the population and sensitivity to food-borne contaminants**. This is an area where there is little direct knowledge pertaining to developing countries. Yet it could be important, both because certain foodstuffs are specific to developing countries and because populations may not have the same levels of tolerance, to conduct original research in this area rather than relying on extrapolations from research done elsewhere. Here again, collaboration among countries could be a key way to proceed.

Another important area where an important public sector role was stressed is in the international arena. **Governments that are not actively present in the WTO and the international standard-setting bodies like the Codex Alimentarius Commission are unable to support their domestic food industries**. This is a critical area for developing countries, both to help determine the agenda of work done on standards, and to defend their industries in the WTO dispute resolution process, once specific trade problems crop up.[9]

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[8] Gupta, K.B. and Saghaian, S.H., "An Institutional Framework for Meeting International Food-Safety Market Standards from a Developing-Country Perspective", *Journal of Food Distribution Research*, vol. 39, No. 1, 2008.

[9] Hanak, E. Boutrif, E., Fabre, P. and Pineiro, M., "Food Safety Management in Developing Countries", Proceedings of the International Workshop, CIRAD-FAO, 11-13 December 2000, Montpellier, France.

2.5. Types of organizational structure for national food control systems

Food control systems may be fragmented between national, state and local bodies, and the thoroughness of implementation depends upon the capacity and the efficiency of the agency responsible at each level. Thus consumers may not receive the same level of protection throughout the country and it may become difficult to properly evaluate the effectiveness of interventions by national, state or local authorities.

While multiple food control agencies may be the norm, they suffer from serious drawbacks including:

- lack of overall coordination at national level;
- frequent confusion over jurisdiction and resultant inefficiencies in performance;
- differences in levels of expertise and resources and hence uneven implementation;
- conflict between public health objectives and the facilitation of trade and industry development;
- limited capacity for appropriate scientific inputs in decision-making processes;
- lack of coherence leading to over-regulation or time gaps in adequate regulatory activity;
- reductions in the confidence of domestic consumers and foreign buyers in the credibility of the system.

There are a number of organizational arrangements that may be appropriate at the national level for food control systems.

2.5.1. Multiple Agency System

Food control systems play a significant role in the following:

- ensuring fair practices in trade;
- developing the food sector on a professional and scientific basis;
- preventing avoidable losses and conserving natural resources;
- promoting the country's export trade.

The systems that deal specifically with these objectives can be sectoral *i.e.* based upon the need for development of the particular sector such as fisheries, meat and meat products, fruit and vegetables, milk and milk products. These systems can be mandatory or voluntary, and put into effect either through a general food law or a sectoral regulation.

Examples include:

- An export inspection law that identifies foods to be covered for mandatory export inspection prior to export; or offers facilities for voluntary inspection and certification for exporters.
- Specific commodity inspection regulations, such as for fish and fish products, meat and meat products, or fruit and vegetable products which are implemented by different agencies or ministries given this mandate under relevant law(s).
- Regulated systems for grading and marking of fresh agricultural produce which go directly for sale to the consumer or as raw material for industry. They are mostly confined to quality characteristics so that the producer gets a fair return for his produce and the buyer is not short-changed.

Where sectoral initiatives have resulted in the establishment of separate food control activities, the outcome has been the creation of multiple agencies with responsibilities for food control. Typically, under such arrangements the food control responsibilities are shared between Government Ministries such as Health, Agriculture, Commerce, Environment, Trade and Industry, and Tourism, and the roles and responsibilities of each of these agencies are specified but quite different. **This sometimes leads to problems such as duplication of regulatory activity, increased bureaucracy, fragmentation, and a lack of coordination between the different bodies involved in food policy, monitoring, and control of food safety.** For example, the regulation and surveillance of meat and meat products may be separate from food control undertaken by a Ministry of Health. Meat inspection is often done by Ministry of Agriculture or primary industry personnel who undertake all veterinary activities, and the data generated may not be linked to public health and food safety monitoring programmes.

2.5.2. Single Agency System

The consolidation of all responsibility for protecting public health and food safety into a single food control agency with clearly defined terms of reference has considerable merit. It acknowledges the high priority that Government places in food safety initiatives and a commitment to reducing the risk of foodborne disease. The benefits that result from a single agency approach to food control include:

- uniform application of protection measures;
- ability to act quickly to protect consumers;
- improved cost efficiency and more effective use of resources and expertise;
- harmonization of food standards;
- capacity to quickly respond to emerging challenges and the demands of the domestic and international marketplace;
- the provision of more streamlined and efficient services, benefiting industry and promoting trade.

While a national strategy helps to influence both the legislation and the organizational structure for enforcement**, it is not possible to recommend a single organizational structure that will universally meet the requirements**.

2.5.3. Integrated System

Integrated food control systems warrant consideration where there is desire and determination to achieve effective collaboration and coordination between agencies across the farm-to-fork continuum. Typically, the organization of an integrated food control system would have several levels of operation:

Level 1: Formulation of policy, risk assessment and management, and development of standards and regulations.
Level 2: Coordination of food control activity, monitoring, and auditing.
Level 3: Inspection and enforcement.
Level 4: Education and training.

In reviewing and revising their food control systems, governments may wish to consider a model which calls for the establishment of an autonomous national food agency which is responsible for activities at Levels 1 and 2, with existing multi-sectoral agencies retaining responsibility for Level 3 and 4 activities. The advantages of such a system include:

- providing coherence in the national food control system;
- politically more acceptable as it does not disturb the day to day inspection and enforcement role of other agencies;
- promoting uniform application of control measures across the whole food chain throughout the country;
- separating risk assessment and risk management functions, resulting in objective consumer protection measures with resultant confidence among domestic consumers and credibility with foreign buyers;
- better equipped to deal with international dimensions of food control such as participation in work of Codex, follow-up on SPS/TBT Agreements etc.;
- encouraging transparency in decision-making processes, and accountability in implementation;
- being more cost-effective in the long term.

Responding to these benefits, several countries have established or are in the process of creating such a policy making and coordinating mechanism at the national level.

By placing management of the food supply chain under a competent, autonomous agency, it is possible to fundamentally change the way food control is managed. The role of such an agency is to establish national food control goals, and put into effect the strategic and operational activities necessary to achieve those goals. Other functions of such a body at the national level may include:

- revising and updating the national food control strategy as needed;
- advising relevant ministerial officials on policy matters, including determination of priorities and use of resources;
- drafting regulations, standards and codes of practice and promoting their implementation;
- coordinating the activity of the various inspection agencies, and monitoring performance;
- developing consumer education and community outreach initiatives and promoting their implementation;
- supporting research and development;

- establishing quality assurance schemes for industry and supporting their implementation.

An integrated National Food Control Agency should address the entire food chain from farm-to-fork, and should have the mandate to move resources to high priority areas and to address important sources of risk. The establishment of such an agency should not involve day-to-day food inspection responsibilities. These should continue to lie with existing agencies at national, state/provincial, and local levels. The agency should also consider the role of private analytical, inspection, and certification services particularly for export trade.

While the actual structure of a National Food Control Agency will vary from country to country, the following notes describe the role, components, and activities of a typical agency:

- independent of any specific sectoral interest/Ministry and of the food industry;
- governed by a Management Board with a Chairperson and Directors;
- management Board has wide ranging powers, including the formulation of food control policy and the provision of advice to Government;
- provides a coordinating mechanism for uniform implementation of food control activities;
- adopts a strategic view across the whole food chain and consults widely with all sectors of the food chain and all interest groups to ensure public involvement in the policy making process;
- utilizes an open and transparent decision-making process, and able to make public its views on issues related to food safety, public health, and food control;
- operates under the principle of protecting the health status of the consuming public, and providing information and advice that enables consumers to make informed choices;
- responsibilities include the identification of legislative needs; monitoring the efficiency and effectiveness of law enforcement and food surveillance activities; commissioning research etc.;
- statutory powers to coordinate, monitor and audit local agency and provincial food control activities, including food analysis, inspection, enforcement, and education;
- possesses reserve powers that can be brought into effect in the event that enforcement bodies default or are negligent in their duties.

2.5.4. Management Board

The Management Board should provide corporate governance of the Agency. The Management Board should preferably be accountable to the Parliament, or another legislative body of the country, through the concerned Minister, for all the Agency's activities and performance.

Representatives from various Ministries and other members of the Management Board will have experience or expertise in one or more of the following fields:

- public health and epidemiology;
- food science and technology;
- food production;

- agricultural science and animal health;
- food marketing and trade;
- human nutrition;
- food law;
- public administration;
- consumer rights and affairs

Possible Organizational Structure of a Food Control Agency (FAO)

Board members should be responsible for taking expert advice and consulting widely to ensure that their decisions are based on the best scientific and technical advice available. As such they will be involved in a strategic role, setting the broad policy and resource framework for the activities of the Agency.

The main responsibility of the Board will be to advise on matters arising out of the administration of the food control system. It will determine matters of policy to the extent provided for within the law and provide overall coordination. It should have the authority to set up sub-committees or sub-groups to deal with specific issues of concern and have the option to co-opt experts for this purpose.

The powers of the Food Control Agency will be vested in the Management Board, and it will decide the extent to which it delegates responsibility for operational activities to the Chief Executive Officer and Agency staff. Ultimately, the Management Board should be accountable for the operations and actions of the Agency.

❑ **Chief executive Officer**

The Board, or the Minister on the recommendation of the Board, should appoint the Chief Executive Officer (CEO) of the Agency whose terms and conditions are determined by the Board.

The CEO sits as a Member on the Board.

The CEO is responsible for the day-to-day operation of the Agency and the supervision of Agency staff, and is directly accountable to the Chairperson of the Management Board.

❑ **The Scientific Committee**

It may also be necessary to have a separate Scientific Committee to assist and advise the Board in matters of scientific nature. The need for appropriate scientific inputs in food control decision-making processes has increased considerably as a result of the SPS Agreement and the norms set by the Codex Alimentarius Commission. Therefore, the need for such a Committee at a national level has increased significantly. The Committee should be consulted on matters such as:

- scientific and technical questions relating to food safety and hygiene, including risk assessment;
- food standards and codes of practice;
- research;
- nutritional value and content of food and labelling;
- implementation and administration of food inspection services;
- monitoring and evaluation including regulatory impact assessment.

❑ **The Consultative Committee**

Broad consultation with industry and trade groups and other concerned stakeholders should be facilitated through the establishment of a 'Consultative Committee'. This Committee would meet as required to provide views and advice to the Management Board on pertinent issues related to food safety and its regulation throughout the food chain.

❑ **Programme Structure**

The internal structure of the Agency will reflect the principal functions underpinning the management of the food control system. Key areas of responsibility may be defined as programmes, with managers who report to the CEO. Programme areas may typically include the following:

a) Food Analysis and Surveillance/Food Research;
b) Food Standards;
c) Food Inspection;
d) Support Services/Communication.

2.5.5. Food safety structure and governance in the Europe

The BSE crisis of the late 1990s produced a political earthquake for the European Commission of a similar magnitude to that in the UK a few years earlier. BSE was not the only difficult food safety problem that had to be managed; disputes between Member States over the acceptable safety of beef hormones and food irradiation remained unresolved. By the late 1990s, moreover, the challenge of genetically modified foods had undermined the sustainability of the Commission's traditional ways of managing risk policy-making.

In January 2000, the Commission proposed establishing a European Food Authority (EFA) separate from and at arms' length from the Commission. The EFA would provide the Directorate General for Health and Consumers (DG SANCO) with 'independent

scientific advice' while DG SANCO would 'decide on the appropriate response'. During the legislative process in 2002, the European Parliament decided that a European Food Safety Authority (i.e. an 'EFSA' rather than an 'EFA') would be established. EFSA has repeatedly been characterized, by itself and the Commission, as a scientific body, responsible for scientific assessments of risks, although in practice it has issued a wide range of different kinds of judgements.[10]

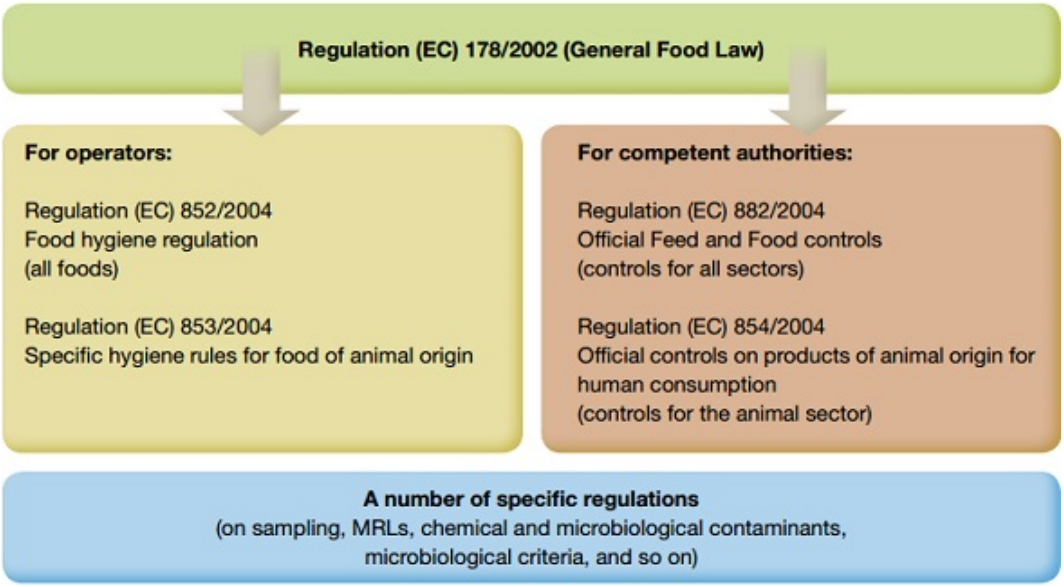
The remit of EFSA differs from that of the UK Food Standards Agency (FSA). The FSA is responsible for both scientific advice and policy-making, whereas EFSA is supposed to be responsible only for providing scientific advice to policy-makers at the Commission and in the Council of Ministers, usually in the form of so-called 'risk assessments'. EFSA also has less responsibility for public health nutrition than the FSA. The FSA is responsible for some aspects of enforcement, while EFSA has no responsibilities in that regard; enforcement of food safety standards is the responsibility of individual Member States. The way EFSA obtains advice from expert committees has evolved. EFSA accept self-nominations from experts rather than just from Member States.

EFSA can even invite experts from outside the EU. EFSA allows experts to belong to advisory panels, even with potential conflicts of interest, but requires those interests to be declared and published (EFSA, 2007). Critics have argued that such conflicts of interest undermine consumer protection and that experts with conflicts of interests should no longer be included in the membership of official advisory panels (Revill, 2007). EFSA advisory panels do not meet in public, unlike those working under the auspices of the UK FSA, and they accept data from unpublished studies and keep them confidential. The ways in which EU food safety policy decisions are taken have become more open and accountable than was previously the case (van Zwanenberg and Millstone, 2005). A variety of different institutional structures and processes are in effect being experimented with in EU Member States.

Institutional structures and practices continue to differ and there are few signs that equilibrium has either been reached or that it is close. The EU food supply may be safer than was previously the case, but the recent decision of the Commission to abandon the long-standing plan to have a uniform EU-wide regulatory framework for the cultivation of GM crops for example, reveals how difficult it can be to achieve consensus and uniformity (European Commission, 2010).

[10] Millstone, E. and Thompson, J., "Foresight Project on Global Food and Farming Futures", The STEPS Centre, Institute of Development Studies, University of Sussex, 2011.

The organization of European regulations



This regulatory framework has been formulated on the basis of general international guidelines issued by the *Codex Alimentarius*. The rules emphasize the responsibility of each stakeholder, starting with the producers themselves. Table below represents (as at 2012) selected EU regulatory requirements with specific relevance to food safety and control.

Regulatory requirements with specific relevance to food safety and control

Regulation No.	Short title	Requirement
EC/1107/2009	Crop protection products permitted in the EU	EU approved pesticides
EC/396/2005	Establishment of CPP MRLs	Mechanism for establishing EU MRLs for pesticides
EC/149/2008	Harmonized MRLs for crop protection products	List of EU MRLs, LOD for all non-approved
EC/882/2004	Harmonized MRLs for crop protection products	Exporting nations to keep records of food safety and risk-assessment procedures at all points of the food production process, including documentation on components of animal feed, the use of pesticides and fertilizers, details of processing and storage techniques
EC/850/2004	Persistent pollutants	List of “Rotterdam Convention” substances (mainly pesticides) which are banned from use on food intended for EU
Directive 2002/63/CE	Sampling of pesticides	Approved method for official sampling

EC/466/2001	MRLs for contaminants other than pesticides in food	MRLs for heavy metals
EC/401/2006, EC/1881/2006, EC/1152/2009, EC/165/2010, EC/178/2010, EC/212/2010 et EC/1277/2011	On the presence and levels of mycotoxins	
EC/2073/2005	Microbiological criteria for foodstuffs	

FAO have published guidelines on 'Developing a National Food Law' containing a broad set of principles and an approach which individual countries may use to tailor existing national legislation.

Food safety authorities all over the world have acknowledged that food safety must not only be tackled at the national level but also through closer linkages among national food safety authorities internationally. Food safety problems discovered and managed in one country often are of interest to other countries and through sharing experiences, food safety issues can be managed more effectively and efficiently.

As such, the International Food Safety Authorities Network (INFOSAN) was developed by the World Health Organization (WHO), in cooperation with the Food and Agriculture Organization of the United Nations (FAO), with the aim of preventing the international spread of contaminated food and foodborne disease and strengthening food safety systems globally, by:

- promoting the rapid exchange of information during food safety-related events;
- sharing information on important food safety-related issues of global interest;
- promoting partnership and collaboration between countries;
- helping countries strengthen their capacity to manage food safety risks.

INFOSAN is operated and managed by WHO's Department of Food Safety, Zoonoses and Foodborne Diseases.

National food incident response protocols should: build upon existing individual organization's protocols; describe the operating procedures, coordination details, and communication processes between agencies and jurisdictions; illustrate the different roles and responsibilities; describe the response phases and activities within each; and embody the principles of emergency management.

The World Health Assembly (WHA) of WHO in May 2000 adopted a resolution calling for improved communication among WHO and its Member States on matters of food safety. The 2002 World Health Assembly expressed serious concern about health emergencies posed by natural, accidental and intentional contamination of food, and requested WHO to provide tools and support to Member States to increase their capacity to respond to such emergencies.

In July 2004, the FAO/WHO Codex Alimentarius Commission adopted a text entitled

Principles and Guidelines for the Exchange of Information in Food Control Emergency Situations, which includes the designation of official contact points for information exchange in each country. The Codex text gives WHO the responsibility of maintaining a list of food safety emergency contact points, which is the list of emergency contact points maintained under INFOSAN.[11]

The WHO International Health Regulations (IHR, 2005) form the global, legally-binding framework against the international spread of a wide range of diseases, including those of biological or chemical nature and transmissible by persons, goods (e.g. food), animals, vectors or the environment. The **scope of the IHR is sufficiently broad to include many foodborne and food safety health risks**. The IHR were adopted by the WHO WHA in May 2005 and entered into legal force globally in June 2007. They are legally binding on all WHO Member States (and all INFOSAN members). Since the regulations have been in operation there have been 11 food safety events reported under them. While many aspects of the IHR are applicable to foodborne disease risks, a particularly relevant provision is that of **reporting**. All WHO Member States are required to notify, report or verify to WHO a range of public health events with potentially significant international implications, including some which may involve foodborne risks and imported or exported contaminated goods (e.g. food). For example, the IHR specify that relevant contexts for notifying WHO can include instances where the disease source is suspected to be a food product or other good that might be contaminated and has been imported or exported. The IHR form a legal reporting framework, whereas INFOSAN is a voluntary technical network. **The IHR apply to all public health risks including those concerning food safety.**

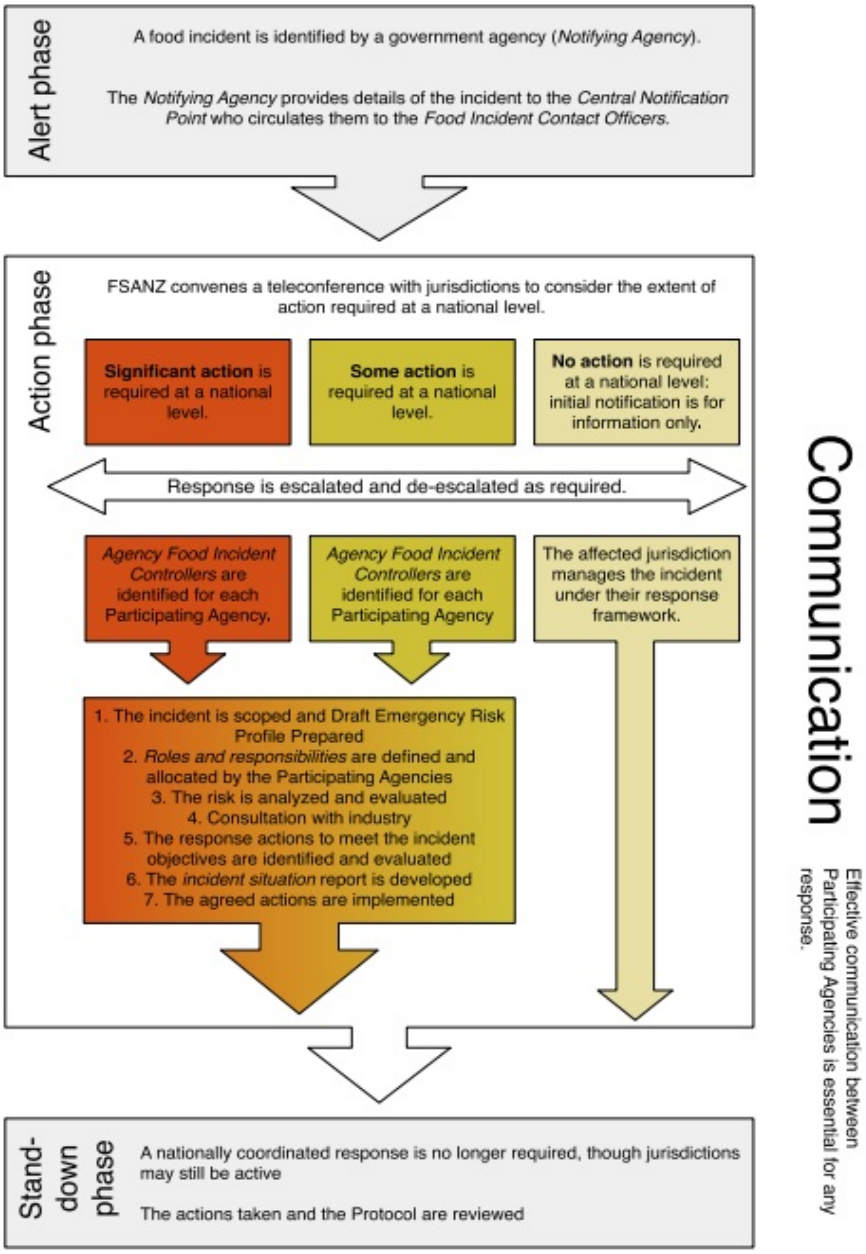
In November 2009, Australia notified WHO through the IHR and INFOSAN of an on-going outbreak of hepatitis A virus (HAV) affecting over 250 people. Case-control studies attributed the outbreak to the consumption of semi-dried tomatoes, and alerts were issued to INFOSAN members. In February 2010, INFOSAN learned of a similar HAV outbreak in France and the Netherlands, also epidemiologically linked to semi-dried tomatoes. In France, a partial trace back of the batch suspected to be contaminated was found to include product from a supplier in Turkey.[12] However, investigations conducted in Australia and the Netherlands could not confirm the exact origin of the semi-dried tomatoes.

For example, Figure below outlines the structure of Australia's food incident protocol.

[11] International Food Safety Authorities Network (INFOSAN), WHO/FAO; October, 2007.

[12] *Report of the first global meeting of the international food safety authorities network* (INFOSAN), Abu Dhabi, UAE, 14-16 December, 2010.

Australia's Protocol organizes response into three phases: 1) Alert; 2) Action; and 3) Stand Down.[13]



The European Food Safety Authority (EFSA) provides scientific advice to the risk manager at both European and Member State levels for the identification of risks present in the food chain. Through the identification of drivers of emerging risks, EFSA also intends to anticipate future risks derived from changes in current food/feed production practices, or factors impinging on food/feed production, or changes in human exposure through food consumption.

[13] *Ibid*.

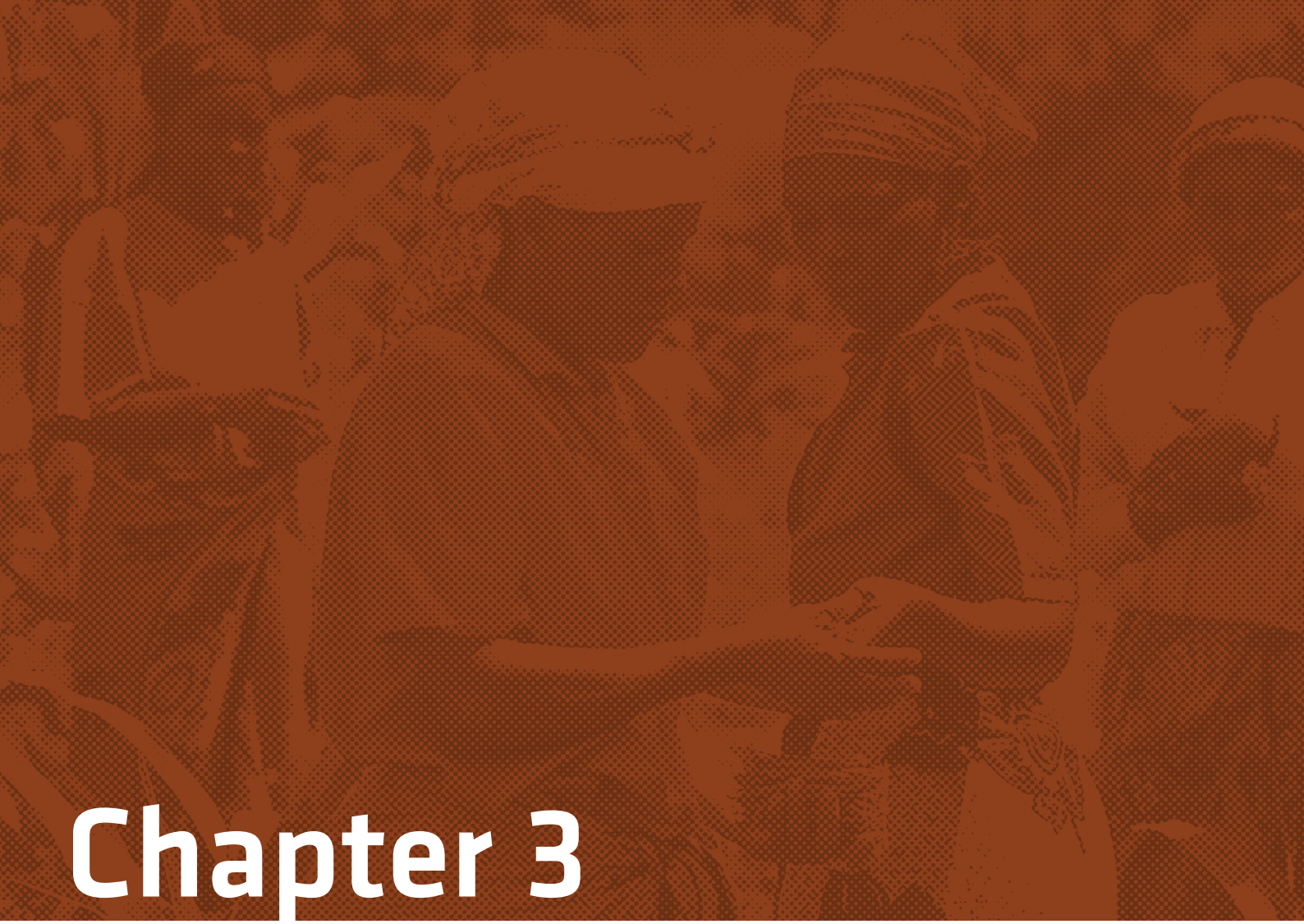
2.6. Funding national food control systems

The compliance cost with SPS-related obligations on some least developed countries can exceed total governmental development budgets for all expenditures. For SMEs, the cost of compliance with export market SPS (including private standards such as GLOBALGAP & BRCGLOBAL) standards can be enormous. However, owing to the wide recognition of the importance of efficient and effective national food control systems in terms of food security, assistance may be sought from international agencies and financial institutions such as the World Bank, Regional Development Banks and bilateral donors.

Maintaining laboratories to support national food control systems requires large initial investments. In addition, the capacities of the systems have to be built up periodically and this also needs resources. Governments tend to provide such resources only when they have recognized economic and health benefits of food control. It is worth noting that economic ministries are thought to be much better than other departments in mobilizing resources for the development of infrastructure and building capacity in food control.

Securing sufficient resources may be also a problem owing to the trend towards reduced public sector spending which is influencing governments to review their priorities and funding arrangements. In countries where food control responsibilities are spread across numerous government bodies, it may be necessary to negotiate a revised funding structure but ensure transition arrangements with continuity of funds and resources. This, though, requires total commitment by the government for establishing appropriate structures and policies to deliver the optimum level of consumer protection.

Cost recovery practices are present in many countries and include fees for licensing, inspection activities, and food analysis. It is important that this is managed carefully as costs passed onto the food industry will ultimately be passed onto consumers as an indirect tax on food, which falls disproportionately on the poorer sectors of society. Countries aiming towards smaller governments are increasingly engaging in contracting out food control services such as food inspection and surveillance to the private sector.



Chapter 3

Role of competent authorities and food business operators

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3.1. Introduction

3.1.1. Participants

The fundamental objective of a food safety system, as stated by *Codex Alimentarius* Commission (CAC), the recognized body with responsibility for developing international standards for food safety and trade in food, is to protect the health of consumers and ensure fair practices in the food trade.[1]

Similarly, EU legislation[2] states that food safety controls are aimed at:

a) preventing, eliminating or reducing to acceptable levels risks to humans, either directly or through the environment; and
b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.

Achievement of these objectives requires the participation of everyone involved in the entire food chain, from primary production at the farm level through all stages up to and including consumption by final consumers of the food.

These participants include:

- Food business operators (FBOs)
  FBOs have the primary role and responsibility for managing the food safety of their products and for complying with requirements relating to those aspects of food under their control
- Consumers
  Consumers have a role in managing food safety risks under their control; they should be provided with information on how to achieve this.
- National Governments
  Governments (through their competent authorities) have the role and responsibility to establish and maintain science-based legislation for food safety, and to ensure the effective operation of national food safety systems.
- Scientific institutions
- Academics and scientists have a role in contributing to a national food control system, as they are a source of expertise to support the risk based and scientific foundation of such a system.

Definitions

Competent Authority

Codex Alimentarius Commission

[1] Proposed Draft Principles and Guidelines for National Food Control Systems. www.codexalimentarius.org/download/report/768/REP12_FCe.pdf.

[2] Regulation (EC) No. 882/2004.

There are a number of slightly different definitions in various Codex texts. The definition below is presented as reflecting the general consensus:
"The official authority charged by or part of the government with the control of food hygiene and the management of official systems of inspection and certification".

European Union
"'Competent authority' means the central authority of a Member State competent for the organization of official controls or any other authority to which that competence has been conferred".

Food business operator

European Union
"Means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control".

"'Food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food".

(Source: Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law)

3.1.2. *Codex Alimentarius* Commission (CAC)

The *Codex Alimentarius* Commission, established by Food and Agriculture Organization (FAO) and World Health Organization (WHO) in 1963 develops harmonized international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair trade practices in the food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

CAC guides and standards are the basis for all national food safety systems and provide information for FBOs and Competent authorities about fulfilling their respective responsibilities for food safety.

The full list of CAC standards, guidelines, codes of practice and advisory texts that compose the Alimentarius can be found on its Web site: www.codexalimentarius.org/standards/list-of-standards/en/.

In addition to providing information about food safety for the protection of a country's consumers, the reference made to Codex food safety standards in the World Trade Organization's Agreement on Sanitary and Phytosanitary measures (SPS Agreement) means that Codex has far reaching implications for developing common standards for international trade in food and for resolving trade disputes. World Trade Organization (WTO) members that wish to apply stricter food safety measures than those set by *Codex* may be required to justify these measures scientifically.

3.2. General principles of food safety

The CAC Recommended International Code of Practice: General Principles of Food Hygiene (CAC/RCP 1-1969) sets out that FBOs should apply the hygienic practices in the Code to:

- provide food which is safe and suitable for consumption;
- ensure that consumers have clear and easily-understood information, by way of labelling and other appropriate means, to enable them to protect their food from contamination and growth/survival of food-borne pathogens by storing, handling and preparing it correctly; and
- maintain confidence in internationally traded food.

The Code recommends that governments should use the Code to decide how best to encourage the implementation of these general principles to:

- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population;
- provide assurance that food is suitable for human consumption;
- maintain confidence in internationally traded food; and
- provide health education programmes which effectively communicate the principles of food hygiene to industry and consumers.

A national food safety system is an integrated structure comprised of two principle parties:

a. The Competent Authority which:
   - establishes and enforces science based regulatory infrastructure that promotes food safety:
   - supports and enables fair trade in food: and
   - advances and fosters knowledge, science, research, education regarding food safety.

b. Food business operators and food industry which
   - have primary responsibility for producing safe food and adhering to the established regulatory requirements: and
   - advance and foster knowledge, science, research, education regarding food safety.

A national food safety system should aim to integrate the activities of FBOs and government to ensure that foods, and their production systems, meet requirements in order to protect consumers against food-borne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate production description. To meet the objectives of a national food safety system the following principles should apply:

- The whole food chain approach
  food safety control measures should cover the entire production to consumption continuum, including primary production, processing, storage, distribution, transport, retail, import and export. Application of risk-based, science-based and evidence-based decision making

National food safety systems should be designed and operated on the basis of risk analysis principles that are consistent with internationally accepted approaches. Risk analysis principles apply to FBOs in addressing food safety hazards in the commodities they produce, and to governments and competent authorities in developing legislative frameworks and inspection, audit and enforcement programmes.

- Responsibility for food safety
  Food business operators (including producers, processors, wholesalers, distributors and retailers) have the primary responsibility for complying with requirements and ensuring safe food on those aspects of food under their control. The competent authority retains the fundamental responsibility to maintain up-to-date and science based legal requirements, ensure the effective operation of the national food control system and verify and provide assurances as to the conformity of food and the associated production with requirements.

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3.3. Food safety hazards

Food safety systems aim to prevent, eliminate or reduce to acceptable levels hazards in food. Hazards are categorized as microbiological, chemical or physical.

Examples of food safety hazards		
Chemical hazards	**Biological hazards**	**Physical hazards**
• Naturally occurring toxins • Environmental contaminants • Pesticide residues • Veterinary drug residues • Food additives • Contaminants from packaging	• Bacteria • Toxin-producing organisms • Viruses • Parasites • Prions	• Stones • Bone chips • Glass • Metal, machine filings

3.4. Food business operators

All FBOs, irrespective of the commodity type they produce or their stage in the food chain, should apply hygienic standards and practices, as appropriate to the commodity and production stage. Although there is no clear definition of the term, Good Hygienic Practices (GHP) is frequently used to describe basic food hygiene activities. 'Food hygiene' has been defined by Codex as "all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain", and GHP can therefore be regarded as all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain. GHP are the universal steps or procedures that control the operational conditions within a food establishment. They are designed to create an environment favorable to the production of safe food. They are basic conditions and activities that are necessary to maintain a hygienic environment. GHP are often described as pre-requisites for Hazard Analysis and Critical Control Point (HACCP)-based systems.

GHP/HACCP pre-requisites include:

- Construction and layout of buildings
- Layout of premises, workspace, employee facilities
- Water management
- Waste management
- Equipment (cleaning, maintenance)
- Management of purchased materials
- Measures to prevent cross contamination
- Cleaning and sanitizing
- Pest control
- Personal Hygiene
- Traceability and product withdrawal/recall,
- Storage and transportation.

❑ **Hazard Analysis and Critical Control Point**

The HACCP system has become the universally recognized and accepted method for food safety assurance. The recent and growing concern about food safety from public health authorities, food industry and consumers worldwide has been the major impetus in the application of the HACCP system. Food business operators are best placed to devise a safe system for supplying food and ensuring that the food they supply is safe.

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to

human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate: expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering, according to the particular study.

The HACCP system is described in Codex texts[3] and many other publications. It will not be considered in detail in this chapter.

❑ Principles of the HACCP system

The *Codex* HACCP system consists of the following seven principles:

1. Conduct a hazard analysis.
2. Determine the Critical Control Points (CCPs).
3. Establish critical limit(s).
4. Establish a system to monitor control of the CCP.
5. Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
6. Establish procedures for verification to confirm that the HACCP system is working effectively.
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

These 7 Principles are then elaborated into a logical sequence of 12 steps for implementation. Guidance in the form of a decision tree is provided for the identification of CCPs. The HACCP system should not be implemented until a food business is operating in accordance with GHPs and in compliance with appropriate food safety requirements.

❑ Primary production

The strict application of the 7 Principles of HACCP may not be appropriate in primary production. In EU legislation, primary production is exempt from the legislative requirement for all FBOs to implement food safety controls based on the principles of HACCP. It is at the primary production stage where many potential food-borne hazards may enter the food chain e.g. chemical contaminants such as heavy metals and residues of pesticides and veterinary drugs. It is therefore essential that food safety control measures are applied in primary production. The CAC Code on General Principles of Food Hygiene states that:

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

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[3] Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application Annex to CAC/RCP 1-1969 (Rev. 4 - 2003).

- avoiding the use of areas where the environment poses a threat to the safety of food;
- controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety;
- adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

❑ Small and less developed businesses

The design of food safety systems based on HACCP should be within the technical and resource capabilities of large food producing and processing companies and organizations. Market forces and export requirements have been central to the implementation of HACCP in many food businesses. The implementation of food safety management systems incorporating HACCP can be a prerequisite to market access. This is particularly evident if businesses are export oriented or if they supply into large retail multinational businesses. It should be noted, however, that the *Codex* HACCP system is the written product of experience gained in the application of HACCP systems in large and relatively technically sophisticated food businesses.

Some governments implement the Codex system according to the 12 steps defined in the guidelines, while others develop or promote systems encompassing the seven principles, without following the 12-step process. Further flexibility is rare, given that the *Codex* HACCP system is the reference standard in international trade disputes.

HACCP can present difficulties for small businesses, employing no or few people, or less developed businesses without technical knowledge. Many small businesses only supply the domestic market and there is no significant presence of large multinational retailers in some countries; as a result, small businesses in catering or supplying direct to consumers or local retailers and caterers have been reluctant to implement HACCP or have experienced difficulties in doing so.

Trade associations have a role to play in promoting HACCP and in assisting individual FBOs in implementing HACCP. Guides to implementation of HACCP, developed by trade bodies, have been beneficial in some countries and their development should be encouraged or supported by government where such bodies are present. However, in many countries trade associations do not exist and, even when they are present, small businesses are likely to be under-represented compared to larger food businesses. In these circumstances, government should take the initiative to promote the up-take and application of HACCP, as discussed below.

3.5. Competent authorities

As defined above, a competent authority is the official authority charged by or part of the government with the control of food hygiene and the management of official systems of inspection and certification.

There are many different models for the delegation of government powers to competent authorities and it is up to each country to decide its mechanisms for this. In many countries competent authorities are part of the government, e.g. Ministry of Health, Ministry of Agriculture. For zoonotic diseases there is often an overlap between agriculture and health departments. Some countries have set up bodies with the specific responsibility of food safety; an example of such a body is the UK Food Standards Agency which is a non-departmental government body, overseen by a board rather than a government minister, acting in the interests of consumers of food and with independence from government.

Deliver of official controls on food safety may be carried out directly by the competent authority or responsibility may be conferred on another body.

❑ Food safety legislation

The government within each country needs to have in place fundamental legal structures, to enable the establishment of food laws and competent authorities, so that they can develop, establish, implement, maintain and enforce a national food control system.

Food safety legislation should be aimed at the reduction, elimination or avoidance of a risk to health and be based on the three interconnected components of risk analysis - risk assessment, risk management, and risk communication to provide a systematic methodology for the determination of effective, proportionate and targeted measures to protect health.

Risk analysis should be based on internationally recognized methods; the *Codex* principles for of risk analysis for governments are presented box below.

Working principles for risk analysis for food safety for application by governments (CAC/GL 62-2007)

- The overall objective of risk analysis applied to food safety is to ensure human health protection.
- These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non-discriminatory manner.
- To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.
- Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.

- Risk analysis should be:
  - applied consistently;
  - open, transparent and documented; and
  - evaluated and reviewed as appropriate in the light of newly generated scientific data.
- The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the *Codex Alimentarius* Commission, each component being integral to the overall risk analysis.
- The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties.
- Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.
- The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.
- There should be a functional separation of risk assessment and risk management to the degree practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest.
- Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.
- National governments should take into account relevant guidance and information obtained from risk analysis activities pertaining to human health protection conducted by *Codex*, FAO, WHO and other relevant international intergovernmental organizations, including OIE and IPPC.
- With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective application of risk analysis principles and techniques in their food control systems.
- National governments should share information and experiences on risk analysis with relevant international organizations, other national governments (e.g. at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate a broader and, where appropriate, more consistent, application of risk analysis.

The outcome of the risk analysis process is decisions about risk management options for food-borne hazards for public health. Implementation of risk management procedures will generally require national legislation.

In the EU, risk assessment is one of the functions of the European Food Safety Authority (EFSA). When requested, EFSA carries out risk assessments on specific hazards and publishes the results of its assessments. These assessments of then used by the law-making institutions of the EU to draft and approve legislation.

Food safety legislation must provide the competent authority with legal powers to carry out controls at all stages of production, manufacture, importation, processing, storage, transportation, distribution and trade.

Legislation may also include provisions for the registration or approval of establishments or listing of certified processing plants. In the EU, all food businesses must be registered before they can trade, and businesses carrying out certain operations deemed to present higher food safety risks, e.g. slaughterhouses, meat and milk processing establishments, are required to be approved to ensure that they comply with additional food safety requirements.

Registration and approval of food businesses enables the competent authority to identify FBOs and to carry out food safety control activities.

Legislation should include provision for enforcing legal sanctions on FBOs who fail to comply with food safety laws.

3.5. Official control programmes

'Official control' means any form of control that the competent authority performs for the verification of compliance food law.

Deliver of official controls on food safety may be carried out directly by the competent authority or may be conferred on another body. In this section the term CA is used to describe both the CA and any body to which responsibility for official controls has been conferred.

❑ National programmes

The competent authorities involved in the functions of a national food safety system throughout the entire production to consumption food chain should have clearly defined responsibilities and authority in order to avoid duplication and gaps. Many countries have responsibilities divided between government departments, e.g. between departments of health and agriculture; it is essential that these responsibilities are clearly set out at a high level to ensure that controls are effectively applied to the entire food chain. Particular attention is required for zoonotic diseases to ensure that there is no duplication of effort or gaps in enforcement.

Where different authorities in the same country have jurisdiction over different parts of the food chain, conflicting requirements must be avoided to prevent legal and commercial problems and obstacles to trade. For example, while provincial or state laws may exist there should be a competent authority at the national level capable of ensuring uniform application.

The example of formal national control plans that EU member states are required to elaborate is a model worthy of consideration. Food safety legislation is harmonized throughout the EU but it is the responsibility of individual member states to determine how the legislation is implemented and enforced in their country, and EU food and feed law[4] requires every Member State to produce so-called multi-annual national control plans to demonstrate how they do this. Multi-annual national control plans:

- describe the roles and responsibilities of the competent authorities and associated bodies responsible for official food controls;
- outline how these authorities meet the requirements of EU legislation;
- provide an overview of how these authorities and other bodies work together to safeguard public health and
- set out the strategic objectives, and planned control activities.

Guidelines have been published on the preparation of these control plans[5] and the content headings of the guidelines are reproduced in the box below to give an indication

[4] Regulation (EC) No. 882/2004.

[5] Commission Decision on guidelines to assist Member States in preparing the single integrated multi-annual national control plan) (2007/363/EC).

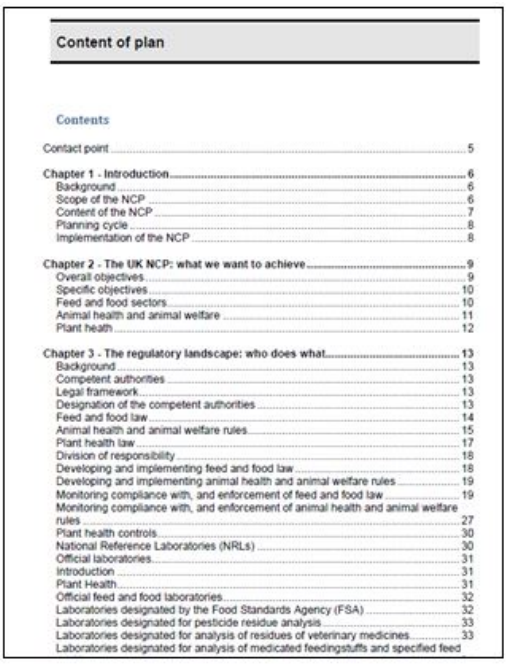
of the topics that that should be considered when developing national food safety systems.

- Purpose of the Guidelines
- Definitions
- Guidance on the legal requirements for national control plans
- National control plans
- General requirements for national control plans
- Strategic objectives of national control plans
- Risk categorization
- Designation of competent authorities
- General organization and management
- Control systems and coordination of activities
- Delegation to control bodies
- Compliance with operational criteria
- Training of staff performing official controls
- Documented procedures
- Operational contingency plans
- Organization of cooperation and mutual assistance
- Adjustment of national control plans

❑ Strategic objectives

Taking into account that the main objective of a food safety system is to protect public health through the effective enforcement of food law, it is essential to develop appropriate objectives and strategies to achieve that purpose. Those objectives and strategies, which may involve the concentration or prioritization of official controls or the allocation of resources on certain activities or at certain stages of the production chain should form the basis of a national control plan.

An example of a national control plan is that of the UK.



www.foodlaw.rdg.ac.uk/pdf/uk-06028-draft-control-plan.pdf

❑ Official control operational procedures

Programmes and training manuals should be developed and implemented to ensure consistent application of requirements. Documentation for competent authorities should include:

- An organizational chart of the official control system:
- Roles of each level in the hierarchy (including other relevant jurisdictions i.e., State, Provincial);
- Job functions and qualifications as appropriate;
- Operating procedures including methods of inspection and control, sampling, and testing;
- Relevant legislation and requirements;
- Arrangements for coordination with key officials in relevant ministries and private sector organizations;
- Relevant information about food contamination and food control;
- Procedures for conducting food recalls and investigations; and
- Relevant information on staff training.
- Programmes and training manuals should be developed and implemented to ensure uniform application.

❑ Competent authority personnel

National food control systems should have, or have access to, a sufficient number of qualified personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law. Personnel

should be capable and appropriately trained in the operation of food inspection and control systems. They should have a status which ensures their impartiality and have no direct commercial interest in the products or establishments being inspected or certified.

Inspection
The examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

Audit
A systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

Competent authorities should have procedures in place for appointing authorized officers and for ensuring that they have the necessary powers to carry out official control activities and for taking legal action against non-compliant FBOs.

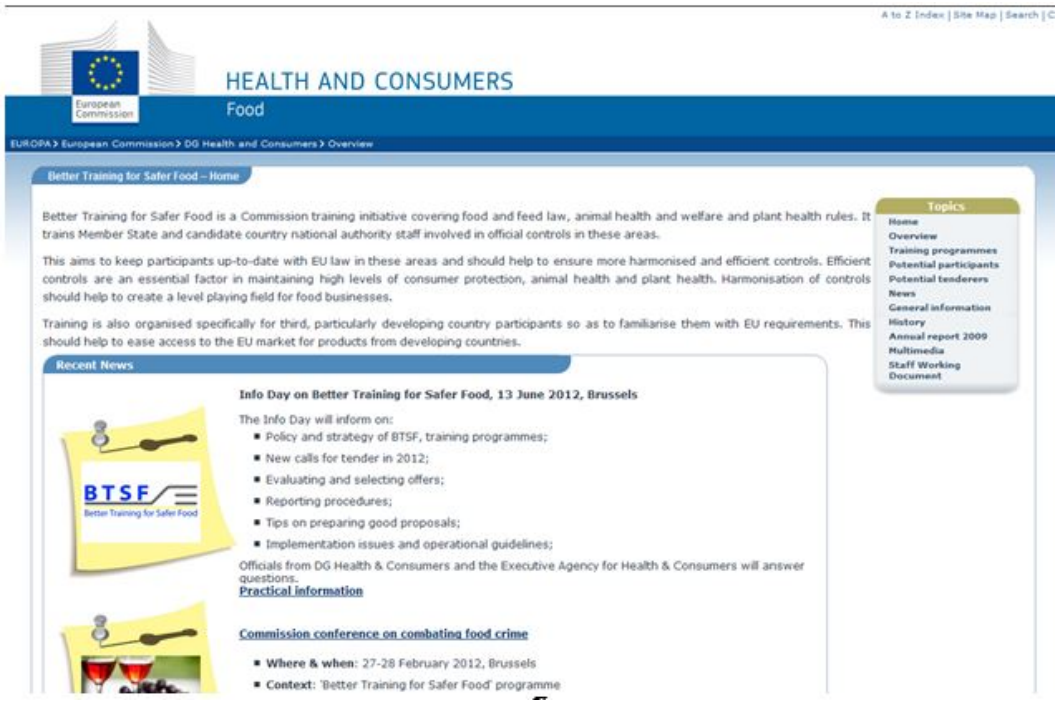
Competent authority personnel should be trained inspection, audit, sampling and other official control activities. In particular, personnel should have a sound knowledge and understanding of the application of HACCP principles and the audit of HACCP systems. Audit of FBOs food business management systems requires a high level of understanding of food safety hazards and their controls; competent authority personnel must have the required standards of education and training and should be provided with opportunities of professional development during their working lives to maintain their level of expertise.

The EU has recognized the importance of training in official controls for competent authority staff through its Better Training for Safer Food programme.

Better Training for Safer Food (BTSF) is a Commission training initiative covering food and feed law, animal health and welfare and plant health rules. It trains Member State and candidate country national authority staff involved in official controls in these areas.

This aims to keep participants up-to-date with EU law in these areas and should help to ensure more harmonized and efficient controls. Efficient controls are an essential factor in maintaining high levels of consumer protection, animal health and plant health. Harmonization of controls should help to create a level playing field for food businesses.

Training is also organized specifically for third, particularly developing country participants so as to familiarize them with EU requirements. This should help to ease access to the EU market for products from developing countries.

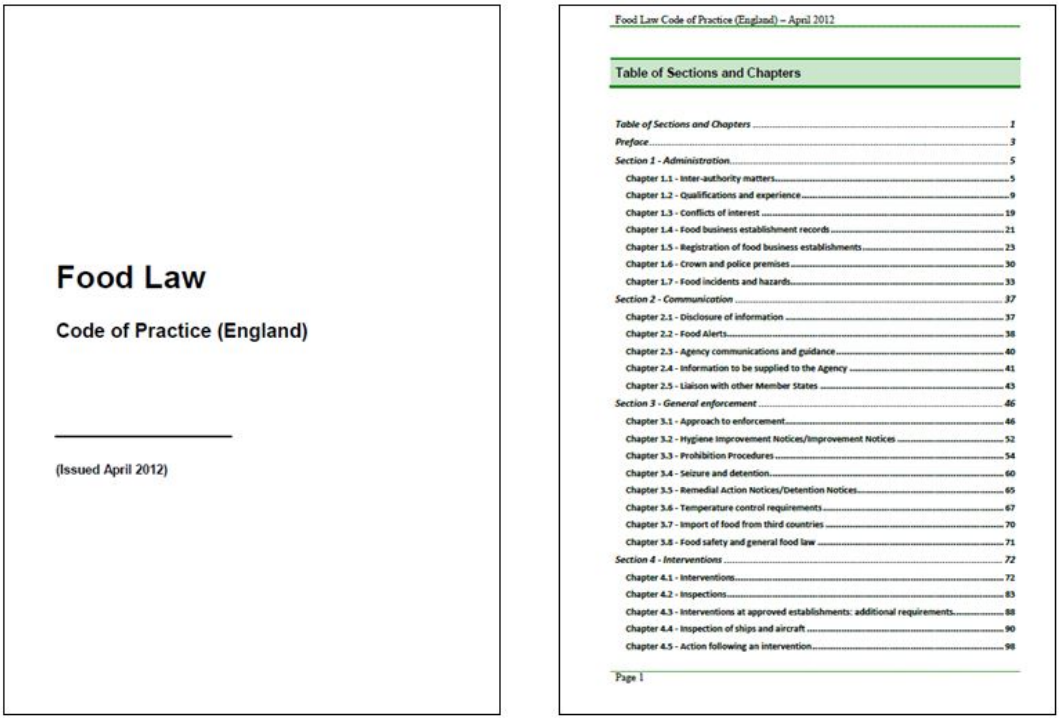


Source: ec.europa.eu/food/training_strategy/index_en.htm

Countries wishing to participate in the BTSF programme can find more information on the EU Web site: ec.europa.eu/eahc/food/index.html

❑ Competent authority operating procedures

Competent authorities should develop guides and codes about operating procedures for their personnel to ensure a consistent approach to official control activities. Competent authorities developing texts can find many examples such codes, guides and manuals used by other countries; some examples are included below.



Food Law

Code of Practice (England)

(Issued April 2012)

Food Law Code of Practice (England) – April 2012

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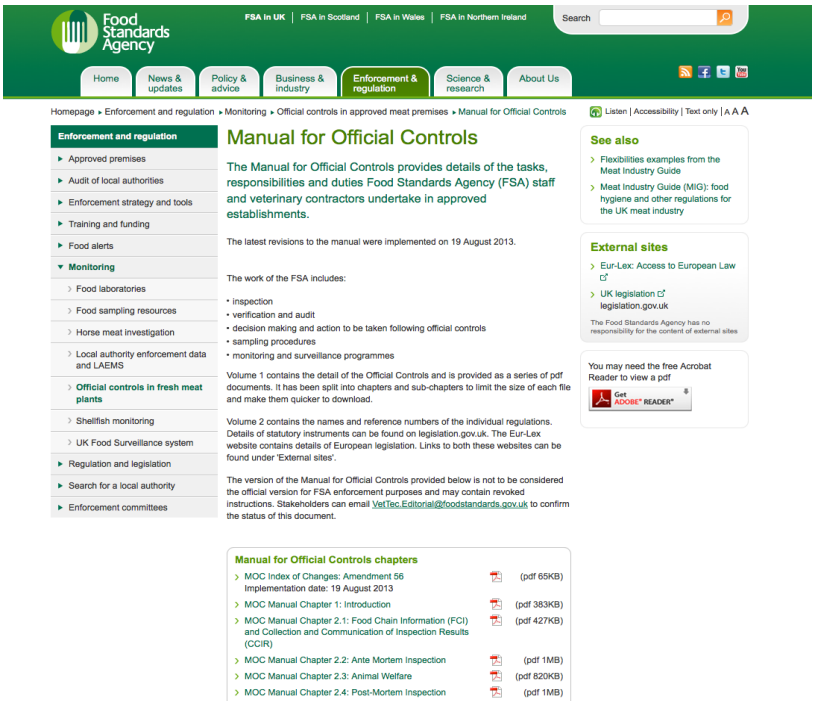
Source: Food Law Code of Practice (England),
www.food.gov.uk/multimedia/pdfs/codeofpracticeeng.pdf.



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Enforcement and regulation

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- Audit of local authorities
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Manual for Official Controls

The Manual for Official Controls provides details of the tasks, responsibilities and duties Food Standards Agency (FSA) staff and veterinary contractors undertake in approved establishments.

The latest revisions to the manual were implemented on 19 August 2013.

The work of the FSA includes:

- inspection
- verification and audit
- decision making and action to be taken following official controls
- sampling procedures
- monitoring and surveillance programmes

Volume 1 contains the detail of the Official Controls and is provided as a series of pdf documents. It has been split into chapters and sub-chapters to limit the size of each file and make them quicker to download.

Volume 2 contains the names and reference numbers of the individual regulations. Details of statutory instruments can be found on legislation.gov.uk. The Eur-Lex website contains details of European legislation. Links to both these websites can be found under 'External sites'.

The version of the Manual for Official Controls provided below is not to be considered the official version for FSA enforcement purposes and may contain revoked instructions. Stakeholders can email VetTec.Editorial@foodstandards.gov.uk to confirm the status of this document.

Manual for Official Controls chapters

- MOC Index of Changes: Amendment 56 Implementation date: 19 August 2013 (pdf 65KB)
- MOC Manual Chapter 1: Introduction (pdf 383KB)
- MOC Manual Chapter 2.1: Food Chain Information (FCI) and Collection and Communication of Inspection Results (CCIR) (pdf 427KB)
- MOC Manual Chapter 2.2: Ante Mortem Inspection (pdf 1MB)
- MOC Manual Chapter 2.3: Animal Welfare (pdf 820KB)
- MOC Manual Chapter 2.4: Post-Mortem Inspection (pdf 1MB)

See also

- Flexibilities examples from the Meat Industry Guide
- Meat Industry Guide (MIG): food hygiene and other regulations for the UK meat industry

External sites

- Eur-Lex: Access to European Law
- UK legislation legislation.gov.uk

The Food Standards Agency has no responsibility for the content of external sites

You may need the free Acrobat Reader to view a pdf

Get ADOBE READER

Source: Manual for Official Controls for meat establishments
www.food.gov.uk/enforcement/approved-premises-official-controls/manual

❑ Registration and approval of food businesses

Competent authorities should have procedures for the registration of all food businesses throughout the entire production chain. It is important to have information about the type and location of all businesses so that official control can be applied.

Some businesses, such as those producing food of animal origin, may be required to comply with specific aspects of food law and there should be a mechanism for the competent authority to assess compliance with additional conditions and for approval of such businesses.

A register of food businesses should be kept and there should be legal and operational procedures available to remove seriously non-compliant businesses from the list.

In the case export of food commodities, some importing countries require that all establishments producing food for export are specifically approved for that purpose. Systems must be in place for the listing (and de-listing) of export approved establishments.

❑ Official controls of food businesses

The specific form of official controls that competent authorities apply is dependent of the many factors, including the stage in the food chain and the type and nature of the commodity. The box below contains the recommendations for the design of official control programmes from the CAC Proposed Draft Principles and Guidelines for National Food Control Systems.

- The elements of a control programme should include, as appropriate:
  - inspection;
  - sampling and analysis;
  - checks on hygiene, including personal cleanliness and clothing;
  - examination of written and other records;
  - examination of the results of any verification systems operated by the establishment;
  - audit of establishments by the national competent authority;
  - national audit and verification of the control programme.
- Administrative procedures should be in place to ensure that controls by the inspection system are carried out:
  - regularly in proportion to risk;
  - where non-compliance is suspected or identified;
  - in a co-ordinated manner between different authorities, if several exist.
- Controls should cover, as appropriate:
  - establishments, installations, means of transport, equipment and material;

- raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs;
- semi-finished and finished products;
- materials and objects intended to come into contact with foodstuffs;
- cleaning and maintenance products and processes, and pesticides;
- processes used for the manufacture or processing of foodstuffs;
- the application and integrity of health, grading and certification marks;
- preserving methods;
- labelling integrity and claims.

- The elements of the control programme should be formally documented including methods and techniques.
- The control programme should be targeted at the most appropriate stages and operations, depending on the specific objectives. Control procedures should not compromise the quality or safety of foods, particularly in the case of perishable products.
- The frequency and intensity of controls by inspection systems should be designed so as to take account of risk and the reliability of controls already carried out by those handling the products including producers, manufacturers, importers, exporters, and distributors.
- When physical checks are to be undertaken, sampling should take into account the level of risk, including the presentation and type of commodity to be sampled.

❑ Risk-based official controls

Official control programmes help to ensure that food control actions relate to objectives, since the results of these programmes can be assessed against the objectives set for the national food safety system. Competent authorities should draw up control programmes based on precise objectives and appropriate risk analysis. In order to make most effective use of available resources, risk analysis methods should be employed to determine businesses which pose the greatest risk to public health and to prioritize control activities accordingly.

The nature and frequency of audit and inspection of food production systems should be based on the risk to human health posed by the product, its origin and the history of conformance to requirements and other relevant information, including potential for fraud. Control should be designed to account for factors such as:

- The risk to human health posed by the product or its packaging;
- The susceptibility of the target consumer group;
- The extent and nature of any further processing of the product;
- History of conformity of producers, processors, manufacturers, transporters and distributors; and
- Potential fraud or deception of consumers and other factors that may prevent fair trade practices.

There are two main components to the risk that food businesses may present to public health:

- Intrinsic risks
  - Type of food and method of handling
  - Method of processing
  - Consumers at risk
- FBO-related risks
  - Level of (current) compliance
  - Confidence in management/control procedures

Intrinsic risks are common to all FBOs producing the same commodity for the same market, whereas there will be differences between the risks posed by individual FBOs depending on their attitudes to food safety and the effectiveness of their food safety management systems.

Formal risk scoring systems may be used to assess the food safety risks posed by individual businesses and to prioritize official control activities. Excerpts from an example of such a scoring system are presented below.

A. Type of food and method of handling

Score	Guidance on the scoring system
40	Manufacturers of high-risk food (including those subject to approval under Regulation 853/2004), wholesalers, and packers who re-wrap or re-pack high-risk foods. In this context, high-risk foods may be regarded as foods which support the growth of micro-organisms, and/or are intended for consumption without further treatment that could destroy pathogenic micro-organisms or their toxins.
30	Preparation, cooking or handling of open high-risk foods by caterers and retailers, except caterers that prepare less than 20 meals a day (see below).
10	Handling of pre-packed high-risk foods; Caterers who prepare high-risk foods but serve less than 20 meals a day; Other wholesalers and distributors not included in the categories above; Manufacture or packing of foods other than high-risk; Establishments involved in the filleting, salting or cold smoking of fish for retail sale to final consumer.
5	Retail handling of foods other than high-risk, such as fruit, vegetables, canned and other ambient shelf stable products. Any other businesses not included in the categories above.

Score:	

Source: Annex 5 - Food establishment intervention rating schemes
www.food.gov.uk/multimedia/pdfs/codeofpracticeeng.pdf

This type of scoring system assigns points to different risk levels for each risk category to arrive at an overall score for a business as a measure of the risks it presents (a higher score representing a higher risk).

Similarly, scores are awarded for the FBOs compliance with structural and operational requirements.

Score	Guidance on the scoring system
25	Almost total non-compliance with statutory obligations.
20	General failure to satisfy statutory obligations – standards generally low.
15	Some major non-compliance with statutory obligations – more effort required to prevent fall in standards.
10	Some non-compliance with statutory obligations and industry codes of recommended practice. Standards are being maintained or improved.
5	High standard of compliance with statutory obligations, industry codes of recommended practice, and minor contraventions of food hygiene regulations. Some minor non-compliance with statutory obligations and industry codes of recommended practice.
0	High standard of compliance with statutory obligations and industry codes of recommended practice; conforms to accepted good practices in the trade.

Score – hygiene:	

Score – structural:	

Overall scores for each business may be used to prioritize official control activities such as the type and frequency of inspection, audit and sampling.

3.7. International trade in food

3.7.1. Food exports

For countries wishing to export food, competent authorities have a critical role in ensuring that the country complies with the requirements of international trade and the conditions set by importing countries.

Specific information about food exports is contained in other EDES Handbooks; the main roles of competent authorities are covered in this text.

Competent authorities must be able to give trading partners guarantees about the safety of the food they wish to export. Effective national food safety systems, based on the guides and standards of CAC, should be the foundation of such guarantees. The WTO SPS Agreement does not require the food safety system in the exporting country to be identical to that of the importing country, but only that it is able to provide the same level of food safety.

In addition, in the case of export of food of animal origin, importing countries will require guarantees about animal diseases in order to protect their animal health status, since animal products can be the source of animal disease transfer between countries. In general, access to international markets is gained by exporting countries being members of the International Organization for Animal Health (OIE) and by following the requirements of the OIE's texts, specifically the Terrestrial Animal Health Code[6] and Aquatic Animal Health Code[7].

Competent authorities have a critical role in implementing OIE animal health requirements.

❑ Official certification

Most international trade in food requires official certification to provide importing countries with guarantees about food safety and, if relevant, animal health issues.

Codex Principles for Food Import and Export Inspection and Certification (CAC/GL 20–1995) states:

"Food inspection and certification systems should be used wherever appropriate to ensure that foods, and their production systems, meet requirements in order to protect consumers against food-borne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description"

and defines certification as:

"The procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that foods or food control systems

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6 www.oie.int/international-standard-setting/terrestrial-code/access-online/.

7 www.oie.int/international-standard-setting/aquatic-code/access-online/.

conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products".[8]

For animal health, OIE places responsibilities on exporting countries:

- An exporting country should, on request, supply the following to importing countries:
  - information on the animal health situation and national animal health information systems to determine whether that country is free or has zones or compartments free from listed diseases, including the regulations and procedures in force to maintain its free status;
  - regular and prompt information on the occurrence of notifiable diseases;
  - details of the country's ability to apply measures to control and prevent the relevant listed diseases;
  - information on the structure of the Veterinary Services and the authority which they exercise according to Chapters 3.1. and 3.2.;
  - technical information, particularly on biological tests and vaccines applied in all or part of the national territory.
- The Veterinary Authority of the exporting country is ultimately accountable for veterinary certification used in international trade.

Competent authorities should have systems in place to:

- Negotiate export conditions and agree certificates with importing countries
- Ensure compliance with export certificate conditions
- Designate officials authority to sign certificates
- Protect the security and integrity of certificates
- Audit the provision and completion of certificates to prevent malpractice and fraud.

3.7.2. Food imports

Competent should have procedures for the control of food imported into the country. Food import control systems should have the following main characteristics:

- requirements for imported food that are consistent with requirements for domestic foods;
- clearly defined responsibilities for the competent authority or authorities;
- clearly defined and transparent legislation and operating procedures;
- precedence to the protection of consumers;
- provision of the importing country for recognition of the food control system applied by an exporting country's competent authority;
- uniform nationwide implementation;
- implementation that ensures the levels of protection achieved are consistent with those for domestic food.

[8] Principles for food import and export inspection and certification (CAC/GL 20-1995).

The competent authority should have systems to control the import of food and to carry out checks on import consignments. The nature and frequency of inspection, sampling and testing of imported foods should be based on the risk to human health and safety presented by the product, its origin and the history of conformance to requirements and other relevant information. Control should be designed to account for factors such as:

- the risk to human health posed by the product or its packaging;
- the likelihood of non-compliance with requirements;
- the target consumer group;
- the extent and nature of any further processing of the product;
- food inspection and certification system in the exporting country and existence of any equivalence, mutual recognition agreements or other trade agreements; and,
- history of conformity of producers, processors, manufacturers, exporters, importers and distributors.

Food import controls are the subject of a specific CAC text: Guidelines for Food Import Control Systems CAC/GL 47-2003.

❑ Laboratories

Competent authorities should utilize laboratories that are evaluated and/or accredited under officially recognized programmes to ensure that adequate quality controls are in place to provide for the reliability of test results. Validated analytical methods should be used wherever available.

3.8. Promotion of food safety to FBOs

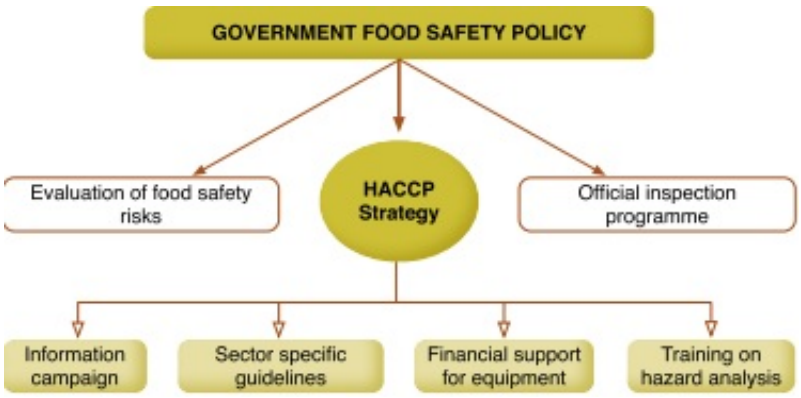
3.8.1. Application of HACCP

The role of governments goes beyond adopting and monitoring compliance with national food legislation: they should actively promote food safety measures through the adoption of food safety management systems such as HACCP. The success with which food businesses establish and implement HACCP may be directly related to the supporting environment created by the government, including alliances with food businesses; this is particularly true in the case of small and less developed businesses. Such businesses face very significant challenges when adopting HACCP and active intervention by the government is required.

In most countries, the small and less developed business sector accounts for a substantial part of the food industry, makes an important contribution to the national food supply and is an important source of employment contributing to the local economy. It is therefore important that a national policy is adopted to increase levels of food safety in this sector. At the same time, advocacy of the HACCP system provides mutual benefits to the government, including safer food and hence increased public health protection, which in turn may increase the confidence of both national consumers and tourists. This, combined with better opportunities to increase trade, results in economic growth and national development.

HACCP is the method that CAC recommends FBOs to use to control food-borne hazards in their businesses and has been implemented successfully by many businesses. However, HACCP presents difficulties for small and less developed businesses which lack resources and technical ability. This problem has been recognized in both developed and developing countries and has resulted in actions to provide assistance to such businesses to enable them to address food-borne hazards more effectively.

The figure below indicates some of the methods that governments and competent authorities can apply to assist FBOs with HACCP.

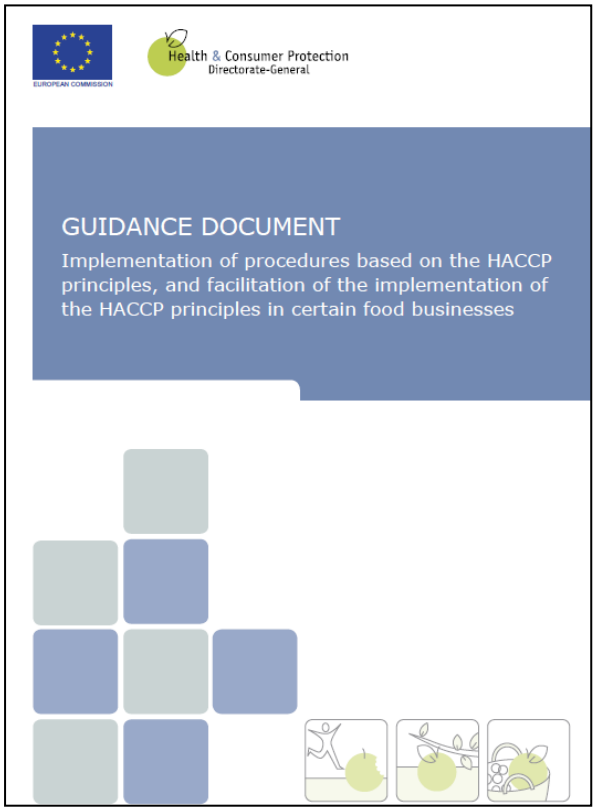


Source: FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses. FAO Food and Nutrition Paper 86

Internationally, FAO and WHO have developed guidance to governments on the application of HACCP in small and/or less-developed food businesses[9]. The information provided in the guidance is applicable to businesses engaged in food processing and preparation, distribution and storage, wholesale, retail and catering activities. Although not specifically aimed at primary food production (animal husbandry and on-farm activities), it can also be of assistance to governments applying HACCP-based systems at farm level.

Competent authorities in many countries have assisted industry by providing information to businesses in the form of manuals, short booklets, leaflets, videos etc. Such guidance is valuable for raising awareness of HACCP in small businesses, providing clear advice and clarifying the HACCP concept. Guidance documents provide information and enhance capacity among food businesses, but also increase consumer awareness of the importance of food safety and good hygienic practices, which can result in pressure being exerted on food businesses to improve overall levels of food safety.

At the EU level, the Commission has published a guidance document on the implementation of HACCP in certain small businesses.



Source: ec.europa.eu/food/safety/biosafety_en

[9] FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses. FAO Food and Nutrition Paper 86.

HACCP systems are generally considered to be a useful tool for food business operators in order to control hazards that may occur in food. In view of the wide range of food businesses to which Regulation (EC) No 852/2004 is addressed, and in view of the great diversity of food commodities and manufacturing procedures that are applied to food, it seems useful to issue general guidance on the development and implementation of HACCP based procedures.

Regulation (EC) No 852/2004 allows the HACCP based procedures to be implemented with flexibility so as to ensure that they can be applied in all situations. Since the adoption of Regulation the Commission has been requested to clarify to what extent flexibility with regard to the implementation of the procedures based on the HACCP principles can be applied.

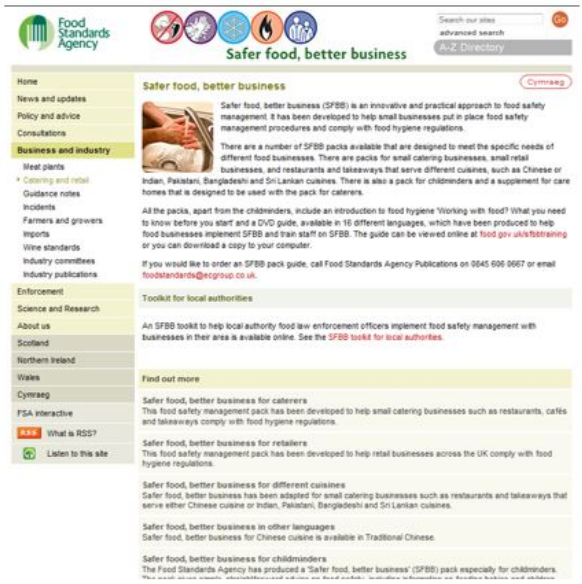
This document aims to issue guidance on the requirement laid down in Article 5 of Regulation (EC) No 852/2004, and on the flexibility that can be applied in particular in small businesses.

The FAO/WHO Guidance provides recommendations for competent authorities for the development of codes and standards documents.

Some features of effective codes and standards documents:

- Cover the related elements (e.g. prerequisite programmes, recall procedures, traceability, management commitment) and provide a full food safety management system.
- Written and approved by governments in collaboration with SLDBs directly or through industry associations.
- Technical decisions carried out by qualified expert.
- Recognized by enforcement officers
- Written in plain and simple language (HACCP jargon may be replaced with simple language – e.g. "hazards" is replaced with "things that can go wrong" and "things that may harm consumers").
- Flexible and "tailor-made" to cater for the needs of SLDBs.
- Sector-specific (e.g. bakery, slaughterhouse, street vendors).
- Identify classical CCPs, critical limits and corrective actions
- Support simple forms of record keeping (e.g. temperature management, cleaning
- programmes, incoming raw materials).
- Accessible and well distributed
- Supported with readily available advice.

In the UK, a programme, Safer Food for Better Business, has adopted an innovative and practical approach to food safety management. It has been developed to help small businesses put in place food safety management procedures and comply with food hygiene regulations.



❑ Provision of technical expertise by consultants and other advisors

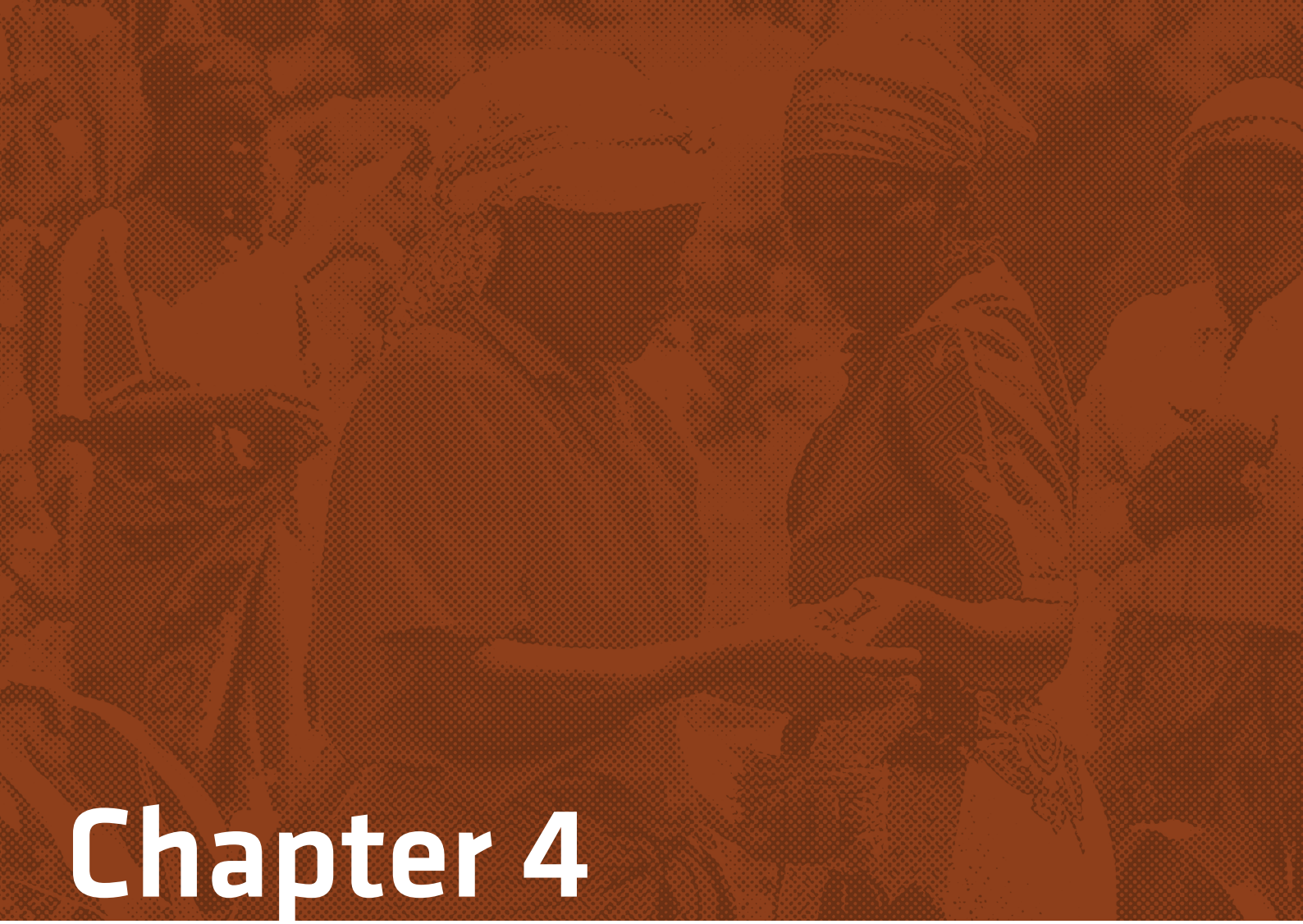
Small businesses are limited by the technical capacity at their disposal and often require external technical help from government, trade associations or commercial advisors. The growth of HACCP is mirrored by the growth in available advice. However, not all advice is appropriate or applicable and the quality of professional advice can vary considerably among consultants. Consultants may have the required HACCP knowledge, but they may makes implementation very complicated; in other cases, consultants may lack practical knowledge in a specific field.

Ideally, competent authorities ensure that the provision of advice is regulated. In reality, governments rarely have the resources to do this. However, governments can seek to ensure that approved sources of advice are available and accessible.

❑ Promotion of food safety to consumers

The storing and handling of food in the home plays a very significant part in food safety; many food-borne diseases are the result of poor practices by consumers. Competent authorities have an important role in educating and advising consumers about how they can store and handle food correctly to prevent food-borne diseases.

Education can take many forms – leaflets, posters, press, radio, TV, Web sites etc.



Chapter 4

Coordination of activities in a food safety system

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4.1. The need for coordination of food safety services

4.1.1. Scope

The World Health Organization (WHO), Food and Agriculture Organization (FAO), along with other national and international bodies have recognized that protecting food safety is a public health function and a global priority.

Food-borne diseases are a major cause of ill-health and death across the world. Poor people are particularly vulnerable as they do not have the necessary knowledge and access to facilities that can ensure food safety.

Changes in patterns of global food production have brought new risks. Increased pressure on land, urbanization, prosperity and changing lifestyles mean that less food is grown and consumed locally and more is consumed outside the home. Modern agricultural methods (for example, the use of crop chemicals and veterinary medicines) need to be strictly controlled.

> Food safety is a public health function and a global priority.

Food production and supply chains in many developing countries are characterized by large numbers of small-scale producers, many without adequate training and access to suitable food handling facilities, clean water, sanitation and refrigeration. Infrastructure for handling and distribution of harvested products is frequently under-developed, making it difficult to maintain good hygiene conditions. Many urban poor rely on street foods prepared under unhygienic conditions. At the same time government ministries have limited resources and expertise to encourage the development of effective food safety systems.

Whereas international food trade used to be mainly in the form of raw materials, it now increasingly comprises pre-packaged or prepared food. This helps to increase the financial returns for exporting countries, but brings increased food safety risks for consumers in importing countries unless proper harmonized controls are put in place.

Traditional food safety controls relied on random sampling and testing of the end product. This approach is no longer suitable when food is produced and delivered through supply chains involving a number of food businesses. It is now necessary to use harmonized risk-based process control measures to ensure that food hygiene is maintained throughout the food chain (the ‘farm to table’ principle), where the business operator at each stage has the main responsibility for food safety.

Reasons for a coordinated food safety system

- Food safety is a public health function that requires the cooperation of food business operators.

- Foodborne illness is an important cause of ill health and death, especially among poor people in developing countries.
- Changing lifestyles and patterns of global food production and supply have created new risks.
- Hygiene standards of producers and suppliers are inadequate, but they lack the knowledge and resources to make improvements.
- There is a need for harmonized food safety standards for international trade.
- Risk-based process controls along the food production and supply chain, from 'farm to table' need coordination and supervision.

A food chain approach to food safety requires coordination of the activities of all those involved in the production, processing, distribution and sale of food. Animal feed is also included. This approach needs to be targeted to areas of high risk. Food producers need to be informed of their responsibilities. In addition the public needs to be informed of the risks and how to minimize them.

A modern food safety system requires coordination of process control measures throughout the food chain.

The World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Measures Agreement sets out rules for the application of standards to facilitate international trade. SPS rules provide a mechanism to allow importing countries to accept the food safety standards of exporting countries.

It is the role of governments to establish a national food safety system that takes a preventative approach to ensure the production and supply of safe food for both its own consumers and for food exports. This includes the supervision of imported food to ensure it meets the same standards. The approach to food safety must be taken in a way that encourages trade in food products and economic development, but at the same time is appropriate to local circumstances.

When establishing coordination mechanisms it is important to recognize that food safety is a cross-cutting issue that requires cooperation and collaboration between different government departments (e.g. agriculture and public health authorities) as well as with private sector businesses.

This handbook explains how food safety services can be coordinated to ensure that food supplied to the consumer is safe to eat. It is based on common principles, standards and guidelines as set by international organizations (the SPS Agreement; FAO/WHO Codex Alimentarius Commission for food standards; the World Organization for Animal Health (OIE) for veterinary public health and zoonoses, and; the International Plant Protection Convention (IPPC) for plant health).

The handbook also takes into account European Union (EU) food policy, strategy and legislation where it is relevant. The European Community is the world's largest trading area and biggest food importer, and it has specific provisions to support harmonization and compliance with exporting countries.

4.2. Food safety principles

According to international standards a food safety system must comply with the following basic principles.

The **guiding principle** of the food safety system is to ensure that all food placed on the market is safe to eat and provides a high level of protection of human life and health.

Food is considered unsafe if it is injurious to health or unfit for human consumption. International food safety standards are set by Codex Alimentarius, OIE and IPPC.

With respect to a national food safety system, it is important to distinguish between food safety and food quality. Food is considered to be either safe or unsafe. Safe food must be free of microbiological hazards; chemical hazards (natural plant chemicals, residues, contaminants, toxins, unsafe food additives); and physical hazards (e.g. glass and other foreign bodies). Food quality can refer to a wide range of attributes of food (such as color, taste, size, organic, place of origin, nutritional composition) as well as the way it is produced; but these are only included in food law when there is an impact on ensuring safe food for the consumer and fair practices in the food trade. Food quality requirements must comply with SPS and TBT measures.

A modern food safety system applies process controls in an integrated farm-to-table approach to maintain food hygiene throughout the production and supply chain.

Individual food business operators are primarily responsible at each stage of the food chain for ensuring that food safety is not compromised. Food manufacturers should base their control mechanisms on hazard analysis and critical control point (HACCP) principles together with good hygiene practice. The application of HACCP principles to primary production is generally not feasible and primary producers should apply specific good practice measures.

A scientific risk-based approach is used to apply the most appropriate risk reduction measures. Risk analysis comprises risk assessment, risk management and risk communication. Risk assessment must be science-based and carried out independently from risk management.

Transparency, consultation and communication are necessary to ensure harmonization and coordination of stakeholders and to increase consumer confidence. Registration of food businesses is necessary to allow integration and supervision of the food safety system.

The public and private sectors must cooperate in an integrated food safety system.

Traceability of food and food ingredients along the food chain must be ensured to enable the identification of food safety incidents and prompt withdrawal of food from the market.

Flexibility of the system is necessary to adapt to local circumstances and specific products (e.g. traditional products), but this should not compromise food hygiene. This is an important consideration for developing countries that have difficulty complying with international standards and the import requirements of developed countries (including the European Community).

Food imports and exports should comply with equivalent standards and requirements to those for domestic production and sale.

To take account of technical and scientific advances and ensure harmonization with international standards, cooperation with relevant international organizations and trading partners is required.

A food law is necessary to designate competent authorities, set minimum hygiene measures, enable monitoring and official controls, and ensure harmonization and the operation of an integrated system.

Basic principles for a coordinated food safety system

- All food placed on the market must be safe to eat
- Process controls should be applied in an integrated farm-to-table approach
- Prime responsibility for food safety lies with the food business operator
- A scientific risk-based approach should be applied to food safety measures
- Transparency, consultation and communication are necessary to ensure stakeholder involvement and consumer confidence
- Food businesses must be registered to enable integrations, supervision and traceability
- Flexibility to local circumstances is necessary
- Imports and exports must meet equivalent standards
- Cooperation with international organizations
- A food law is required to operate a national food safety system.

4.3. Components of a national food safety system

A national food safety system includes the following components:

1. National policy for food safety
2. Risk analysis
3. Food and feed business control systems
4. Official controls
5. Laboratories
6. Communication and awareness
7. Training and professional development
8. Information

The purpose of this section is not to describe each component in detail, but to highlight areas where coordination is needed. A table showing all the components and sub-components is presented in Annex 1.

4.3.1. National policy for food safety

Component	Sub-components
1. National policy for food safety	1.1 Food safety objectives, principles and responsibilities 1.2 Legislation 1.3 Structure of food safety system 1.4 Public-private roles and relationships 1.5 Financing of public services 1.6 Import and export 1.7 Other considerations (environment, sustainable agriculture, animal welfare, food quality, production methods) 1.8 International discussion, harmonization and equivalence 1.9 Representation on international bodies 1.10 Strategy for development of the food safety system

A key stage in the development and coordination of a national food safety system is to develop a national policy for food safety. A food safety policy sets the objectives, scope, principles, priorities and responsibilities for the food safety system.

The food safety policy will provide the background for developing and implementing a food safety law, which will enable the functioning of the system. It should confirm the guiding principles on which it will be based. The policy will review the current law and

regulations and propose how it can be updated to meet the defined objectives and principles.

The effective implementation of the food safety system depends on clear legislation and precise designation of areas of competence between different control bodies.

National food regulations can be based on international standards set by *Codex Alimentarius*, OIE and IPPC and should be consistent with the SPS and Technical Barriers to Trade (TBT) Agreements. The regulations will determine the appropriate level of protection to be applied.

Increasing consumer awareness of food safety issues may have a positive effect in encouraging improvements.

Whilst products for export have to comply with international standards, it may be unrealistic for some developing countries to achieve international standards in the short to medium term for local produce. In this case the possibility of a phased or targeted approach to adopting standards for the local market may be appropriate. The policy may acknowledge constraints to developing the necessary structures and that technical assistance and capacity building support will be sought to facilitate the process. Domestic consumers may have a low level of awareness of food safety issues and risks and a programme of informing consumers may help to encourage the improvement in food safety controls.

The policy will identify the stakeholders and structure of the food safety system. It will designate the bodies responsible for risk assessment, risk management and risk communication and define the responsibilities of other stakeholders.

The development of the food safety policy as well as the development of administrative structures and other elements of the food safety system should be undertaken with full consultation and involvement of stakeholders. The willing participation of stakeholders is critical to success.

A key factor is the designation of a coordinating body to oversee the development of the food safety system.

The food safety policy may take into consideration other indirect issues relevant for the protection of consumer health and fair trade. These might include, for example: environmental concerns; sustainable agriculture; animal welfare; product quality issues such as food additives and the nutritional value of foods, and; specific production and process methods. Advice on the inclusion of such issues in regulatory standards is available from the *Codex Alimentarius* and SPS and TBT Committees.

The policy may also covering food labelling requirements for some types of food to ensure consumers are informed on food contents. However, the extent to which labelling can be effective needs to be considered in the light of the education of the population and the ways in which most food is sold.

The food safety policy should take into account the international dimension, including harmonization with international standards and representation on international committees. Representation of developing countries in international consultation is important to ensure that international rules fairly reflect the position of all countries.

> The food safety policy should take into account the international dimension to facilitate exports and fair trade.

4.3.2. Risk analysis

Component	Sub-components
2. Risk analysis	2.1 Risk assessment (information gathering and scientific advice) - Scientific Committees - Monitoring and surveillance of food-borne illness - Scientific research and networks - Database of food-borne disease - Rapid alert systems 2.2 Risk management - Regulation - Control 2.3 Risk communication - Dialogue and consultation - Scientific opinions

	- Consumer health protection

In a preventative food safety system control measures are targeted towards the areas of greatest risk. The traditional method of routine sampling and testing no longer applies.

Risk analysis enables targeting of control measures and makes the best use of resources.

Risk analysis comprises risk assessment, risk management and risk communication. Risk analysis enables the identification and implementation of priority actions as well as providing a mechanism for rapid response to arising concerns and flexibility to address them in the most effective manner. The aim of risk analysis is to reduce to acceptable levels risks to human and animal health and wellbeing, and guarantee fair trade.

Risk assessment involves gathering information and providing scientific advice on the food safety risks related to particular foods. Mechanisms have to be in place for surveillance and monitoring to provide the necessary scientific data (e.g. epidemiological information and prevalence figures) for analysis to inform the scientific assessments. Some of this information may be supplied using existing scientific networks (including international networks) as well as a database of information related to food borne diseases.

Risk assessment is very often carried out by scientific committees or under a separate agency. It must be: scientifically based; independent of commercial and political interests, and; transparent. Transparency involves the clear and open presentation of opinions as well as open and publicly verifiable assessment procedures.

Risk assessment is science based.

The risk assessment body must be prepared to react to crises by mobilizing scientific resources and providing scientific advice on the most effective actions.

It is appropriate for the risk assessment body to operate the rapid alert system, which receives notifications of disease outbreaks and provides appropriate information to stakeholders.

Risk management involves regulatory and control functions. Regulation may be contained in primary legislation and implementing legislation. Risk management is carried out by competent authorities who are responsible and accountable to government, and official control bodies.

Risk management is policy based.

Risk management involves consideration of risk assessment and other factors (infrastructure, resources, techniques, priorities) and selection of the most appropriate

controls options for the specific situation. It involves implementing the decisions and monitoring the results.

Operators are responsible for compliance with regulations and the minimization of risk. The competent authorities are responsible for ensuring operators maintain food safety standards through a system of official controls and enforcement provisions.

As well as supervision and control of the food production and supply chain, risk management includes border controls to prevent the entry of food ingredients and products that do not comply with standards.

Risk management may include other preventative actions, such as the provision of advice, education and training.

Risk communication involves the exchange of information between concerned parties. It includes providing scientific opinions to address food safety concerns; dialogue and consultation with stakeholders; and providing information to consumers on wider issues concerning consumer health protection related to food.

Risk communication concerns both risk assessment and risk management.

The nature of the risk assessment and risk management functions such that they must be carried out separately from each other. Risk assessment must be free of commercial and political influences; whereas risk management involves weighing up the most practical options, is accountable to government and requires collaboration with commercial operators.

Risk communication concerns both risk assessment and risk management. Communications must be clear and precise and address consumer uncertainties.

The possible combinations of the three functions is illustrated below.

Successful use of the risk analysis approach depends on the complete food safety system being in place, *i.e.* legal and regulatory base; institutions and coordination mechanisms, food inspection and laboratory services, and human resources.

4.3.3. Food and feed business control systems

Component	Sub-components
3. Food and feed business control systems	3.1 Internal control systems based on HACCP principles 3.2 Good Hygiene Practice (GHP) 3.3 Product traceability 3.4 Handling animal by-products (ABP) 3.5 Producer associations 3.6 Certification bodies

The general guiding principles establish that food business operators have primary responsibility for ensuring compliance with food law and the safety of the food or food ingredients within the business.

Under EU regulations the key obligations of food and feed business operators are:

Safety:	Operators shall not place on the market unsafe food or feed
Responsibility:	Operators are responsible for the safety of the food which they produce, transport, store or sell
Traceability:	Operators shall be able to rapidly identify any supplier or consignee
Transparency:	Operators shall immediately inform the competent authorities if they have a reason to believe that their food or feed is not safe
Emergency:	Operators shall immediately withdraw food or feed from the market if they have a reason to believe that it is not safe
Prevention:	Operators shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points
Cooperation:	Operators shall cooperate with the competent authorities in actions taken to reduce risks. Operators are required to keep up-to-date documents and provide evidence of compliance to the competent authority when required.

The most effective way to achieve a high level of food safety is through the use of good practice guidelines and the application of HACCP principles. Certification can be used to ensure the achievement of certain operating standards.

Businesses operating in a food chain may have contractual obligations to meet industry specifications for food safety and food quality. These obligations can result in greater joint responsibility for food safety. However each operator within the chain must ensure that the necessary measures are taken as required for its own business. Operators must cooperate to ensure food chain traceability. Training may be required to meet the required skill levels.

Cooperation between operators is required to maintain food safety throughout the food chain. In some cases one or more larger operators in the chain (e.g. a processing plant or a supermarket) may coordinate the roles of others. Producer associations may also be involved and may assume communication and organization roles.

Food business operators must cooperate with other food businesses in the food chain as well as with competent authorities.

4.3.4. Official controls

Component	Sub-components	
4. Official controls	4.1	Official control of food businesses
	4.2	Programming of control plans
	4.3	Inspection, sampling and compliance checks
	4.4	Monitoring plans
	4.5	Registration and approval of establishments
	4.6	Authorization and control of veterinary medicinal and phyto-pharmaceutical products
	4.7	Residue plans
	4.8	Border controls
	4.9	Official certification
	4.10	Other activities, including animal health, plant health and public health, in particular concerning zoonoses

Whilst primary responsibility for food safety lies with food businesses, competent authorities are responsible for ensuring the controls are implemented. Food and feed businesses must be registered and approved for operation. Controls may be carried out using a variety of techniques including surveillance checks, inspections, verifications, audits, sampling and testing.

Controls should be carried out using documented procedures and operators should be informed of reports on their compliance. All control activities should be transparent.

Competent authorities may delegate some official control activities (e.g. to other organizations at the national level or to regional and district levels) and must ensure efficient coordination with control bodies, as well as between departments within the competent authority. Coordination is essential to ensure clear delegation of responsibilities and tasks, full understanding of the legal requirements and techniques, and avoid duplication and overlapping of tasks. It is also necessary to avoid conflicting priorities and interests from different ministries.

Official controls may be carried out by various bodies and responsibilities must be clearly defined.

Competent authorities must coordinate with border control authorities concerning import and export of food and feed. In the case of regional free trade areas, harmonized measures may apply to allow the free movement of feed and food ingredients and products.

For exports to the European Community, competent authorities may be required to provide details of official controls to the European Commission. They may also be subject

to inspection by the European Commission (Food and Veterinary Office) to ensure that exported feed complies with EU import requirements.

4.3.5. Laboratories

Component	Sub-components
5. Laboratories	5.1 Laboratory structure, services and facilities 5.2 Reference laboratories 5.3 Good Laboratory Practice (GLP) 5.4 Laboratory accreditation 5.5 Administration and financial management 5.6 Human resources 5.7 Budgeting

Competent authorities are required to designate laboratories to carry out analysis of samples taken during official controls. The authorities must ensure that the designated laboratories have the infrastructure, competence, expertise, resources and financing to carry out their duties.

4.3.6. Communication and awareness

Component	Sub-components
6. Communication and awareness	6.1 Communication network 6.2 Consumer awareness 6.3. Labelling and advertising

Communication is a key element of the food safety system and is one of the three risk analysis functions.

Communication mechanisms are required to:

- Deliver information, training and advice to food chain stakeholders. This can include: information on food-borne disease status; training to stakeholders; operational guidelines, and; reference literature;
- Provide information to consumers on: food-borne diseases; reported outbreaks and actions taken, including action required by consumers: and general advice on food hygiene and minimizing the risks of contracting food-borne disease;
- Ensure uniform and consistent application of control measures;
- Ensure transparency and accountability in decision making actions.

The food safety policy and strategy should include a communications strategy to describe the requirements for developing a communication system.

4.3.7. Training and professional development

Component	Sub-components
7. Training and professional development	7.1 Training methods 7.2 Training needs analysis 7.3 Training programmes 7.4 Training tools 7.5 Case studies 7.6 Presentations

Training of both administration staff and food business operators is critical to the successful development of effective food safety systems. Many food producers lack knowledge and information on food hygiene and how to apply it in modern agricultural and processing systems.

Studies have shown that involving and educating food business operators through participatory approaches helps to provide greater understanding of food safety issues, resulting in improved compliance. These then need to be backed up with formal control measures. Applying prescriptive approaches alone may stimulate an immediate compliance response but fail to develop the same understanding and therefore there is little lasting benefit.

Participation is better than prescription.

Food business operators are more likely to respond to a participatory approach to food safety rather than to prescriptive actions.

4.3.8. Information

Component	Sub-components
8. Information	8.1 Guidelines and manuals 8.2 Lessons learned and best practice 8.3 Relevant documents 8.4 List of reference material

The operation of a food safety system needs to be supported by access to appropriate information to support food chain operators in achieving compliance, as well as to inform consumers.

4.4. Models for a national food safety system

National food safety systems around the world use different models to coordinate activities. In some countries responsibilities are divided between several ministries or other bodies. In others a single food agency is established to provide coordination, although the range of responsibilities of food agencies differs between countries. Thus, there is no single ideal structure: the key factor is to have good communication and coordination.

FAO and WHO have identified three basic models for a food safety system that may be considered.

Possible models for a food safety system

1. Multi-agency system
2. Single agency system
3. Integrated system

4.4.1. Multi-agency system

A multiple agency food safety system is the traditional model in many countries. In many cases it evolved within the existing structures as food safety activities were developed by different ministries and bodies.

A typical organization has the ministry responsible for agriculture responsible for primary production and the early stages of the food chain, whereas the ministry responsible for health is involved at the later stages.

Other ministries (such as for trade and environment) may also be involved. It is also possible to have sectoral approaches with, for example, different departments responsible for animal production and crop production.

Food safety responsibilities may also be delegated to different bodies at regional and district levels e.g. local agricultural and veterinary inspection services, and local departments of health.

The advantages of a multiple agency approach are that it makes use of existing structures and concentrates specialists in their own sectors.

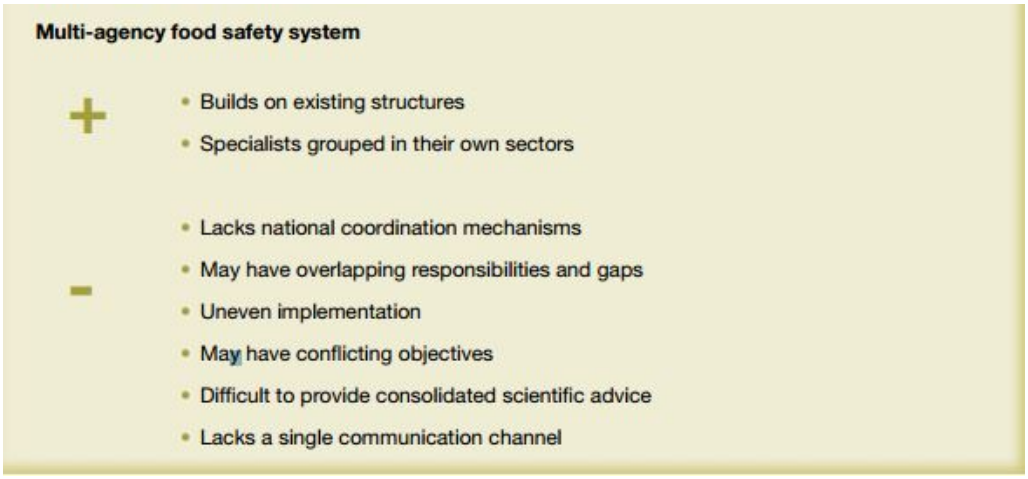
Possible drawbacks of a multiple agency approach include:

- lack of coordination mechanisms at national level preventing an integrated approach to risk analysis;
- overlapping jurisdiction and duplication of regulatory activities (e.g. both veterinary and health services involved in inspecting consignments of meat at the border) or gaps due to lack of coordination;

- uneven implementation due to differences in expertise and available resources;
- different objectives (e.g. achieving a high level of public health may conflict with maximizing trade);
- difficulties in delivering comprehensive risk assessments and scientific advice;
- no single body responsible for communication may lead to conflicting messages and lowered public confidence.

To achieve a successful multi-agency system that fulfils the key principles for food safety, it is necessary to have a national policy and strategy to define the responsibilities and roles of each agency so as to achieve a cohesive system.

A multi-agency system may build on existing structures but may have disadvantages in terms of cohesion.



4.4.2. Single agency system

A single agency system brings advantages in terms of consolidating activities. Particular benefits include:

- a unified approach to food safety prevention and control measures; it particularly enables risk assessment to be based on the best science;
- allows the scientific risk assessment to take place (under a separate division) with consideration of the practical issues for risk management. This could enable more inclusive decision making without compromising the independence of the risk analysis;
- provides a mechanism for harmonization of standards and procedures across all sectors;
- provides a focus point for harmonizing export compliance;
- facilitates the establishment of clear communication lines with the food sector, consumers, and international organizations;
- centralization allows more direct control of enforcement and coordination;
- more efficient coordination of border controls;
- supports a rapid and harmonized response to food safety issues and alerts;

- offers efficiency savings through streamlining of services.

However, the establishment of a single agency system would be likely to entail a major reorganization of existing structures, which may be difficult for political and practical reasons. When setting up the agency it would be necessary to ensure the separation of risk assessment and risk management functions.

A single agency system brings advantages in terms of consolidation, simplicity and cohesion; but may be difficult to bring about and may mean less contact at local.

Possible disadvantages of centralized control are:

- a loss of relationships with local authorities;
- more difficulty in interacting with consumers at local level;
- less knowledge and contact with local food businesses;
- slower notification of food safety alerts.

Single agency food safety system

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- Unified approach
- Allows more practical risk assessment
- Mechanism for harmonisation of standards and procedures
- Focus point for export compliance
- Clear communication lines
- Efficient coordination of border controls
- Facilitates rapid and harmonised response to alerts
- Streamlining and efficiency

−
- May entail major restructuring
- Loss of relationships with local authorities
- Difficult to interact with consumers at local level
- Less knowledge and contact with local food businesses
- Slower notification of food safety alerts

4.4.3. Integrated system

Integrated food safety systems provide variations on the single agency approach by combining coordination at the national level with delegation of risk management functions at national, regional and local levels.

Typically an integrated system involves setting up a food agency to provide centralized activities at the national level focused on risk assessment, scientific advice and coordination activities. Risk management activities are undertaken separately, possibly under existing structures at national, regional and local levels.

Various permutations of the above arrangements are possible to suit specific country situations.

The advantages of an integrated system are that it provides coherence at the national level and supports uniform application of control measures without losing the benefit of local contacts. The agency is not involved in risk management and therefore separation from risk assessment is achieved.

An integrated system can achieve coordination through a food safety agency whilst risk management is performed through existing structures.

It is critical when setting up such an advisory and coordinating body that it established within a proper structure and with a clear mandate, full funding and suitably trained staff to enable it to undertake its responsibilities and engage with stakeholders.

Integrated food safety system

\+
- Unified national coordinating structure
- Responsibility for overall strategy across the food chain
- Independent of government and sectoral interests
- Separation of risk assessment and risk management
- Utilises existing structures for localisation of food inspection and enforcement
- Enables centralised coordination of outbreak response
- Provides a single contact point for food safety advice and communication
- Contact point for liaison with international organisations

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- Possible issues with delegation of responsibilities
- The agency may be ineffectual unless it has a clear mandate, full funding, has full access to required information and is staffed with suitably trained experts who are able to take a collaborative approach to engage with stakeholders

4.4.4. Structure of a food safety agency

Single agency and integrated systems requires a central coordinating authority. Many countries do this by setting up a food safety agency, although this is not essential. In the experience of the European Union, national food authorities have had a positive effect where they have been established.

The roles of food safety agencies vary between countries. Some countries limit the activities to risk assessment and scientific advice. Others include risk communication, coordination of risk management, or risk management itself.

The food agency should be statutory authority backed by legislation and with defined and clear roles and responsibilities. One of the main functions should be risk assessment and the provision of science based advice.

Prerequisites for a national food agency:

- legal base
- transparency and accountability
- focus on consumer health
- scientific basis
- independent from government
- integration along the food chain
- multi-disciplinary

The food safety agency must be a body created by a legislative decision, with clear and defined tasks and competences. One of its main tasks should be risk assessment and the provision of scientific advice.

Its missions and activities must be transparent and respect the chain of responsibilities in order to ensure consumer confidence.

The decision-making process must be open and involve stakeholders in the agri-food chain. This is important in order to encourage stakeholders to cooperate and fulfill their obligations.

The agency should have an approved and published strategic plan for a specific period and its performance should be accountable against targets set in the plan. Its primary aim should be to protect the health of the consumer by guaranteeing food safety.

The agency should have a scientific base to enable the provision of advice on scientific and technical questions related to food safety and hygiene, which can include:

- reviewing the national food safety strategy and providing policy advice;
- coordinating scientific research and the development of new methods;
- development of standards and regulations;
- risk assessment and setting of priorities;

- coordinating surveillance of food-borne diseases;
- risk communication;
- coordination of risk management activities, including monitoring and auditing of inspection and enforcement;
- specified quality issues, such as the nutritional content of food;
- developing education and training programmes;
- liaison and participation with international organizations.

Agencies may carry out risk management functions (*i.e.* inspection and enforcement, which may be accompanied by advice, education and training. If so, the structure of the agency must provide a clear separation between the risk assessment and risk management functions. Alternatively, risk management may be carried out by separate bodies.

The agency should have independence from government to allow unbiased decision making based on scientific assessment.

The agency should follow the farm-to-table approach where control measures are applied throughout the food chain and food business operators have primary responsibility for the safety of their products. The agency has a secondary responsibility to support the food sector in achieving a high level of food safety.

The agency should have access to multi-disciplinary skills to address the needs of the sector.

The agency statute should provide for its funding. Different funding models are used, including annual government budgets and possibly by fees from the food industry and trade.

Structure of a food safety agency

Mission

A food safety agency provides a central coordinating authority to guarantee food safety and protect public health.

Role

Possible roles include:

- risk assessment;
- risk assessment + risk communication;
- risk assessment + risk communication + risk management.

Organisation

- Statutory authority with a legal base and clearly defined purpose and lines of responsibility.
- Statutory powers to coordinate and supervise food safety control.
- Governed by a management board, supported by scientific and technical committees.
- Independent of government but reporting to government.

- Work is undertaken according to an approved strategic plan within agreed codes of practice.
- Some functions may be delegated to other bodies at national, regional and local levels.
- Activities are carried out transparently to ensure consumer confidence.
- Decision making should be science based and include participation of food chain stakeholders.
- Government commitment to ensure continuity of funding.

Possible tasks

- Review of strategy and providing policy advice to government.
- Coordination of scientific research.
- Development of standards and regulations.
- Risk assessment and setting of priorities.
- Coordinating surveillance of food-borne diseases.
- Risk communication.
- Coordination of risk management activities, including monitoring and auditing of inspection and enforcement.
- Specified quality issues, such as the nutritional content of food.
- Developing education and training programmes.
- Liaison and participation with international organizations.

4.4.5. Coordination in a regional trade area

As well as coordination of national food safety activities, developing countries may consider coordination of food safety systems within regional trade areas. Preferably this should be carried out at the same time as the strengthening of national systems. Many trading areas are already adopting this approach.

The advantages of regional coordination are:

- Harmonization of controls facilitates the development of a regional single market and the free movement of livestock, feed and food ingredients, and food products with consequent economic trade benefits.
- Improved control of animal, plant, zoonotic and food-borne diseases. Animal diseases in particular do not respect national boundaries and outbreaks may easily transfer across borders. The adoption and implementation of coordinated control plans helps to prevent and control outbreaks.
- Regional harmonization and collaboration allows sharing of expertise and information leading to efficiency savings in food safety controls for the common good. There are also benefits to be gained from cooperation between laboratories.
- Harmonization of standards and cooperation in production and processing may bring mutual benefits for imports and exports out of the region.
- Harmonization of standards and cooperation can be a means for developing countries to bring a stronger representation to international committees, *i.e.* SPS, TBT, OIE, IPPC, *Codex Alimentarius*.

The challenges to be faced would include:

- Harmonized legislation would be required for the setting up of regional systems.
- Difficulties of harmonization of standards between countries with different levels of development ('development gaps'), either nationally or within specific sectors.
- Achieving consensus for common approaches, particularly for rapid responses to food safety alerts.
- Obtaining long-term agreement and commitment on funding of the regional coordination body.

Regional coordination of food safety activities

\+
- Facilitates regional trade in food products
- Improved control of animal, plant, zoonotic and food-borne diseases
- Efficiency savings in food safety control
- Facilitates extra-regional trade in food products
- Stronger representation on international committees

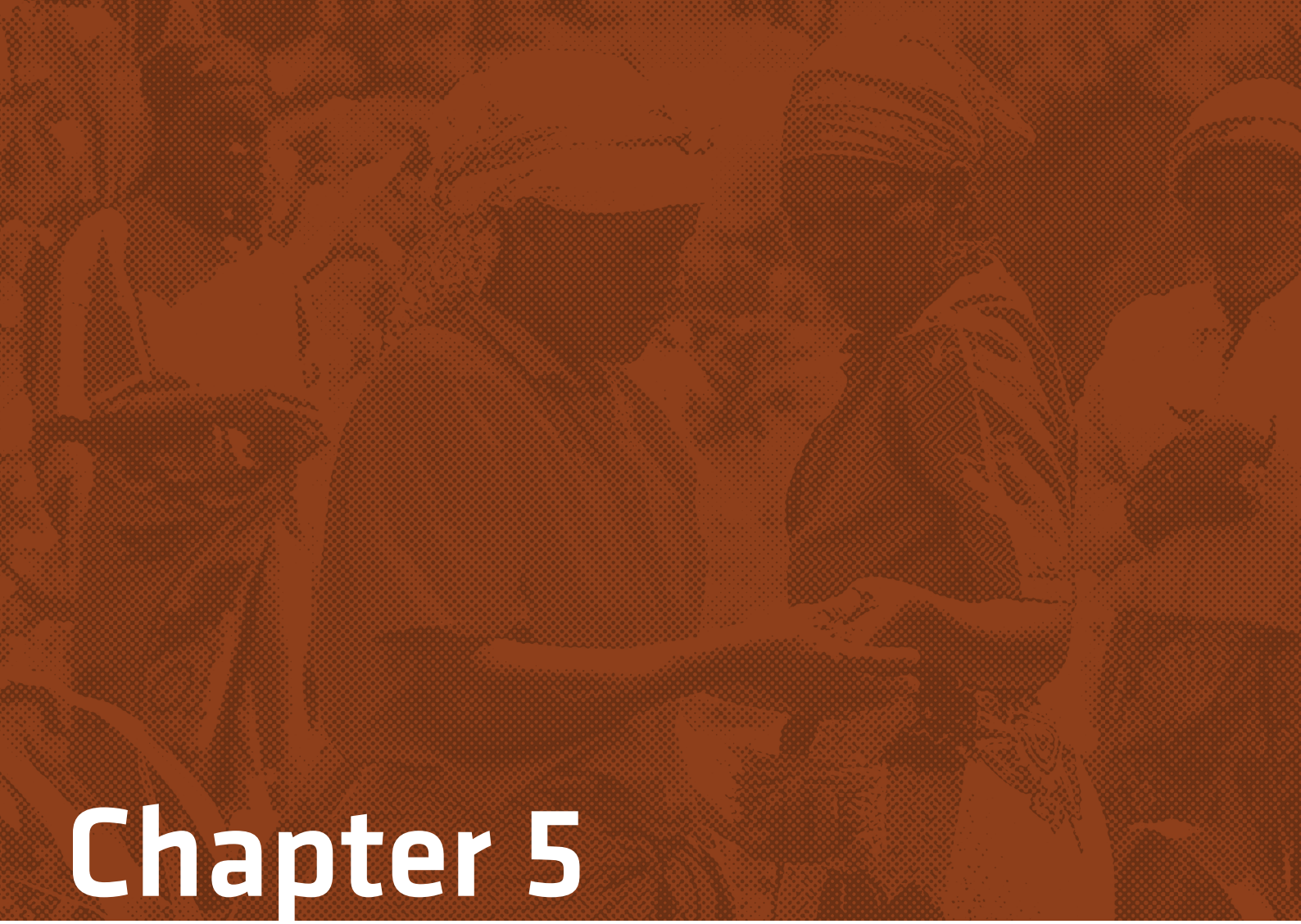
−
- Requires harmonisation of national legislation
- Harmonisation may be difficult where there are different levels of development at national or sectoral levels
- May be difficult to achieve consensus for common approaches, particularly rapid responses to food safety alerts
- Difficulties in obtaining long-term commitment on funding

Appendices

A.1. Components of a food safety system

Components of a Food Safety System	
Main components	**Sub-components**
1. National policy for food safety	1.1 Food safety objectives, principles and responsibilities 1.2 Legislation 1.3 Structure of food safety system 1.4 Public-private roles and relationships 1.5 Financing of public services 1.6 Import and export 1.7 Other considerations (environment, sustainable agriculture, animal welfare, product quality, production methods) 1.8 International discussion, harmonization and equivalence 1.9 Representation on international bodies 1.10 Strategy and action plan for development of the system
2. Risk analysis	2.1 Risk assessment (information gathering and scientific advice) - Scientific Committees - Monitoring and surveillance of food-borne illness - Scientific research and networks - Database of food-borne disease - Rapid alert systems 2.2 Risk management - Regulation - Control 2.3 Risk communication - Dialogue and consultation - Scientific opinions - Consumer health protection
3. Food and feed business control systems	3.1 Internal control systems based on HACCP principles 3.2 Good Hygiene Practice (GHP) 3.3 Product traceability 3.4 Handling animal by-products (ABP) 3.5 Producer associations 3.6 Certification bodies
4. Official controls	4.1 Official control of food businesses 4.2 Programming of control plans 4.3 Inspection, sampling and compliance checks 4.4 Monitoring plans 4.5 Registration and approval of establishments 4.6 Authorization and control of veterinary medicinal and phyto-pharmaceutical products 4.7 Residue plans

	4.8 Border controls 4.9 Official certification 4.10 Other activities, including animal health, plant health and public health, in particular concerning zoonoses
5. Laboratories	5.1 Laboratory structure, services and facilities 5.2 Reference laboratories 5.3 Good Laboratory Practice (GLP) 5.4 Laboratory accreditation 5.5 Administration and financial management 5.6 Human resources 5.7 Budgeting
6. Communication and awareness	6.1 Communication network 6.2 Consumer awareness 6.3 Labelling and advertising
7. Training and professional development	7.1 Training methods 7.2 Training needs analysis 7.3 Training programmes 7.4 Training tools 7.5 Case studies 7.6 Presentations
8. Information	8.1 Guidelines and manuals 8.2 Lessons learned and best practice 8.3 Relevant documents 8.4 List of reference material



Chapter 5

General principles of national surveillance and control system

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5.1. Background

Food-borne disease is a major public health problem in both developed and developing countries. Reducing the burden of food-borne disease is recognized internationally as an essential public health function.

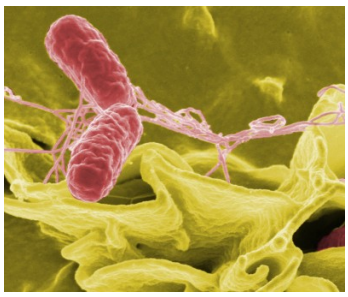
The availability of safe food improves the health of people and is a basic human right. Safe food contributes to health and productivity and provides an effective platform for development and poverty alleviation. People are becoming increasingly concerned about the health risks posed by microbial pathogens and potentially hazardous chemicals in food. Up to one-third of the populations of developed countries are affected by food-borne illness each year, and the problem is likely to be even more widespread in developing countries.

Food-borne diseases encompass a wide spectrum of illnesses and are a growing public health problem worldwide. They are the result of ingesting contaminated foodstuffs, and range from diseases caused by a multitude of microorganisms to those caused by chemical hazards.

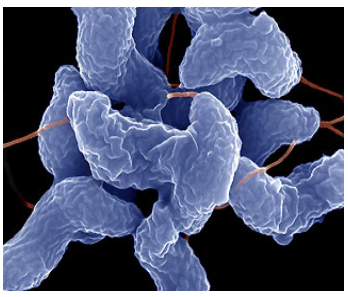
The most common clinical presentation of food-borne diseases takes the form of gastrointestinal symptoms but such diseases can also lead to chronic, life-threatening symptoms including neurological and immunological disorders as well as multiorgan failure, cancer and death.

Recent global developments are increasingly challenging international health security. These developments include the growing industrialization and trade of food production, the rapid urbanization associated with a more frequent food preparation/consumption outside the home and the emergence of new or antibiotic-resistant pathogens.

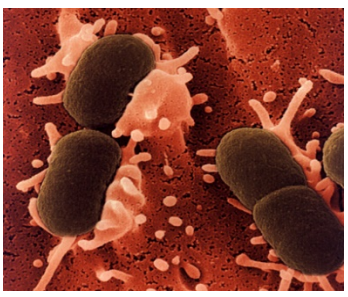
Microbiological hazards and the food-borne diseases they cause are an increasingly important public health problem. In many countries significant increases have been reported in the incidence of diseases caused by microorganisms transmitted mainly by food, such as *Salmonella spp*. and *Campylobacter spp*. New, serious hazards have emerged in the food chain, such as enterohaemorrhagic *Escherichia coli* and bovine spongiform encephalopathy.



Salmonella spp.
(Source: Wikipedia)



Campylobacter spp.
(Source: Health Picture)



Escherichia coli
(Source: E. coli Blog)

Chemical hazards remain a significant source of food-borne illness. Chemical contaminants in food include natural toxicants, such as mycotoxins and marine toxins, environmental contaminants, such as mercury and lead, and naturally occurring substances in plants. Food additives, pesticides and veterinary medicines are deliberately used in the food chain and may be a source of food safety hazards if not used correctly.

Control measures to address microbiological and chemical food safety hazards are essential to protect the health of a country's population. In order to address and manage food safety, it is imperative to have knowledge on the current situation and trends with regard to the occurrence and spread of hazards in the food production chain. Surveillance of food–borne hazards and the diseases they cause is the basis for the formulation of national strategies to reduce food-related risks. Detailed and accurate knowledge about the nature and level of food-borne diseases is a prerequisite for action to control risks.

In developed countries, surveillance of food-borne disease is a fundamental component of food safety systems. Surveillance data are used for planning, implementing and evaluating public health policies. There is therefore a strong need to strengthen surveillance systems for food-borne disease.

Surveillance makes a major contribution to the economy of a country by enabling resources to be directed in the most efficient manner to food safety and by promoting export of food through the provision of guarantees to trading partners.

5.2. The need for surveillance

In the past, many food control systems were based on sampling and testing of end products to assess their safety for human consumption. This approach is now recognized as ineffective in controlling the range of food-borne hazards of concern now. **There is international consensus that the modern approach to food safety controls is to apply preventative measures throughout the production chain to minimize the occurrence of food safety problems.** This approach is enshrined in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement" (SPS)) and *Codex Alimentarius* Commission (CAC) texts, and comprises three main principles:

- Food safety controls should be based on an assessment of risk;
- Control measures should be applied throughout the food production chain;
- Food producers have primary responsibility for the safe production of food.

5.2.1. Risk-based food safety controls

Approaches to food safety have evolved internationally in recent years away from traditional controls based on end-product testing towards a preventative approach that aims to eliminate or control food safety hazards at source. This approach has led to the development of systems based on the analysis of risks posed by the presence of hazards in food. Internationally, risk-based systems have been driven by the World Trade Organization SPS Agreement. This Agreement requires signatory countries to ensure that their sanitary and phytosanitary measures are based on an assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organizations. Risk assessment is the scientific component of risk analysis and should be functionally separated from risk management, which draws upon the outcome of risk assessment to consider and select strategies and policy options for food safety, to avoid interference from economic, political or other interests.

5.2.2. The food production chain

An important component of the risk-based approach is its application to the entire food production chain, from 'production to consumption'. Food safety can be best delivered by an integrated approach that covers the entire production chain and identifies the most effective points in the chain where interventions can be applied to eliminate or reduce food safety hazards.

5.2.3. Responsibilities for food safety

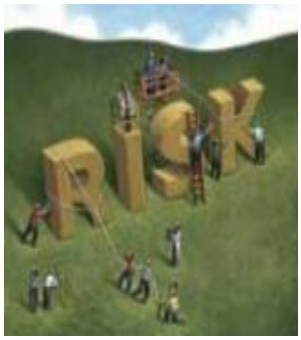
The traditional approach, where food operators were primarily held responsible for food quality while regulatory agencies were charged with assuring food safety, has been

replaced by more sophisticated systems that give food operators, including primary producers, responsibility for the safety of the foods they place on the market.

The internationally recognized method for food business operators to fulfil their responsibilities, and the method recommended by CAC in its general tests on food safety, is the application of food safety management systems based on the principles of Hazard Analysis Critical Control Point (HACCP).

The role of government authorities and inspection services is to analyze scientific information as a basis to develop appropriate food safety standards (both processing and end product standards) and verification inspections to ensure that the control systems used by food operators are appropriate, validated, effective and operated in such a way that the standards are met. In the event of non-compliance, regulatory agencies are responsible to ensure that appropriate corrective actions are taken and sanctions are applied.

5.3. Food safety risk analysis



Risk analysis must occur in a context and, to be done effectively, requires a formal process. In a typical instance, a food safety problem or issue is identified and risk managers initiate a risk management process, which they then see through to completion. This is best accomplished within a systematic, consistent and readily-understood framework in which scientific knowledge on risk and evaluations of other factors relevant to public health protection are used to select and implement appropriate control measures. The responsibilities of risk managers during this process also include commissioning a risk assessment when one is needed, and making sure that risk communication occurs wherever necessary.

A wide range of factors need to be considered when addressing a food safety risk analysis, and many of these require surveillance information, including:

- initial statement of the food safety issue;
- assessment of the human health impact of the hazard;
- description of the hazard and food(s) involved;
- how and where the hazard enters the food supply;
- which foods expose consumers to the hazard and how much of those foods are consumed by various populations;
- frequency, distribution and levels of occurrence of the hazard in foods;
- identification of possible risks from the available scientific literature;
- nature of values at risk (human health, economic, cultural etc.);
- distribution of the risk (who produces, benefits from, and/or bears the risk);
- characteristics of the commodity/hazard that might affect the availability and feasibility of risk management options.

At the national level risk analysis is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied. It can be used to support and improve the development of standards, as well as to address food safety issues that result from emerging hazards or breakdowns in food control systems. It provides food safety regulators with the information and evidence they need for effective decision-making, contributing to better food safety outcomes and improvements in public health. Regardless of the institutional context, the discipline of risk analysis offers a tool that all food safety authorities can use to make significant gains in food safety.

Risk analysis can be used to obtain information and evidence on the level of risk of a certain contaminant in the food supply, helping governments to decide which, if any, actions should be taken in response (e.g. setting or revising a maximum limit for that contaminant, increasing testing frequency, review of labelling requirements, provision of advice to a specific population subgroup, issuing a product recall and/or a ban on imports of the product in question). Furthermore, the process of conducting a risk analysis

enables authorities to identify the various points of control along the food chain at which measures could be applied, to weigh up the costs and benefits of these different options, and to determine the most effective one(s). As such, it offers a framework to consider the likely impact of the possible measures (including on particular groups such as a food industry subsector) and contributes towards enhanced utilization of public resources by focusing on the highest food safety risks.

Once food safety control measures have been put in place as a result of the risk analysis process, surveillance plays an important role by providing information about the effectiveness of the measures. Continued surveillance enables national authorities to assess the results of control systems for food safety hazards and to amend and refine them as necessary.

In summary, surveillance is essential for the identification of food related public health issues, for the provision of data to inform the risk analysis process and the selection of risk control options, and to assess the effectiveness of food safety control measures applied.

A national surveillance system for food related public health hazards should aim to deliver the following results:

- provide evidence for informed action to protect public health;
- provide evidence to effect specific actions and programmes to prevent or reduce as far as practicable the incidence of food-borne disease;
- permit an assessment of the application of food safety programmes including enforcement and education policies;
- identify specific trends and emerging issues. The identification of such trends will instruct and inform the discussions required for directing surveillance programmes;
- ability to compare local, regional, national and international data and to establish benchmarks between local and national data sets;
- provide evidence to ensure the most effective use of surveillance resources;
- provide information which will direct further research into areas of public health and consumer concern;
- provide evidence which will inform public information and improve consumer confidence.

5.4. Surveillance for food safety

Surveillance may be carried out at any point in the entire food production, processing, distribution, preparation consumption chain – from 'production to consumption'. There are three main areas where surveillance may be carried out for food safety control purposes:

- food borne disease in humans
- hazards in food
- zoonotic diseases in animal populations

A necessary prerequisite for risk-based strategies based on optimized surveys is an interdisciplinary approach involving strong collaboration among all sectors dealing with food-borne disease surveillance and food safety in the health sector. Effective surveillance for food safety requires collaboration between experts in human health, veterinary, and food-related disciplines.

The report below about surveillance in the EU for food-borne zoonoses is a good example of coordination between all the disciplines involved in food safety, and includes information about surveillance in humans, food and animals.

Abstract (© European Food Safety Authority, 2012)

The European Food Safety Authority and the European Centre for Disease Prevention and Control analyzed the information on the occurrence of zoonoses and food-borne outbreaks in 2010 submitted by 27 European Union Member States. In 2010, 99,020 salmonellosis cases in humans were reported and decreasing trend in case numbers continued. Most Member States met their *Salmonella* reduction targets for poultry, and *Salmonella* is declining in these populations. In foodstuffs, *Salmonella* was most often detected in fresh broiler and turkey meat. *Campylobacteriosis* was the most commonly reported zoonoses with 212,064 human cases. *Campilobacter* was most often detected in fresh broiler meat. The number of human listeriosis cases decreased slightly to 1,601. *Listeria* was seldom detected above the legal safety limit from ready-to-eat foods at retail. A total of 4,000 confirmed verotoxigenic *Escherichia coli* (VTEC) infections were reported and this number has been increasing since 2008. VTEC was also observed in food and animals. The number of human yesiniosis cases have been decreasing in recent years and 6,776 cases were reported in 2010. *Yersinia enterocolica* was isolated also from pig meat and pigs; 133 cases of *Mycobacterium bovis* and 356 cases of brucellosis in human were also reported. The prevalence of bovine tuberculosis in cattle increased, and the prevalence of brucellosis decreased in cattle, sheep and goat populations. Trichinellosis and echinococcosis caused 223 and 750 confirmed human cases, respectively. These parasites were mainly detected in wildlife. The number of Q fever cases in humans decreased to 1,414. In animals, Q fever was found in domestic ruminants. There were two human cases of rabies in 2010 and the number of rabies cases in animals slightly increased. Most of the 5,262 reported food-borne outbreaks were caused by *Salmonella* viruses. *Campylobacter* and bacterial toxins and the main food sources were eggs, mixed or buffet meals and vegetables.

Source: www.efsa.europa.eu/fr/efsajournal/pub/2597.htm

There are a number of definitions of surveillance, with slight variations depending on the subject of the surveillance:

- "the ongoing systematic collection, collation, analysis and interpretation of data, followed by the dissemination of information to all those involved so that directed actions may be taken";[1]

- “an ongoing, systematic collection, analysis and interpretation of health-related data essential to the planning, implementation, and evaluation of public health practice” (WHO);[2]

- “the systematic, continuous or repeated, measurement, collection, collation, analysis, interpretation and timely dissemination of animal health and welfare related data from defined populations, essential for describing health hazard occurrence and to contribute to the planning, implementation, and evaluation of risk mitigation measures”.[3]

1 WHO/CDS/CSR.
2 www.who.int/immunization_monitoring/burden/routine_surveillance/en/.
3 www.animalhealthsurveillance.org.

5.5. Types of surveillance

Different types of surveillance activity may be applied depending on the purpose and desired outcomes of the surveillance. Surveillance may be classified in a number of ways according to factors such as the disease focus, population or commodity studied and desired output, and a wide range of surveillance types and definitions are published;[4] the main categories are scanning (or passive) surveillance and targeted (or active) surveillance.

- **Scanning (passive) disease surveillance**

Scanning disease surveillance is the routine gathering of information on disease incidents in populations (human or animal) from readily available sources.

- **Targeted (active) surveillance**

Targeted surveillance involves examination of selected sub-populations to determine their status for a specific disease over a defined time period. This frequently involves structured surveys. Targeted surveillance is usually conducted in response to perceived concerns about specific diseases or hazards, and is often used to fill the gaps in knowledge obtained from scanning surveillance. The strength of targeted surveillance is that it provides information that is scientifically valid. However, targeted surveillance is often costly and may be conducted only for a defined period of time.

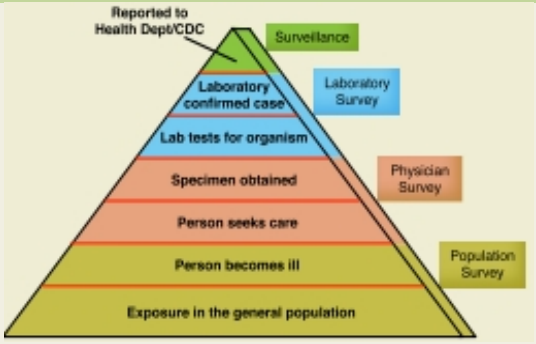
[4] *Ibid*.

5.6. Surveillance of food-borne disease in human populations

Data from surveillance systems and sentinel sites indicate a high disease burden for food-borne diseases caused by microorganisms alone. Such data, however, tend to show only the tip of the clinical iceberg and cannot sufficiently describe true disease burden. For affected persons to feature in such health statistics, they not only have to seek medical care, provide a specimen for laboratory investigation, and test positive on laboratory methods but must also be reported to the relevant health authorities.

FoodNet Surveillance – Burden of Illness

The burden of illness pyramid is a model for understanding foodborne disease reporting. This illustrates steps that must occur for an episode of illness in the population to be registered in surveillance.



Starting from the bottom of the pyramid,

1) some members of the general population are exposed to an organism;
2) some of these exposed persons become ill;
3) some of these ill persons seek medical care;
4) a specimen is obtained from some of these persons and submitted to clinical laboratory;
5) a laboratory tests some of these specimens for a given pathogen;
6) the laboratory identifies the causative organism in some of these tested specimens and thereby confirms the case;
7) the laboratory-confirmed case is reported to a local or state health department.

FoodNet conducts laboratory surveys, physician surveys, and population surveys to collect information about each of these steps. This information is used to calculate estimates of the actual number of people who become ill. Other information is used to estimate the proportion of these illnesses transmitted by food.

Source: USA CDC, www.cdc.gov/foodnet/surveillance.html.

Innovative strategies and methods are needed for surveying food-borne disease and food contamination. A laboratory-based surveillance system should be based on sentinel sites and regional and/or international laboratory networks. The absence of reliable data on the burden of food-borne disease impedes understanding about its public health importance and prevents the development of risk- based solutions to its management. To circumvent the problems posed by such under-reporting and describe disease burden more adequately, a number of innovative and creative approaches have been used in recent years for some food-borne diseases from various causes. These include the use of active

surveillance and field studies, risk assessment methods, and epidemiological disease modelling. For many other food-borne diseases, however, including some zoonoses and diseases caused by chemical hazards, no such data or studies exist.

In order to estimate disease burden comprehensively and provide more complete information for policy makers it is important to move beyond the mere quantification of morbidity and mortality and describe burden in a summary measure that includes elements of severity and duration of disease, as well as resulting disability. Recognition of the problems encountered in surveillance of food–borne diseases has led to a number of international initiatives to address them.

5.6.1. WHO initiative to estimate the global burden of food-borne diseases[5]

The real impact and costs of food-borne diseases globally is unknown. The Initiative to Estimate the Global Burden of Food-borne Diseases was launched out of the need to fill this data vacuum by the Department of Food Safety and Zoonoses (FOS) of the World Health Organization (WHO. This Initiative primarily strives:

- Provide data and tools to support policy-makers and other stakeholders to set appropriate, evidence-informed priorities of food safety at country level.
- Through the support of a special advisory group, the Food-borne Disease Burden Epidemiology Reference Group (FERG), the Initiative aims to:
- Strengthen the capacity of countries in conducting burden of food-borne disease assessments and to increase the number of countries who have undertaken a burden of food-borne disease study.
- Encourage countries to use burden of food-borne disease estimates to set evidence-informed policies.
- Provide estimates on the global burden of food-borne diseases according to age, sex and regions for a defined list of causative agents of microbial, parasitic, and chemical origin.

5.6.2. Global Food-borne Infections Network (GFN)

The aim of GFN is to build capacity to detect, control and prevent food-borne and other enteric infections throughout the ‘production to consumption’ chain.

GFN promotes integrated, laboratory-based surveillance and fosters intersectoral collaboration among human health, veterinary and food-related disciplines through training courses and activities around the world.

5.6.3. Surveillance systems

Surveillance for food-borne diseases is a component of a general surveillance system for all communicable diseases. A functional national communicable diseases surveillance system is essential for action on priority communicable diseases. It is a key part of public health decision-making in all countries (e.g. priority setting, planning, resource

[5] www.who.int/foodsafety/foodborne_disease/ferg/en.

mobilization and allocation, prediction and early detection of epidemics, and monitoring and evaluation of disease prevention and control programmes).

Strong national systems form the basis of an effective regional and global network for the surveillance and control of communicable diseases. The development and strengthening of national surveillance requires a substantial and long-term commitment of human and material resources, usually beginning with a systematic assessment of national surveillance activities. This should eventually lead to a national plan for the surveillance of communicable diseases, including food-borne diseases.

Surveillance for food-borne diseases should be integrated as part of a multi-disease approach to disease surveillance. This approach involves looking at all surveillance activities in a country as a common public service. These activities involve similar functions and very often use the same structures, processes and personnel.

Disease surveillance should be based on collecting only the information that is required to achieve the control objectives. The data required may differ from disease to disease. Specialized surveillance systems are important, especially where surveillance is complex and has specific information needs.

For the system to function as an early warning system, reporting, confirmation, decision-making and response must be rapid. On the other hand, for more endemic diseases, the aim may be to carefully consider data collected in order to adjust or target the control programme. The national surveillance system should therefore be able to accommodate both needs, and will require two-speed reporting mechanisms.

All surveillance systems involve similar functions. It is possible to look at the system as a whole and approach development and strengthening in a coordinated way. The challenge is to identify where synergy between systems is possible, and identify opportunities for coordination or integration of activities, while at the same time recognizing the special needs of some programmes for supplementary information or alternative methods of surveillance.

The core functions in surveillance of any health event, including food related events, are:

- case detection
- reporting
- investigation and confirmation
- analysis and interpretation
- action
- control/response
- policy
- feedback

These functions are made possible by support functions that improve core surveillance functions:

- setting of standards (e.g. case definitions)
- training and supervision
- setting up laboratory support
- setting up communications
- resource management

The level of coordination/integration in the national surveillance system can affect:

- performance of the system
- cost of the system
- sustainability of the system

As an example, the core functions for the surveillance of Salmonellosis, an important food-borne disease, are shown in the table below.

Rationale for surveillance
Salmonellosis is one the main causes of food-borne disease. Detection and control of outbreaks is complicated by the fact that there are over 2200 serotypes of *Salmonella* species, several of which have multiple phage types. Laboratory-based surveillance of salmonellosis with definitive typing and antibiograms allows for rapid identification of clusters. Investigations can then concentrate on individual cases infected with the epidemic strain and lead to better identification of risk factors and implicated food items. Utilization of molecular methods can lead to even more accurate identification of epidemic strains.
Recommended case definition
Clinical description An illness with the following symptoms: diarrhea, abdominal cramps, fever, vomiting and malaise. **Laboratory criteria for confirmation** Isolation of *Salmonella* spp. from the stool or blood of a patient. **Case classification** ***Suspected:*** An individual showing one or more of the clinical features. ***Confirmed:*** A suspected case with laboratory confirmation.
Recommended types of surveillance
National: The surveillance of salmonellosis is a laboratory-based exercise. The samples examined by laboratories must be generated from cases presenting at health centers, hospitals, or in private practice, and practitioners must be aware of the importance of requesting examination of stool specimens for public health purposes, especially in cases where food- or water borne transmission is suspected. Surveillance is based on a network of laboratories that routinely report data on isolation of *Salmonella* spp. to central levels. All suspected outbreaks of salmonellosis must be reported to the central level and investigated. In addition, isolates of *Salmonella* spp. may be sent to a reference laboratory for further typing. Definitive typing data can be analyzed on a broad geographical basis; this allows for the detection of outbreaks that may not otherwise be detected. A minimum data set should be collected on each outbreak at intermediate and central levels. This should be done after the outbreak investigation and include key variables on the nature and extent of the outbreak (time, place, person, possible source). **Note:** The laboratory network for surveillance of salmonellosis should be as wide and complete as possible. The concentration of facilities for definitive typing in reference laboratories is useful in order to maintain quality. However, care must be taken when

relying on the samples processed in such laboratories as they may not always be representative in terms of clinical spectrum or geography.
Recommended data analyses, presentation, reports
Surveillance data Frequent review of laboratory data for clusters of cases in time, place or person All suspected clusters must be investigated to establish whether an outbreak has occurred. Incidence of laboratory identifications by week, geographical area, organism, age group and sex (map incidence by geographical area if possible). **Outbreak investigation data** Incidence of outbreaks by species, phage type, month, geographical area, setting of outbreak, attack-rate, duration of outbreak, foods implicated and factors contributing to the outbreak.
Principal uses of data for decision making
• Determine the magnitude of the public health problem • Detect clusters / outbreaks in good time • Track trends in salmonellosis over time • Identify high risk food, high risk food practices and high risk populations for specific pathogens • Identify emergence of new species and phage types • Guide the formation of food policy and monitor the impact of control measures • Assess risks and set standards

Source: WHO Recommended Surveillance Standards, www.who.int/csr/resources/publications/surveillance/WHO_CDS_CSR_ISR_99_2_EN/en.

5.7. Surveillance of food

Hazards in food are categorized as biological, chemical or physical.

5.7.1. Biological hazards

The table below provides examples of biological hazards:

Bacteria	*Salmonella, Campylobacter, verotoxigenic E. coli, Yersinia, Mycobacterium bovis, Brucella mellitensis, Listeria*
Bacterial toxins	Staphylococcal toxins
Viruses	Norovirus
Parasites	*Trichinella, Taenia, Toxoplasma*
Prions	BSE/Variant CJD
Organisms resistant to antimicrobial agents	

Most biological hazards in food are zoonotic – agents that are naturally transmissible between animals and humans.

Some zoonotic diseases cause disease in both animals and humans e.g. *M bovis*, *Brucella mellitensis*. Control and surveillance of these diseases are generally directed at animal populations themselves.

The most important food-borne microbiological hazards of current concern are zoonotic agents that cause disease in humans but do not cause clinical disease in animals e.g. *Salmonella*, *Campylobacter*, *verotoxigenic E. coli*. These agents are frequently carried asymptomatically in the intestines animals and are transmitted to humans on contaminated food, causing enteric diseases in humans. Food of animal origin is most commonly the source of human infections, but other foods e.g. vegetables, can become contaminated by environmental spread of animal wastes.

Control of these microbiological hazards should be the responsibility of food producers. The internationally recognized method for food business operators to fulfil their responsibilities, and the method recommended by CAC in its general texts on food safety,[6] is the application of food safety management systems based on the principles of Hazard Analysis Critical Control Point (HACCP).

For some foods which will be consumed without further treatment (e.g. cooking), national food safety criteria may be set. For example, EU legislation sets such criteria for Listeria and Salmonella in certain foods – see table below. Food in these categories which

[6] General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 2, 1985), Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System (CAC/GL 18-1993).

exceeds the criteria may not be sold for human consumption. As part of their HACCP-based food safety controls, food business operators should monitor the effectiveness of their systems by testing finished products for the relevant organisms.

	Food category	Micro-organisms/their toxins, metabolites	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
			n	c	m	M		
1.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2	Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g (5)		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
			5	0	Absence in 25 g (7)		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3	Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
1.4	Minced meat and meat preparations intended to be eaten raw	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.5	Minced meat and meat preparations made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.6	Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.7	Mechanically separated meat (MSM) (9)	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.8	Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

❑ Food Safety Criteria, Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Surveillance of all foods may be carried out at a national level for specific pathogenic organisms to measure the success of intervention strategies and to better understand the contribution of different food sources to human disease. Surveillance of Salmonella in food in the EU is an example. Salmonella spp. is one of the most common and widely distributed food-borne pathogens in the European Union. Surveillance programmes and intervention strategies to control food-borne salmonellosis have been implemented in EU Member States. The box below, taken from the 2010 EU report on food-borne outbreaks,[7] records the results of surveillance of food for Salmonella.

Foodstuffs

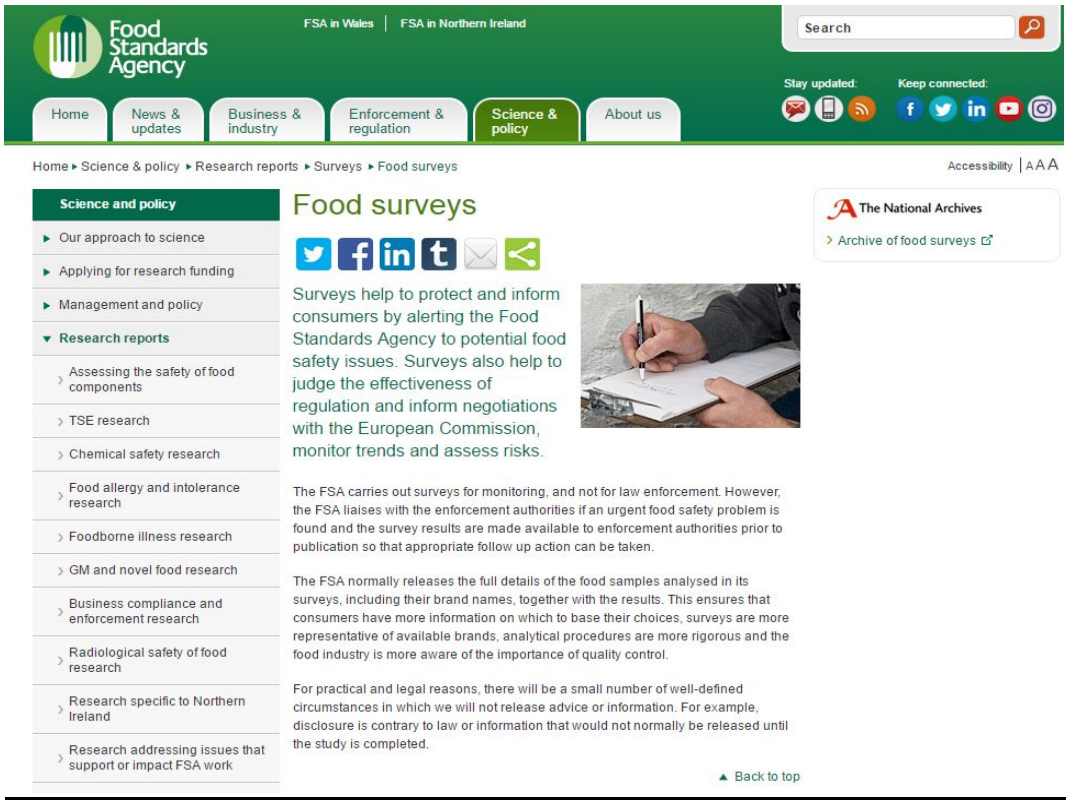
Information on salmonella was reported from a wide range of foodstuff categories in 2010, but the majority of data were from various types of meat and product thereof. The highest proportions of *Salmonella*-positive units were reported for fresh broiler meat and fresh turkey meat, at average levels of 4.8% and 9%, respectively. In fresh pig meat, 0.9% of tested samples were found positive for *Salmonella* in the reporting MSs group, and in the case of fresh bovine meat 0.2% of sampling units were positive.

7 The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2010.

Salmonella was only found in a very low proportion of table eggs, at levels of 0.3%, which was a reduction from 2009 (0.5%). In vegetables, fruit and herbs, 0.6% of units tested were reported positive. However, as in 2009, a higher occurrence (up to 3.6%) was reported for herbs and spices by some MSs.

Non-compliance with the EU *Salmonella* criteria was, once again, most often observed in food categories of meat origin. Minced meat and meat preparations from poultry intended to be eaten cooked had the highest level of non-compliance (5.3% of single samples). In batch samples, 4.3% of mechanically separated meat was found to be contaminated with *Salmonella* was detected in 1.8% of single samples and 0.3% of batch samples. The proportion of egg products (single samples) not in compliance with *Salmonella* criteria 0.7%) increased slightly compared with 2009 (0.2%). In other categories, the proportion of units in non-compliance with the criteria was very low, apart from the proportion of positives in live bivalve mollusks (1.5% of single samples).

Examples of surveillance of food for food-borne zoonotic agents are the reports below of two surveys carried out in the UK.



www.food.gov.uk/science/research/surveillance/food-surveys

www.food.gov.uk/science/research/foodborneillness/b14programme/b14projlist/b180002

5.7.2. Antimicrobial resistance

Antimicrobial resistance is becoming a cause of major concern worldwide. There is debate about the relative importance in the development of resistance of the use of antimicrobials in humans and animal, but there is no doubt that the use of an antimicrobial agent in any species exerts selection pressure for resistance. The use of antimicrobials in animals can present a hazard for human health through the development of resistance in zoonotic organisms pathogenic to man, or the selection of commensal organisms with transmissible resistance factors.

Antimicrobial resistance is a food-borne hazard for public health since it is well known that organisms in the intestines of animals can be passed to humans through contaminated food.

Details of surveillance programmes for antimicrobial resistance are beyond the scope of this general text. Readers are referred to specific websites and publications, including those in the box below.

Guidelines for Risk Analysis of Food-borne Antimicrobial Resistance CAC/GL 77- 2011

Code of Practice to Minimize and Contain Antimicrobial Resistance CAC/RCP 61-2005

Harmonization of National Antimicrobial Resistance Monitoring and Surveillance

Programmes in Animals and Animal Derived Food
http://www.oie.int/doc/ged/D2010.PDF

Standardization and Harmonization of Laboratory Methodologies Used for the Detection and Quantification of Antimicrobial Resistance:
www.ncbi.nlm.nih.gov/pubmed/11732427

5.7.3. Chemical hazards

Chemical hazards fall into a number of categories, including:

- naturally occurring contaminants from the environment (e.g. heavy metals – lead, mercury);
- naturally occurring toxins (e.g. mycotoxins, marine biotoxins);
- industrial contaminants - persistent organic pollutants (e.g. dioxins, PCBs);
- pesticides and other agrochemicals;
- residues of veterinary medicines;
- radionuclides.

Food contamination monitoring is an essential component of assuring the safety of food supplies and managing health risks at the international level. Within the Codex Alimentarius Commission, the chemical contamination of food is addressed by a number of Codex Committees dealing with food additives, contaminants, pesticide and veterinary drug residues. Each Committee publishes texts concerning surveillance, including sampling and analytical methods. The box below contains examples of standards and texts produced by these Committees.

Codex Standards
www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en

Codex Committee on Pesticide Residues (CCPR)
CAC/GL 33-1999, Recommended Methods of Sampling for Pesticide Residues for the Determination of Compliance with MRLs

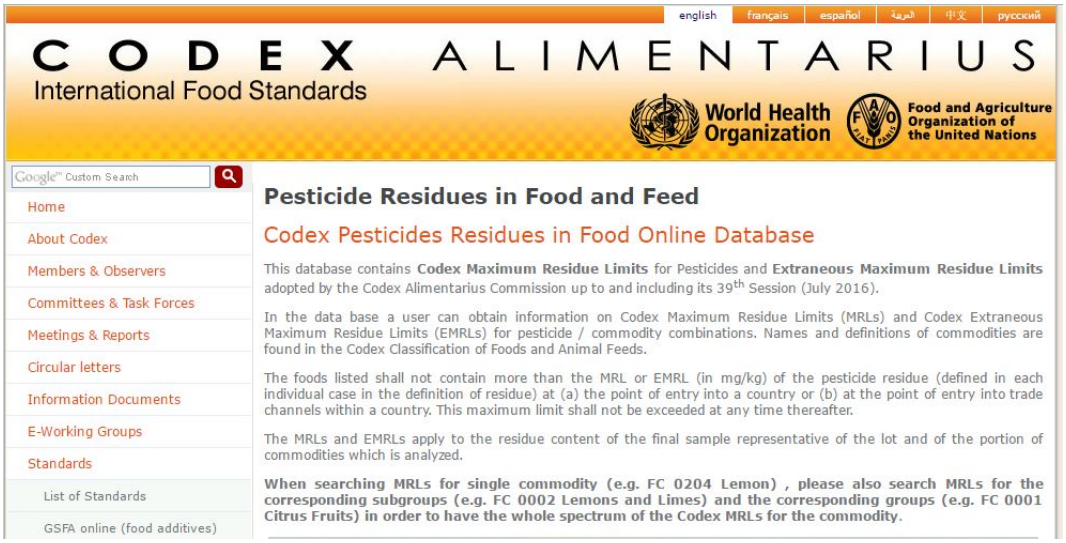
Codex Committee on Food Additives (CCFA),
CAC/GL 3-1989 Guidelines for Simple Evaluation of Food Additive Intake

Codex Committee on Contaminants in Food (CCCF)

CAC/RCP 49-2001 Code of Practice Concerning Source Directed Measures to Reduce Contamination of Foods with Chemicals

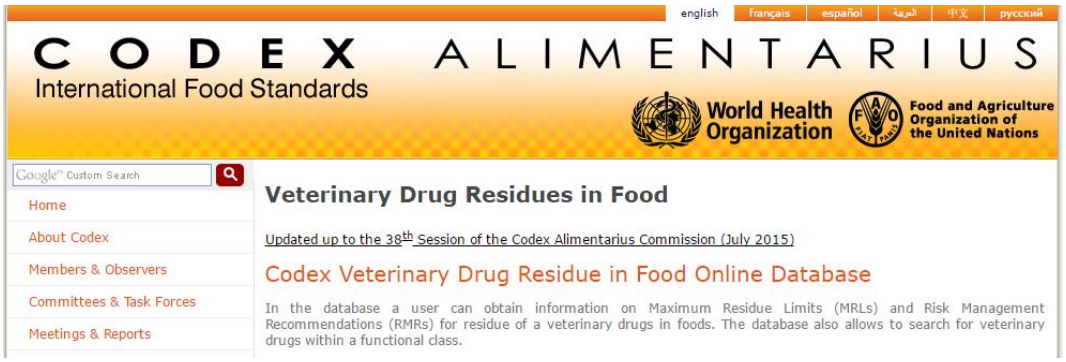
Codex Committee on Veterinary Drug Residues (CCVDR)
CAC/GL 71-2009 Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals

The *Codex* Web site contains Maximum Residue Limits (MRLs) for pesticides in both primary and processed food of animal origin:



Source: http://www.fao.org/fao-who-codexalimentarius/standards/pesticide-mrls/en

Maximum Residue Levels for veterinary drugs have been set by Codex and can be found at:



Source: www.fao.org/fao-who-codexalimentarius/standards/vetdrugs/en

The WHO Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food)[8] provides information at the international level

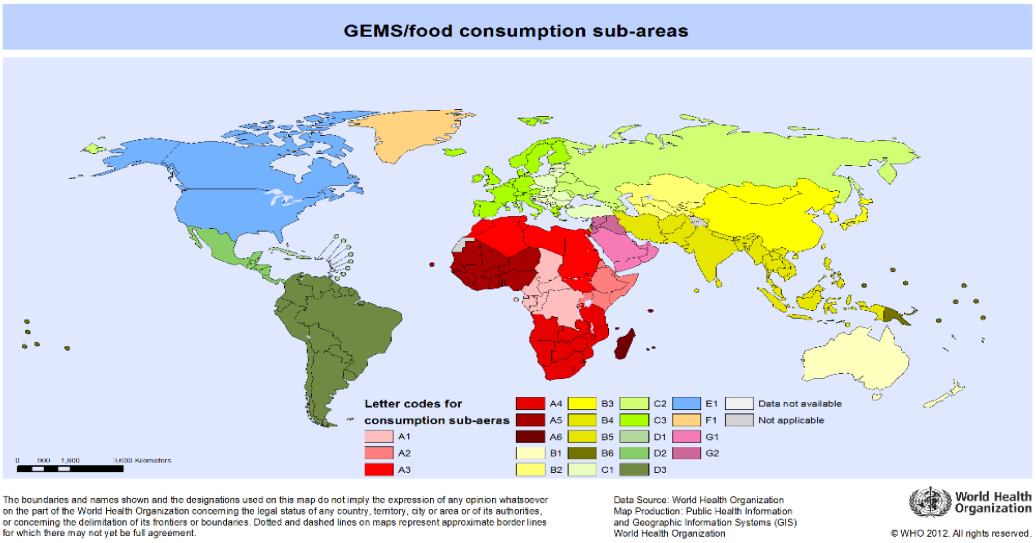
[8] who.int/foodsafety/en.

levels and trends of contaminants in food, their contribution to total human exposure, and significance with regard to public health and trade.

The potential health impact posed by the presence of chemical hazards in food is estimated by calculating the likelihood that the consumer will be exposed to a substance and to quantify the extent of such exposure in relation to health based guidance values. Exposure assessments combine data on concentrations of a chemical substance present in food with data on the quantity of those foods consumed.

Two types of monitoring and surveillance data for assessing the concentration of a defined chemical in a food are frequently used: results of a random nature from stratified sampling plans or targeted sampling. The first tries to obtain a representative picture of chemical levels present in food whereas the second is aimed at sampling those products expected to contain higher levels in a cost effective way. Targeted data are often collected for enforcement purposes in response to specific problems.

A number of different methods are available for assessing dietary exposure to food and per capita food consumption. GEMS/Food has developed supra-national model diets which are currently used for predicting dietary intake of various chemicals according to internationally accepted methodologies. GEMS/Food Diets are based on per capita data compiled by the Food and Agriculture Organization of the United Nations (FAO). These data provide statistics on a country's annual food production, imports and exports and are accessible through the FAO web site: http://faostat3.fao.org/home/index.html.
An example is the GEMS/Food Consumption Areas, below, based on geographic proximity between countries.



Areas	Cereals	Roots and tubers	Vegetables and pulses	Fish marine	Fish freshwater	Fish unknown	Fruits	Milk and dairy products	Meat and offals	Beverages	Eggs and eggs products	Fats	Herbs, herbal tea and condiments	Oilseeds and treenuts	Other
A	125.8	103.9	66.8	0.6	2.2	4.6	50.0	30.5	17.2	37.7	2.2	9.6	1.5	2.8	0.5
B	141.5	38.1	149.2	4.4	7.1	5.2	53.6	44.5	29.5	21.9	8.6	11.0	2.2	5.6	0.3
C	110.3	84.3	123.4	1.2	1.6	11.2	72.8	119.7	65.2	139.1	12.1	27.7	2.0	2.6	2.4
D	105.9	44.7	65.2	1.4	1.5	4.5	97.4	76.8	63.4	59.6	9.5	15.9	1.1	6.9	0.9
E	88.1	59.2	124.6	1.5	1.3	10.5	71.5	123.6	100.4	122.3	13.9	35.1	1.4	3.4	0.4
G	140.6	19.6	103.8	0.5	1.0	4.0	57.7	42.5	33.7	17.8	4.7	14.9	2.8	2.9	2.7

Population-weighted area consumption (kg/person/year) - 2007

Source: www.who.int/foodsafety/chem/Global_GEMS_subareas.png

5.8. Surveillance in food animals

The whole chain approach to food safety requires hazards to be analyzed throughout the chain and control measures to be applied at the most effective point. For many food safety hazards, preventative measures are best applied in primary production and the live animal level. Decisions about risk mitigation options and subsequent assessment of their effectiveness are informed by surveillance activities in food animals.

Many food-borne zoonotic agents that cause disease in animals are the subject of measures to control animal diseases. Examples of such diseases are tuberculosis caused by *Mycobacterium bovis*, and brucellosis, both of which are often subject to control and surveillance and control programmes at the national or regional level.

Surveillance in animal populations for diseases that affect only animals is an important factor in international trade in food of animal origin. Since imports of food of animal origin may pose threats to both public and animal health in importing countries, guarantees will be required by importing countries about the animal health status of the exporting country, in addition to guarantees about the food safety aspects of the commodities. Many importing countries will require exporting countries to be free of transboundary animal diseases – diseases of economic significance such as food and mouth disease and classical swine fever. Reliable systems for surveillance of these diseases are necessary to provide credible guarantees of disease freedom.

The livestock sector plays a significant role in the economic development of many countries. The production of meat and other animal-based food items generates income, jobs, and foreign exchange for all stakeholders in the animal industries.

Diseases affecting animals can have a devastating impact on animal productivity and production, on food security, on trade in live animals, meat and other animal products, on human health and, consequently, on overall economic wellbeing and development.

Effective control and surveillance of diseases within a country will deliver benefits across a wide range of areas, including:

- ***Animal production***
  Increase in the quantity and quality of foods of animal origin and other animal products.

- ***Food security***
  Animal diseases have an impact on the access that people have to sufficient, safe, nutritious food to maintain a healthy and active life.

- ***Economics***
  The loss of animals and reduced production that result from animal diseases cause serious loss of income not only by livestock producers but also throughout the production and processing industries.
  Loss of income from exported products and import substitution adversely affect national economies.
  Measures to control or mitigate the effects of animal diseases can be a considerable drain on resources.

- ***International trade***
  Control of diseases and demonstration of freedom from specified diseases enables access to international markets and export of animals and animal products.

- ***Public health***
  Many diseases of animals are zoonotic – naturally transmitted between animals and man – by the food-borne or other routes. Public health protection through the control of zoonotic diseases delivers both direct health benefits and indirect social and economic gains.

- ***Environment***
  Animal diseases cause inefficient production by food-producing animals and produce a greater environmental impact for the food they produce. Sustainability of production is aided by the control of animal diseases.

- ***Social factors***
  In addition to the direct financial losses of livestock producers, animal diseases have a widespread impact other sectors of society including jobs and incomes, with consequent indirect affects.

Surveillance of animal diseases is an essential component of disease control systems. Surveillance is a critical tool to detect new threats, to inform decision making across the animal disease control system and to measure the success of the system. Surveillance has a major role in international trade by allowing access to export markets by providing evidence of disease freedom, and by giving justification for conditions for import of animal products.

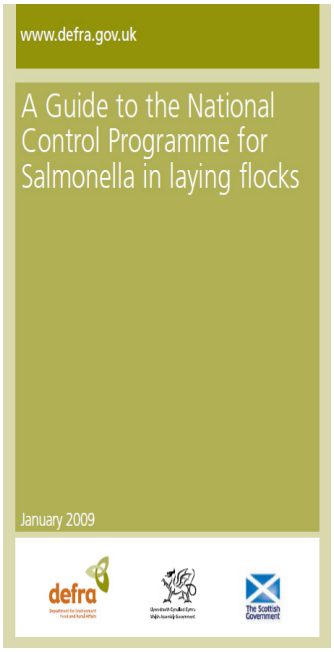
The World Organization for Animal Health (OIE) is recognized under the WTO SPS agreement as the international body with responsibility for elaborating standards and related texts for the prevention, control and eradication of animal diseases and zoonoses. The OIE Terrestrial Animal Health Code focuses on standards for animal diseases and specified hazards of biological origin, and contains a specific chapter[9] on animal disease surveillance, as well as chapters devoted to individual diseases.

Specific details of animal disease surveillance systems are beyond the scope of this general text, but can be found in the OIE Terrestrial Code and in other EDES handbooks.

Surveillance for zoonotic agents carried asymptomatically by animals, such as Salmonella and Campylobacter, may be carried out in animal populations as part of a complete surveillance programme to gain better understanding of the epidemiology of the agents and to assess the benefits of measures applied in primary production to control or reduce them.

The EU has a mandatory requirement for the surveillance of Salmonella in poultry as part of a programme to reduce the prevalence of Salmonella in poultry meat and eggs. Each member state of the EU must implement surveillance in its own country. Details of such surveillance activities can be found in the UK guide:

[9] www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.1.4.htm.



Source: webarchive.nationalarchives.gov.uk/20130402151656/http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/zoonoses/documents/reports/ncp-salmonella.pdf

5.9. Surveillance systems

Whatever their immediate purpose or population/commodity under study, all surveillance systems have a number of common features necessary to enable maximum use to made of the data gathered. The main features are:

- ***Data Collation and Storage***
  The success of a surveillance system is dependent on a reliable process for data collection and management, and the use of integrated information management systems. The process may be based on paper records or computerized. The consistency and quality of data collection and event reporting in a format that facilitates analysis is critical.

- ***Surveillance Analysis***
  Surveillance data should be analyzed using appropriate methodologies, and at the appropriate organizational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

  Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant host species, pathogens, varying production and surveillance systems, and types and amounts of data and information available.

  The methodology used should be based on the best information available and should also be in accordance with international standards (CAC guides and texts, the OIE Terrestrial Code), fully documented and supported by reference to the scientific literature and other sources, including expert opinion.

- ***Communication of results***
  Summaries and analytical reports
  Frequent reports - Weekly, monthly, quarterly, annual reports
  Reports should be tailored to the varied needs of the audience - decision-makers, programme managers, field operations, laboratories, other stakeholders including the general public

- ***Coordinating body***
  An 'intelligence hub' of people and IT facilities
  - to support data capture, exploration, collation, analysis, reporting and use of surveillance findings,
  - to trigger risk mitigation measures or further research
  - supported by ready access to relevant population and risk factor data

5.10. Surveillance strategy

The principal objectives of a national surveillance strategy are to identify surveillance needs to protect the health of consumers, to set priorities, and to allocate resources effectively and efficiently. An important goal is to achieve a higher benefit-cost ratio with existing or reduced resources.

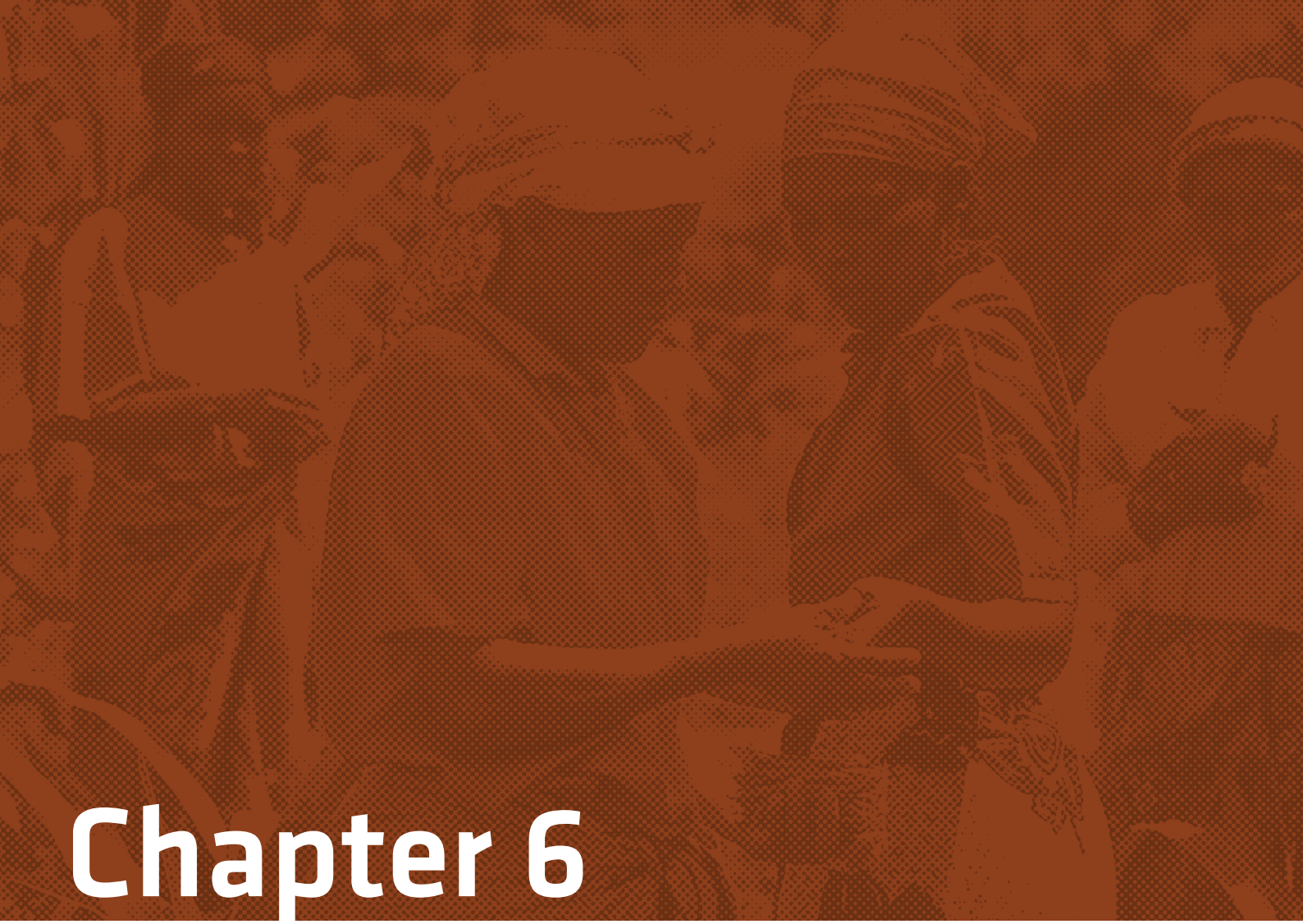
Surveillance supports disease control programmes by providing data to inform disease management decisions and to measure the success of control programmes. Prioritization of surveillance activities is therefore related to a country's public health and food safety strategy.

In terms of public health, one of the important components of the national surveillance plan is a list of priority diseases for surveillance. This list, as short as possible, should be established with the close participation of national health authorities. The rationale for prioritizing diseases could use the following series of questions. These questions should be addressed not only from the national perspective but also from a regional, and possibly international, viewpoint.

- Does the disease result in a high disease impact? (morbidity, disability, mortality)?
- Does the disease have a significant epidemic potential?
- Is the disease a specific target of a national, regional or international control programme?
- Will the information to be collected lead to significant public health action?

Current surveillance activities should be reviewed against what is needed and any gaps identified. Some diseases may already be subject to routine surveillance (*i.e.* the periodic reporting of data on cases of selected diseases) or there may be a requirement to report the disease or syndrome immediately on suspicion or diagnosis. This is especially true for diseases that may lead to epidemics. However, certain diseases may have alternative or supplementary surveillance methods such as laboratory-based or sentinel surveillance. The emphasis should be on a minimum set of data to be collected, analyzed and acted upon at each level of the system. Only that information that aids public health decision-making should be collected.

Once priority diseases have been selected and the gaps identified, a plan of action for surveillance should be developed. An integrated approach which aims to coordinate and streamline all surveillance activities is advised. To this end a central body should coordinate all the surveillance activities.



Chapter 6

Organization of official control systems

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6.1. The purpose of official controls for food safety

6.1.1. Scope

The World Health Organization (WHO), Food and Agriculture Organization (FAO), along with other national and international bodies have recognized that protecting food safety is a public health function and a global priority.

Around the world, food is increasingly produced, processed, traded and delivered through supply chains involving many food businesses. Food is traded internationally and purchased from retailers in a prepared state. Much food is eaten outside the home.

It is no longer feasible to ensure that food is safe through random sampling and testing of the end product combined with thorough cooking or other food safety measures by the consumer before eating. It is necessary to use harmonized risk-based process control measures to ensure that food hygiene is maintained throughout the food chain continuum (the 'farm-to-table' principle).

Codex Alimentarius (meaning the food code) was set up by the World Health Organization (WHO) and Food and Agriculture Organization (FAO) to set and maintain internationally accepted food standards, codes of practice and guidelines to protect the health of consumers and ensure fair practices in food trade. The objectives of the Codex General Principles of food hygiene are presented in Appendix 2.

Codex works in conjunction with two other international standards setting organizations: the World Organization for Animal Health (OIE), which sets standards for veterinary public health and zoonoses, and; the International Plant Protection Convention (IPPC), which sets standards related to plant health.

The World Trade Organization (WTO) Agreements on Sanitary and Phytosanitary measures (SPS Agreement) and Technical Barriers to Trade (TBT) refer to Codex, OIE and IPPC standards as part of their mission to ensure fair trade in food ingredients and food products.

One of the basic principles of international food safety control is that food business operators at all stages of production, processing and distribution have primary responsibility for providing feed that is safe and suitable for consumption. They must ensure that consumers have information enabling them to protect their food from contamination and spoilage by food-borne pathogens, and they must maintain confidence in food products.

The role of governments is to:

- enforce food law and protect consumers through policies that consider the risk to the population;
- provide assurance that food is suitable for human consumption;
- maintain confidence in internationally traded food, and;

- provide health education programmes to communicate the principles of food hygiene to industry and consumers.

Governments should ensure the safety of food imports and exports to the same standards as are applied to domestic production and consumption.

Governments must ensure good hygiene and food safety throughout the food chain.

The European Union (EU) is the world's largest trading area and biggest food importer and its food safety regulations are harmonized with international standards and guidelines. The European Commission (EC) ensures that food exports from EU Member States and imports into the Community comply with EU legislative requirements. In accordance with SPS and EU requirements, the European Commission supports exporters of food products to Europe in complying with EU requirements.

The European Commission is able to approve specific pre-export checks to be carried out by third countries prior to dispatch to reduce or replace checks required at the EU border.

Importing countries are not able to dictate specific control measures that must be taken by the exporting country. They operate on the principle of equivalence, where the exporting country's measures must achieve the appropriate level of protection as in the importing country.

The purpose of official controls

- Food safety is a public health function
- The guiding principle of food safety control is to ensure that all food placed on the market is safe to eat and provides a high level of protection of human life and health
- Food safety controls must take into account the diversity of supply and the need to facilitate trade
- Food business operators are primarily responsible for producing safe food by applying good hygiene and process control measures in their businesses
- The role of government is to:
  - ensure that food safety measures are applied throughout the food chain;
  - provide assurances to the consumer;
  - educate the industry and consumers on food safety.

This chapter covers the organization of official control systems to enable governments to meet their obligations to ensure that food is safe to eat, protect the consumer and ensure fair practice in trade.

6.2. Challenges for official control systems in developing countries

Achieving effective food control at the national level is a joint effort involving government, producers, processors, caterers and retailers, as well as consumers.

Developing countries face particular challenges that make it difficult to achieve universal food safety controls, as described below.

- General lack of infrastructure, facilities, skills and resources. Basic facilities required for safe food production include: reliable and safe water supplies and sanitation; dependable electricity supply; adequate storage facilities, including cold storage; suitable transport facilities and transport network. Sufficient resources and funds may not be available to provide adequate laboratory testing as a means of enforcing controls.

- Lack of knowledge of farmers and processors concerning the safe use of agro-chemicals and pharmaceutical products. For both their own health and consumer protection, producers and processors need to be properly educated and controlled in their access and use of hazardous products.

- Fragmented food sectors with both sophisticated industries and small-scale producers and processors, some of whom may be unregistered and operating outside the formal economy. This fragmentation hinders the uniform application of controls along the food chain.

- Dual standards for domestic and export markets. A focus on export markets for food products is good for trade, but may mean that the domestic market is neglected with regard to food safety. Whilst the focus on exports is perhaps inevitable, strategies can be developed so that there are spin-off benefits for the local market.

The food export market can provide a stimulus for improving domestic food safety.

- Private standards (such as GLOBALGAP) are sometimes confused with formal international standards in producer countries. Although private standards have a role in food safety, some developing countries have complained to the SPS Committee that private standards are a barrier to trade. Higher standards for consumers - as sometimes required by private standards - may be to the detriment of exporters, who face increased costs in meeting the standard. This issue is under active discussion by the World Trade Organization and the other international committees.

- Lack of awareness and knowledge of food safety by food business operators and consumers. With education and awareness, consumers can exert an influence on food producers and processors to improve the safety of food put on the market.

Food safety is a joint effort involving government, industry and consumers.

- Relative high food prices compared to income mean that low-income consumers in developing countries may be reluctant or unable to pay a price premium to cover the costs of ensuring good hygiene and food safety. Poor people may be unaware of the risks and cannot afford to reject food that does not comply with food standards and may be unsafe to eat. This is why food safety is a public health issue.

Additional problems faced by governments regarding food safety controls include:

- Inadequate or out-of-date legislation that does not encompass the risk-based process control approach;
- food safety responsibilities split between a number of ministries and departments, and not harmonized;
- Inconsistencies and gaps in enforcement, surveillance and monitoring.

Challenges for official control systems in developing countries

- Lack of infrastructure, skills and resources.
- Ignorance on the safe use of agro-chemicals and pharmaceuticals.
- Fragmented food sectors make it difficult to apply controls along the food chain.
- Dual standards for domestic and export markets may be to the detriment of local consumers.
- Confusion between formal and private standards may make it more difficult to deliver clear awareness messages on how to improve food safety.
- Lack of awareness on food safety by operators and consumers.
- Relative high food prices compared to incomes act as a disincentive for consumers to pay a premium for good hygiene and safe food.
- Inadequate or out-of-date legislation.
- Government responsibilities split between ministries and departments.
- Inconsistencies and gaps in enforcement, surveillance and monitoring.

6.3. Basic principles for official control of food safety

National official control systems for food safety should be developed to harmonize with Codex Alimentarius and the other international agreements and standards (SPS Measures, TBT Agreement; OIE and IPPC standards).

Official controls should be consistent with internationally accepted basic principles for food safety.

- All food placed on the market must be safe to eat and provide a high level of protection of human life and health.

All food must be safe to eat.

- Suitable legislation and statutory procedures are required for enforcement of official controls.
- A scientific risk-based approach should be used by the industry to apply the most appropriate food safety control measures according to the circumstances.

Food safety measures should be targeted according to the risks.

- Risk analysis comprises risk assessment, risk management and risk communication. Risk assessment must be science-based and carried out independently from risk management, which is policy based. Risk communication is linked to both risk assessment and risk management. Governments play a leading role in risk analysis and official controls are part of the risk management function.
- Official controls should be appropriate to the food safety risks in each food business.
- Food business operators shall apply process controls in an integrated farm-to-table approach to maintain food hygiene throughout the production and supply chain.
- Prime responsibility for food safety lies with the food business operator at each stage of the food chain. Food processors should base their control mechanisms on Hazard Analysis and Critical Control Point (HACCP) principles together with good hygiene practice. The application of HACCP principles to primary production is generally not feasible and primary producers should apply specific good hygiene measures.
- Transparency, consultation and communication are necessary to ensure stakeholder involvement and consumer confidence at all stages.

Official controls should be transparent.

- Food businesses should be registered (where required by legislation) to facilitate supervision and traceability.

- Flexibility of the food safety system is necessary to adapt to local circumstances and specific products (e.g. traditional products), but this should not compromise food hygiene. This is an important consideration for developing countries that have difficulty complying with international standards and the import requirements of developed countries (including the European Community).

Basic principles for official control of food safety

- All food placed on the market must be safe to eat
- A legal base is required to implement official controls
- Food business operators should targeted control measures according to the risks to food safety
- Food business operators should apply a farm-to-table approach to food safety
- Prime responsibility for food safety lies with food business operators at each stage of the food chain. Food processors should base their controls on good hygiene practices and HACCP principles. Primary producers should apply good practices
- Official controls should be appropriate to the food safety risks in each food business
- Official controls should be transparent, involving consultation and communication with stakeholders
- Food businesses should be registered (when required) to facilitate supervision and traceability
- The food safety system and official controls should be flexible and adaptable to local circumstances.

6.4. Organization of official controls

This section covers the following issues:

- Government responsibility
- Competent authorities
- Objectives of official controls
- Components of official controls
- Key components for organization of official control systems.

6.4.1. Government responsibility

Governments have overall responsibility for:

- food safety policy;
- the development of food law and regulations;
- ensuring the necessary infrastructure for official controls, including surveillance and laboratory networks;
- ensuring the provision of an effective inspection and enforcement service with suitably qualified staff.

❑ Food law and regulations

Official controls should be based on legislation and regulations to allow powers of enforcement. The laws must accommodate changes that take place in the food sector, the use of modern technology and the development of new food products.

Food law has to cover a range of issues beyond basic food hygiene, such as additives, flavors, food supplements, natural contaminants (e.g. toxins), labelling, food composition, nutrition, and genetic modification. Increasingly food law is being extended to cover indirect food safety issues such as the environment, animal health, animal welfare and plant health.

There are various options for organizing official controls at national level. FAO and WHO (FAO/WHO, 2003) have produced guidelines for the development of national policies and effective food safety controls. The European Union legislation is comprehensive and covers controls on exports from third countries to the EU. These and other sources have all been used in compiling the following guidance. A list of reference material is included in Annex2.

Individual countries must develop food safety policies, regulations and strategies to steer the development of official controls and effective food safety systems that will protect consumers and facilitate trade and economic development.

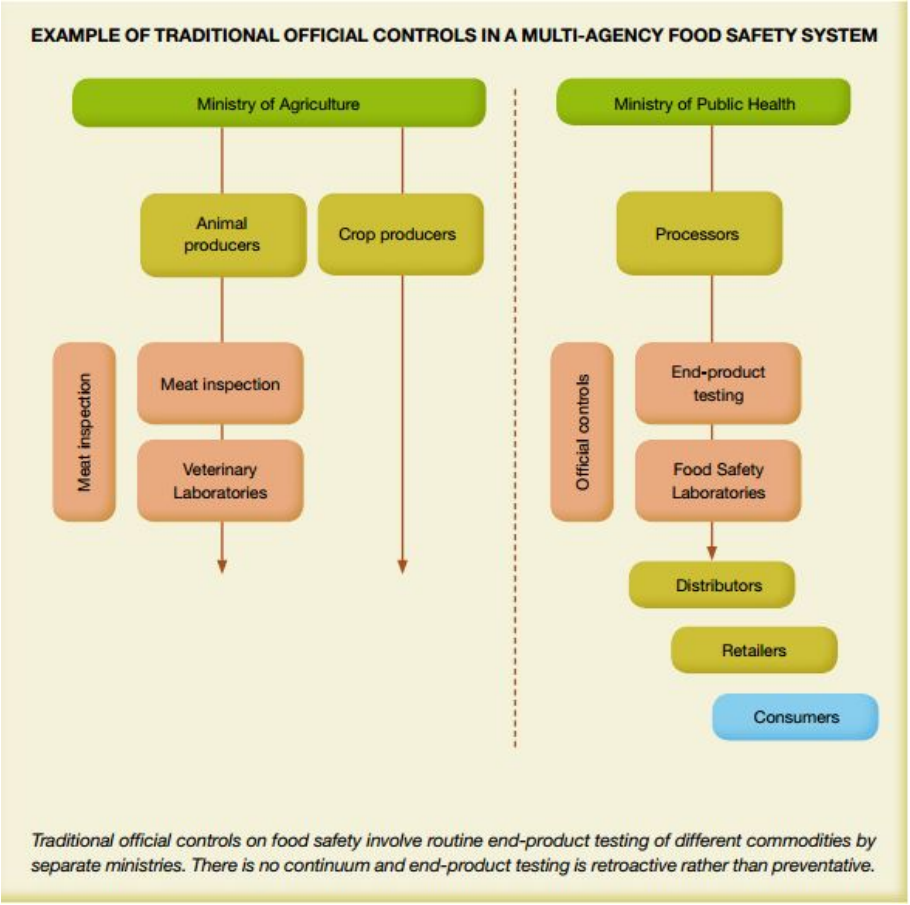
❑ Food safety systems

FAO/WHO guidelines describe three basic models for national food safety systems, as described below.

National food safety systems encompass all three functions of risk analysis: risk assessment, risk management and risk communication. Official controls fall within the risk management function.

➢ *Multi-agency food safety system*

This is the traditional food safety model in many countries, where different ministries have responsibility for different stages in the food chain. Within each ministry there may be subdivision of food safety activities by commodity sector (e.g. animal production and crop production). Typically the ministry of agriculture would be responsible for food safety aspects in primary production and primary processing, whereas the ministry of health would be responsible for further processing, distribution and retail sale. The tendency would be for each ministry to work independently without sharing food chain information. The focus of control would be routine testing of end-products.



The main advantage of the multi-agency approach is that it makes use of existing structures without major reorganization. However the disadvantages include lack of

coordination at national level, overlapping responsibilities and duplication of activities, and uneven implementation. It can be difficult to apply the risk-based farm-to-table approach in a multi-agency system.

- ***Single agency food safety system***

Consolidating all official control activities in a single agency brings advantages in terms of cohesion and a unified approach. It allows a food chain approach to risk analysis based on science.

Setting up a separate agency creates a separation from government and overcomes conflicting priorities from different ministries and departments.

However, a possible drawback is that setting up a separate agency responsible for official food safety controls involves major restructuring with relocation of experts from their home ministries. Such a move may be politically or logistically difficult in some countries.

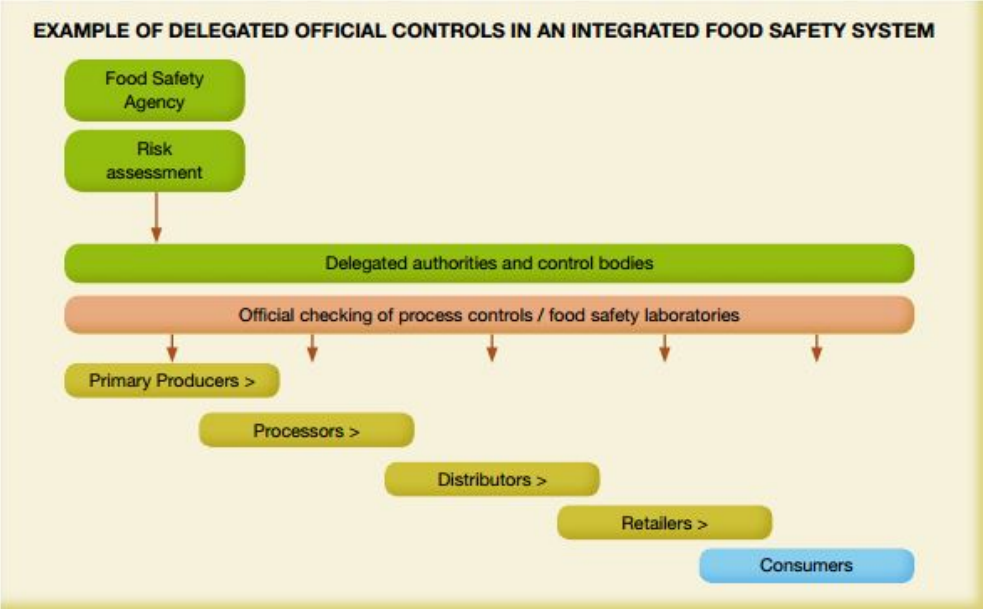
Another potential disadvantage is that the centralized control makes it more difficult to interact with food business operators and consumers at the local level. This may hinder consultation and cooperation with industry and consumers.

- ***Food safety system***

An integrated system is a variation of a single agency model where some functions are delegated to other competent authorities or to independent control bodies; at national, regional and local levels.

This allows harmonization and the uniform application of control measures in a farm-to-table approach, but retains the benefits of local contacts and the participation of different ministries. It may therefore be more feasible to set up than a single agency system. Various options of integrated system are possible. Official controls can be delegated to another competent authority with a local network, or directly to local control bodies. Figure below gives an example of delegated official controls in an integrated food safety system.

Whilst the food agency approach has been widely adopted in developed countries, take-up has been less in developing countries. One of the complications may be the dual nature of food safety systems in developing countries, where it is necessary to priorities the allocation of scarce resources resulting in different levels of control being applied to the export sector and food products for the domestic market. The dual control system may work better in a sector specific approach.



❑ Private standards

Private standards have an important impact of food safety control systems. They can serve two purposes.

➢ *Provide a mechanism for compliance with official standards and regulations*

Certain non-governmental standards such as the International Organization for Standardization (ISO) are considered by regulators as providing formal verification mechanisms for food businesses to comply with official food safety standards. They are not referred to as private standards.

➢ *Demonstrate achievement of private criteria and quality schemes*

Private sector food businesses (particularly large supermarkets in importing countries) may require producers and suppliers to conform to private quality standards (e.g. GLOBALG.A.P.). These are unofficial standards used by food businesses to increase consumer confidence in their products.

Where national food safety systems in developing countries are not yet developed to the level of international standards, private standards may provide a mechanism for international compliance (as described in the previous paragraph). They provide a process control, food chain approach in specific export sectors.

However, private standards may go beyond official requirements (i.e. set stricter requirements) for commercial reasons. This means they may not follow WTO disciplines for international standards. Consequently, they have been the subject of complaints by developing countries to the SPS committee that they are a barrier to trade.

Unofficial private standards help producers in developing countries achieve export compliance.
But they may be costly for producers to achieve and may be barriers to trade if they set limits beyond official levels without scientific justification.

Food producers in developing countries may also be faced with high costs of complying with several different private standards, as might be required to access certain market outlets.

The role of private standards in food safety systems is under active discussion by the SPS Committee and other international organizations.

❑ HACCP

The Hazard Analysis and Critical Control Point system (HACCP) is a universally recognized and accepted method of food safety assurance in food businesses. The HACCP approach is endorsed by WHO and adopted by Codex Alimentarius. Regulators such as the European Union recommend the use of HACCP based approaches.

The HACCP system is a process control system that identifies where food safety hazards may occur in a food production process and puts into place stringent controls to prevent the hazards from occurring.[1] This provides a system for food businesses to assure the safety of the food they produce.

HACCP is a preventative approach that can be applied throughout the food chain, from primary production to final consumption. However, it is generally more appropriate for food processors than for primary producers, where good hygiene practices may provide a more suitable and practical approach.

Use of the HACCP approach and pre-requisite measures provides a means for verifying regulatory compliance and thus forms part of an official control assessment.

Implementation of HACCP principles will only succeed if food business operators show commitment to the system. Pre-requisite measures for good hygiene practice must already be in place within the business in order to implement HACCP principles. HACCP is then applied to control steps in the process that are critical for ensuring the preparation of safe food.

HACCP – Hazard Analysis and Critical Control Points

- HACCP is a process control system adopted by *Codex Alimentarius.*
- It is based on the application of control measures to a food business operation at critical steps in the production process.
- It is a tool for food businesses to assure the preparation of safe food.
- It is a preventative approach that can be applied throughout the food chain, although simpler good hygiene practices may be more suitable for primary producers.

[1] www.standards.org/standards/listing/haccp.

- HACCP can be used to verify regulatory compliance in an official control assessment.
- Pre-requisite good hygiene measures must already be in place to implement HACCP.
- Successful implementation depends on the full commitment of food business operators.

➢ ***Pre-requisite measures and HACCP principles***

The pre-requisite hygiene measures for HACCP implementation include:

1) cleaning and disinfection;
2) maintenance;
3) Personnel hygiene and training;
4) pest control;
5) plant and equipment;
6) premises and structure;
7) services (compressed air, ice, steam, ventilation, water etc.);
8) storage, distribution and transport;
9) waste management;
10) zoning (physical separation of activities to prevent potential food contamination).

The HACCP system is based on seven principles:

1. Conduct a hazard analysis
2. Determine the Critical Control Points (CCP)
3. Establish critical limits
4. Establish a system to monitor control of the CCP
5. Establish the corrective action to be taken when monitoring
6. Establish procedures for verification to confirm that the HACCP system is working effectively
7. Establish documentation concerning all procedures and records appropriate to these principles and their application

➢ ***HACCP in practice***

Although HACCP is a proven technique for improving food safety in food businesses, official control inspectors cannot take for granted that it will automatically ensure food safety. HACCP has to be applied accurately and diligently to be effective. Inspectors must be suitably trained and experienced to check that the HACCP principles are functioning properly in the food establishment.

HACCP must be applied accurately and diligently to be effective.

It is important for official control inspectors to be aware of potential difficulties with implementing HACCP as described below.

- **Hazard analysis**
  Hazard analysis requires specific expertise and knowledge of chemical and microbiological hazards and their risks. Such expertise may not always be available. Proper training in hazard analysis and the availability of suitable qualified staff is therefore important for precise hazard analysis.

- **Validation of critical limits**
  Critical limits are borderlines between acceptability and unacceptability of the food product, such as temperature and time for heat treatment. It is necessary to ensure the critical limits are properly validated to check that they are effective and that the HACCP process will ensure safe food.

  Validation must be carried out in food businesses to ensure that critical limits are appropriate for the actual operating conditions. This may be a particularly difficult procedure for small businesses and expert support may be required.

- **Inconsistent implementation of HACCP**
  Implementation of HACCP involves monitoring, corrective action and verification. If the documented procedures are not carried out effectively, the HACCP controls may fail to provide proper control of food safety. Problems can arise if the HACCP controls are too restrictive as frequent deviations may occur during working time and staff may decide to bypass the HACCP procedures in order to keep the production process going and meet targets. Such problems can arise when external experts prepare the HACCP plan without full collaboration with company staff, as they may set unrealistic control measures.

  When preparing the HACCP plan it is necessary to see that staff directly involved with the process are consulted in order to sure that the plan is practical to use.

- **Inadequate internal verification**
  Verification is an important tool to check the proper functioning of the HACCP system. Food business operators may confuse validation, monitoring and verification procedures. In particular the overall system verification process may not be carried out thoroughly including review of documents and records.

- **Monitoring data**
  HACCP monitoring generates data, which can be used to analyze trends. The data analysis requires knowledge and skills that may not be present in small businesses. It is important to ensure that this data is collected and analyzed thoroughly.

➢ ***Official control of the HACCP system in a food business***

Official control inspectors need to be properly trained in HACCP procedures in order to carry out meaningful assessment visits to food businesses. Official control assessment should cover the following points:

- the overall objective of official control of the HACCP approach in a food business is to obtain evidence that the seven HACCP principles have been effectively applied and the HACCP plan and pre-requisite measures have been correctly implemented and the system maintained;

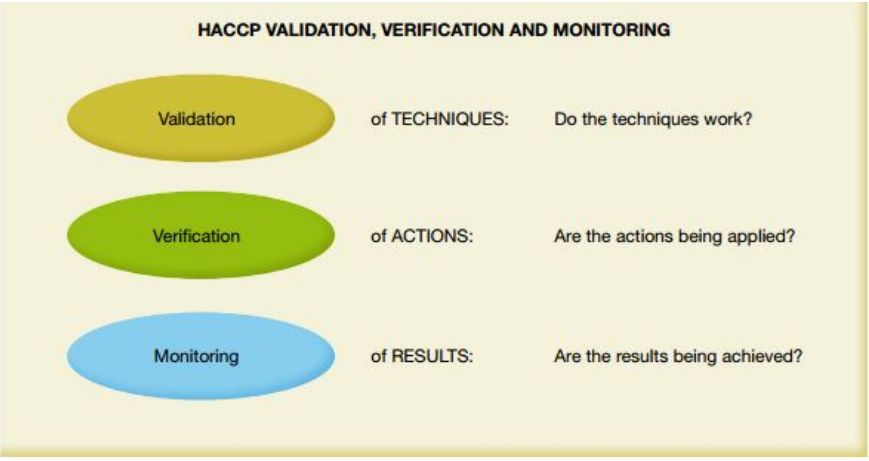
- the specific purpose of the assessment is to ascertain whether the HACCP system is effective in assuring that the business is capable of producing safe food;
- the adequacy of the pre-requisite measures should be assessed, as well as other regulatory requirements regarding food safety.

The official control assessment should determine:

- whether the HACCP plan includes and addresses all the necessary requirements;
- whether the system is satisfactory for maintaining food safety;
- whether the implemented processes comply with the documented procedures in the HACCP plan.

The assessment should cover:

- HAACP management - compliance history, level of training, availability of required technical knowledge within the business or available to it, the existence of satisfactorily documented procedures and food safety management systems;
- HACCP planning - the accuracy of the plan, process description and flow diagram, the level of expertise reflected in the plan, the adequacy of the pre-requisite measures;
- Hazard analysis - hazards have been identified and analyzed, validation records, sample results, product safety history, generic plans, predictive models;
- effectiveness of the control measures – adequacy of the critical control points, appropriateness of the critical limits including whether they are realistic and how they were determined and validated, adequacy and frequency of monitoring;
- verification procedures carried out by the food business operator – details and results of the verification, actions taken to address HACCP deficiencies, other deficiencies and new hazards;
- documentation – description of the food product, flow diagram with location of critical control points and other parameters, HACCP worksheet, list of verification activity, records of pre-requisite measures;
- overall HACCP implementation – adequacy of implementation, maintenance and function of the HACCP plan, sufficient training of operators, complete records;



The frequency of assessment should be based on the following risk factors:

- classification of the business according to potential hazards related to the process or product, compliance history, and food safety management system;
- history of food safety incidents;
- any other risk factors.

HACCP and the pre-requisite hygiene measures are one of the most important risk management tools available to food businesses. However, HACCP alone is not enough to ensure food safety: it must be complemented with other measures such as, traceability, labelling and laboratory analysis.

HACCP alone is not enough to ensure food safety.

❑ ISO standards

ISO is the International Organization for Standardization.[2] It has a current membership of 164 national standards bodies. ISO is a non-governmental organization and its standards are voluntary, although in some cases they have become market requirements, for example with regard to laboratories. ISO does not itself provide certification.

Although not specifically designated as such, ISO standards are considered to be formal international standards as ISO uses principles and codes of practice set out in the WTO SPS and TBT agreements. They are thus distinct from 'private standards' that do not specifically follow WTO disciplines.

In developing countries ISO standards are important to primary producers as a means of gaining technical knowledge and of demonstrating capability to export. Certification to an ISO 22000-based food safety management system is widely accepted as a benchmark for companies to gain export status.

ISO certification in food businesses is an indicator of good hygiene practice and therefore facilitates official control procedures and contributes to enhanced food safety.

Similarly ISO certification of laboratories and specific laboratory tests is an indicator of reliability for laboratory testing.

6.4.2. Competent authorities

Competent authorities are appointed by government to carry out official controls. The appointment is covered by legislation so that the competent authority has the necessary statutory powers to carry out official controls.

Official controls are the responsibility of competent authorities, who may delegate some tasks to other authorities or independent control bodies.

Depending on the legislation, competent authorities may delegate specific tasks to other authorities or suitably qualified control bodies at national, regional or district levels.

[2] www.iso.org/iso/home.htm.

Some tasks, such as meat inspection, may be delegated to control bodies, which could be private contractors who charge fees to the food businesses for their services.

The competent authority should ensure efficient coordination between other authorities and control bodies, particularly regarding the allocation of responsibilities and tasks. Each delegated authority and control body must have a clear understanding of the legal requirements and procedures to be used.

It is necessary to avoid duplication and overlapping of actions by different competent authorities and control bodies. At the national level, it is necessary to avoid conflicting priorities between different ministries and government departments.

6.4.3. Objectives of official controls

Based on the example of EU legislation, official controls are required to:

- enforce food law and regulations, and monitor and verify that they are fulfilled by food business operators at all stages of production, processing and distribution;
- prevent, eliminate or reduce risks to human health, either directly or through the environment;
- guarantee fair practices in feed and food trade to protect consumer interests, including food labelling and other forms of consumer information.

Official controls are necessary to enforce food law.

6.4.4. Components of official controls

Official controls may include the following components.

Components of official controls

- Procedures for official controls of food safety
- Programming of control plans
- Control tasks: surveillance checks, inspection, verification, audit, sampling
- Laboratory testing
- Monitoring plans
- Registration and approval of establishments, where required
- Authorization and control of veterinary medicinal and phyto-pharmaceutical products
- Residue plans
- Border controls
- Official certification
- Other activities, including animal health, plant health and public health, in particular concerning zoonoses and traceability systems
- Communication with consumers

- Training of inspection staff performing official controls
- Communication, training and awareness for food business operators

This section considers key components regarding the organization of official controls: procedures; control plans; inspection tasks; and communication, awareness and training.

❑ Procedures for official controls

Procedures for official controls should address the following subject areas:

- the organization of the central competent authority and the relationship between other authorities that have been delegated certain official controls;

Different organizational structures are possible: the critical factor is to have clear relationships and responsibilities.

- the relationship between competent authorities and control bodies to which they have delegated tasks related to official controls;
- a statement of the objectives for official controls;
- tasks, responsibilities and duties of staff;
- sampling procedures, control methods and techniques, interpretation of results and consequent decisions;

Official controls should be carried out according to documented procedures and control plans.

- monitoring and surveillance programmes;
- cooperation with other countries and international organizations;
- action to be taken following official controls;
- cooperation with other services or departments with relevant responsibilities;
- verification of the appropriateness of sampling, analytical and detection methods;
- any other activity or information relevant to the effective functioning of official controls.

❑ Control plans

Competent authorities for official controls on food safety should prepare control plans based on the procedures outlined in the preceding section.

A control plan is a description of the structure and organization of the official control system of a competent authority.

Control plans provide a description of the organization and structure of the official control system.

The purpose of a control plan is to establish a solid base for the inspection services to carry out regular official controls. It should provide a means to confirm that official controls

are carried out according to the requirements of the competent authority. Official controls cover imported food ingredients and products as well as domestic production.

The control plan should describe the general structure and organization of the national food control system, including related issues such as the control of animal health and welfare, and respect for the environment, as appropriate.

The control plan should address the following issues:

- the strategic objectives of the plan and the prioritization of controls and allocation of resources to meet the objectives;
- the risk categorization of the activities concerned;
- the designation of competent authorities and their tasks at central, regional and local levels, and the resources available to these authorities;
- the general organization and management of official controls at national, regional and local levels, including official controls in individual food businesses;
- control systems applied to different sectors and coordination between the different sectors of the competent authorities responsible for official controls in these sectors;
- delegation of tasks to other authorities and control bodies, where appropriate;
- methods of compliance with operational criteria covering: effectiveness of the controls; conflicts of interest; laboratory capacity; equipment and facilities; legal powers; contingency plans for emergencies; obligations of food business operators to cooperate in the official controls;
- training of control staff;
- organization of cooperation and mutual assistance.

Control plans should be prepared on a multi-annual basis and updated as necessary.

The control plan should take into account the following guidelines:

- take a consistent, comprehensive and integrated approach to official controls (including feed and food, animal health and animal welfare, as included in the scope of the official controls) and embrace all sectors and all stages of the feed and food chain, including imports;
- identify risk-based priorities and criteria for the risk categorization of the activities concerned and the most effective control procedures;
- identify other priorities and the most effective control procedures;
- identify the stages of production, processing and distribution of feed and food, including the use of feed, which will provide the most reliable and indicative information about compliance with feed and food law;
- encourage the adoption of best practices at all levels of the control system;
- encourage the development of effective controls on traceability systems;
- provide advice on the development of systems to record the performance and results of control actions;
- reflect relevant international bodies' standards and recommendations regarding the organization and operation of official services;
- lay down criteria for the conduct of audits;
- lay down the structure and information to be included in reports;

- indicate the main performance indicators to be applied in assessing the delivery of control plans.

The control plan provides a baseline for monitoring the performance of official controls.

❑ Official control tasks

Types of official control task include surveillance checks, inspections, verifications, audits, sampling and testing.

'Surveillance' means a careful observation of one or more feed or food businesses, feed or food business operators or their activities.

'Inspection' means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules.

'Verification' means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled.

'Audit' means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

As appropriate according to the circumstances, governments should carry out the following official control tasks:

- procedures to ensure the registration of food and feed businesses, where required;
- routine surveillance checks, inspections, verifications, audits, sampling and testing;
- laboratory testing based on internationally approved procedures;
- effective, proportionate and dissuasive actions against breaches of food law and regulations;
- public communication on surveillance regarding food safety;
- training of staff performing official controls;
- control of imported food and exports to ensure compliance or equivalence with national food safety standards for domestic food production.

Official controls should be carried out at an appropriate frequency as determined by the risks to food safety in each food business. The risk analysis should take into account: identified risks to food or feed; the compliance record of the food business operator, any information regarding non-compliance, and; the reliability of the checks that are carried out.

Official controls should be appropriate to the risks to food safety.

Official controls should be carried out without warning, except when it is necessary for the food business operator to prepare for the visit. Ad hoc visits can also be carried out. Official controls shall be carried out at any stage of the production, processing and distribution process, including feed production and primary production.

Official controls should be based on documented procedures to ensure uniformity and consistency. Where different control bodies are involved, their actions should be effectively coordinated. Similar coordination is required where activities have been delegated to regional or district levels. Official control staff shall be suitably trained. Official controls should particularly focus on the following points regarding food businesses:

- the implementation of good hygiene practice and HACCP principles, as appropriate;
- food safety management systems;
- the microbiological, physical and chemical safety of food and feed.

Official controls should focus on:

- HACCP implementation
- food safety management systems
- food safety criteria

Food business operators should be provided with a copy of the inspection report, at least in the case of non-compliance.

❑ Communication, training and awareness

➢ *Training of official control staff*

Training of official control staff is required to ensure the correct implementation of control techniques. It is also necessary to provide training to ensure staff make uniform decisions, in particular with regard to HACCP principles. Training is also required for laboratory staff involved in testing samples taken under official controls.

The 2nd Global Forum of Food Safety Regulators, 2004 (National School of Veterinary Services, France) identified three levels of training.

1. **Prior training**
   Prior training refers to the education required for the recruitment level: professional staff or support staff.

2. **Post-recruitment training**
   Post-recruitment training refers to occupational training for the specific job. In some countries, this is acquired whilst working on-the-job. Other countries provide short-term training for a few days or weeks. Elsewhere staff obtain professional qualifications.

3. **Staff development training**
   Staff development training or Continuous Professional Development (CPD) is required to keep up-to-date with technical developments, administrative changes and to for career development.

Training may cover the following subject areas:

- control techniques, such as auditing, sampling and inspection;
- control procedures;
- feed and food law;
- the different stages of production, processing and distribution, and the possible risks for human health, and where appropriate for the health of animals and plants and for the environment;
- assessment of non-compliance with feed and food law;
- hazards in animal feed and food production;
- the evaluation of the application of HACCP procedures;
- management systems such as quality assurance programmes that feed and food businesses operate and their assessment in so far as these are relevant for feed or food law requirements;
- official certification systems;
- contingency arrangements for emergencies, including communication with international organizations and other countries;
- legal proceedings and implications of official controls;
- examination of written, documentary material and other records, including those related to proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with feed or food law; this may include financial and commercial aspects;
- any other area, including animal health and animal welfare, necessary to ensure that official controls are carried out in accordance with food law and regulations.

➢ ***Awareness and education of food business operators***

Studies have shown that involving and educating food business operators through participatory approaches including training helps to provide greater understanding of food safety issues, resulting in improved compliance. These then need to be backed up with formal control measures.

Applying prescriptive measures alone may stimulate an immediate compliance response but fail to develop the same understanding and therefore there is little lasting benefit.

PARTICIPATION with food business operators to improve their understanding works better than PRESCRIPTIVE measures against non-compliance.

6.4.5. Key components for organization of official control systems

Appendix

A.1. *Codex* General Principles of food hygiene

❑ Section 1: Objectives

➢ ***The Codex General Principles of food hygiene:***

- identify the essential principles of food hygiene applicable throughout the food chain (including primary production through to the final consumer) to achieve the goal of ensuring that food is safe and suitable for human consumption;
- recommend an HACCP-based approach as a means to enhance food safety;
- indicate how to implement those principles, and;
- provide a guidance for specific codes that may be needed for sectors of the food chain, processes, or commodities to amplify the hygiene requirements specific to those areas.

❑ Section 2: Scope, use and definition

2.1. Scope

2.1.1. The food chain
This document follows the food chain from primary production to the final consumer, setting out the necessary hygiene conditions for producing food that is safe and suitable for consumption. The document provides a base-line structure for other, more specific, codes applicable to particular sectors. Such specific codes and guidelines should be read in conjunction with this document and "Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application" (Annex).

2.1.2. Role of governments, industry and consumers
Governments can consider the contents of this document and decide how best they should encourage the implementation of these General Principles to:

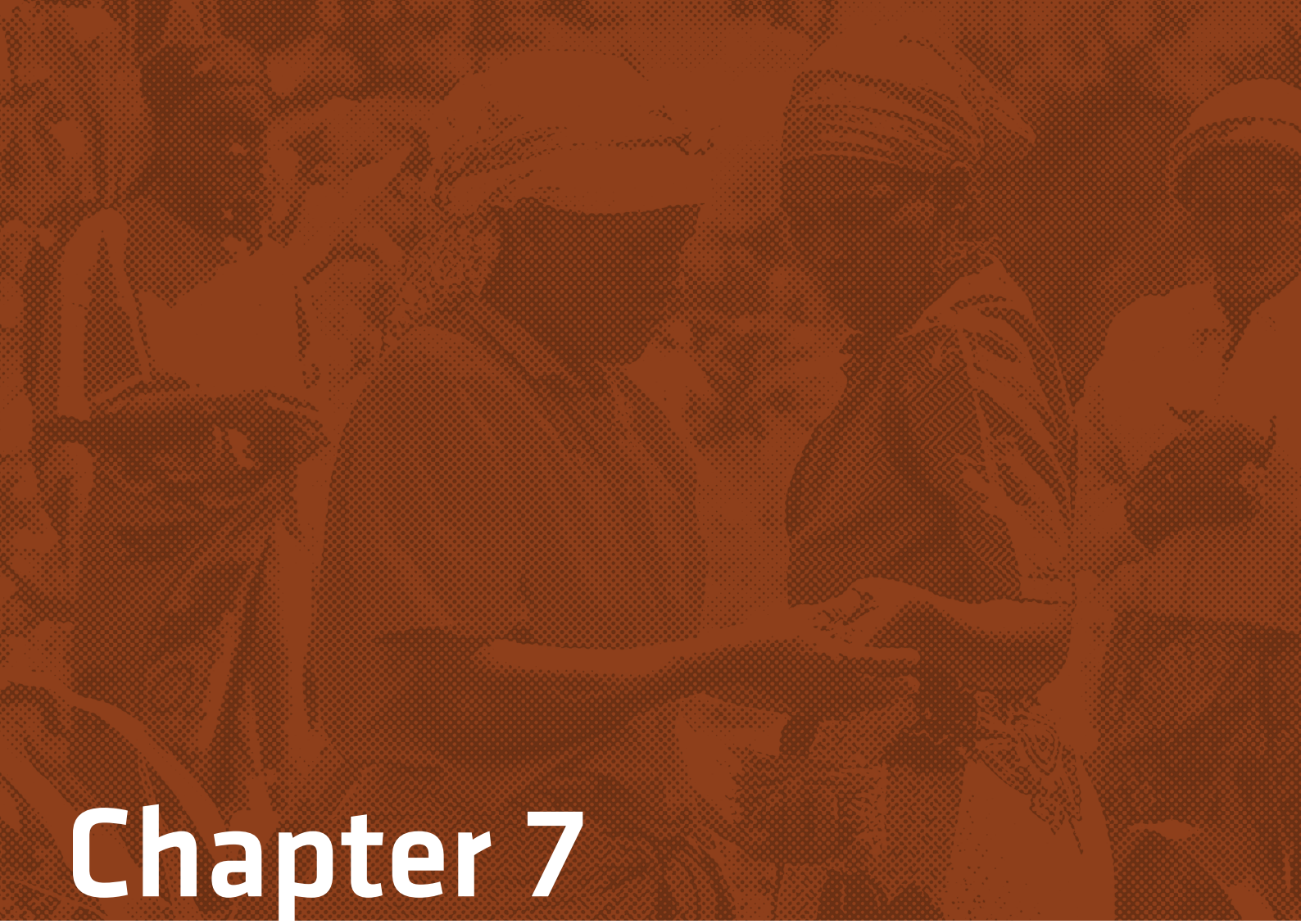
- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population;
- provide assurance that food is suitable for human consumption;
- maintain confidence in internationally traded food;
- provide health education programmes that effectively communicate the principles of food hygiene to industry and consumers.

Industry should apply the hygienic practices set out in this document to:

- provide food that is safe and suitable for consumption;
- ensure that consumers have clear and easily-understood information, by way
- of labelling and other appropriate means, to enable them to protect their food

- from contamination and growth/survival of foodborne pathogens by storing,
- handling and preparing it correctly;
- maintain confidence in internationally traded food.

Consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures.



Chapter 7

Role of laboratories in food safety system

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7.1. Introduction

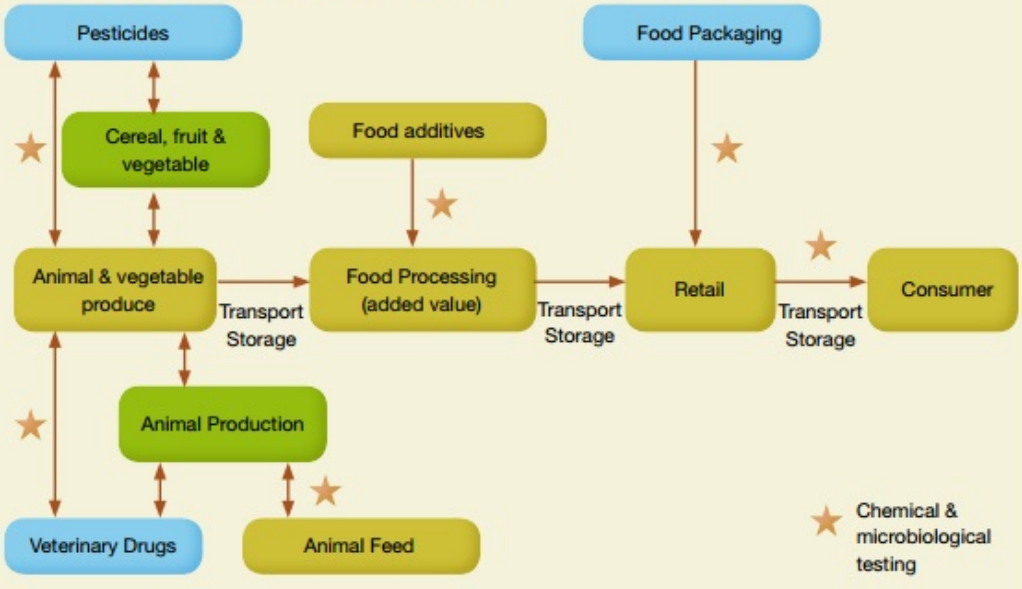
At all stages in food safety systems there is a requirement for analytical data on foods and this is generated by chemical, microbiological, veterinary and molecular biology laboratories. At the stage of risk assessment, laboratories are required for the identification of food hazards, to generate exposure data and to undertake toxicological studies which are needed for risk characterization.

At the later stage where regulations are in place covering microbiological safety, food additives, residues, contaminants, authenticity and packaging there is a need:-

1) For the agriculture and food industries to ensure compliance and to be able to demonstrate 'due diligence',
2) For 'policing' by the authorities through laboratory testing as part of systematic food control enforcement programmes.

Both the food industry and the authorities therefore must have the capability to test and analyses raw materials and processed foods throughout the food chain, with fit-for-purpose suitably equipped laboratories. A 'farm-to-fork' approach is required for testing foods by both industry and government laboratories with differing degrees of sophistication required for food testing at different points in the chain. Box below shows some of the points in the integrated food chain at which microbiological and chemical testing of foods is necessary. Prevention is critical in food safety. Testing of raw materials at an early stage in the food chain can ensure elimination of contaminated materials.

Box 1 - Testing across the integrated food chain



This is particularly important with for example testing animal feed and ensuring the proper use of veterinary drugs, where it is far easier prevent contaminants and residues entering

the food chain, than it is to subsequently control processed animal products. From a food industry perspective testing as close as possible to the point of production makes economic sense. The most damaging and expensive problems arise when packaged processed foods have been distributed throughout the retail chain and a withdrawal from the market is needed due to laboratory testing having identified a microbiological or chemical contamination problem in a finished product.

At the national level, the government has international responsibilities with regard to bi-lateral trade with other countries. Government policy makers and food control agencies must ensure that adequate food control legislation is in place to enable control of all food risk factors, and for adequate consumer protection. In addition to legislation, government at all levels has the responsibility to adequately fund the pre-market approval process for food additives, flavorings, and the use of agrochemicals and veterinary medicines. This licensing requires laboratory monitoring operations that are designed to ensure that food legislative requirements are being met.

It can become very easy for analytical testing of foods to be used as a 'barrier to trade' which is why at a national level governments actively participate in the work of the FAO/WHO *Codex Alimentarius* Commission that prepares international standards, recommendations and guidelines for foods that are the benchmark for judging the acceptability of foods in international trade. This *Codex* work is specifically recognized in the World Trade Organization agreements, and should be closely followed for domestic food supplies and exports to assure consumer protection and avoid international food risk problems.

The role of any individual laboratory in the food safety system will depend on its position in the system, its capabilities and the 'customer' for its services. Looking at laboratories in terms of the customer is one useful categorization.

Different categories of laboratories

- In-house laboratories are where the customer for the work is part of the same organization as the laboratory itself – Governmental or industry.
- Contract laboratories are where the customer is external and the laboratory sells its services in the market place. Contract laboratories are usually privately owned but some Governmental laboratories and some industry laboratories also undertake contract work.
- University laboratories are where the motivation is teaching through research, but this is primarily where innovation is provided in terms of improved methods of analysis.

The above divisions are not 'black' or 'white' are there are exceptions within all three categories, but the role of the laboratory is determined to a significant extent by where it sits with respect to the customer. In-house laboratories belonging to large organizations are typically further organized into networks of one kind or another, either being hierarchical within the same organization, or organized into specialist centers to concentrate expertise and resources within one expert laboratory. With a hierarchical system basic screening might be carried out at one level and confirmation and more sophisticated testing carried out by referring questionable samples up the chain. Organization around specialist laboratories recognizes that for some areas sophisticated equipment is required, as well as maintaining an adequate flow of sample numbers. In

this situation it makes sense to concentrate expertise in one laboratory and maintain a flow of samples to that center rather than trying to do everything in one place.

7.2. In-house food safety laboratories

In-house laboratories may be entirely independent in terms of determining their work-programme or might have an internal customer and a more formal customer-contractor relationship within the organization. The food industry tends to have in-house laboratories e.g. factory laboratories closely aligned to food production. However, the food industry may also outsource some of its laboratory work to contract laboratories or Universities. Government Departments or Ministries responsible for food safety or independent National Food Authorities may have their own in-house laboratories. These laboratories are frequently described as National Institutes or National Reference Laboratories, and within a hierarchal system sit at the top of the structure. Government laboratories are frequently organized into geographical structures at both national and local government level. Large Federal countries may also have an additional tier of Provincial or State government laboratories. Each level in the structure within a country has a discreet role to play in ensuring the overall quality and safety of the food supplies.

One of the distinctions between in-house laboratories and contract laboratories is that in-house laboratories do not have to compete in the market place for their work. This means that there is less pressure on the cost of undertaking analytical work, and less pressure on the speed of analysis, *i.e.* turnaround time. In-house laboratories can however be extremely flexible in the analytical services being delivered, and can be more pro-active and questioning in their approach. The quality and reliability of analytical data whether generated in-house or externally tends to be comparable nowadays as both in-house and contract laboratories operate under the same system of ISO17025 accreditation, use only validated methods and demonstrate competence through regular participation in proficiency testing.

7.2.1. Food control laboratories

Food control laboratories are an essential part of all national food control systems. Analysis of food samples for physical, chemical and microbiological contamination is important to verify the safety and quality of food (including compositional characteristics, nutrition values, adulteration, presence of contaminants, etc.) that is produced domestically, imported and/or exported, and to enable appropriate action to be taken to protect consumers whenever necessary. Official laboratories are also responsible for analyzing specimens from humans and foods implicated in food-borne illness outbreaks to identify the causes and sources.

Source: FAO

Authorities on the one hand should be aware of the destination of food exports from their country and should ensure that they meet the requirements of importing countries. On the other hand the authorities also have the responsibility to ensure that food imports are

properly controlled. This means that at country level there is a need for testing foods intended for export and issuing appropriate certificates, and at entry points for imported foods, there is a need to examine certificates from outside the country and if necessary institute further analytical testing. The scientific information produced by food control laboratories also informs and supports policy and decision making processes related to food safety and quality, for instance to design surveillance and monitoring programmes that target priority hazards or to investigate adulteration, misleading information, fraud, consumer complaints, disease outbreaks, etc. and other emerging food safety and quality issues.

Many countries have a mixed system where food control is undertaken both by in-house laboratories managed by the local authorities as well as by contract laboratories authorized or licensed to undertake food control work. For example, in the UK the local authorities (local Government) and Port Health authorities have responsibility for food control, although there is oversight by the national competent authority (Food Standards Agency). Some local authorities have their own in-house laboratories, whilst there are also contract laboratories offering competitive services for the analysis of foods.

Official laboratories are appointed by the competent authorities to undertake chemical analysis or microbiological examination of samples that have been taken for official control purposes. In the UK, these include Public and Agricultural Analysts, the Health Protection Agency and hospital trust laboratories undertake work for local authorities and district councils. Other laboratories also undertake work for the central authorities such as the Chemicals Regulation Directorate of HSE, and the Veterinary Medicines Directorate. There is no licensing of food control laboratories, but there is a formal qualification of a 'Public Analyst' who is solely recognized legally to sign certificates of analysis of foods for enforcement purposes.

Official samples taken in the UK are divided into three parts, one for the food control laboratory, one given to the producer/importer for independent testing (is so desired) and the third is retained as a referee sample. In the event of a dispute between the results of the official sample and that analyzed on behalf of the producer, the third sample is analyzed by the referee laboratory which in the UK is the Laboratory of the Government Chemist (LGC). Despite the fact that LGC was privatized, in law it still retains the position of Government Chemist and the independent role of the UK referee laboratory for food control purposes.

In the EU all food control laboratories must comply with certain formal requirements. The Regulation covering food control is the Official Control of Foodstuffs Directive which was supplemented in October 1993 by the adoption of the Additional Food Control Measures Directive (93/99/EEC). This Directive continued the process of harmonizing food law enforcement between EU Member States by:

1. Requiring that all Member States have, or have access to, a sufficient number of qualified and experienced food control officials;
2. Setting standards for food control laboratories, and criteria for validating methods of analysis;
3. Establishing a small Commission Food Inspectorate;
4. Improving the exchange of information between Member States and between the European Commission and Member States

Some of the standards expected of an Official Laboratory are set out in box below.

Definition of an official laboratory

This is a laboratory, including those laboratories of official scientists, currently appointed for official food control purposes by governments in accordance with existing national legislation and that comply with the requirements set out in the Food Control Directive 83/397 and the Additional Food Control Measures Directive 93/99. These requirements are:

- accreditation by a national accreditation body
- satisfactory performance in external proficiency assessment schemes
- the use of validated methods
- the employment of suitably qualified persons to carry out analysis.

Such laboratories are publicly controlled and accountable by virtue of the appointments described above, which may, if necessary, be withdrawn.

A close liaison between sampling inspectorates and food control laboratories is essential. This should recognize and acknowledge the mutual dependence each upon the other in order to achieve effective enforcement (control) and to optimize the use of resources. The aims and objectives of sampling programmes should be mutually agreed and should recognize:

a) the need of analysts to specify the requirements to be met in order to establish the degree of certainty necessary to achieve the objectives sought. For example sample sizes required to ensure representative samples are taken, and avoidance of contamination by selection of appropriate containers for storing samples.
b) the need of food inspectors to be able to apply their initiative in sampling foods which they have reason to investigate.

The core competences of the official laboratory and the food inspectors are complementary in auditing and supervising HACCP systems. The scientists of the official laboratories can give expert advice to inspectors on criteria for samples taken at critical control points of food processing and for end-products. The findings of the inspectors supplemented by the interpretation of results of the analysis of the right process samples or samples of the end-products are essential to the final professional judgement of food safety.

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The data produced by an officially recognized laboratory must be seen to be independent of outside influence and above all must be recognized by both consumers and the food industry to be of the highest quality. These characteristics may only be achieved by a reliable blend of qualifications, expertise and experience applied in a well-equipped, accredited and quality assured environment. A further characteristic is the requirement to

be able to apply these skills over a very wide range of potential problems, (in contrast to the more limited range of many specialist laboratories).

In the USA in January 2012 the US Food Modernization Act (FSMA) was signed into law representing a significant change in the approach adopted for food control for both domestic and imported foods. Specifically for Laboratories this Act requires that by January 2014, the Food & Drug Administration (FDA) must develop a programme for laboratory accreditation. FDA will establish a program to recognize accreditation bodies that will be able to accredit laboratories based on model standards established by FDA. The model standards will include sampling and analytical procedures, internal quality systems and training for individuals conducting sampling and analysis. The goal of the program is to increase the number of qualified laboratories. Both domestic and foreign laboratories are eligible for participation and both must meet the model standards. Two and a half years from the date the law was signed, laboratories will be required to be accredited to conduct any regulatory testing.

By January 2014, importers of food into the USA will be required to perform risk-based foreign supplier verification to ensure that all imported food is produced in compliance with the preventive control requirements, the produce safety standards, and other U.S. laws and regulations. FDA is required to issue guidance within one year to assist importers in developing verification programmes and issue a regulation within one year that outlines the requirements for verification programmes.

The FSMA requires FDA to establish a programme to recognize accreditation bodies and third party auditors. Third-parties can be a foreign government or a private entity. Third-party audit certifications will be used to ensure that the product offered for import is in compliance with U.S. laws and regulations and to determine if a facility is eligible to offer food for import under the voluntary qualified importer program. To a large extent the requirements of the FSMA align laboratory testing of food in the USA with requirements of the EU.

The Food & Agriculture Organization (FAO) of the WHO have developed a set of benchmarks for official control laboratories reproduced in next box which encompass the statutory requirements of both the EU and the USA.

Analysis for official purposes is not restricted to the simple reporting of analytical results. It also depends crucially upon the interpretation of results by analysts with appropriate qualifications and sufficient experience to provide an expert opinion recognized and acknowledged by the courts. Such professional interpretation is required with respect to the numerical value of the result taking into account statistical considerations concerning the methods of analysis used and the likely variation within the product itself. Interpretation of the significance of the result also needs to be given in relation to any established legal limit, health considerations, the validity of claims made concerning the properties of the food and the composition of the food with regard to its name and description and the list of ingredients listed.

From an economic point of view it may be preferable to have large laboratories where there is a requirement to serve large populations (e.g. exceeding one million people). However, in some circumstances for geographical, climatological or population density reasons only smaller laboratories are possible. Smaller official laboratories can nevertheless join forces and cooperate, for example by forming networks, thus enabling them to establish expertise to cover many different analysis of various commodities.

Official laboratories, which are not in direct competition, are actually in a unique position to cooperate nationally, even to the extent of merger.

Internationally accepted benchmarks for official food control laboratories

1. Adequate number of suitably located food control laboratories to support the food control system
2. Adequate number of specialized (reference) laboratories for contaminants, food-borne disease organisms, etc.
3. Documented procedure for the approval and accreditation of official food control laboratories according to international standards
4. Existence of a network of official food control laboratories, accredited to carry out specific analytical tests, and for appellate purposes as necessary
5. Adequate number of:
   - food analyst with suitable qualifications, training, experience and integrity;
   - management staff;
   - support staff
6. Official food control laboratories have adequate infrastructure, facilities, equipment, supplies and reference materials, and access to calibration and maintenance
7. Official food control laboratories have an operating quality assurance programme including participation in inter-laboratory proficiency testing
8. Validated analytical methods are used wherever available
9. Existence of a manual of official analytical methods and Standard Operating Procedures (SOPs)
10. Effective linkage between official food control laboratories and the food control system including food inspection
11. Effective linkage between official food control laboratories and the public health system for foodborne disease surveillance, as well as any other relevant laboratories

Taken from "Strengthening national food control systems -guidelines to assess capacity building needs", *FAO, 2006.*

7.3. Contract laboratories

Contract laboratories are distinguished from in-house laboratories in that they are offering independent analytical services in the market place. Contract laboratories invariably operate to the same quality standards (ISO17025) as in-house laboratories, so accuracy and reliability should be equivalent. However, as private companies the main motivation of a contract laboratory is to operate as a successful and profitable business and to offer competitive services. All other things being equal the price of an analytical test and the speed of analysis (turn-around time) are the critical features of testing services offered by contract laboratories. Speed of analysis is about efficient operations within the laboratory, automation of analytical methods and effective management of processes from sample receipt to electronic issuing of certificates using Laboratory Management Information Systems (LIMS). This is not to say that in-house laboratories are not equally efficient, but there is more pressure on contract laboratories from competition, to improve operational efficiency than there is on in-house laboratories.

Improved efficiency can be achieved through economy of scale, as analytical costs can be minimized and capital expenditure on automated systems justified by high sample numbers. It makes economic sense to have full batches of samples to maximize use of calibration and make efficient use of technician's time in sample preparation. A number of the larger contract laboratories achieve economy of scale by distributing samples within their own network, which also maximizes utilization of expensive equipment required for some specialized testing e.g. for dioxins and PCBs. It is notable that one of the recent trends in analytical method development for chemical residues and contaminants has been the move towards multi-analyte, multi-class methods for simultaneous screening of a large number of target compounds. Although these methods rely of the use of expensive and sophisticated instrumentation, as the screening can be for several hundred target compounds (e.g. pesticide residues) the cost per analyte for the analysis is relatively low. These multi-residue analytical methods offer significant efficiency gains for the laboratory and can be expected to grow in number in future years.

Contract laboratories in some countries are licensed to operate as official control laboratories, and also analyses samples provided by industry for a variety of purposes. Some analysis for industry might be 'due diligence' samples, surveillance or trouble-shooting. Increasingly industry is looking pro-actively at the supply chain and trying to anticipate any future problems that might arise in areas outside of regulated quality and safety standards. High profile problems with adventitious contamination from food packaging materials and cases of deliberate adulteration such as the melamine scandal have heightened the need for a much more pro-active approach through food testing.

7.4. University laboratories

Research needs in food safety should really be provided at the national or international level. This research should be strategic and might be undertaken by central Government laboratories or Universities. In the EU a number of significant food safety projects have involved consortia of laboratories working closely together. To support food safety systems there remains a need for improved methods of analysis whether in the chemical or microbiological fields. There have been a number of critical innovative techniques which have been initially developed by Universities e.g. developments in molecular biology such as PCR, developments in instrumental techniques such as LC-MS, developments in monoclonal antibodies, developments in use of nanoparticles. These milestone developments have subsequently been exploited by commercial companies such as instrument manufacturers and made more widely available to the food safety community.

Much of the initial uptake of novel techniques has been by the University community demonstrating the applicability and benefits of new methods to food safety areas. Universities are driven by the need to secure peer-reviewed publications and being the first to publish a new application is also a major driver. Unfortunately this can lead to methods being published which are insufficiently well validated and not tested for robustness. There is also a proliferation of published analytical methods in the food safety area, making it difficult to select the best and most appropriate method for a particular application. In-house validation of a method provides the minimum assurance that a method is possibly suitable for routine use e.g. by food control laboratories, but ideally methods should be subjected to a full collaborative study to establish method performance parameters.

Some food surveillance data is also published by Universities as a means of demonstrating the applicability of a new method. Unfortunately Universities are generally not accredited to ISO17025, and do not have the volume of samples to really test whether methods when applied routinely over a long period of time are sufficiently robust. For example, some of the very rapid methods which propose direct analysis of crude food extracts without any purification (clean-up) frequently suffer from a lack of adequate specificity and cause problems with contamination of the instruments which require spending a lot of time with cleaning and re-optimization. Such methods despite being published can often be counter-productive in efficiency gains and unlikely to have any take-up by control or contract laboratories.

7.5. Laboratory networks

7.5.1. Reference laboratories

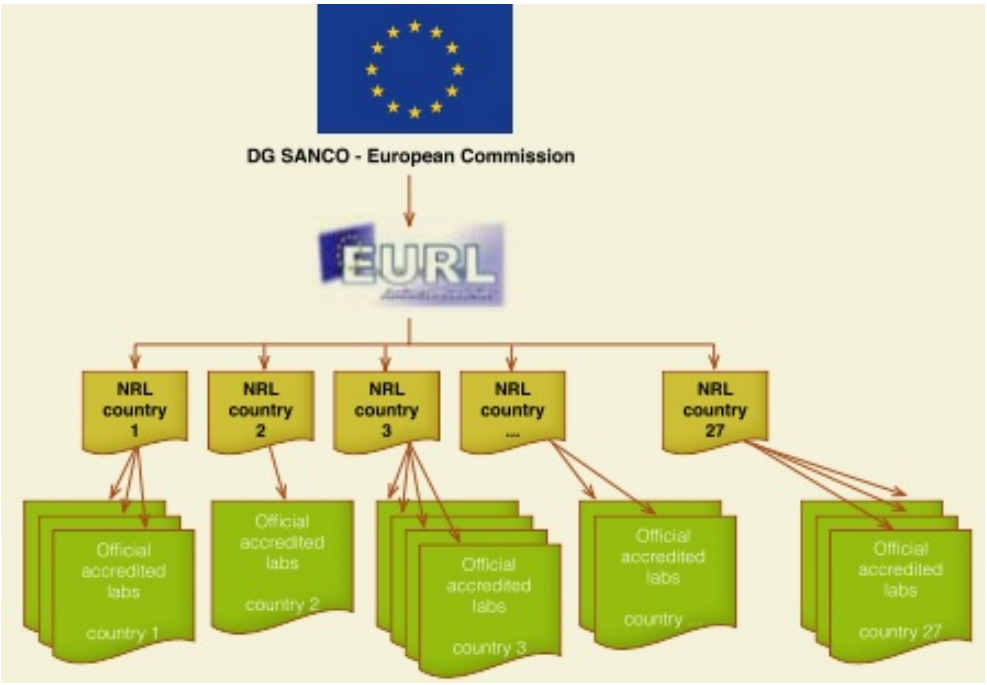
As part of the system of food control it is common in many countries to have one or more reference laboratories exercising a referee function in the event of a disputed analytical result. This referee role assumes that the designated laboratory is more experienced, better equipped, or in some other way more likely to produce a definitive result than the initial analysis undertaken by the control laboratory. Although reference laboratories tend to have the more sophisticated instrumentation, by definition they do not handle the same volume of routine samples as a control laboratory and may therefore may lack experience from only infrequently being requested to undertake a specific analysis. In the case of microbiological contamination the control laboratory may only undertake a classical examination of the food sample, and the referee function might be to confirm the result by more sophisticated typing using PCR.

At EU level experience has shown that reference laboratories play an important role as a scientific and technical support in the area of feed and food safety and animal health. This is particularly important as problems have been encountered in trade of animals or products where conflicting test results may arise. Expert laboratory assistance to risk managers has also proven necessary for emerging risks. Reference Laboratories can also contribute in the international arena, such as standardization of analytical methods. In the area of microbiological hazards, surveillance of zoonotic agents like salmonella and control measures like the implementation of microbiological criteria for foodstuffs are examples of areas where laboratory analyses are essential. In the residues sector, Reference Laboratories have been periodically involved in the detection and quantification of new chemical substances and in development of analytical methods. They largely contributed to the establishment of Community legislation establishing performance criteria for analytical methods and assist laboratories to its implementation.

7.5.2. EU Reference Laboratories (EURLs)

The EU has established a hierarchal network of Control Laboratories (CLs), National Reference Laboratories (NRLs) and EU Reference Laboratories (EURLs). The EURLs sit at the top of this network and deal directly with NRLs, of which there are one or more from each Member State for the designated activity. The NRLs in turn are responsible for co-ordination and information activities for the network of CLs within their own Member State. The relationship between EURLs, NRLs and CLs is illustrated in box below.

Relationship between EURLs, NRLs and CLs

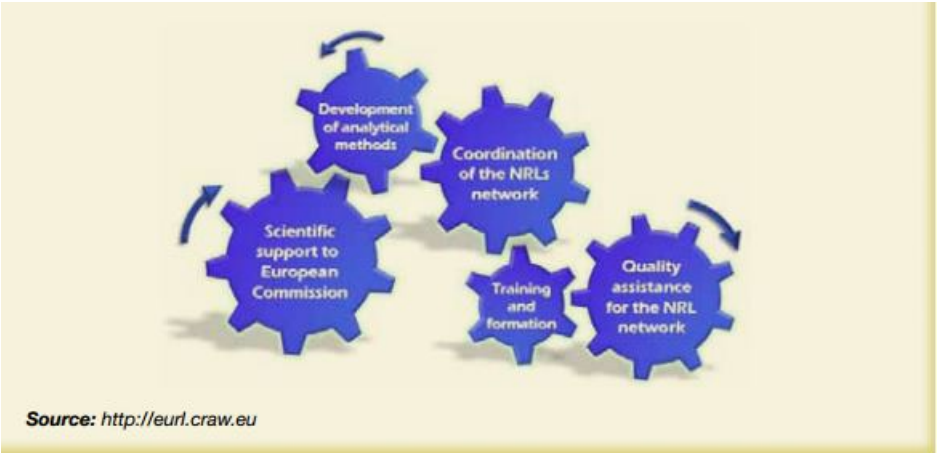


Source: eurl.craw.eu/index.php?page=155

The concept of the EURLs, NRLs is set out in the Regulation (EC) No 882/2004 of the European Parliament and of the Council. The overall objective of the EURLs and NRLs is to improve the quality, accuracy and comparability of the results of official control laboratories. The hierarchal network in fact illustrates more the goal of cascading best practice from the EURL to the NRL who in turn co-ordinates and improves the practice of the control laboratory. In this way a common standard can eventually be achieved by control laboratories across the EU.

The approach of moving together and of dependencies between EURLs, NRLs and CLs is illustrated below.

EURLs, NRLs and CLs working together



The EURLs were each appointed by the European Commission for a 5-year period after an open invitation to tender and each one of the EURLs has contractual responsibilities for the activities set out in box below.

Designated responsibilities of the EURLs

- Providing information and guidance on relevant analytical methods
- Working with NRL's on the application of methods (by comparative testing in particular)
- Co-ordinating research into new methods
- Organizing training courses and workshops
- Collaborating with third country laboratories
- Providing scientific and technical assistance to the European Commission
- Helping NRLs implement quality assurance systems

Each year the EURL agrees and publishes an annual work-programme which can be found on the relevant EURL website. Although the EU no longer has designated Official methods and uses a criteria approach, relevant methods of analysis in each area of responsibility of the EURL are freely available. Each EURL has responsibility for co-ordinating a group of at least 27 NRLs (one or more for each Member State) who each differ significantly in the level of experience in the specialist areas. Through a series of activities the EURL aims to raise the level of the least experienced NRL to the level of the best, and at the same time push the boundaries forward within the specialist area. The EURLs mostly organize at least one annual round of proficiency testing which can highlight shortcomings in the performance of the NRL, and an annual meeting of EURLs provides a focal point for activities. The EURLs are encouraged to collaborate with third countries particularly in sectors where imports into the EU have been frequently rejected though failure to meet EU standards. Finally the EURLs provide a technical resource to the risk managers in the European Commission when technical support is required, particularly in the areas of methods of analysis and sampling.

Designated EURLs for Biological Risks

1. Salmonella (RIVM, Netherlands), www.eurlsalmonella.eu
2. Biological risks in milk and milk-products (ANSES, France, www.anses.fr/en/content/laboratory-food-safety-maisons-alfort-and-boulogne-sur-mer
3. Bacteriological and viral contamination of bivalve molluscs (CEFAS, Weymouth, UK), www.crlcefas.org/
4. Marine biotoxins (AESAN, Spain), www.aesan.msssi.gob.es/en/CRLMB/web/home.shtml
5. TSEs (VLA, UK), science.vla.gov.uk/tse-lab-net/
6. *Listeria monocytogenes* (ANSES, France) www.anses.fr/en/content/listeriosis
7. *Coagulase positive Staphylococci, including Staphylococcus aureus* (ANSES, France), sites.anses.fr/en/minisite/staphylococci/european-union-reference-laboratory-staphylococci
8. *Escherichia coli*, (ISS, Italy), www.iss.it/vtec/chis/index.php?lang=2&tipo=1
9. *Campylobacter* (SVA, Sweden), www.sva.se/en/service-and-products/eurl-campylobacter
10. Parasites (ISS, Italy), www.iss.it/crlp/index.php
11. Antimicrobial resistance (DTU Food, Denmark), www.crl-ar.eu
12. Animal proteins in feeding stuffs (CRA-W, Belgium), eurl.craw.eu

The network of EURLs is broken down into the areas of:

1) Biological risks (12 EURLs);
2) Animal health risks (13 EURLs);
3) Chemical/physical risks in the food chain (13 EURLs);
4) GMOs (1 EURL);
5) Feed additives (1 EURL).

These 40 EURLs have an annual budget exceeding €10 million provided by the European Commission. The designated EURLs for biological risks are listed in previous box and the EURLs for chemical/physical risks are listed in box below. There are four EURLs for pesticides covering different matrices but co-ordinated though a single Web site. The EURL for mycotoxins in food and feed focuses particularly on aflatoxin B_1, total aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins B_1 and B_2, T-2 toxin, HT-2 toxin and ergot alkaloids. The EURL for heavy metals in feed and food covers in particular cadmium, lead and mercury in food of plant origin, wild caught fish and animal feed. These two EURLs are complementary to the EURLs for food of animal origin.

Designated EURLs for chemical/physical risks

1. Residues of pesticides, www.eurl-pesticides.eu/docs/public/home.asp?LabID=100&Lang=EN
   - Cereals and feeding stuffs (DTU, Denmark)
   - Fruits and vegetables (University of Almeria, Spain)

- Food of animal origin and commodities with high fat content (CUVA, Germany)
- Single residue methods (CUVA, Germany)

2. Mycotoxins in food & feed (JRC, Belgium), irmm.jrc.ec.europa.eu/EURLs/eurl_mycotoxins/Pages/index.aspx
3. Heavy metals in food & feed (JRC, Belgium), irmm.jrc.ec.europa.eu/EURLs/EURL_heavy_metals/Pages/index.aspx
4. Dioxins and PCBs in feed and food (State Institute for Chemical and Veterinary Analysis of Food, Germany), www.crl-dioxin-freiburg.eu
5. Polycyclic Aromatic Hydrocarbons (JRC, Belgium), irmm.jrc.ec.europa.eu/EURLs/EURL_PAHs/Pages/index.aspx

1. Food contact materials and articles (JRC, Italy), ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m

In addition to the EURLs listed in previous box there is also a EURL for Genetically Modified Organisms in Food & Feed (GMFF). This EURL for GMFF is the Joint Research Centre in Italy (http://gmo-crl.jrc.ec.europa.eu/ which has a wider role is the scientific assessment and validation of detection methods for GM Food and Feed as part of the EU authorization procedure. The Molecular Biology and Genomics Unit of the Institute for Health and Consumer Protection (IHCP), has the mandate for the operation of the EU-RL GMFF activities which are carried out in close collaboration with European Network of GMO Laboratories (ENGL).

The total of 40 EURLs is completed by the originally established EURLs for residues of veterinary medicines and contaminants in food of animal origin. These EURLs are divided by class of substance.

The German Federal Office of Consumer Protection and Food Safety (BVL – www.bvl.bund.de/EN/09_Laboratories/01_Tasks/02_reference_laboratories/01_reference_laboratories_EURL/reference_laboratories_EU_node.html) is designated EURL for the following substance groups:

- β-Agonists (pharmacologically active substances which, in certain dosages, can be used to increase the fattening performance of animals)
- Substances active against worm infestations (anthelmintics)
- Substances active against unicellular parasites (anticoccidials)
- Non-steroidal anti-inflammatory drugs (NSAID)

The Food Safety Institute (RIKILT, Netherlands) (www.wageningenur.nl/en/Expertise-Services/Research-Institutes/rikilt.htm) is the EURL for:

- Stilbenes,
- Stilbene derivatives and their salts and esters
- Antithyroid agents
- Steroids
- Resorcylic acid lactones (RALs) including zeranol
- Sedatives
- Mycotoxins

The Istituto Superiore di Sanità (ISS, Italy) (www.iss.it/lcdr) is the EURL for chemical elements in food of animal origin.

ANSES – (Laboratoire de Fougères, France, www.anses.fr/fr) is responsible for:

- Antibacterial substances, including sulphonamides and quinolones
- Dyes
- Carbadox and olaquindox
- Chloramphenicol
- Dapsone
- Nitrofurans

7.5.3. National Reference Laboratories (NRLs)

The European Commission has created a network of National Reference Laboratories (NRLs) coordinated by the EU-RLs. This network of laboratories is responsible for setting up EU-wide standards for routine procedures and reliable testing methods in the areas of feed and food and animal health. Each Member State must designate an NRL to correspond to each EU-RL, although the NRL does not have to be located in the designating Member State. These laboratories must collaborate with the EU-RL in their particular area of expertise and disseminate nationally the information provided by the EU-RL. In addition, they provide scientific and technical assistance to the national competent authorities.

According to Article 33 of Regulation (EC) No. 882/2004, duties of the NRLs include collaboration with the EU-RLs and coordination of the activities of official laboratories, organization of comparative tests and ensuring appropriate follow-up, dissemination to the competent authority and official national laboratories information that the EU-RLs supply, provision of scientific and technical assistance.

It is a requirement of Regulation (EC) No. 882/2004 that NRLs:

a) collaborate with the EU-RL in their area of competence;
b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples;
c) organize comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;
d) ensure the dissemination to the competent authority and official national laboratories of information that the EU-RL supplies;
e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53 (coordinated control plans).

7.5.4. European Network of GMO Laboratories (ENGL)

The European Network of GMO Laboratories (ENGL) is a unique platform of EU experts that play an eminent role in the development, harmonization and standardization of means and methods for sampling, detection, identification and quantification of Genetically Modified Organisms (GMOs) or derived products in a wide variety of matrices, covering seeds, grains, food, feed and environmental samples. The network was inaugurated in Brussels on December 4th 2002 and it currently consists of more than 100 national enforcement laboratories, representing all 27 EU Member States plus Norway and Switzerland. Its plenary meetings are open to particular observers, such as to representatives from Acceding and Candidate Countries.

(Source : Joint Research Centre)

The ENGL has a number of projects which directly support GMO laboratories e.g.:

1) ENGL Molecular Register which contains all molecular details of EU-approved GMOs and the necessary on-line tools to analyze these sequences. It is organized around a central database storing the GMO molecular details including elements on the associated detection method;
2) EnGLnet which is a collaboration tool and central point for the exchange of common information among all ENGL members;
3) Plasmid project which is a collection of plasmids that contain cloned amplicons for qualitative and quantitative GMO analysis in food and feed control. The plamids serve as control samples independent of the availability of reference material produced from dried plant material.

7.5.5. The Food Emergency Response Network (FERN)

(Source : dscxn.com)

The Food Emergency Response Network (FERN) integrates the nation's food-testing laboratories at the local, state, and federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. The **FERN** structure is organized to ensure federal and state inter-agency participation and cooperation in the formation, development, and operation of the network. The **FERN** plays a number of critical roles related to food security and food defense. These include:

- Prevention – provides for an early means of detecting threat agents in the American food supply;
- Preparedness – prepares the nation's laboratories to be able to respond to food-related emergencies;
- Response – offers significant surge capacity that will strengthen the nation's response towards widespread complex emergencies, intentional or inadvertent related to agents in food;
- Recovery – enhances the ability of the country to restore confidence in the food supply following a threat or an actual emergency targeting the nation's food supply.

The operational structure of FERN consists of the National Program Office (NPO) with personnel located in Athens, Georgia and Rockville, Maryland. Additionally, there are Regional Coordination Centers, (RCCs), located in each of the (5) FDA regions across the United States. The FERN has held Regional Coordination Center (RCC) meetings to establish operational and communication guidelines within each FERN region; communicating its objectives, policies and current activities; enhancing collaboration between FERN laboratories within a region, and providing an opportunity for individual regions to tailor response plans to their state policies and regional needs.

The FERN National Program Office coordinates support program activities in the following areas: Method Development and Validation, Training, Proficiency Testing, Surveillance, and Electronic Communication.

7.5.6. Laboratory Response Network (LRN)

LRN is a United States diverse network of local, state and federal public health, hospital-based, food testing, veterinary and environmental testing laboratories that provide laboratory diagnostics and the capacity to respond to biological and chemical threats and other public health emergencies.

(Source : nj.gov)

LRN is a partnership involving key stakeholders in the preparation and response to biological and chemical threats. The Centers for Disease Control and Prevention (CDC) in conjunction with the Federal Bureau of Investigation (FBI), and Association of Public Health Laboratories are founding partners. Established in 2005 the LRN mission is to develop, maintain and strengthen an integrated national and international network of laboratories that can respond quickly to needs for rapid testing, timely notification and secure reporting of results associated with acts of biological or chemical terrorism and other high priority public health emergencies.

The network comprises more than 150 federal, state, local, veterinary, and food labs in 50 states and overseas. National labs such as the CDC and military laboratories perform definitive testing and designated Reference Laboratories are used for confirmatory testing for hazardous agents such as *B. anthracis*, and *C. botulinum* toxin. LRN international membership includes laboratories in Australia, Canada, Mexico, United Kingdom, and South Korea.

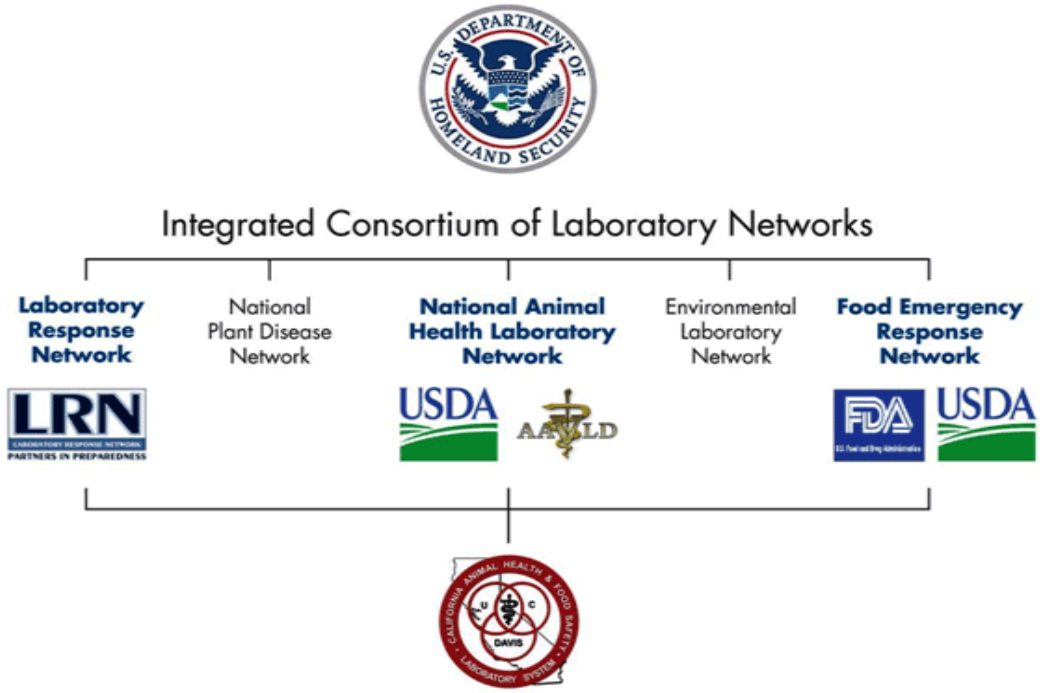
7.5.7. United States Integrated Consortium of Laboratory Networks (ICLN)

In recent years, several laboratory networks have been developed independently to provide coordinated, nation-wide analytical services to counteract potential chemical, biological, or radiological threats. The ICLN was established in 2005 through the creation of a Memorandum of Agreement for an Integrated Consortium of Laboratory Networks among the Departments of Agriculture (USDA), Commerce (DOC), Defense @OD),

Energy (DOE), Health and Human Services (DHHS), Homeland Security (DHS), Interior (DOI), Justice (DOJ), State (DOS), and the Environmental Protection Agency (EPA).

The ICLN is a coordinated and operational system of laboratory networks that is designed to provide timely, high-quality, and interpretable results for early detection of events such as bioterrorism that require integrated laboratory-response capabilities. The ICLN's focus is much wider than food safety and has responsibility for detecting biological threat agents that affect humans, animals, or plants and that contaminate the air, water, or food supply.

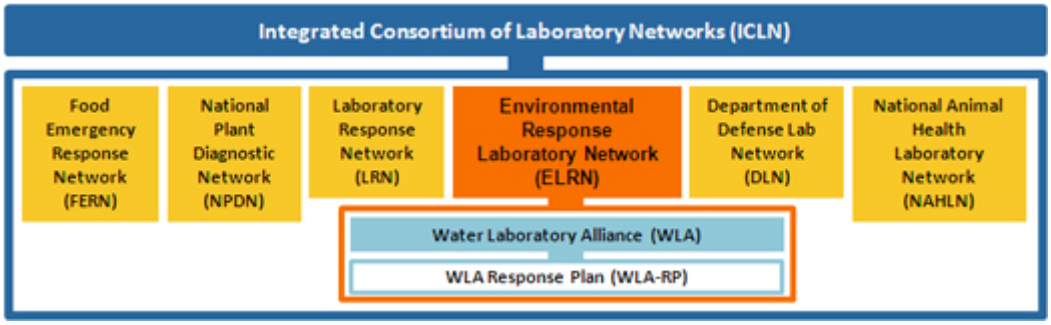
Structure of Integrated Consortium of Laboratory Networks[1]



The laboratory networks that constitute the ICLN are: Laboratory Response Network (LRN); National Animal Health Laboratory Network (NAHLN); U.S. Department of Agriculture's Animal and Plant Health Inspection Service and NIFA's National Plant Diagnostic Network; U.S. Department of Agriculture's Food Safety Inspection Service and Department of Health and Human Services' Food and Drug Administration's Food Emergency Response Network (FERN); and the Environmental Protection Agency's Environmental Response Laboratory Network (ERLN).

[1] cahfs.ucdavis.edu/about/national_networks.cfm.

Membership of the ICLN [2]



The ICLN has created a capabilities assessment of member network laboratories and established working groups to address deficiencies identified by member lab networks. Additionally, the ICLN provides a forum for laboratory network representatives to provide assistance in the event of a biological, chemical, or radiological contamination emergency.

[2] water.epa.gov/infrastructure/watersecurity/wla/index.cfm.

7.6. Imported foods

7.6.1. EU Rapid Alert System for Food and Feed (RASFF)

The Rapid Alert System for Food and Feed (RASFF) is a communication tool used in the EU to rapidly inform food safety authorities from one member state to another as to the results obtained when foods are tested at border inspection posts.

(Source : ec.europa.eu)

The system was put in place by the European Commission to help Member States to act more rapidly and in a coordinated manner in response to health threats caused by food or feed. Prior to introducing the RASFF it was possible for a consignment of food to be rejected at one port of entry to the EU and then to attempt importation to a port in another Member State.

Since RASFF was introduced there is an immediate notification of any rejected consignment of food to all Member States. This makes it impossible for re-entry into the EU, and additionally has the added benefit that resources can be focused on recurring problem areas.

Notifications under the RASFF system are made by a designated contact point in each Member State that is responsible for sending RASFF notifications to the Commission.

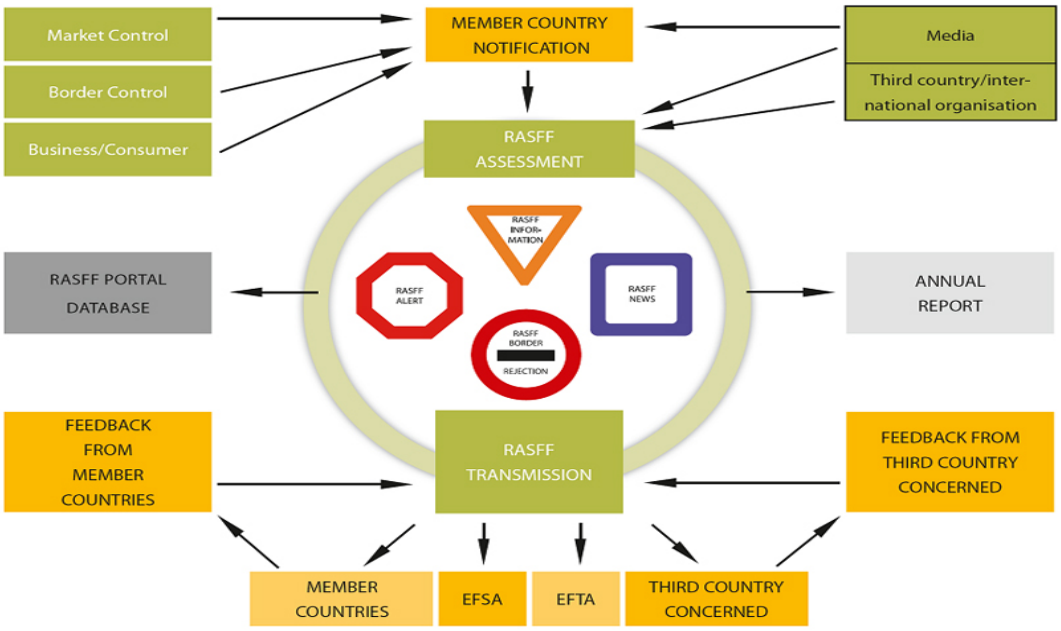
The Member States shall immediately notify the Commission under the rapid alert system of:

1. any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;
2. any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;
3. any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

Any RASFF notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn. The Commission shall immediately transmit to members of the network the notification and supplementary information. Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.

Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.

Relationship between RASFF and other food safety systems[3]



The relationship between all players in the RASFF is shown in previous box. Participation in the rapid alert system may also be opened up to applicant countries, third countries or international organizations, on the basis of agreements between the EU and those countries or international organizations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the EU.

The analytical results from food control laboratories in the EU are critical in the whole process of the RASFF. It is essential that laboratories are working to the same standards and there is equivalency in the methods and in the results being generated. Mutual recognition of laboratories is a cornerstone of the RASFF.

The European Commission has overall responsibility for managing the RASFF, in providing knowledge and a technological platform to facilitate transmission and handling of the RASFF notifications. It receives all notifications from members of the network and performs the following checks on them, prior to making them available to all members of the network:

- completeness check;
- check of legislative requirements;

[3] ec.europa.eu/food/food/rapidalert/about_rasff_en.htm.

- verification if the subject of the notification falls within the scope of the RASFF;
- translation into English of the information on the notification form;
- classification of the notification;
- members of the network flagged for action;
- recurrences of similar problems relating to the same professional operator and/or hazard/country of origin.

The Commission must inform a non-member of RASFF (third countries) if a product subject to a notification has been exported to that country or when a product originating from that country has been the subject of a notification. In this way, the country can take corrective measures where needed and appropriate.

There are two kinds of RASFF notifications: market notifications and border rejections. A member of the network sends a market notification when a risk is found in a food or feed product placed on the market. A border rejection is sent when a product was refused entry into the EU. There are two types of market notifications: alert and information notifications. Together with the border rejections and the news notifications, that makes a total of four different notifications:

Alert

Notifications are sent when a food or feed presenting a serious health risk is on the market and when rapid action is required. The RASFF member that identifies the problem and takes the relevant actions (e.g. withdrawal of the product) triggers the alert. The goal of the notification is to give all RASFF members the information to confirm whether the product in question is on their market, so that they can also take the necessary measures.

Information

Notifications are used when a risk has been identified about food or feed placed on the market, but the other members do not have to take rapid action. This is because the product has not reached their market or is no longer present on their market or because the nature of the risk does not require rapid action.

Border rejections

Concern food and feed consignments that have been tested and rejected at the external borders of the EU (and the European Economic Area – EEA) when a health risk has been found. The notifications are sent to all EEA border posts in order to reinforce controls and to ensure that the rejected product does not re-enter the EU through another border post.

News

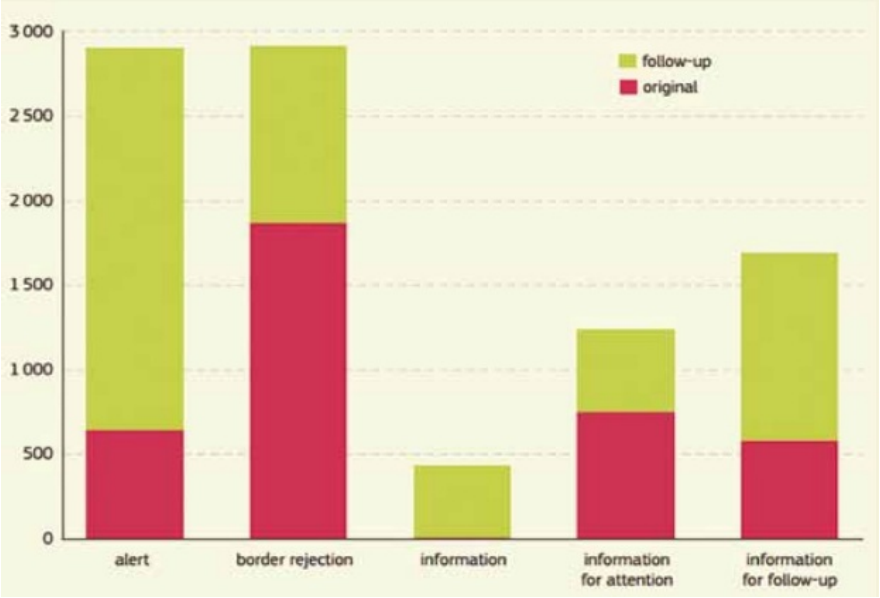
RASFF NEWS

Any information related to the safety of food and feed products which has not been communicated as an alert or an information notification, but which is judged interesting for the control authorities, is transmitted to the members under the heading **'News'**.

Some of the best sources of information concerning the safety of food imports into the EU and the measures taken by the authorities can be found in the RASFF Annual reports which are freely available from the internet. The 2011 Annual Report can be found at ec.europa.eu/food/food/rapidalert/docs/rasff_annual_report_2011_en.pdf.

These reports are a good source of information on trends in foods safety with the charts indicating for example trends such as the number of border rejections rising from 1554 in 2010 to 1828 in 2011 which was an increase of 17.8%. The breakdown in RASFF notifications in 2011 is illustrated in next box. The Annual reports give 2011 notifications by hazard category, by classification and by basis, by product category, by country of origin and world region. There is also an on-line database which provides weekly updates and can be searched against any of the categories as well as for different periods of time.

Breakdown in RASFF notifications in 2011



7.6.2. Foods imported into the USA

The 2011 FSMA aims to ensure that both FDA and USDA regulations and inspection methods for imported foods are driven by risk-based analysis; that the regulatory and inspection process are applied in a uniform manner by both agencies; that resources for import activities are distributed equally across both agencies; and that state food safety agencies who meet federal accreditation standards be a key partner in the import activities.

International trade agreements have dramatically increased the quantity of imported and exported food products to and from the United States. Most trade agreements addressed the issues of non-tariff trade barriers and other mechanisms often used to support domestic production programmes. Phytosanitary restrictions, intended to provide safeguards against the importation of new, exotic, or serious pest problems, are still in place and allowable under the trade agreements. However, an issue that has not been adequately addressed is harmonization of food safety standards among trading partners. While the United States has imposed many restrictions on domestic food producers - limiting use of pesticides, mandating production under HACCP plans, mandatory labeling and container requirements - these requirements are not uniformly imposed upon imported products. This creates problems in two areas – uniformity of food safety for United States consumers and economic uniformity among the industry. NASDA strongly encourages the federal government to seek legislative and trade agreement reform that will ensure a uniform standard for food safety on both domestically - produced and imported food products.

All regions of the United States have been faced with significant and continuing problems regarding the safety and threat posed by certain imported foods, and the potential for a bioterrorism threat involving the safety of foods from deliberate contamination is a reality. The federal government must assure that all imported food is subject to the same food safety standards required of US food manufacturers. This will require the federal agency with jurisdiction over a particular category of food products to make an equivalency determination in regard to a country's food safety system for that product before imports are allowed into the US from that country. Additionally the federal agency must also establish appropriate auditing and monitoring systems to assure that the food safety system is operating effectively. Furthermore, for those items that are involved in a previous food contamination and food safety incident, a full risk assessment, analytical testing, and certification of food items should be required before importation of those items.

The United States imports some products from foreign countries without regard to whether those countries have equivalent inspection systems to assure the safety of those products, subject only to spot-checking of these products on arrival in the United States, except in cases where state laws have forced state authorities to establish more stringent controls.

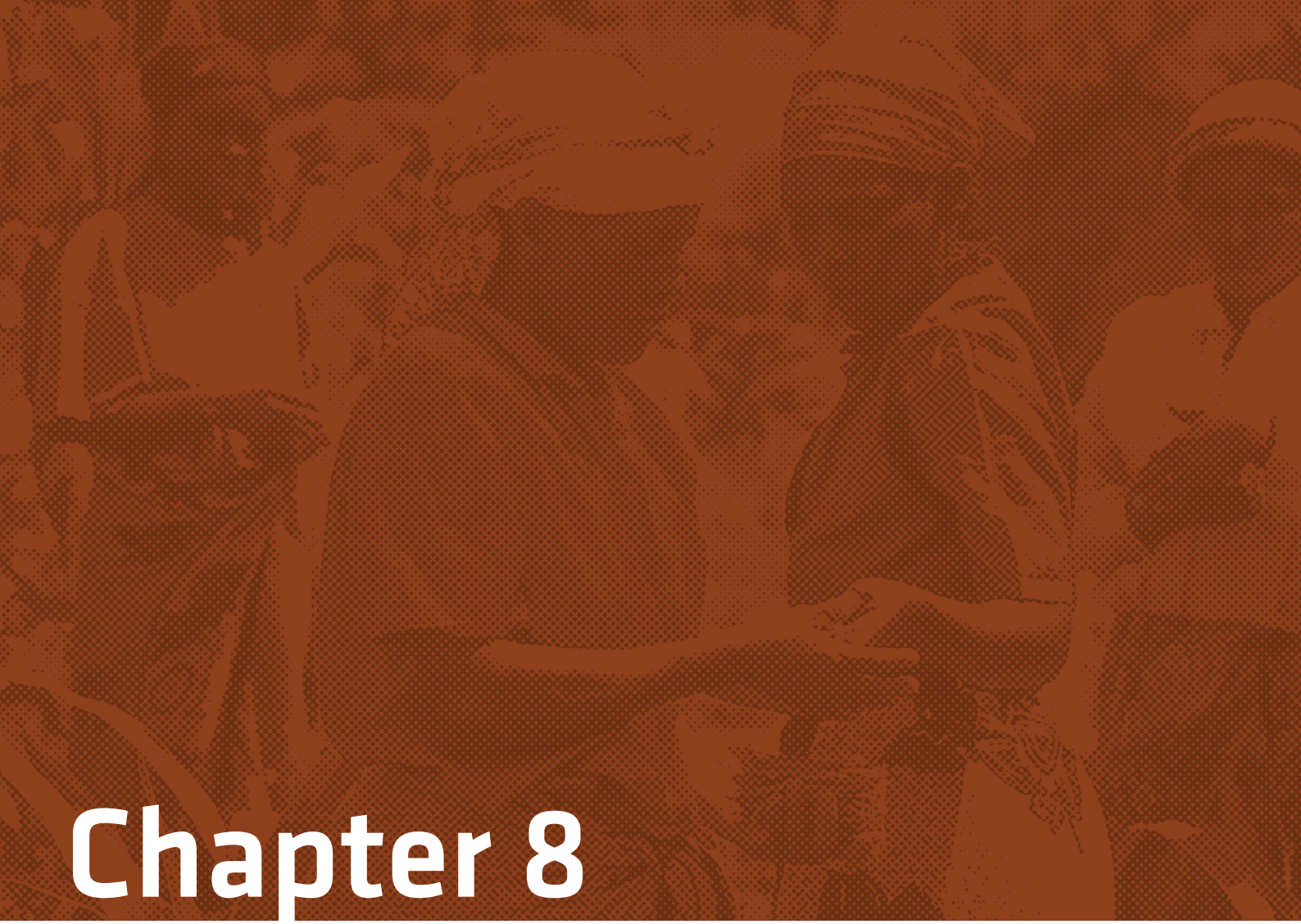
The FDA maintains a database which can be found at the following link:-. http://www.fda.gov/forindustry/importprogram/importalerts/default.htm which provides similar information to that of the RASFF. Despite the added resources provided to FDA, less than 1% of imported foods entering into the USA is physically examined.

7.7. Maintaining state-of-the-art food testing laboratories

Laboratories are an essential component of a food safety system. The establishment of laboratories requires considerable capital investment and they are expensive to maintain and operate. Therefore careful planning is necessary to achieve optimum results. The number and location of the laboratories should be determined in relation to the objectives of the system and the volume of work. As discussed above in considering laboratory networks, if more than one laboratory is required, consideration should be given to apportioning the analytical work to achieve the most effective coverage of the food analyses to be performed and also to having a central reference laboratory equipped for sophisticated and reference analyses.

Laboratories should have adequate facilities for physical, microbiological and chemical analyses. In addition to simple routine analysis, the laboratories can be equipped with more sophisticated instruments, apparatus and library facilities as required. However, it is not only the type of equipment that determines the accuracy and reliability of analytical results, but also the qualification and skill of the analyst and the reliability of the method used. Analysts must be able to draw upon in-depth experience in specific areas of food safety, so that they can advise on whether analytical results are meaningful in the context of the specific area. This means that the analyst should know whether an analytical result is reasonable both in qualitative and quantitative terms – is it likely that this analyte will be found in this matrix, and is the level reported reasonable.

There are some difficult strategic decisions to be taken in managing a food safety laboratory. On the one hand there are pressures to maintain a stable system with analysts trained in validated methods which are formally accredited, and used routinely as part of the laboratory portfolio. On the other hand there are commercial pressures to reduce the cost per test of carrying out food analysis, to improve speed of analysis (turnaround times) and to integrate improved technologies into the laboratory. There is a considerable lag time between identifying a new technology, carrying out method development work, validating new methods and finally introducing into routine operation. The cost of introducing new methods is high and the commercial benefits must be clearly identifiable. On the other hand any laboratory which does not continually investigate new methods and stay up-to-date with new technologies risks being left behind and becoming uncompetitive. The skill of the laboratory manager is staying up-to-date with technology developments, and deciding at what point to make a capital investment. At the same time there is a need for continual recognition that staff are the most important laboratory resource and staff need to have a programme of continued training and development, consistent with the laboratory investment programme.



Chapter 8

Glossary of food safety terms

8.1. Glossary

8.1.1. A

Action limit/level
Value set for a parameter in a given matrix.

Threshold established to launch an 'action' such as: notification, product recall, counter-analysis, destruction. Thresholds are based on regulatory admissible value limits (e.g.: MRL). In the absence of a reference standard, the threshold is proposed by the industry and validated by an authority.

Action threshold
Threshold at which the source of pollution must be determined and measures taken to reduce or exterminate it. See 'Action limit/level'.

Additional declaration
A statement required by an import country to be entered on a phytosanitary certificate and which provides specific additional information on a consignment regarding regulated pests.

Aggregate sample
The combined total of all the incremental samples taken from the lot or sub-lot.

Approval
Procedure by which a local or regional authority officially recognizes that a body (e.g.: ICB), a laboratory (e.g.: laboratory accredited for microbiological analyses) or an individual (e.g.: self-evaluation system inspector) is competent to undertake specific tasks.

Approved/Accredited laboratory
Laboratory officially authorized, on the basis of its performance, to examine samples (which may be official samples). It can also be an 'accredited' laboratory under ISO 17025.

Attribute sampling plan (n, c, m, M)
A 3-class attribute sampling plan is determined by the number of samples that must be tested (n), the level (or number of germs) authorized (m), the maximum level authorized (M) and the number of samples showing a result between m and M (c).

Audit
A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives (source: Regulation No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules). The term 'audit' is used in the internal validation of self-evaluation systems.

Authority
(Competent Authority) central authority of a State (e.g.: food agency, ministry, etc.) competent to organize official controls and to validate self-evaluation systems.

8.1.2. B

Bacteria
Tiny, one-celled microorganisms found in the environment. Bacteria multiply rapidly in food under the right conditions, and some bacteria can cause foodborne illness. Helpful bacteria can be used to make yogurt, vinegar and some cheeses. Bacteria are found in all foods. Most are killed by high temperatures, but some form toxins which may or may not be killed by heat.

Base
A substance with a pH above 7.0. Substances with a base pH include soap (pH 10.0) and ammonia (pH 11.2).

Biological hazard
Exposure to food by disease-causing microorganisms or toxins that are found in some plants and fish.

Botulism
Toxin produced by Clostridium botulinum.

8.1.3. C

Calibration
The process of standardizing a temperature monitoring instrument to ensure that it will measure within a specific temperature range in which the instrument is designed to operate.

Campylobacter jejuni
Pathogenic microorganism that causes foodborne illness.

Cause
An activity, factor or situation responsible for introducing a hazard or increasing it to an unacceptable level.

Checklist
Tool comprising a complete inventory of the points to be checked, which is completed by inspectors on the basis of what they observe.

Chemicals
Chemical foodborne illnesses are among the most deadly. Chemicals and other “natural” toxins formed in food include agents such as scombrotoxin and ciguatoxin. Store cleaning supplies in a different area away from stored food.

Chemical hazards
Substances such as cleaning solutions and sanitizers.

Clean
Free of visible soil.

Clean water
Water that does not compromise food safety in the circumstances of its use.

Cleaning
The removal of soil, food residue, dirt, grease or other objectionable matter.

Codex Alimentarius
Set of internationally recognized laws and standards applicable to processes, directives and recommendations on food, food production and food safety. The name is Latin for 'food book'.

The texts that make up this system of laws and standards are drawn up by the *Codex Alimentarius* Commission (CAC), an institution set up by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

Commodity
A type of plant, plant product or other article being moved for trade or other purpose.

Commodity pest list
A list of pests occurring in an area which may be associated with a specific commodity.

Compliance procedure (of a consignment)
Official procedure used to verify that a consignment complies with phytosanitary import requirements or phytosanitary measures related to transit.

Consumer Control Points
Points in the process of food preparation when harmful microorganisms can contaminate the food. When conditions such as time, temperature or moisture may encourage the growth of microorganisms. Food handling practices that prevent foodborne illness are critical at these points.

Contaminant
Any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

Contamination
Introduction or occurrence in a food product, storage area, means of transport or container of pests or other regulated contaminants, without there being infestation. Occurrence or introduction in a food product of biological, chemical or physical substances, in a quantity sufficient to endanger health or to render this food product unfit for human consumption.

Control
The state wherein correct procedures are being followed and criteria are being met.

Control measures
Actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. All necessary actions taken to ensure and maintain compliance with criteria established in the HACCP Plan.

Control point
A step in a system where specific procedures can be applied to achieve a defined effect and can be measured, monitored, controlled and corrected.

Cooking
A Consumer Control Point to remind consumers that thorough cooking will destroy harmful bacteria.

Corrective action
Actions to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP)
A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.

Critical limit
A criterion which separates acceptability from unacceptability. Deviation: Failure to meet a critical limit.

Cross-contamination
The transfer of harmful bacteria from one food to another. Harmful bacteria can not only be transferred from food to food, but also from hands to food. Cross-contamination is when bacteria spread between food, surfaces or equipment.

Cryptosporidium parvum
A one-celled animal (protozoa) that can cause foodborne illness.

Cultivation
Any agricultural action or practice used by growers to preserve and improve the conditions for growing fresh fruits or vegetables in the field.

8.1.4. D

Detergent
A chemical used to remove grease, dirt and food, such as washing-up liquid.

Disinfectant
A chemical that kills bacteria.

Disinfection
The reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

Distribution
Placing of a product on the market without any major changes to the nature of the product.

Dose-response
Determining the relationship between the amount of exposure (dose) to a chemical, biological or physical agent, and to severity and/or frequency of the resulting effects on health (response).

8.1.5. E

Efficacy (treatment)
A defined, measurable, and reproducible effect of a prescribed treatment.

Employee
Any person working in or for a food service establishment who engages in food preparation or service, who transports food or Food containers, or who comes in contact with any food utensils or equipment.

Equipment
All stoves, ranges, hoods, meat blocks, tables, counters, Refrigerators, freezers, sinks, dishwashing machines, steam tables and similar items, other than utensils, used in the operation of a food service establishments.

Establishment
Any building or area in which food is handled, as well as the surroundings under the control of the same management.

Export
Sending plants, vegetables or other materials to another country.

8.1.6. F

FAO (Food and Agriculture Organization)
The United Nations Food and Agriculture Organization is an organization that fights hunger in the world.

Fixed food establishment
A food service establishment which operates at a specific location and is connected to electric utilities, water, and a sewage disposal system.

Flow diagram
A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

Foodborne Illness
A general term often used to describe any disease or illness caused by eating contaminated food or drink.

Foodborne Illness Outbreak
The Centers for Disease Control define an outbreak of foodborne illness as illness that involves two or more persons who eat a common food, with the food confirmed as the source of the illness by a laboratory analysis. The only exception is that a single case of botulism qualifies as an outbreak.

Food born infections
These occur when “enough” of the live bacterial cells that have reproduced in the food, small intestine, or both are consumed. The severity of the infection depends on the virulence of the bacteria, resistance of the victim, and the number of cells that survive digestion.

Foodborne intoxications
These result from a poison or toxin produced by reproductive bacterial cells in food or in the human body. Bacterial toxins have varying resistance to heat; some can even survive boiling. Other toxins can be a natural part of the food, for example, certain types of mushrooms.

Food contact surfaces
Surfaces of equipment and utensils with which normally comes in contact, and those surfaces from which food may drain, drip, or splash back onto surfaces normally in contact with Food.

Food handler
Any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

Food hygiene
Comprises conditions and measures necessary to ensure safe and suitable food at all steps of the food chain (guaranteeing fitness for human consumption).

Food or foodstuff
Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

Food poisoning
An illness that occurs when people eat food that has been contaminated with harmful germs (particularly bacteria and viruses) or toxins (poisonous substances).

Food preparation
The manipulation of foods intended for human consumption by such means as washing, slicing, peeling, chipping, shucking, scooping and/or portioning.

Food safety
Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food service establishment
Any facility, where food is prepared and intended for individual portion service, and includes the site at which individual portions are provided.

Food suitability
Assurance that food is acceptable for human consumption according to its intended use.

Fresh
Living; not dried, deep-frozen or otherwise conserved.

Fruits and vegetables
Category of commodity corresponding to the fresh parts of plants intended for consumption or processing, not for planting (FAO, 1990; revised ICPM, 2001).

8.1.7. H

HACCP
A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP Plan
A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard
A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse effect to human, animal or vegetable health.

Hazard analysis
Approach that consists of collecting and evaluating data on risks and the factors that lead to these risks, in order to decide which pose a threat to food safety and should thus be taken into account in the HACCP plan.

Host pest list
List of pests that that infest a plant species, globally or in an area.

8.1.8. I

Incidence
The number of new cases of a disease per population for a given time unit. Incidence should not be confused with prevalence, which indicates how many people/animals in a given population suffer from a disease at a given time.

Incremental sample
A quantity of material taken from a single place in the lot or sub-lot.

Inspection
Controlling the performance of the self-evaluation system, either by an authorized ICB or by an official control service.

Inspector
Person authorized, by a public or private, national or international, organization to carry out this task. Synonym of “controller”.

IPPC (International Plant Protection Convention)
The IPPC is an international plant health agreement that aims to undertake actions to prevent the introduction and spread of pests and to promote adequate pest control measures.

Iteration
Process that is repeated, making it possible to perform calculations.

8.1.9. J

JECFA (Joint FAO/WHO Expert Committee on Food Additives)
The JECFA is an international scientific expert committee administered jointly by the FAO and the WHO. Initially set up to evaluate the safety of food additives, its work now also includes the evaluation of contaminants and naturally occurring toxicants

8.1.10. K

Kitchenware
All multi-use utensils, other than tableware (such as pots, pans).

8.1.11. L

Laboratory sample
The sample sent to, or received by, the laboratory. A representative quantity of material removed from the bulk sample.

Latent infection
Infection for which no clinical signs of infection can be detected.

Legislation
The set of laws, decrees, regulations, directives or other administrative measures adopted by a government. Phytosanitary legislation refers to the phytosanitary regulations of the FAO.

Limit of detection (LOD)
The lowest quantity of a substance that can be distinguished, by analytical testing, from the absence of that substance within a pre-determined acceptable statistical certainty. For substances that have no admissible values, the detection capacity is the smallest concentration at which an analysis method can demonstrate that a sample is in fact polluted.

Limited Food Service Establishment
Any establishment with a food operation, so limited by the type and quantity of foods prepared and the equipment utilized, that poses a lesser degree of risk to the public's health, and, for the purpose of fees, requires less time to monitor.

Lot (for animals)
A group of animals living together.

Lot (plants)
Set of units (plants or plant products):

1) belonging to the same plot of land or same section of this plot, which was planted at approximately the same time, received the same treatments, and which has not yet been harvested;
2) single commodity, identifiable by its homogeneity of composition, origin etc., forming part of a consignment.

According to the standard ISPM No 31, a lot to be sampled (to control the consignment) should be a number of units of a single commodity identifiable by its homogeneity in factors such as:

- origin;
- grower;
- packing facility;
- species, variety, or degree of maturity;
- exporter;
- area of production;
- regulated pests and their characteristics;
- treatment at origin;
- type of processing.

8.1.12. M

Manure
Animal excrement which may be mixed with litter or other material.

Mark
An official stamp or brand, internationally recognized, applied to a regulated article to attest its phytosanitary state.

Maximum authorized levels
Maximum residue levels of plant protection products and nitrates, established respectively in Regulation (EC) No 396/2005 and Regulation (EC) No 1881/2006 on maximum residue levels of certain contaminants in food.

Maximum residue level (MRL)
Upper legal level of a concentration for a pesticide residue in or on food or feed set on the basis of good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.

Mesophile (flora or germ)
Mesophilic micro-organisms are those that multiply between 20 and 45°C, with optimum growth at 37°C. They can be found in foods kept at room temperature. The main species of germs and bacteria can be classified as mesophiles, in particular pathogens, but also spoilage bacteria.

Microbiological criterion
A microbiological criterion for food defines the acceptability of a product or a food lot based on the absence, presence or number of micro-organisms including parasites, and/or the quantity of their toxins/metabolites per unit(s) of mass, volume, area or lot.

Micro-organisms
Includes yeasts, moulds, bacteria, viruses and parasites or any other live organism not observable to the naked eye. Occasionally, the term ‘microbe’ is used.

Moisture content
The amount of water in food.

Monitor
The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

8.1.13. N

NOAEL (No Observed Adverse Effect Level)
Level of exposure, expressed, for example, in µg/kg bw/day, for which no negative effect on health has been found. This level is determined through testing on animals.

Notification level
Limit value from which an operator/laboratory/certification or inspection body is obliged to notify authorities about a given parameter/matrix.

8.1.14. O

OIE (World Organization for Animal Health)
Intergovernmental organization responsible for promoting animal health at global level.

Operator
Natural or legal person responsible for respecting the rules established in regulations on self-evaluation, mandatory notification and traceability in the food chain under its management.

Organism
Any biological entity that can reproduce and multiply in its natural state (ISPM No 3, 2005). A quarantine pest is a pest of potential economic importance to the endangered area and either not yet present there or present but not widely distributed and being officially controlled.

Oro-faecal route
Transmission route of a pathogen found in the faeces (excrement), which is involuntarily ingested through contact between the mouth and soiled hands or when this agent has been transmitted to food by unwashed hands or soiled objects. Many parasites are transmitted in this way.

8.1.15. P

Packaging
Placing a product in a container or recipient in direct contact with the product concerned. Also the actual container or recipient.

Parasites
These tiny organisms can cause severe illness. Parasites need nutrients from their host to complete their life cycle. They are always associated with raw or undercooked meat and fish, including pork, bear meat and others.

Pathogen
Micro-organism capable of causing injury or illness.

Percentile
A percentile of a set of data is one of the 99 points along the orderly set of data divided into 100 parts of equal size. The 95th percentile, for example, is a number that is higher than or equal to 95% of the data and less than or equal to 5%.

Performance criteria
Result required by one or more control measures that have been implemented, at one or more production stages, to guarantee food safety. If performance criteria are established, they must account for the foodstuff's initial degree of contamination by the microbiological hazard and any changes that occur in this degree of contamination during production, processing, distribution, storage, preparation and consumption of this foodstuff.

Performance objective (PO)
The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to a Food Safety Objective (FSO).

Personal hygiene
The way a person maintains their health, appearance and cleanliness.

Pest
Any animal or insect of public health importance including, but not limited to, cockroaches, rodents, etc. that may carry pathogens that can contaminate food.

Pesticide residues
Remnants, including active substances, metabolites and/or products generated by the degradation or reaction of the active substances used, presently or in the past, as contaminants on or in a food.

pH
Symbol for degree of acidity or alkalinity of a substance, measured on a scale from 0 to 14.0.

Physical hazard
The presence of foreign particles, like glass or metal, in foods.

Phytosanitary Certificate
Certificate patterned after the model certificates of the IPPC.

Phytosanitary inspection
Official visual examination of plants, plant products or other regulated articles to determine whether pests are present and/or to determine compliance with phytosanitary regulations (FAO, 1990; revised CEPM, 1999).

Place of production
Any premises or collection of fields operated as a single production or farming unit. This may include production sites which are separately managed for phytosanitary purposes.

Plant products
Unmanufactured material of plant origin (including grain) and those manufactured products that, by their nature or that of their processing, may create a risk for the introduction and spread of pests.

Potable water
Water which meets the quality standards of drinking water as described in the WHO Guidelines for Drinking Water Quality.

Potentially hazardous food
Any perishable food that is capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms.

Moist, high-protein, low acid foods that consist, in whole or in part, of milk or milk products, shell eggs, meats, poultry, fish, shellfish, baked or boiled potatoes, tofu and other soy-protein foods, plant foods that have been heat-treated, raw seed sprouts, or synthetic ingredients.

Precautionary principle
Regulation (EC) No 178/2002 describes the precautionary principle as follows: In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

Pre-harvest control
Control of certain fruit and vegetable species made before harvest by an approved producers' organization or other approved body. This control consists in sampling the lot and analyzing it in an accredited laboratory (for example, to detect certain residues and, if one or more maximum levels are exceeded, to monitor the batch concerned).

Preparing
A Consumer Control Point to remind consumers that food can cause foodborne illness when conditions in the environment encourage bacterial growth.

Preserve
Maintain quality and safety of food by removing moisture and/or air.

Prevalence
How many people/animals in a given population suffer from a disease at a given time.

Primary production
Those steps in the food chain up to and including, for example, harvest, slaughter, milking and fishing. The set of steps taken in the growing and harvesting of fresh fruits and vegetables such as planting, irrigation, application of fertilizers, application of agricultural chemicals, etc.

Primary production - plants
The production of plants, fruits and vegetables intended for trade and processing, or as fresh food or feed. Primary production: production and growing of primary products, including harvest.

Product inspection
Controlling whether the quality and quantity of a lot corresponds to the conditions contained in the order form.

PS
Private, or voluntary, standard: industry-defined production standard compiled in reference systems or technical specifications. Also called 'PVN' (private voluntary norms).

Purchasing
A Consumer Control Point to remind consumers that they can control food safety from the moment they put food in their grocery cart.

8.1.16. Q

Quality
All characteristics relating to the nature, state, composition, nutritional aspects, packaging and labelling.

Quarantine
Official confinement of products for observation and research or for further inspection, testing and/or treatment.

8.1.17. R

Recall
Any measure applied after distribution that aims to prevent consumption or use of a product and/or to inform about the danger involved if the product has already been consumed.

Registration
(1) Document in a quality system;
(2) Data;
(3) Identification of a product or an operator and his establishment.

Regression analysis
Statistical technique for analyzing data which focuses on a (possible) specific relation (called a regression function) between variables.

Risk
Probability that a hazard will cause an effect considered to be 'harmful' to consumer health (health risk) or to that of plants (phytosanitary risk). When hazards can be identified and the risks analyzed their impact on health can generally be predicted. Food risk is that to which the consumer is exposed on eating.

Risk assessment - deterministic
The deterministic method, for each variable of the model, uses a single point estimate (such as the average) to determine the result of the model.

Risk assessment - probabilistic
In the probabilistic method, the model variables are considered as distribution values.

8.1.18. S

Safe Temperatures
As applies to potentially hazardous foods, means Temperatures of 41 degrees F or below, or 140 degrees F or above.

Salmonellosis
Infection with Salmonella species. Found in meat, poultry, eggs or milk products.

Sampling
Controlling a product based on analysis of a sample taken for this purpose. The act of taking a sample.

Sampling plan
The steps, collection method and number of samples that must be taken and tested to ensure the control and monitoring of a process.

Sanitize
Free of harmful levels of disease-causing microorganisms and other potentially harmful contaminants.

Sanitizer
A two-in-one product that acts as a detergent and a disinfectant.

Sanitizing solution
One tablespoon chlorine bleach in one gallon clean water.

Saprophyte (flora or germ)
Micro-organisms that develop from food products or non-living organic matter (milk, excrement, humus, etc.) which they decompose and putrefy. Many fungi and bacteria are saprophytes. Although they are not often directly pathogens, they can produce toxins that can lead to poisoning.

Scenario analysis
In a scenario analysis, various risk management measures ('scenarios') are compared in order to study which is more apt to limit the risk. Scenario analysis can also be used when the current state of knowledge precludes a single evaluation of risks, i.e. if information is missing or insufficient to attribute a probability to different scenarios.

Self-assessment
Set of measures taken by operators to ensure that the products they manage at all production, processing and distribution stages meet food safety legal requirements and product quality and traceability requirements; and that there is effective control of these requirements. The term 'self-assessment system' means the application of rules regarding hygiene and record-keeping.

Sell-by
Dates used by retailers to guide rotation of shelf stock.

Sensitivity analysis
Method used to examine which variables, in a hazard analysis model, have the greatest impact on the results of this model.

Serving
A Consumer Control Point to remind consumers to choose a serving style which will allow food to be served as quickly as possible, while maintaining desirable temperatures.

Single-Service Articles
Any cups, containers, closures, plates, straws, place mats, napkins, doilies, spoons, stirrers, paddles, knives, forks, wrapping materials, and all similar articles, which are constructed wholly or in part from paper or paper material, foil, wood, plastic, synthetic or other readily destructible materials, for one time and one person use and then discarded.

Spreading
The transfer of contamination to the healthy (parts of) plants through contact with the diseased (parts of) plants. Spreading is often associated with the presence of exudate on the (parts of the) plants infected by the bacteria. Large quantities of bacteria accumulate in an oozing substance (exudate) formed in specific conditions. The exudate also protects bacteria against unfavorable external conditions such as drying, sunlight or heat. Bacteria can thus survive several months in this exudate.

Standard
(1) Limit established by regulation
(2) Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Staphylococcus
Toxin produced by certain strains of *Staphylococcus aureus*; often found in custard or cream-filled baked goods, ham, poultry, eggs, potato salad, cream sauces, sandwich fillings.

Step
A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Storage area(s)
The place or set of places where foodstuffs are stored.

Stored product
Unmanufactured plant product intended for consumption or processing, stored in a dried form (this includes in particular grain and dry fruits and vegetables).

Storing
A Consumer Control Point to remind consumers that proper storage maintains the quality of food and helps prevent contamination.

Surveillance/monitoring
Careful observation of events that have a risk or significant impact on health.

National monitoring/surveillance plans are an essential tool for food safety and for added value in exported products:

- effective and complete plans provide a guarantee of product quality;
- regular publication of their results provides information on the stringent controls conducted by a State's inspection and phytosanitary services in order to protect

consumer health.

8.1.19. T

Tableware
Multi-use eating and drinking items, including flatware, knives, forks, spoons, glasses, cups, etc.

Temperature
A critical measurement for ensuring the safety and quality of many food products.

Third party
See ICB. Party that has no vested interest in its action.

Tolerance level (for a pest)
Incidence of a pest. Specifies a threshold for action to control that pest or to prevent its spread or introduction.

Traceability
The ability to follow the movement of a food through all the stages of production, distribution and processing.

TRV (Toxicological reference value)
A general expression to designate toxicological parameters such as ADI (acceptable daily intake), AOEL (acceptable operator exposure level) etc.

8.1.20. U

Uncertainty
Also called epistemic uncertainty, this is a lack of perfect knowledge. When uncertainty is associated with variability, it becomes impossible to predict what will happen in the future.

Utensil
Implements such as pots, pans, ladles or food containers used in the preparation, storage, transportation or serving of food.

8.1.21. V

Validation
Obtaining evidence that the elements of the HACCP plan are effective.

Variability
Variability means heterogeneity or diversity in a pre-defined population. It can also mean the consequence of incomplete knowledge and thus, when associated with uncertainty, makes it impossible to predict what will happen in the future.

Variability - interspecies
Variability among different species.

Verification
The application of methods, procedures, and tests, in addition to those used in monitoring to determine compliance with the HACCP plan, and/or whether the HACCP plan needs modification.

Viruses
Viruses grow or reproduce only on living cells. They are often found in untreated water or sewage-contaminated water, and viruses from human feces on unwashed hands can infect others by passing the virus to food. Normal cooking may lower the risk of illness but may not destroy all viruses.

8.1.22. W

Water activity
The amount of water that is available for bacterial growth. Water activity (A_w) is the amount of water available for deterioration reactions and is measured on a scale of 0 to 1.0. Bacteria, yeast, and mold multiply rapidly at a high water activity--above 0.86. Meat, produce and soft cheeses have A_w in this range (between 0.86 and 1.0).

WHO
The World Health Organization (WHO) is a United Nations organization established to provide an overview of global public health aspects, coordinate public health activities and improve the health of the global population.

Withdrawal
Any measure aiming to prevent the distribution and display for sale of a product, as well as its availability to consumers.

Wood packaging material
Wood or wood products (excluding paper products) used to support, protect or carry a commodity (includes dunnage) (ISPM No. 15, 2002).

Most used abbreviations and acronyms

Most used abbreviations and acronyms

ACP	African, Caribbean and Pacific (Group of ACP States that have signed a series of agreements with the EU, called the 'Cotonou Agreements')
ADI	Acceptable daily intake
AESAN	*Agencia Española de Consumo, Seguridad Alimentaria y Nutrición* (Spanish Agency for Food Safety and Food)
ANSES	*Agence nationale de sécurité sanitaire, de l'alimentation, de l'environnement et du travail* (French Agency for Food, Environmental and Occupational Health & Safety)
AOEL	Acceptable operator exposure level
ARfD	Acute reference dose
A_w	Water activity
BLV	*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* (German Federal Office of Consumer Protection and Food Safety)
BRC	British Retail Consortium
BSE	Bovine spongiform encephalopathy
CA	Competent Authority
CAC	*Codex Alimentarius* Commission
CAP	Conformity assessment procedure
CBD	Convention on Biological Diversity

CCP	Critical control Points
CDC	*Centers for Disease Control and Prevention*
CEFAS	*Centre for Environment, Fisheries and Aquaculture Science*
CEMP	*Community Environmental Management Program*
CL	Control laboratory
CMP	Commission on Phytosanitary Measures
COLEACP	Liaison Committee – Europe-Africa-Caribbean-Pacific
DDT	Dichlorodiphenyltrichloroethane
DHHS	US Department of Health and Human Services
DHS	US Department of Homeland Security
DL	Detection limit
DOC	US Department of Commerce
DOD	US Department of Defense
DOE	US Department of Energy
DOI	US Department of the Interior
DOJ	US Department of Justice

DOS	US Department of State
DSP	Diarrheic shellfish poison
EEC	European Economic Community
EFA	European Food Authority
EFSA	European Food Safety Authority
EMRL	Extraneous Maximum Residue Limits
ENGL	European Network of GMO Laboratories
EPA	Economic Partnership Agreements
EPA	Environmental Protection Agency
ERLN	Environmental Response Laboratory Network
EU	European Union
EURL	European Union Reference Laboratory
FAO	Food and Agriculture Organization
FBD	Foodborne diseases
FBI	Foodborne illness outbreaks
FDA	Food and Drug Administration

FERG	Foodborne Disease Burden Epidemiology Reference Group
FERN	Food Emergency Response Network
FOS	US Department of Food Safety and Zoonoses
FSA	UK Food Standards Agency
FSMA	Food Safety Modernization Act of 2011
FSO	Food Safety Objective
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GFN	Global Foodborne Infections Network
GHP	Good Hygiene Practices
GMO	Genetically modified organism
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
HAV	Hepatitis A virus
HSE	Health & Safety Executive
ICLN	Integrated Consortium of Laboratory Networks

ICO	International Cooperation Agencies
ICPM	Interim Commission on Phytosanitary Measures
IEC	International Electrotechnical Commission
IHCP	Institute for Health and Consumer Protection
IHR	International Health Regulation
IICA	Inter-American Institute for Cooperation on Agriculture
INFOSAN	International Food Safety Authorities Network
INS	International Numbering System
IPP	International Phytosanitary Portal
IPPC	Integrated Plant Protection Convention
ISO	International Standards Organization
ISPM	International Standard for Phytosanitary Measures
ITC	International Trade Center
JECFA	Joint Expert Committee for Food Additives
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meeting on Pesticide Residues

LDC	Least developed country
LGC	Laboratory of the Government Chemist
LIMS	Laboratory Information Management System
LRN	Laboratory Response network
MFN	Most Favored Nation
MRL	Maximum residue level
MRLVD	Maximum residue limit for veterinary drugs
NAHLN	National Animal Health Laboratory Network
NASDA	National Association of State Departments of Agriculture
NFSS	National food safety systems
NGO	Non-governmental organization
NIFA	National Institute of Food and Agriculture
NOAEL	No Observable Adverse Effect Level
NPO	*National Program Office*
NPPO	National Plant Protection Organization
NRL	National Reference Laboratories

NSAI	Nonsteroidal anti-inflammatory
OECD	Organization for Economic Co-operation and Development
OIE	World Organization for Animal Health (*Office international des épizooties*)
OIRSA	Official agreement between the OIE and the *Organismo Internacional Regional de Sanidad Agropecuaria* (International Regional Agriculture and Livestock Health Organization)
OJEC	*Official Journal of the European Communities*
OJEU	*Official Journal of the European Union*
PAH	Polycyclic aromatic hydrocarbons
PCB	Polychlorinated biphenyl
PCR	Polymerase chain reaction
pH	Potential of hydrogen
PIP	Pesticide Initiative Programme, a European cooperation programme managed by COLEACP for sustainable development of the ACP horticultural industry
PMDTI	Provisional maximum tolerable daily intake
POP	Persistent organic pollutant
PSP	Paralytic Shellfish Poisoning
PTWI	Provisional Tolerable Weekly Intake
RASFF	Rapid Alert System for Food and Feed

RCC	Regional Coordination Centers
RIKILT	Netherlands Institute for Food Safety
RIVM	*Rijksinstituut voor Volksgezondheid en Milieu* (National Institute for Health and Environment – Netherlands)
RPPO	Regional Plant Protection Organization
SCS	Self-checking system
SLDBS	Small and/or less-developed food businesses
SME	Small and medium-sized enterprise
SPS	Sanitary and Phytosanitary (Agreement)
STDF	Standards and Trade Development Facility
TBT	Technical barriers to trade
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRV	Toxicological reference values
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Development Organization
UNO	United Nations Organization
USDA	US Department of Agriculture

WAHID	World Animal Health Information Database
WHO	World Health Organization
WTO	World Trade Organization

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Useful Websites

Useful Websites

Agencia española de Consumo, Seguridad alimentaria y Nutrición: www.aesan.msssi.gob.es

Anses: www.anses.fr

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit: www.bvl.bund.de

Cefas: www.cefas.co.uk

COLEACP: www.coleacp.org/en

Codex Alimentarius: www.fao.org/fao-who-codexalimentarius/codex-home/en

Department for Environment Food & Rural Affairs: www.defra.gov.uk

EFSA: www.efsa.europa.eu

EUFIC: www.eufic.org

EURL: eurl.craw.eu

EUR-LEX: eur-lex.europa.eu

FAO: www.fao.org/home/en

Food and Drug Administration: www.fda.gov

Food Standard Agency: www.food.gov.uk

IPPC: www.ippc.int/en

Istituto Superiore di Sanità: www.iss.it

Ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt France: agriculture.gouv.fr

National Food Institute: www.crl-ar.eu

NCBI: www.ncbi.nlm.nih.gov

OECD: www.oecd.org

OIE: www.oie.int/en

SVA: www.sva.se/en

UNECE: www.unece.org/info/ece-homepage.html

United States Environmental Protection Agency: www.epa.gov

Wageningen University Reserach: www.wur.nl/en.htm

WHO: www.who.int

WTO: www.wto.org

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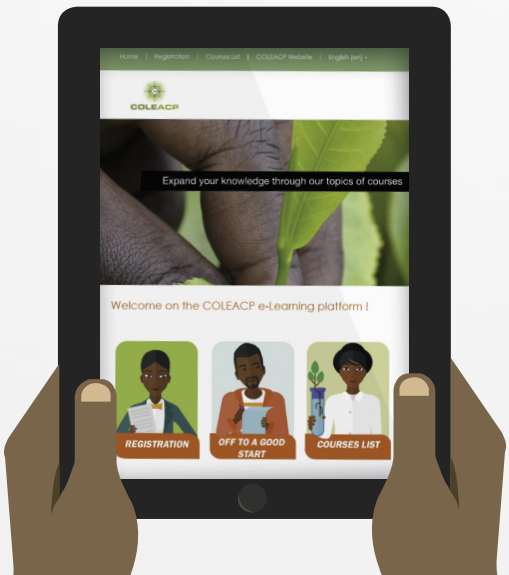

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