

# Table of Contents

Preface .....	3
<b>Chapter 1: Introduction .....</b>	<b>4</b>
<b>Chapter 2: Food Safety Policy Development Process .....</b>	<b>7</b>
2.1 Overview of the Policy Development Process .....	7
2.2 Formulation of a National Food Safety Policy .....	8
2.3 Implementation of the Food Safety Policy .....	12
2.4 Monitoring and Evaluation .....	13
<b>Chapter 3: Fundamentals of Food Law .....</b>	<b>14</b>
<b>Chapter 4: Developing Food Law .....</b>	<b>18</b>
4.1 Preliminary stage .....	18
4.2 Drafting the new law .....	20
4.3 Adoption of the law .....	25
4.4 Implementing the law .....	25
<b>Chapter 5: Food Law Components .....</b>	<b>26</b>
5.1 Scope and Definitions .....	27
5.2 General Principles .....	34
5.3 Administrative Provisions .....	37
5.4 Enforcement Provisions .....	41
5.5 Regulations .....	48
5.6 Repeal and Saving .....	50
<b>Chapter 6: Conclusion .....</b>	<b>52</b>
<b>References.....</b>	<b>53</b>
<b>Annex</b>	
Annex 1.1: Basic Food Laws and Enabling Regulations and the Ministries, Departments and Agencies involved .....	54
Annex 2: Food Law Examples from Outside the African Region .....	66
<b>Boxes</b>	
Box 1: Sections of Food Safety Policy Text .....	11
Box 2: Suggested Terms of Reference for Task Force .....	19
Box 3: Contents of the FAO/WHO Model Food Law .....	26
Box 4: Examples of Sections on Scope from Tanzania and Zambia .....	27
Box 5: Examples of Definitions of Food .....	28
Box 6: Examples of Definitions of other terms from other countries .....	31
Box 7: Examples of Definitions of other terms from the Codex Alimentarius .....	32
Box 8: Examples of Definitions of other terms from the WTO .....	33
Box 9: Examples of Offences .....	34
Box 10: Examples of Defences .....	36
Box 11: Examples of Administrative Provisions .....	39
Box 12: Examples of Enforcement Provisions .....	43
Box 13: Examples of Legal Procedures for Sampling .....	45
Box 14: Examples of Regulations .....	49
Box 15: Examples of Instruments on Repeal and Saving Old Legislation .....	51

Box 16: Food Safety Country Situation Analysis .....	64
Box 17: Examples of Details to be included in the Section on Scope on Food Law .....	66
Box 18: Examples of Definitions of Food: European Union .....	67
Box 19: Examples of Definitions of other terms .....	68
Box 20: Examples of Offences from the European Union and the United States of America .....	70
Box 21: Examples of Defences from the United Kingdom .....	72
Box 22: Examples of Enforcement Provisions from the European Union and the United Kingdom .....	73
Box 23: Examples of Legal Procedures for Sampling from the European Union .....	76

## **Preface**

Foodborne diseases are widespread and represent significant threats to health and economies of countries. It is estimated that more than 70% of the approximate 1.5 billion episodes of diarrhea that occur in the world annually are caused by biological or chemical contamination of foods. The high incidence of diarrhoeal diseases, particularly among children in the region, estimated at 3.3 to 4.1 episodes per child per year is an indication of the magnitude of the problem.

Food safety is an area in which there is both an individual and governmental role. As individuals we need to store, prepare and cook food in a hygienic manner. However, the food supply chain has become more complex. There are now growers, manufacturers, distributors, wholesalers and retailers creating a formal food supply and frequently many additional components creating an informal system. It is the role of governments to ensure that the supply chain operates in a manner which does not put health of the ultimate consumer at risk.

The establishment of an effective food control system is the key element in the process. And a key part of that system is the creation and maintenance of a modern food law. This has been recognized in several African countries but the process is complex and demands a level of commitment which has often been lacking. Most national policies and programmes indicate gaps and inadequate linkages between strategies to ensure food safety.

The WHO has realized that assistance in the preparation and drafting of food law could greatly enhance the progress being made in establishing modern food control systems. At its fifty-third session in September 2003, the Regional Committee for Africa affirmed the importance of food safety and identified key actions at strengthening national food safety programmes, including calls to develop national food safety policies and legislation. The FAO/WHO Regional Conference on Food Safety for Africa on October 2005 concluded with the drafting of a Recommended Five-Year Strategic Plan for Food Safety in Africa. It encouraged the strengthening of legislative and institutional frameworks in countries.

These Guidelines build upon other international work but have a direct focus on the needs of African countries. They focus on the process that can be used for the development of Food Legislation and key components of a modern Food Law. The guidelines have been written to help all those directly involved in the process of development of new food law – whether government officials, policy makers, senior enforcement officers, scientific advisors, consumer representatives and food industry advisors.

## Introduction

### 1.2 Overview of food safety policies and legislation within the Region

Policy development and implementation could facilitate the reduction in the burden of food borne diseases. In order to achieve the desired outcomes, all interests and food safety concerns must be addressed. A food safety policy provides a basis for the establishment of national food safety objectives and requirements, and guidance for application to specific sectors of the food continuum (production, processing, storage, transportation and marketing). In most countries within the Region, food safety policies are either non-existent or inadequate due to various reasons including lack of clarity, poor enforcement and monitoring.

An analysis conducted by the WHO Regional Office in 2002 showed significant gaps in national food laws and inadequate linkages between strategies to ensure food safety. The study further showed that a limited number of countries had legislation that adequately tackled current and emerging food safety problems in relation to pesticide residues, food additives, contaminants and biotoxins. (Table 1)

**Table 1:**  
**Acts or ordinances on food safety: the situation in the WHO African Region**  
(WHO AFRO 2002 Food Safety Survey)

Parameter	No. (%) of responding countries (n = 28)
Availability of Act or Ordinance	22 (79)
Availability of satisfactory Act or Ordinance	12 (42)
<b><i>Food Safety Issues covered by Legislation</i></b>	
Microbiological standards for high risk foods	16 (57)
Food Additives	12 (42)
Pesticide Residues	12 (42)
Food Premises	17 (61)
Availability of a code	13 (46)
<b><i>International harmonization</i></b>	
Membership in the Codex Alimentarius Commission	27(96%)

Twenty-two of the responding countries had an Act or Ordinance governing food safety standards and regulations, however, only 12 countries found existing legislation satisfactory. Even with a Food Act and regulations, countries lacked complete and effective food control infrastructure and institutional capacities to ensure compliance and to provide consumer protection. More often than not, existing laws were outdated and traditionally prescriptive and fail to adequately address the whole range of food safety concerns.

Many African countries have an historical association with a former colonial power – frequently the United Kingdom or France but also Portugal, Belgium, Germany and the Netherlands. Early legislation, and food law in particular, in these countries was drafted on the basis of the law and the administrative system operating in the colonial power. In some countries this basis has been retained in new legislation whilst in others the legislation has not been updated and may now not serve the needs of the country.

The WHO survey concurs with a situation analysis report on food safety systems presented at the FAO/WHO Regional Conference on Food Safety for Africa held in October 2005. The report provided some insight into the current status of food legislation in Africa (1) (refer to annex 1.1). It noted that food legislation that is in line with international requirements such as the Codex is lacking in many African countries. Enforcement of food legislation is also problematic, often resulting in insufficient consumer protection against fraudulent practices and contaminated food products, and leading to the importation and domestic production of substandard food items as well as trade rejections of food exports from the region. It was further noted that the informal sector, which is often a significant producer and distributor of fresh and processed food products for direct consumption, is often outside the scope of official control systems and remains the least controlled, except by municipal environmental hygiene authorities.

The administration of food safety is complicated by the fact that food safety has many facets. National food control systems within the Region have often a sectorial or fragmented structure. Compounding the problem is the patchwork of food safety laws and fragmented institutional instruments, resulting in non-uniformity of policy implementation and duplication of efforts. In South Africa it has been noted that at least four sets of legislation and six different authorities at all levels are involved in the control of milk and dairy products. Import control is conducted by three different authorities. Each authority may only inspect and sample specific aspects in terms of its own legislation. Samples are submitted for analysis to a number of different laboratories. The Foodstuffs, Cosmetics and Disinfectants Act, 1972 and the Agricultural Product Standards Act, 1990, both set standards for milk and dairy products, including the labelling thereof. The former are health related and are enforced by local authorities and provincial health authorities while the latter are quality related and are enforced by the Directorate: Food Safety and Quality Assurance of the national Department of Agriculture. The Animal Diseases Act, 1984 also controls milk and dairy products from an animal health point of view and regulates the Bovine TB and Brucellosis Eradication Schemes. Milking shed regulations which have been elaborated under the terms of the Health Act, 1977 are enforced by provincial and local authorities but not always by the local authorities into whose areas the milk is distributed. Provincial animal health officers who visit farms regularly and who are involved in mastitis control, which includes milking shed hygiene, are not authorized to inspect milking sheds. Local authorities have their own by-laws governing milk premises in their areas of jurisdiction (2).

In Nigeria, several legislative provisions have been enacted in different statutes in response to the food safety challenge. Some of these legislative provisions include: Public Health Ordinance Cap 165 of 1958; The Standards Organization of Nigeria Decree No 56 of 1971; The Food and Drugs Decree No 35 of 1974; The Animal Disease Control Decree No 10 of 1988; The Marketing of Breast Milk Substitute Decree No 41 of 1990; The National Agency for Food and Drugs Administration and Control Decree No 15 of 1993. The need to revise and harmonize existing legislation has been recognized. The national Policy on Food Hygiene and Safety was put together and launched by the Honorable Minister of Health in July 2000. The national policy is an integral part of the Nigerian Health Policy and the Abuja Health Declaration, which are both based on achieving health for all Nigerians by the year 2020. The policy seeks to stimulate and promote all government regulations concerned with food production, storage and food handling, food manufacturing/processing/preservation, food trade and distribution as well as food preparation.

In Botswana, the responsibilities of food control, food safety and food quality are mainly shared among four ministries. The Ministry of Health coordinates the implementation of the Food Control Act and Public Health Act, including food regulations under these Acts through

the National Food Control Board. Ghana has twelve institutions and agencies involved in food control activities, including the Ghana Standards Board, Food and Drugs Board and the Ministry of Food and Agriculture. However, there is an on-going review of the statutes to realign the functions and responsibilities of these agencies to overcome overlapping areas (3).

Most countries with food standards have generally set their standards in accordance with the Codex Alimentarius Commission. The *Codex Alimentarius* Commission (CAC) is the principal organ of the FAO/WHO programme on food standards. The *Codex* has become the global reference point for consumers, food processors, national food control agencies and the international food trade. It offers a framework for states to use in establishing national food control legislation and a system to protect the right of consumers to safe and fair trade. It is worth noting that nearly all countries are members of the Codex Alimentarius, however active participation of the health sector in relevant standard-setting bodies is limited. Resource constraints have severely limited the participation of countries. With the recently established Codex Trust Fund, there are increased opportunities for countries to participate more actively in Codex activities.

The document has been drafted to provide a practical approach to the development of modern food law. However, the drafting of a new law will only prove effective if it is in the context of a commitment to a national food safety policy. For this reason, these Guidelines provide guidance as to how such a policy can be developed (Chapter 2). It is expected that, from such a policy, there will come the recognition that an enhanced food law is an essential component. These Guidelines explore the main elements of a modern food law (Chapter 3) and propose a mechanism by which this can be brought about (Chapter 4). Key components of the food law are discussed in more detail (Chapter 5) along with examples taken from modern national laws in the Region. Wherever possible the text refers to international guidance and some additional national examples are provided from countries outside Africa (Annex 3).

# Chapter 2: Food Safety Policy Development Process

## 2.1 Overview of the Policy development process

Paying particular attention to the technical content of food safety policies is only part of the equation to achieving satisfactory policy results. Of equal importance is the process by which the content of the policies is formulated and put into action. The process of developing food safety policies involves three interlocking stages, comprising several steps:

- (i) **Development of the policy**, which includes the purpose of determining the need for policy development, drafting and promulgating the national food safety policy;
- (ii) **Implementing** the policies;
- (iii) **Monitoring** the performance and implementation of the policy.

A national government agency should coordinate and facilitate the development of a National Food Safety Policy in cooperation with appropriate national ministries and partners. The Ministry of Health can assume the lead role in the development of the policy whilst other national government agencies support. It is important to immediately consider the processes for identifying the structure of the policy and main objectives. By the same token, identify the main players to be potentially involved in the policy process, the nature and role of stakeholder dialogue, the provision of public information and the required resources.

The aim of the policy formulation process should be to identify and recommend a policy for the long-term management and control of food safety that commands consumer confidence and ensures public health. The success of the policy planning and implementation processes will depend, in part, on the incorporation of a meaningful structure for channelling and considering *stakeholder input* as well as gaining *political commitment* in the development and implementation of the policy.

### ***Stakeholder identification and participation***

An important step in any National Food Safety Policy process is to explicitly identify who are either affected by, or have a vested interest in food safety and hence in the design, discussion and implementation of the policy. This is important to ensure consultations include all stakeholders to build a broad-base commitment and make the end result as effective and achievable as possible.

A county's food safety or supporting administrative statues should establish procedures to ensure that regulations, policies and directives are developed and enforced in a consistent, transparent and interactive manner and that the associated processes are generally open to the public in a manner that ensures the objectivity and integrity of all food safety decision making. (4) This stakeholder involvement should be viewed as an ongoing partnership that encompasses all aspects of the development and implementation phase of the policy.

Policy dialogue may take place in a variety of forums, employing different avenues for the exchange of ideas and eliciting views e.g. *multi-stakeholder forums*, *workshops*, discussions at *seminars* and *conferences*, *informal meetings*, *facilitated negotiations* etc. An immediate concern is to consider the scope and how broadly to design the consultations in terms of stakeholders and complexity of issues.

Stakeholders generally include government ministries, agencies, institutions, and non-governmental organizations who are or may be affected by the National Food safety Policy.

Involvement of consumer organizations is also invaluable to the policy process. It has been noted that one of the assets consumer organizations bring to the table in the food policy process is sensitivity to a broad range of societal and ethical issues. Consumer organizations can often articulate concerns that should be given weight in policy. Consumer participants in policymaking can serve as an “ethical compass”, pointing in directions that government and industry will need to go in order to meet public expectations (5).

### *Political commitment*

Effectively formulating and implementing national food safety policies is also dependent upon consistent and high profile political commitment and support. Political commitment signifies the capacity of decision-makers to follow through on rhetorical statements of support and to provide adequate programme resources. In order to stimulate political will this necessitate, creating an understanding of the depth and breadth of problems to be grappled with and the incentives for interventions.

## **2.2 Formulation of a National Food Safety Policy**

### **Step 1: Situation Analysis**

---

The development and implementation of a National Food Safety Policy is a complex process that needs to be grounded into firm and informed analysis of the issues at hand. Analysis is important to identify food safety problems and their underlying causes, as well as limitations of existing policies and relevant constraints to addressing the problem.

#### *Data gathering and analysis*

The multi-sectoral nature of food safety issues require the involvement of a broad-based appropriately qualified multi-disciplinary team at the highest level of government, involving sectors such as agriculture, health, nutrition, commerce, environment and consumer group representatives in the analysis of the food safety situation. The situation analysis should be holistic and broad-based capturing both existing and emerging trends as well as dynamics influencing food safety at each stage of the food chain. Considering the fact that food safety management and control is a shared responsibility of many institutions/agencies, the analysis should also take into account the relevance and failures of other sectoral policies. Box 16 in the annex provides an illustrative example of the type of information to gather. Due to the wealth of data often available, it will be necessary to prioritize the issues and problems to address.

#### *Data sources/tools for situation analysis*

Information for the situation analysis can draw from review of documents and studies – inspection records/documents, toxicological and epidemiological studies, records of ill-health, academic research or any other relevant statistical data source. In addition the methodology can also draw from written surveys or formulated questionnaires, discussions with key informants/policy-makers, and health surveillance data.

### **Step 2: Drafting of the national policy**

---

A national food safety policy should fit within the framework of the national health policy, and be consistent with the overall health objectives. A drafting team, composed of sectoral representatives who have been involved in the earlier stages of the policy process can be



convened to draft the national food safety policy. Each team member should bring a range of policy, scientific and potential expertise to prepare the first draft of the policy.

The development of the content of the policy should be based on the situation analysis and review, scientific evidence and broader national food safety goals. It should encompass and consider all facets of a national food control system. The policy should clearly define the objectives, principles and regulatory mechanisms to enable the development of action to address the main food safety issues and concerns of the sector. (Box 1)

The following fundamental elements *inter alia* should further guide the drafting of the food safety policy (6):

- Maximizing risk reduction by applying the principle of prevention as fully as possible throughout the food chain.
- Addressing the farm-to-table continuum.
- Developing science-based food control strategies.
- Establishing priorities based on risk analysis and efficacy in risk management.
- Establishing holistic, integrated initiatives, which target risks and impact on economic well-being.
- Recognizing that food control is a widely shared responsibility that requires positive interaction between all stakeholders.

***Maximizing risk reduction by applying the principle of prevention as fully as possible throughout the food chain.***

The principle of prevention throughout the food system is the preferred method to reducing the burden of food borne disease. A preventive approach that has grown in importance is the Hazard Analysis Critical Control Point (HACCP). HACCP, a state-of-the art approach to food safety is recognized by the Codex Alimentarius Commission as the most cost-effective approach for assuring food safety at all stages of the food supply. The system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food.

***Addressing the farm-to-table continuum.***

The farm-to-table approach is based on the premise that food borne disease is commonly caused by multiple factors arising at dispersed points along the farm-to-table continuum and involving many actors. It addresses the notion that quality needs to be managed along the entire supply chain, from the initial stages of raw material production to the final stages of food preparation for consumption.

***Developing science-based food control strategies.***

Efforts to improve food safety must encourage the adoption of science-based regulatory measures that cross all aspects of the food production continuum. In order to achieve this, risk analysis will play a central role in designing and managing a more science-based, integrated food safety system.

***Establishing priorities based on risk analysis and efficacy in risk management.***

Risk based systems approach is considered as the best way to proactively identify hazards along the entire food chain, understand risk outcomes and focus resources on those interventions that have the greatest impact in minimizing food-borne illness. Risk analysis is a

key feature of decision-making and comprises three components: *risk assessment*, *risk management* and *communication*.

- a. *Risk assessment*: Risk assessment is a quantitative evaluation of information on potential health hazards from exposure to various agents.
- b. *Risk management*: Risk management is defined within the Codex Alimentarius as the process of weighing policy alternatives in the light of the results of a risk assessment and, if necessary, selecting and implementing appropriate control options including regulatory measures.
- c. *Risk communication*: The fundamental goal of risk communication is to provide meaningful, relevant and accurate information, in clear and understandable terms targeted to a specific audience.

***Establishing holistic, integrated initiatives, which target risks and impact on economic well-being.***

Effectively managing food safety risks require a shift from the traditional sectoral approach of dealing with food-related risks to more holistic and multi-faceted strategies to mitigate hazards along the food chain.

***Recognizing that food control is a widely shared responsibility that requires positive interaction between all stakeholders.***

Food safety is a joint responsibility which extends along the whole food chain – farmers, fishermen, food processors, transport operators, retail etc. Food producers at all levels of production bear a responsibility for the production of safe foods. At the farm level, farmers and workers must control pesticide and other chemical inputs and recognize potential sources of microbial contaminants from water, soil, animals and humans. Fishermen must understand that the safety and quality of their catch is linked to the levels of contaminants in the harvest waters (4).

The food processing and transportation industries must assess where food safety may be jeopardized at critical points in food production and transport and take appropriate measures to control these potential hazards. Retail establishments, restaurants and other food vendors must also understand how to ensure proper sanitary practices and temperature controls. The consumer's role may be the *most important* in that s (he) controls food safety at the point closet to food consumption (4).

### **Step 3: Circulation and finalization of the policy document**

Additional consultations will be required both from the Ministry of Health and other relevant government ministries and departments, institutions, academia, consumers etc to gain their inputs and view of the document. Selected further consultation with affected ministries of the Government and other sectors seeking response to their concerns should be expected. Basically, the following principles governing the review should be applied:

- (i) *A wide circulation process*, ensuring representation of all the main stakeholders.
- (ii) *The review process should be objective and transparent.*

The draft should be revised and finalized based on the suggestions and feedback received during this stage of consultation.

### **Box 1: Sections of Food Safety Policy Text**

A National Food Safety Policy may contain *inter alia* the following sections:

- *Foreword* – how did this arise and why, the commitment of the Government;
- *Introduction* – a look at the country's food safety issues, priorities and needs, including emerging challenges;
- *Guiding principles* – Principles are the fundamental premises used to develop and test policy and subsequent actions including, decision-making, regulation and enforcement. Define the key technical, operational and philosophical principles that guide the policy. Examples would include inter-sectoral cooperation, stakeholder participation, sectoral policy integration, etc.
- *Policy goals, objectives and targets* – Policy goals, objectives and targets influence all aspects of the policy process, most importantly the content of the policy, inputs/resources needed as well as implementation of the policy. Goals, objectives and targets should broadly reflect the food safety priority needs of the country.
- *Institutional structures* – National institutional arrangements and structures for the administration of food safety services. Define the roles and responsibilities of the different tiers of government. Institutional structures must provide for effective inter-ministerial coordination to adequately provide support to the national food safety policy.
- *Policy implementation strategies* – the definition of strategies, followed by action items to ensure that policy principles are applied and action is taken to reach specified objectives.
- *Policy details* – the main body of the policy document covering a comprehensive range of issues which make a holistic body of policy covering all aspects of food safety control and management. The following are examples of the policy items, the list is not exhaustive:
  - Policy guidance to promote and guide adequate research, monitoring and food surveillance activities of the sector;
  - Policy is also required for human resources development, which seeks to ensure that skills are established to carry out the essential functions of the sector. In addition to ensure consistency between the food safety needs of the country and the number of personnel that are trained and their skills and functions.
  - Regulatory and legislative control for food safety;
  - Policy is required to give guidance for the promotion of public education, information and communication.
- *Monitoring and evaluation* – Drawing mechanisms for assessing the effectiveness and performance of the policy.

### **Step 4: Formal Endorsement and approval**

---

It has been noted that although policy requires technical expertise to develop, it requires political will to implement. Political endorsement and support is therefore a central element of policy development. A number of factors will govern what constitutes the most effective or desirable level at which the national food safety policy is adopted or approved. Formal adoption involves a legal or administrative requirement for a referendum, parliamentary or cabinet endorsement in order to create legitimacy for the policy and supportive constituencies.

### **Step 5: Dissemination of the policy**

---

Once formally approved, the food safety policy should be disseminated as widely as possible. Such dissemination should encompass all the national stakeholders. A public event and

announcement by the Government can be planned. Possible dissemination mechanisms/channels that can be employed include: *press materials, media* and *meetings* with specific implementation partners.

## **2.3 Implementation of the Food Safety Policy**

Setting up efficient and strategic mechanism in implementing policies is crucial in ensuring that policies are applied, translated into action and that goals are achieved. Implementation of the policies will include several pre-implementation activities to clarify, legalize, and operationalize the *policy changes*; clarify, formalize and assign *institutional roles*; *strengthen staff capacities* in implementing institution; and *mobilize financial* resources (7).

### **Defining and developing Implementation strategies**

Food safety policies should include specific, measurable implementation strategies. The strategies should foster the desired level of cooperation and involvement of other interests. In addition, it requires *broad political and institutional support*, guaranteeing continued follow-up and implementation.

A food safety implementation plan can describe how each policy component is to be achieved, over the short and longer-term. The action plan should focus on the actual food safety situation and challenges within the country identified in the situation analysis. Participatory mechanisms and processes should be established to enhance the involvement of all stakeholders in formulating and implementing the action plan. More so, in concretely defining *what priority interventions are needed, at what stage and how soon, who is responsible, what are the budgetary requirements, timeframe* with clearly defined *milestones* and *reporting mechanisms* so that progress can be monitored. To support timely and effective implementation of the different components of the plan, capacity building and training should be considered.

In Nigeria for example, the target of the National Food Hygiene and Safety Policy is to immediately establish strong and viable intra/inter-ministerial, inter-agency and multisectoral working committees to be coordinated by the Federal Ministry of Health, to carefully articulate a plan of action to translate the policy into implementable programmes. A National Committee comprising Public/Private Sector and other Stakeholders was set up to develop guidelines for the implementation of the National Policy on Food Hygiene and Safety.

In Uganda, the Ministry of Health in consultation with stakeholders developed a National Food Safety Strategic Plan whose aim is to: guide the implementation of the Food Safety Laws, programmes, activities and other Food Safety Control Systems in the country; provide the food laws direction and translates it into a tool for an effective food safety control system through creation of consumer awareness; and clearly spell out the roles and responsibilities of the key stakeholders, address issues of institutional linkages, collaboration and harmonization of activities aimed at promoting and improving the status of food hygiene and safety in Uganda (8).

### **Defining implementation responsibilities**

Given the diverse range of stakeholders' influence on food safety, the success of the policy implementation strategy rests on these stakeholders recognizing their role and embracing new and actively collaborative approaches for food safety management.

The Ministry of Health as the lead coordinator and facilitator should work closely with the various ministries, partners and stakeholders for promoting, coordinating and implementation of the national food safety policy initiative. It is also particularly important to clearly spell out the roles of the other ministries and agencies with responsibilities for food safety policy implementation. A central element in the implementation is national coordination.

### **Defining resource needs**

Effective implementation requires resources and sustained commitment to monitor and enforce the policies. Implementation plans should recognize that relevant stakeholders may require assistance as actors in implementation, and should ensure that sufficient resources and support mechanisms are available for implementation and for effective participation.

Every effort needs to be made to ensure that adequate finances are available for implementation of the national food safety policy initiative. Expenditures and funding requirements should be considered at the earliest stage of planning. This would necessitate an analysis of *what* financial resources are needed; *who* should contribute to mobilizing these resources; *how* can resource mobilization be maintained.

Certain types of food control interventions require large fixed capital investments in equipment and 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.

In addition to adequate funding, successful food safety policy implementation requires personnel with appropriate managerial, technical and financial skills. Key skills span a wide range: analytical skills, monitoring and enforcement etc. Capacity-building and training activities should aim to develop and strengthen the capacities of all stakeholders to facilitate the effective implementation of the policy.

## **2.4 Monitoring and Evaluation**

### **Purpose of monitoring and evaluation**

Once the policy has been in place and implemented, its effectiveness and success should be evaluated. Monitoring and evaluation procedures need to be incorporated at every stage of implementation. Any shortcomings should be noted and suggestions put forward as to how strategies would need modification in the future.

Monitoring and evaluation go hand in hand. The primary purpose of monitoring and evaluation is to inform the decision maker of the progress toward achieving goals and objectives. They are interactive processes, involving constant feedback loops to facilitate future planning and resource allocation.

### **Determining indicators**

Indicators are indispensable to the conduct of evaluations yet they are nothing more than variables that reflect a situation or make it possible to measure change related to a food safety programme etc.

*Examples of indicators and ideas for selecting indicators*

On major policy matters, the answers to the following questions may be used as indicators:

- Is there a national policy on food safety that is reflected in laws, regulations?
- Have resources been allocated to implement the policy?
- Have food safety or food control programmes been established and staffed to carry out the policies?

The answers to such questions help to evaluate the relevance of policies related to food safety, as regards political commitment and adequacy. Other indicators that help determine the effectiveness and efficiency of policies can be derived selectively from the components that support policy implementation such as *strategy, programmes, services* and *institutions*.

Monitoring and evaluation results depend largely on the appropriate set of data to be collected. Evaluations can be conducted using quantitative and/or qualitative methods. Where data from past surveys, current reporting or monitoring mechanisms, or other sources are available, quantitative analysis can be performed in order to help measure the effectiveness or efficiency of food safety programmes, policies etc. (10)

## Chapter 3: Fundamentals of Food Law

Food safety laws and regulations are essential for providing the legal framework for establishing an effective food safety control infrastructure. Whilst also encompassing other consumer protection issues such as fraud, food law serves as a mechanism for formalizing and codifying strategies and policies for food safety. It is an important means by which food safety policies are enforced.

The purpose of food legislation like food safety policies is to ensure high level of health protection by providing controls along the food production, processing, storage and distribution chain. Food legislation serves to define what is expected as the minimum standard for a large and diverse industry. To the consumer, it defines what is safe and wholesome for consumption. To the industry, it also specifies the criteria to be met if a manufactured food is to be accepted as safe (11). It informs producers' and processors of requirements regarding production, processing methods and product standards and provides the consumer expectations of a given food (12).

### 3.1 Food Law Fundamentals

Several key issues are fundamental to the creation of a new food law and these include the following:

#### *Consumer Protection*

Food law is normally considered to have two fundamental purposes – the protection of the consumers' health and the prevention of fraud. Internationally, within the Codex Alimentarius Commission, these purposes can be seen in the Statute 1 of the Codex which defines its purpose. The relevant clause states that the first purpose of the Codex is: “protecting the health of the consumers and ensuring fair practices in the food trade.”

The law therefore needs to contain key provisions which are designed to protect the consumer in both these areas. A simple example will illustrate the two aspects. Milk supplied to the consumer should be free of food poisoning microorganisms – it should be safe to drink. However, it is possible to produce safe ‘milk’ but to have added extra water. If it is still sold to consumer as ‘milk’ then they are being defrauded and food law should provide access to a legal sanction.

Ensuring a healthy supply of food can require provisions relating to many different aspects. Freedom from food poisoning organisms would probably be the first item in a listing of health issues. The food supply chain is however complex and there are many areas where safety is an issue. These include other biological hazards as well as chemical and physical hazards and these all need to be considered and appropriate controls implemented. In developed food supply systems it is increasingly common to require the use of internationally accepted quality systems such as the HACCP to minimise the risks to the consumer. However detailed legislation may be needed to cover issues such as food additives, processing aids, veterinary and pesticide residues, aflatoxins and other hazards.

Unfair practices can involve several different issues relating to the composition of a food, the prices and weights used, advertising activities and the information given (whether verbally or in the form of a notice or label). Unfair traders will frequently try to sell a poorer quality item in place of a higher quality item. In a traditional market, the consumer will often be able to see

the foods on offer and will make their own selection. Increasingly, as more foods are manufactured and sold pre-packaged, the consumer depends upon the labelling information to make their informed selection. With this trend, the food industry develops new and more varied foods and traditional food compositions may decline. In this situation, legislators have two approaches:

- (a) To develop detailed labelling requirements and provide the consumer with the choice,  
or
- (b) To maintain traditional compositional standards by the adoption of certain minimum standards.

Where consumers have been exposed throughout their lives to pre-packaged foods meeting detailed food labelling requirements, they may be able to make informed choices about the food that they are buying. Labelling legislation in many countries has now become a very complex area with requirements relating to such things as legal names, ingredient listing, date marking, nutrition labelling, allergen warnings, health marks and statements relating to genetic modification. Consumers use this information to make an informed choice. National food control authorities focus their efforts in ensuring compliance with the labelling rules and, in some countries, it is legally required that labels are submitted for approval prior to use so as to ensure compliance.

However, with a less educated consumer, labelling controls on their own are unlikely to provide adequate consumer protection. In many countries it is common practice to establish detailed compositional requirements on many standard foods. Manufacturers are then only permitted to produce foods according to the legally defined 'recipe'. However, this system is difficult to extend beyond a limited number of key food items. When international trade is taken into account, it is very hard to impose a national compositional standard onto an imported food.

#### *Responsible Ministry/Authority*

As with the development of a national food safety policy, many ministries can be involved in different aspects of food provision within a country. These might include Ministries related to: Trade, Agriculture, Health, Local Government, Fisheries, or Industry. Several countries have created a separate body to provide national standards and have used this route to establish legally enforceable requirements on food producers.

In many countries around the world there has been a trend towards establishing an independent body with responsibility for certain aspects of food supply. These may be limited to certain scientific tasks (risk assessment) or may be given very extensive powers to control all aspects of the food supply. It is unlikely that a totally independent authority would be appropriate where many aspects of the food supply are still a key role of government as is the case with many African countries. An alternative approach, favoured by some African countries, has been to develop the status of the national standards organisation and to provide them with legal powers to control aspects of food hygiene, food additives and food labelling.

Although structures are important, what is most important is that those bodies which are involved in the food control process recognise their strengths and their weaknesses so as to collaborate to the benefit of the country as a whole. Where resources are limited, it is vital that those which are available (e.g. trained staff, analytical laboratories, data analysis) are used efficiently and to best effect.



### *International and Regional Harmonisation and trade*

As mentioned above, decisions have to be taken as to the fundamental purpose of any food law. Whilst a country may be capable of establishing a national food control framework for its own territory without reference to any regional or international activities, the reality these days is that a country has to take into account developments in neighbouring territories, in regional blocks (both those to which it belongs and to those with which it trades) and in international agreements.

The ability to export and to earn foreign currency is key to national development. The need for coordination, cooperation and collaboration at national, regional and international levels cannot be over emphasised. Countries in Africa have to develop their legislation with this in mind. There are regional groupings within Africa which are trying to assist cross-border trade. These include Southern African Development Community (SADC) and Economic Community of West African States (ECOWAS). By working with these organisations and ensuring that food law develops in harmony with other countries in the region, development can be helped.

Frequently though the priority is to develop exports to either the European Union (EU) or to the United States of America (USA). Both the EU and the USA impose high standards as they have a commitment to provide their consumers with a high level of protection. See for example the statement included in Article 1(1) of EU Regulation 178/2002 given in Box 17 in Annex. For African countries, this creates a complex situation and a balanced approach is necessary. Whilst there will be a desire to provide a similar level of protection, it is likely that they will have to achieve a balance between developing legislation which shows a commitment to match the advanced requirements of, for example, the EU and the USA and the need to provide appropriate minimum standards for their domestic food supply. In recognition that with limited resources an interim approach might be needed, a dual system may be necessary which could include a licensing scheme for export premises linked to frequent inspections for compliance to, for example, the EU or USA requirements.

## Chapter 4: Developing Food Law

There are several stages in the process for updating food law. It also involves many players whose vision and commitment alone will guarantee success. It requires all components of the food control system to be involved and to adopt new procedures. It also will require the allocation of sufficient resource to enable the drafting and implementing of the law to be completed efficiently and effectively.

The drafting of a new food law will involve change. It is an opportunity to establish a framework which will provide for the development of food safety and security for many years. With a political commitment to change and with a decision to modernise a country's food law having been taken, it is important that the opportunity is used effectively. All involved in the process should use all available guidance on best practice to ensure that the new legislation meets the country's needs.

It is convenient to consider the process of fully adopting new food law as having four main stages as follows:

1. Preliminary stage
2. Drafting the new law
3. Adoption of legislation
4. Implementing legislation

### 4.1 Preliminary stage

The priority given to food law is frequently low as the benefits that come from a modern food control system may not be fully appreciated within Government. Recognising that there is a strong health dimension to food control provides a clear link since safe food could provide a healthy workforce which will contribute economic growth and national development. However, if the process of adopting a national food safety policy, described in earlier chapters has been followed, the necessary commitment and vision may already have been established.

#### *Involving all Stakeholders*

A national food control system is made up of many components and has links to many more. Key official components will include some or all of the following:

- Ministry of Health
- Ministry of Agriculture
- Ministry of Industry
- Ministry of Trade and Development
- Ministry of Local Government
- Ministry of the Environment
- National Standards Body
- Universities and research institutions

Other stakeholders include

- Food manufacturers
- Food importers/exporters
- Food producers
- Food retailers
- Catering companies

- Street food vendors
- Consumers
- Training organisations
- Media

For the new food law to be effectively implemented all these stakeholders must be involved in the process. Failure to involve them will result in disrespect for the new law and an unwillingness to comply with its provisions. Although their demands may not be met, by involving the various stakeholders, they will appreciate the overall intention of the law and the necessity for change and, if necessary, additional controls and restrictions.

Effective enforcement will only be possible where the great majority of those covered by the legislation are willing to comply. Whilst it is possible to force compliance with a law by the imposition of heavy penalties and a powerful enforcement regime, the national needs are more likely to be met by voluntary compliance and an acceptance of the overall objective.

With the range of interested official bodies and of other stakeholders, the process of moving to a new national food control system based on a new food law will inevitably need co-ordination. For the process to be successful, it will need to be moved forward by an individual or by a group of committed people. The creation of a Task Force with clear Terms of Reference is valuable. The Task Force will need to hold regular meetings and to have the power to take decisions about the direction food control will take. Key to the process is the authority given to this Task Force and its Chairman. With the range of ministries having a stake in the food supply chain, ideally the Task Force will have been given direct authority from the Head of Government and will report direct to them. Alternatively it will be based in one of the lead Ministries (Health, Agriculture or Food) but with a clear mandate to involve the other Ministries.

In establishing a Task Force, it is helpful to provide clear Terms of Reference. Possible Terms of Reference could be based on those given in Box 2

**Box 2: Suggested Terms of Reference for Task Force**

- (1) The Task Force shall be responsible for the development of proposals for an effective national food control system based upon an updated food law.
- (2) In particular, the Task Force shall:
  - analyse the current national food control system and identify its strengths and weaknesses;
  - propose a food control system which provides a high level of consumer protection consistent with the available resources;
  - draft a new food law based upon national legal practice but including recognition of regional and international requirements;
  - apply recognised good practice for food control systems and food law;
  - allow all stakeholders to be involved in a process of consultation including representatives of consumers and all aspects of the food supply;
  - propose an implementation strategy incorporating requirements for restructuring, training and further developments in the system and supporting legislation.
- (3) The Task force may establish working groups to progress aspects of its work.
- (4) The Task Force should submit its final report to Government with recommendations and a draft food law within 2 years. Interim reports should be submitted every 6 months.

With the resources available to food control being limited, there is a need to establish national food control systems which make efficient use of available resources. The initial analysis provides an opportunity to identify those resources which already exist and where there are significant gaps. In drafting proposals for a new system it is important to be realistic and not too ambitious. In some situations it might be possible to collaborate with neighbouring countries so as to create a regional rather than a national resource.

## **4.2 Drafting the new law**

Although the focus of this Guide is on the process of developing and drafting new food law, this stage is only reached after recognition that new law is needed as part of a modern food control system. It should be noted that the development and drafting of new food law is an opportunity to review many aspects of the national food control system. More specific guidance on the wider issues of strengthening national food control systems can be found in 'Assuring food safety and quality – Guidelines for strengthening national food control systems', FAO Food and Nutrition Paper 76, FAO, 2003.

The precise nature of the structuring of the work will need to be tailored to meet the usual national systems and procedures. Where appropriate the following steps (refer also to figure 1) can be adjusted but it is considered likely that similar steps will be necessary whatever system is used.

### *Step 1 Establishing a Task Force*

As discussed above, it is important to involve key players in the national food control system in the drafting of new legislation for food control. It is likely that the establishment of a Task Force will be a Government decision. Membership needs to come from the key Ministries as well as from representative stakeholder organisations. A balance has to be achieved where the people on the Task Force have sufficient authority to ensure that the objectives of the Task Force are carried out. However if they are too senior it is likely that, due to other commitments, it will be very difficult to arrange meetings where all members can be present. For the same reason, membership needs to be restricted to avoid excessively large meetings. As mentioned above, it is likely that the Task Force will need to establish Working Groups to undertake key tasks and organisations not directly represented on the Task Force could be allocated roles on one or more Working Groups.

### *Step 2 Task Force Adopts Plan of Action*

With only a limited time in which to draft an appropriate new law, it is recommended that at an early stage the Task Force clearly identifies the various stages in its work. The early adoption of a Plan of Action specifically focussed on the work of the Task Force is recommended. This will enable progress to be measured and should provide a realistic timescale for all the steps in the process.

### *Step 3 Audit of Current Food Control System*

This would include an audit of the present system. Everything from the legislative structure to the laboratory equipment, from the number and training of the enforcement officials to the main components of the food supply chain. A thorough understanding of the food control system will enable its strengths and weaknesses to be identified and corrected in the development of the new legislation. This task could be allocated to one

or more Working Groups who could arrange for the data to be gathered in a systematic way by interviews or by questionnaires.

The following provides an example of key elements in this audit (6):

*Government organization of food control systems*

- Listing of government departments and authorities concerned with food safety and food control activities.
- Description of the food control system and an overview of the resources, responsibilities, functions, and coordination between the entities; methods of determining priorities for action; options for raising resources.

*Food Legislation*

- Current food legislative arrangements, including regulations, standards, and codes of practice.
- Information on experts empowered to prepare regulations and standards, and how they coordinate their activities and consult with industry and consumer organizations.
- Capacity to carry out risk assessment.

*Food control infrastructure and resources*

- Organization of inspection, surveillance, and enforcement activities (national, provincial, and local levels).
- Number and qualifications of inspection personnel.
- Resources within inspection agency, and assessment of strengths and weaknesses.
- Analytical support facilities (number of laboratories, facilities and equipment, monitoring programmes, etc).
- Codes of hygienic practice.
- Licensing arrangements for food premises.

*Step 4 Fact Finding – International Perspective*

Although the new food legislation will be drafted to meet the needs of the country, the wider international perspective needs to be considered. There are four key aspects to this:

- (i) Learning from other country's experiences – their successes and their failures.
- (ii) Enhancing international, regional, sub-regional and national co-operation.
- (iii) Ensuring compliance with international, regional and national obligations.
- (iv) Helping meet requirements of the export market.
- (v) Assuring safety of food imports including other food for local consumption.

A Working Group could be formed to provide detailed information on these aspects. External assistance could also be used based upon the technical assistance provided by international agencies.

*Step 5 Consultations on Issues*

As work is being done on obtaining factual information, a wider consultation can be held with all stakeholders within the country giving them an opportunity to contribute to the process at an early stage. Although stakeholders will be represented on the Task

Force, a wider and more public consultation will raise awareness and may identify issues which had not been previously considered.

The consultation process should attempt to be inclusive and should therefore not be restricted to the publication of a written document and the submission of written comments. At this stage, the publication of a Press Release, the placing of an advertisement in national papers or television and radio interviews given by the Chairman of the Task Force should be considered so as to stimulate interest. Subsequently meetings with key stakeholders (for example consumers, enforcement officers and food industry representatives) and public meetings would help ensure the widest coverage of the consultation.

#### *Step 6 Identifying Options for Change*

With the completion of Steps 3 and 4 above, data should be available from both the national issues and the wider international perspective. This will allow the Task Force to discuss alternative approaches to solving the issues raised in Step 5 above. This should lead directly to discussion of key aspects of the new food legislation. Important issues which will be considered at this point would include:

- Should a separate food agency be established or should responsibility be with a Ministry or with a Standards Organisation?
- What enforcement system should be established?

These aspects are discussed further in this document (see Section 5.3).

#### *Step 7 Consultations on Options*

It is recommended that the various alternatives are circulated to and discussed with stakeholders. At this stage the Task Force might indicate its preferred options but the opportunity should be given for all stakeholders to understand the alternatives and the reasoning behind any preferred option.

#### *Step 8 Recommendation of Best Option*

As this point it is suggested that the Task Force should use the results of the consultation to reach a recommendation on the key elements of the food control system to be incorporated into new legislation. It is possible that the consultation will have identified many additional issues and that the process will have to return to Step 6 above for a further round of consultations. Once a best option is agreed by the Task Force, this recommendation should be submitted to the Government for approval before more detailed work is initiated. It is also recommended that the recommendation of the Task Force be available as a public document.

#### *Step 9 Decision on New Structure*

The Government will give its decision on the recommendation of the Task Force taking into account any wider national issues. At this point the Government is likely to assess the resource issues associated with the proposed option. Government commitment to the allocation of sufficient funds will ultimately be necessary if the new law is to be effective. By getting the support of the Government at this step in the process, it is more likely that subsequent funding will be available.

### *Step 10 Preparation of Draft New Food Law*

Having obtained the approval of the Government, detailed drafting can now be undertaken to convert the ideas into a draft legal document. It is likely that this process will again generate alternative approaches which may need wider discussion. More detailed guidance on the components of the draft is given in Chapter 5.

### *Step 11 Consultations on Draft*

Stakeholders will be given a final opportunity to contribute to the content of the food legislation. The draft should be made publicly available along with a discussion document on any outstanding issues. As with Step 5 above, the process needs to be planned and allow for both oral and written submissions so as to ensure that all views are gathered.

### *Step 12 Preparation of Final Draft*

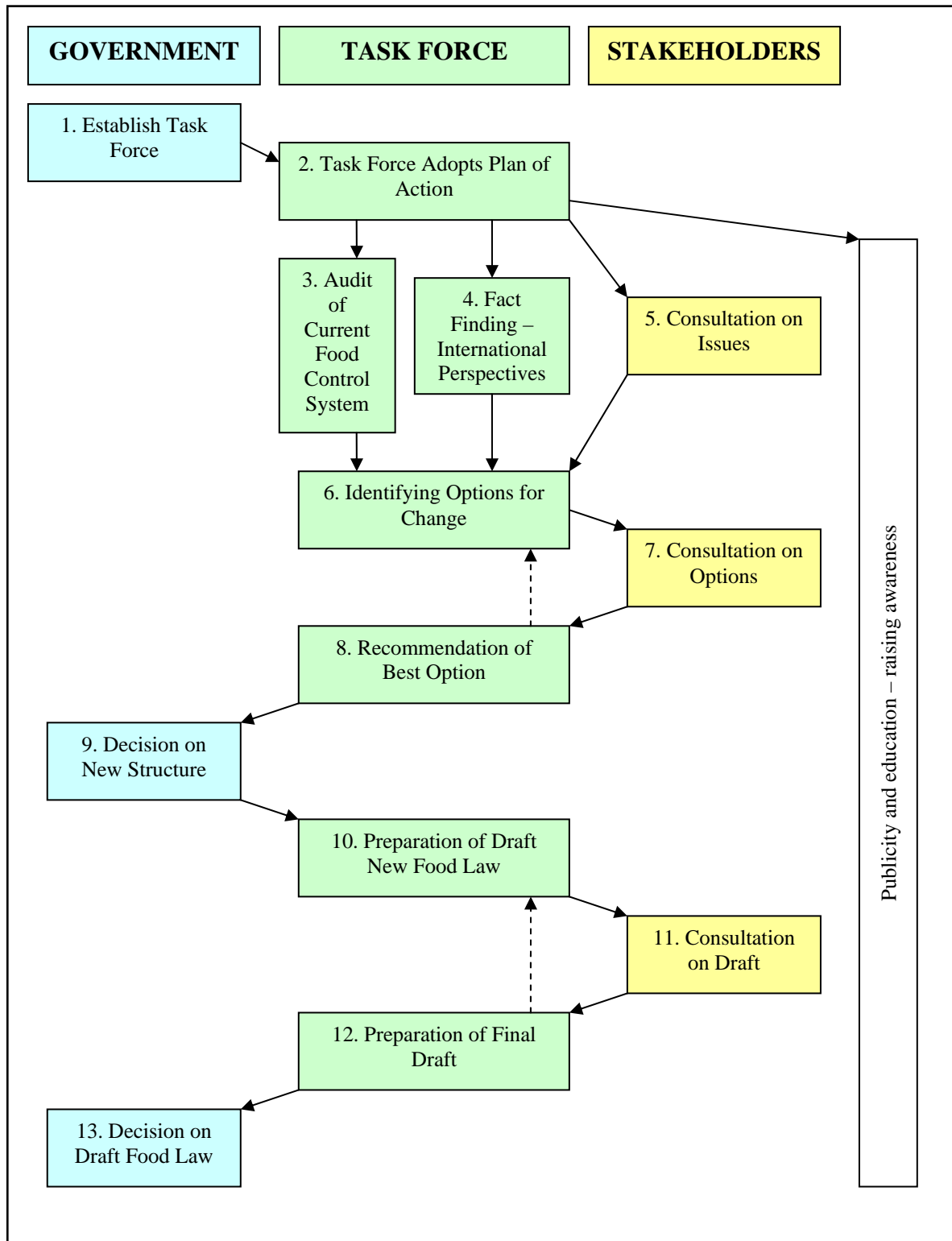
Based on the comments received, it may be decided to make some amendments to the draft before the adoption of a Final Draft. Again, if significant adverse comments are made on the draft, a further round of drafting (Step 10) and consultation (Step 11) may be necessary.

It is recommended that the Final Draft is published along with an account of the issues raised during the consultation (Step 11) and the Task Force's response to those issues.

### *Step 13 Submission of Final Draft Food Law to Government*

With the final drafting of the draft food law, the work of the Task Force is completed. The document is submitted to the Government and it is now their responsibility to decide whether to accept the draft or whether some further amendments might be needed. If the Task Force has successfully involved all stakeholders (both within Ministries and those representing non-Governmental interests) it is to be hoped that the draft will be rapidly accepted.

Throughout the process described above, it is recommended that there is a systematic attempt to raise awareness through publicity and education. This can cover a range of topics linked to the national food safety plan and should encourage the public to recognise the value of good quality food and to generate support for a strengthened food control system based on new legislation.



**Figure 1: Schematic representation of procedure for the development of new food law**



### **4.3 Adoption of legislation**

The agreement of the government to the new law will be seen as a major achievement by all those who had participated in its development. Depending upon the system of government in a country, the draft is likely to be subject to scrutiny by the legislative body and might be subject to unexpected amendment. It would be appropriate for the Chairman of the Task Force, and some or all of its membership, to be available to assist the Government during the adoption of the legislation. Scrutiny by the legislative body may identify issues which had not been fully considered or may lead to detailed questioning of the Government. A strong defence of the draft may be necessary when other interests might seek to challenge some of its components.

It is likely that a major issue at this point will be the question of the cost of implementing and operating the new law. The allocation of adequate resources will be essential if the law is to be fully effective. It is critical that adequate human and financial resources are available. If these issues have been taken into account in developing the proposal, the Government should have been able to identify the source of funding and should, at this point, remain committed to providing the necessary amount.

### **4.4 Implementing the Law**

The adoption of the law will also be seen as a milestone on the route to a modern food control system. Much additional work will be needed for it to be successful in its objective. Depending upon the degree of change incorporated into the new legislation, there may be major reorganisation to be planned and carried through. With regard to the legislation, detailed work will be needed to ensure a satisfactory transition. It is recommended that responsibility for managing this is given to either one person, with sufficient authority and access to a team of people or to a further task force composed of stakeholders affected by the new legislation – including relevant civil servants and enforcement officials in particular.

The main food act is likely to contain enabling clauses which permit the adoption of additional secondary controls – the regulations, decrees or standards. These will be an essential part of the legislation. There is likely to be a number of secondary controls in existence already which will need revision to take into account of the new legislative framework.

With regard to enforcement, the officers will need additional training and support to effectively implement the controls and ensure that their procedures comply with the new legislation. Official guidance documents may need to be drafted to ensure consistent application of the new controls. Food businesses subject to the new controls will need to be alerted to any new requirements and be given advice on how to meet them. If the process of education and discussion during the development of the legislation has been successful, all stakeholders should be willing to support the new law. Ideally those subject to new requirements will willingly change their practices to meet the new requirements. Voluntary compliance, rather than being based on strict enforcement, is likely to be much more successful in ensuring that the food safety objectives of the new law are met. Particular care may be needed with imports as information on any new requirements may not be widely known outside the country. Transitional arrangements may be necessary.

The legislation is only effective if it can be used and offenders successfully prosecuted. Legal professionals will need to be well prepared to ensure that the early court cases are effectively prepared and brought. Successful prosecutions will enhance the status of the law and there is likely to be increased compliance by other businesses when they are aware that the new law is being used.

Despite the extensive process of drafting and consultation, the legislation may have unexpected consequences or contain clauses which need clarification. It should be possible to introduce a quick amendment to the law if this is necessary in order to meet the original intention so that it will not be seen as a panic measure.

## Chapter 5: Food Law Components

Any legislation will be drafted according to the legal traditions of a country. However, many components of food law are now considered fundamental to the objective of providing consumer protection and they are usually found in all modern food law. Precise wording will be different so as to reflect national history and language. The key components are identified and illustrated with examples from the African Region and from international bodies (the Codex Alimentarius Commission and the World Trade Organisation). It is frequently valuable to also make use of experience from elsewhere and to help extend the range of examples available, Annex 2 includes examples from countries other than Africa.

The FAO and WHO published an example of a 'Model Food Law' (13). Although many aspects of the model may be considered too prescriptive for direct transposition into a new national law, it does provide an example of how a law might be drafted. Specific national issues will have to be incorporated and the sections which follow provide evidence as to how this has occurred in several different African countries. Box 3 provides the contents list from the Model Food Law which can serve as a template for the development of the national law.

### **Box 3: Contents of the FAO/WHO Model Food Law**

#### **PART I - PRELIMINARY**

1. Short title and commencement
2. Interpretation

#### **PART II - GENERAL PROVISIONS**

3. Prohibition against sale of poisonous, unwholesome or adulterated food
4. Deception
5. Standards of foods
6. Prohibition against sale of food not of the nature, substance or quality demanded
7. Sale and preparation of food under insanitary conditions

#### **PART III - IMPORTATION AND WARRANTY**

8. Importation
9. Warranty
10. Defences

#### **PART IV - REGULATIONS RELATING TO FOOD STANDARDS, FOOD SAFETY AND OTHER MATTERS**

11. Regulations

#### **PART V - ADMINISTRATION AND ENFORCEMENT**

12. Food Standards Board
13. Powers of authorised officers
14. Appointment and duties of authorised officers for official laboratories
15. Other authorised officers
16. Power of Minister to obtain particulars of certain food ingredients

## **PART VI - LEGAL PROCEDURES**

17. Power of court to order licence to be cancelled and articles to be disposed of
18. Prosecution
19. Penalties
20. Certificates of analysis and presumptions
21. Saving of other written laws.

The following sections are based around guidance of a more general nature that has recently been published (6). To help ensure a common approach to the construction of a new food law, relevant extracts have been included at the start of each section.

### **5.1 Scope and Definitions**

The first category describes the ambit of the law and provides the tools for its interpretation. A provision in the food law stating its purpose, objectives and/or scope must clearly precede all others. This provision may have no real legal effect, but instead operates as a kind of policy statement explaining why the law was enacted and what purpose it is intended to serve. It also can state the areas covered by the law (6).

Countries often include a list of definitions of the main terms employed. In drafting the definitions, internationally agreed sources should be consulted, along with other national legislation on related issues. It must be emphasized that the list of definitions is not a glossary of food control terms in general. Those definitions that are included must be only those that appear in the body of the law. The definitions should not be overly detailed but should be designed solely for the purpose of application and interpretation of the law in question. In particular, the definitions should be drafted with consideration to who might challenge the law at some future date. For example, if the law contains a definition of to sell that provides that to sell means to exchange for money, and if the law prohibits selling adulterated food, then someone charged with violating the law might hide proof of sale and attempt to argue that since he or she gave away the food for free (and not for money) the law was not violated (6).

#### **5.1.1 Scope**

The content of a section on ‘scope’ varies considerably and, as indicated above, it may have no legal effect although it may serve to provide guidance in any complex legal arguments (box 4).

#### **Box 4: Examples of Sections on Scope from Tanzania and Zambia**

##### **Tanzania**

Food, Drugs and Cosmetics Act 2003

An Act to provide for the efficient and comprehensive regulation and control of food, drugs, medical devices, cosmetics, herbal drugs and poisons and to repeal the Food (Control of Quality) Act, 1978, the Pharmaceuticals and Poisons Act, 1978 and to provide for related matters.

##### **Zambia**

Food and Drugs Act 1972

An Act to protect the public against health hazards and fraud in the sale and use of food, drugs, cosmetics and medical devices; and to provide for matters incidental thereto or connected therewith.

## 5.1.2 Definitions

Although definitions given in legislation may be similar to those found in a dictionary, there are many cases where this is not the case. Legal definitions have the specific purpose of providing legal clarity for the legislation covered by them. Dictionary definitions may leave uncertainty as to the distinction between two related terms – if both are used in legislation, it is important to know more precisely which applies. As a simple example, in common usage, there can be confusion as to whether the term ‘food’ includes ‘drink’. It is quite common to use the phrase ‘food and drink’ which implies that they are two separate categories. In other circumstances though, ‘food’ would include liquids. It is therefore very common to make it clear in legislation that ‘food’ includes drinks.

### *Definition of Food*

There are a number of issues surrounding the concept of ‘food’ which make a definition important. Uncertainties exist at a number of ‘boundaries’ relating to:

- drink/water
- ingredients of food
- drugs
- animals
- animal feed
- cosmetics
- chewing gum

Most legal documents therefore contain a definition of food which tries to eliminate the uncertainty.

Although developed for use by the Commission itself, the definition of food that the Codex Alimentarius Commission has adopted can be usefully applied, adapted as necessary, within national food law (box 5). The definitions given below from Nigeria, Tanzania and Zambia are all interesting examples of a difficulty which can sometimes occur with definitions. These definitions of ‘food’ include reference to the word ‘food’. This can cause difficulties in interpretation and should be avoided unless the case law within a country has established the correct interpretation. In these cases it is likely that the word ‘food’ used within the definition is the normal dictionary definition but, for the purposes of the legislation, this is extended and clarified by the other components of the legal definitions.

#### **Box 5: Examples of definitions**

##### **Codex Alimentarius**

Procedural Manual

**Food** means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.

##### **Mauritius**

Food Act 1998

**Food -**

- (a) means any article or substance meant for human consumption and includes –
- (i) drinks and bottled water
  - (ii) chewing gum and other products of similar nature and use; and
  - (iii) articles and substances used or intended for use as ingredients in the composition or preparation of food;

- (b) does not include -
- (i) live animals, birds or live fish which are not used for human consumption while they are alive;
  - (ii) fodder or feeding stuffs for animals, birds or fish;
  - (iii) drugs or medicine as defined in the Pharmacy Act; and
  - (iv) hormonal products or veterinary products for use in livestock feed;

### **Nigeria**

Food and Drugs Act (as amended by the Food and Drugs (Amendment) Decree 1999)

**Food** – includes any article manufactured, processed, packaged, sold or advertised for use as food or drink for human consumption, chewing gum and any ingredient which may be mixed with food for any purpose whatsoever and excludes

- (a) live animals, birds or fish;
- (b) articles or substances used as drugs

### **South Africa**

Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972

**'Foodstuff'** means any article or substance [except a drug as defined in the Drugs Control Act, 1965(Act 101 of 1965 ordinarily eaten or drunk by man or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substances;

### **Tanzania**

Food, Drugs and Cosmetics Act 2003

**Food** means any article other than drugs, cosmetics and tobacco used as food or drink for human consumption and includes any substance used in manufacture or treatment of food;

### **Zambia**

Food and Drugs Act 1972

**Food** includes any article manufactured, sold or represented for use as food or drink for human consumption, chewing gum, and any ingredient of such food drink or chewing gum;

### **Zimbabwe**

Food and Food Standards Act

**Food** means any substance which is, in whole or in part, intended for human consumption or which is intended for entry into or be used in the manufacture of, any such substance.

Within legislation, definitions do not have to comply with the usual dictionary interpretation. They can provide a shortened way of referring to a group of items or activities. For example, food legislation frequently applies controls to the 'sale' of food. In common usage this would involve the exchange of money. However, it is frequently considered necessary to apply control to food provided under other circumstances. The following is an example from Mauritius Food Act of 1998 where an extended meaning is defined:

*“sale” includes the offering or giving away of food as a prize or reward in connection with any entertainment or advertisement, or for the promotion of any trade or business, whether on payment of money or not.*

It is also useful to consider whether the definition is being used to define all items included in the term or whether the main aim is to define the boundary and distinguish it from other products. For example, no would be tempted to argue in a court that a loaf of bread was not food. Equally the flour used to make the loaf of bread is food. However, is the grain, which is used to make the flour, food? Or the seed that was planted to grow and produce the grain? It is not necessary to ensure that bread is defined but it is necessary to define the boundary. Failure to make this clear can lead to lengthy legal arguments and uncertainty for the people subject to the law.

## *Definitions of Other Terms*

The range of definitions can be huge. However, unless a word is used in the Act, it is probably best not to include the definition. Some countries however do use the Act to include additional definitions (box 6). For example, frequently Acts do not contain any provisions relating to food additives and therefore do not include a definition. However, since additives may be subject to detailed controls in various other secondary legal documents, it could be considered appropriate to include a definition in the Act so as to avoid any dispute later.

Typical definitions might be included to cover the following (this list is taken from the Mauritius Food Act of 1998):

- advertisement
- analysis
- animal
- appliance
- authorised officer
- business
- commercial operation
- component
- contact material
- container
- entertainment
- examination
- fish
- food business
- food microbiologist
- Government Analyst
- importer
- injurious to health
- licensee
- medical examination
- Minister
- package
- novel food
- Permanent Secretary
- physical examination
- premises
- preparation
- sale
- seal
- sell
- treatment

Food law is based on risk analysis so consideration could be given to including definitions of this and of the related terms: risk assessment, risk management and risk communication. The Codex Alimentarius Commission now has definitions of these which could be incorporated into national legislation if it is considered appropriate. This could be where:

- (a) the allocation of responsibilities for different aspects of risk analysis is provided in the Act, or
- (b) where a clear link to international obligations would be valuable.

In drafting food law, it will be necessary to bear in mind the intended scope of the legislation. If the emphasis is to provide a minimum level of consumer protection for food within the country then it is unlikely that the definitions linked to risk analysis will be needed. However, if it is intended to include trade and to align legislation with international commitments (for example, under the Sanitary and Phytosanitary Agreement of the WTO, Article 5(1) (Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection) of the SPS Agreement which states: 1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations) then it might be appropriate to introduce provisions linked to risk analysis and, in particular, risk assessment. The terms may also be used in the legislation if a food control authority or board is being established (refer to boxes 7 and 8). Again, this might need the inclusion of the related definitions.

## **Box 6: Examples of definitions of other terms from countries**

### **Ghana**

Food and Drugs Law 1992 (as amended by Food and Drugs (Amendment) Act 1996)

**Label** – includes any legend, work or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or chemical substance.

**Manufacture** – with respect to food means the making or composition of a product, including its production, preparation, processing or preservation in combination with other components, substance, ingredients or products.

**Premises** – includes any building, hut, shed, kiosk or tent together with the and on which it is situated and any adjoining land used in connection with it, and includes any vehicle, conveyance or vessel.

### **Mauritius**

Food Act 1998

**Premises** –

(a) means any building or any other structure permanent or otherwise together with the land on which the building or other structure is situated, any adjoining land used in connection therewith; and

(b) includes any vehicle, conveyance, ship, aircraft, floating craft, street, place, open space or place of public resort, bicycle, tricycle, any vehicle motorised or not, used for or in connection with the preparation, preservation, packaging, storage, conveyance, distribution or sale of any food.

**Preparation** - in relation to food, includes manufacturing, producing, processing and any form of treatment.

**Sale** - includes the offering or giving away of food as a prize or reward in connection with any entertainment or advertisement, or for the promotion of any trade or business, whether on payment of money or not

### **Seychelles**

Food Act 1987

**Label** – includes any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on or attached to or included in, belonging to or accompanying any food

**Premises** – includes any building, tent or other structure permanent or otherwise together with the land on which the same is situated and any vehicle or conveyance, vessel or aircraft.

**Sell** – includes transmit, convey or deliver in pursuance of a sale, exchange, raffle or other disposal.

### **Tanzania**

Food, drugs and Cosmetics Act 2003

**Label** – means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any food, drug, cosmetics or medical devices.

**Manufacture** – includes all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labelling of products regulated under this Act.

**Premises** – includes land, buildings, structures, basements and vessels and in relation to any building includes a part of a building and any cartilage, forecourt, yard, or place of storage used in connection with the building or part of that building; and in relation to “vessel”, means ship, boat, air craft, and includes a carriage or receptacle of any kind, whether open or closed.

**Sell or sale** – means sell by wholesale or retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange supply or dispose of to any person whether for a consideration or otherwise.

## **Box 7: Examples of Definitions of other Terms from the Codex Alimentarius**

### **Codex Alimentarius procedural Manual**

**Food hygiene** comprises conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption.

**Food additive** means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities.

**Contaminant** means any substance not intentionally added to food, which is present in such 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 or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

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

**Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

**Risk Analysis:** A process consisting of three components : risk assessment, risk management and risk communication.

**Risk Assessment:** A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

**Risk Management:** The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

**Risk Communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.



## **Box 8: Examples of Definitions of other Terms from the WTO**

### **WTO Sanitary and Phytosanitary Agreement**

For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

**Sanitary or phytosanitary measure** - Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

**Harmonization:** The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

### **International standards, guidelines and recommendations**

- (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
- (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

### **WTO Technical Barriers to Trade Agreement**

**Technical regulation** - Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

**Standard** - Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

**Conformity assessment procedures** - Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

## 5.2 General Principles

In some legal systems, the basic food law contains a group of provisions articulating general principles that will govern the food control system. For example, the law may provide that all food in circulation in the country must be safe for human consumption, or the law may prohibit the adulteration of food. Other provisions may set out the basic rules to be observed by all persons engaged in the production, processing or sale of food. It should be borne in mind, however, that there exist many differences between countries. Some countries have a detailed statement of principles in the basic law, whilst others leave these principles to be laid down in general enforcement regulations, and still others include only a statement of objectives and purposes and do not elaborate principles at all (6).

The food law will contain many substantive provisions relating to food control, production, import, export, transport, distribution and sale. These provisions may be very basic (“all food in the country must be safe for human consumption”), or may be more detailed, in which case the details are more likely to be found in the subsidiary legislation. For example, the regulations issued under the food law may outline all the precise information that must be contained on food labels (weight, name of manufacturer, sell-by date, etc.) and may even contain model labels in a specific format that must be followed throughout the country (6).

### 5.2.1 Key Offences

Offences are practices which are considered to be unacceptable and which the law is designed to prevent. They usually provide the key components of consumer protection – both with regard to food safety and with regard to prevention of fraud. The precise wording will vary but key elements are usually present and can be found in the various examples given in box 9.

#### Box 9: Examples of Offences

##### **Ghana**

Food and Drugs Law 1992 (as amended by Food and Drugs (Amendment) Act 1996)

##### **Section 1**

- (1) Any person who sells or offers for sale any food that –
- (a) has in or upon it any poisonous or harmful substances;
  - (b) is unwholesome or unfit for human consumption;
  - (c) consists in whole or in part of any filthy, putrid, rotten, decomposed or diseased substances;
  - (d) is adulterated;
  - (e) is injurious to health;
  - (f) is not of the nature, substance or quality prescribed by standards
- commits an offence.

##### **Section 3**

A person who manufactures, labels, packages, sells or advertises any food in a manner that is false, misleading or deceptive as regards its character, nature, value, additives, substance, quality, composition, merit or safety commits an offence.

##### **Mauritius**

Food Act 1998

##### **Section 16 - Offences**

- (1) (a) No person shall import, prepare, supply or sell any food unless such food is of merchantable quality.
- (b) For the purposes of paragraph (a), “merchantable quality” means as fit for the purpose for which the food is sold as it is reasonable to expect, having regard to all the relevant circumstances.
- (2) Any person who –

- (a) obstructs, impedes, molests or assaults any authorised officer in the course of his duty or prevents the execution by the authorised officer of his duty in any manner;
- (b) fails to furnish his name and address or who knowingly makes any false or misleading statement either verbally or in writing to any authorised officer engaged in carrying out his duty;
- (c) being the owner, occupier or person in charge of any premises to which an authorised officer has gained access under section 4, or any person found therein who does not give to the authorised officer such reasonable assistance or furnish him with such information as he may reasonably require;
- (d) fails to comply with a request or notice under this Act;
- (e) fails to comply with an order of the District Magistrate or of the Permanent Secretary under this Act, or removes the copy of an order affixed under section 10 (6) (b);
- (f) in respect of any food sold by him as principal or agent, gives to the purchaser a false warranty or written statement, unless he proves that when he gave the warranty he had reason to believe that the statements or descriptions contained therein were correct; and
- (g) otherwise contravenes any provision of this Act or any regulations made under this Act, shall commit an offence.

3) Any person who imports, prepares, supplies, distributes or sells any food which –

- (a) is poisonous, harmful or injurious to health;
- (b) contains any foreign matter;  
is unfit for human consumption;
- (d) is the product of a diseased animal or an animal which has died otherwise than by slaughter;
- (e) is the product of a decomposed vegetable or vegetable substance; or
- (f) is adulterated,

## **Seychelles**

### **Food Act 1987**

Any person who adds any substance to food, uses any substance as an ingredient in the preparation of food, abstracts any constituent from food or subjects food to any process or treatment, so as to render the food injurious to health with intent that the food shall be sold in that state is guilty of an offence.

#### **Section 5**

Any person who sells food which –

- (a) contains any substance which is poisonous, harmful or otherwise injurious to health;
- (b) consists in whole or in part of any filthy, putrid, rotten, decomposed or diseased substance or foreign matter; or
- (c) is otherwise unfit for human consumption  
is guilty of an offence

#### **Section 6**

Any person who labels, packages or advertises or is a party to the publication of an advertisement of any food in contravention of this Act, or in a manner that is false, misleading or deceptive as regards its character, nature, substance, quality, composition, merit or safety, is guilty of an offence.

#### **Section 7**

(1) Any person who sells to the prejudice of a purchaser any food which is not of the nature, substance or quality demanded by the purchaser is guilty of an offence.

(2) In proceedings under this section it shall not be a defence to allege that the purchaser bought for analyses or examination and therefore was not prejudiced.

#### **Section 8**

Any person who sells, prepares, packages, stores or displays for sale any food under insanitary conditions, whereby the food may be contaminated with filth or may be rendered unfit for human consumption, is guilty of an offence.

## **Tanzania**

Food drugs and Cosmetics Act 2003

### **Section 30**

(1) No person shall with intent to cause food to be sold for human consumption

(a) add any substance to the food, use any substance as an ingredient of that food in its manufacture or abstract any constituent from it;

(b) subject the food to any other process or treatment, so as, in any such case, to produce food of a quality below the prescribed standard, whether or not that food thereby becomes injurious to health;

(c) if that food does not comply with requirements prescribed by the Authority.

... continues...

### **Section 31**

(1) Any person who sells any food which is not of the nature, substance or quality of the food demanded by the purchaser shall be guilty of an offence.

### **Section 32**

(1) Any person who

(a) distributes, sells, or offers or has in his possession for the purpose of distribution, sale or manufacture for sale; or

(b) deposits with, or consigns to, any person for the Purpose of distribution or sale or manufacture for distribution or sale, any food intended, but unfit, for human consumption, shall be guilty of an offence.

... continues ...

## **5.2.2 Defences**

Food law can be an effective measure in preventing food businesses from producing unsafe food or misleading consumers. However the legislation could potentially be used against people who have, through no fault of their own, have food in their possession which does not comply with the legal requirements. Defences are one way in which the law can distinguish between those who are responsible and those who are not.

A food business owner e.g. a retailer who purchases food for manufacturing or for re-sale and requests for food complying with the legislation is usually provided a warranty by the supplier. The food business can use the warrant as defence should the food not meet legal requirements. This form of defence can be seen in the examples given in the boxes for the Seychelles and Tanzania. One of the problems with the warranty defence is that it can be used by food businesses to avoid prosecution when really they should have recognised that the food might have been suspect.

### **Box 10: Examples of defences**

#### **Seychelles**

##### **Section 23 – Defence of warranty**

(1) Subject to this section, in any proceedings under this Act for an offence consisting of the sale of any food it shall be a defence –

(a) that the food was purchased by the person charged for that offence as food that could be lawfully sold and with a written warranty for that effect;

(b) that he has no reason to believe at the time of the commission of the offence that the food was otherwise; and

(c) that the food was at the time of the commission of the offence in the same state as when he purchased it.

(2) A warranty shall only be a defence under subsection (1) if the person charged –

(a) has not later than 3 days before the date of the hearing sent to the prosecutor a copy of the warranty with a notice that he intends to rely on it and specifying the name and address of the person from whom he received it; and

(b) establishes to the satisfaction of the court that he has sent a similar notice of his intention to the person from whom he received the warranty.

(3) When the person charged for an offence described in subsection (1) is a servant or employee of the person who purchased the food under the warranty, he shall be entitled to rely on the provisions of this section in the same way as his employer would have been entitled to do if the employer had been charged.

#### **Tanzania**

Food, Drugs and Cosmetics 2003

##### **Section 111 - When warrant be pleaded as defence**

(1) In any proceedings for an offence which consists of selling or offering or exposing or advertising for sale or having in possession for the purpose of sale, any food, drug, cosmetics, medical device, herbal drug or substance, it shall be a defence for the defendant to prove that-

(a) he purchased it as being an article or substance which could lawfully be sold or dealt with under the name or description or for the purpose under or for which he sold or dealt with it, and with a written warranty to that effect; and

(b) he had no reason to believe, at the time when the alleged offence was committed, that it was something other than what he says it was in paragraph (a); and

(c) it was then in the same state as when he purchased it.

(2) A warranty shall only be a defence in proceedings under this Act if:

(a) the defendant -

(i) has, not later than three days before the date of the hearing, sent to the prosecutor a copy of the warranty with a notice that he intends to rely on it and specifying the name and address of the person from whom he received it; and

(ii) has also sent a similar notice to the person from whom he received the warranty; and

(b) in the case of a warranty given by a person resident outside Tanzania, the defendant proves that he had taken reasonable steps to ascertain, and did in fact believe in, the accuracy of the statement contained in the warranty.

(3) A defendant who is an employee or agent of the person who purchased the article or substance under a warranty may rely on this section in the same way as his employer or principal would have done had he been the defendant.

(4) The person by whom the warranty is alleged to have been given may appear and give evidence at any hearing, and the court may, if it thinks fit, adjourn the hearing.

(5) For the purposes of this section and of the provisions of section 113, a name or description entered in an invoice shall be deemed to be a written warranty that the article or substance to which the entry refers can be sold or dealt with in any other way under that name or description by any person without contravening this Act.

### **5.3 Administrative Provisions**

Most food laws contain a category of provisions that set up particular administrative structures to carry out the activities necessary to enforce the law. For example, the law may establish a Food Control Agency, which brings together the many official actors from various ministries who are implicated in food control in the country. The food law does not usually delve into great detail on the functioning of the Food Control Agency, but instead describes its mandate, defines its membership, outlines some basic rules regarding the appointment and resignation of members and the establishment of technical committees, and provides for a Secretariat, if any (6).

The law may provide that all other details that will govern the actions of the Food Control Agency will be established by regulation or by by-laws elaborated by the Agency itself. Other administrative structures that may or may not be created or defined in the food law are an inspection service and a licensing authority (for example to grant licenses to food manufacturers or importers). The law may also empower the Agency to delegate or license certain types of enforcement activities to different government agencies (6).

In establishing an organisational structure for a national food control system, it is common practice to try and ensure coordination across all those government departments whose activities have an impact on the food supply system. This may take the form of inter-departmental committees or less formal contact. However, it has frequently been found that departmental priorities are to pursue their own key activities and collaboration may not be pursued vigorously if kept informal. It is for this reason that there has been a growth of more formal arrangement often including the establishment of an official body responsible for a range of food control activities.

In many developed countries, a totally independent body has been established to remove responsibilities from the government. This is seen as a way of restoring consumer confidence in the food control system when failures have occurred due to political decisions. The range of responsibilities given to the independent body varies from country to country and may be limited to scientific risk assessment or may include many risk management activities. In some

countries the body is able to produce legally binding controls or standards without reference to Parliament. In others, proposals for regulations may be prepared by the body but it is left to the government to adopt the regulations or to ensure their passage through any parliamentary process.

Most African countries who have recently updated their legislation have recognised the need, as a minimum, to establish a formal system of collaboration. Collaboration between Ministries is usually achieved through the creation of a special food committee with representatives from all those ministries with an interest in food safety or food security. In this context, it will probably be necessary to include representatives of many non-governmental bodies – it is regarded as particularly important to include people with consumer knowledge. The legislation frequently will specify the membership and some of the rules of procedure – for example who should chair the meeting and how frequently meetings should be held. Some countries have established a body with its own funding and staff. In this case, responsibilities are usually allocated to it by taking these away from other government departments.

The different approaches have been categorised into 3 main systems:

- **A system based on multiple agencies responsible for food control - Multiple Agency System** – 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 etc. While multiple food control agencies may be the norm, they suffer certain drawbacks including lack of coordination at national level, frequent confusion over jurisdiction and resultant inefficiencies in performance, lack of coherence leading to over-regulation or time gaps in adequate regulatory activity.
- **A system based on a single, unified agency for food control - 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. The benefits include among others, uniform application of protection measures, improved cost efficiency, more effective use of resources and expertise, as well as harmonization of food standards.
- **A system based on a national integrated approach - 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-table continuum. The advantages of such a system include, among others coherence in the national food control system, uniform application of control measures across the whole food chain throughout the country and, efficiency in dealing with international dimensions of food control.

It is important to ensure effective interaction with the many components of work of the FAO/WHO Codex Alimentarius Commission. The Codex recommends that countries have a single National Codex Contact Point which handles issues and documentation relating to the Codex Alimentarius Commission. Detailed information on the functions and operation of a National Codex Contact Point is provided in ‘African Regional Guidelines for National Codex Contact Points and National Committees’ which were approved by the Codex Alimentarius Commission in June 2003. It is advisable for this Contact Point to have direct access to any food control body and placing it within any food control body will usually be beneficial. However, many countries will have established procedures in which, for example, the national standards body undertakes Codex work. Reallocating tasks may not be sensible when an effective system is already working. Box 11 provides examples of administrative provisions.

## **Box 11 : Examples of Administrative Provisions**

### **Cameroon**

Arrêté n° 011 /CAB/PM du 02 MARS 2004 portant création d'un comité ad hoc sur la sécurité sanitaire des aliments au Cameroun

#### **Article 1<sup>er</sup>** :

Le présent arrêté porte création d'un comité ad hoc sur la sécurité sanitaire des aliments au Cameroun, ci-après désigné le **Comité**.

#### **Article 2** :

Placé auprès du Ministère chargé de la normalisation, le Comité a pour missions de:

- poser le diagnostic des systèmes actuels de contrôle des aliments au Cameroun;
- réfléchir sur de nouvelles techniques procédurales de contrôle de la qualité des aliments;
- proposer des mesures tendant à améliorer la sécurité sanitaire des aliments au Cameroun..

#### **Article 3** :

(1) Présidé par le Ministre chargé de la normalisation ou son représentant, le Comité comprend, en outre, les membres ci-après :

- un représentant des Services du Premier Ministre ;
- un représentant du Ministère chargé de l'agriculture ;
- un représentant du Ministère chargé de l'élevage, des pêches et des industries animales;
- un représentant du Ministère chargé de la santé publique;
- un représentant du Ministère chargé de l'administration territoriale et de la décentralisation;
- un représentant du Ministère chargé des mines, de l'eau et de l'énergie;
- un représentant du Ministère chargé de la recherche scientifique et technique;
- un représentant du Ministère chargé de l'environnement et des forêts;
- deux (2) représentants des laboratoires publics chargés respectivement de la santé publique et de la santé animale;
- un représentant - des associations de protection des consommateurs.

(2) Le Président du Comité peut inviter toute personne physique ou morale en raison de ses compétences sur les points inscrits à l'ordre du jour à prendre part aux travaux avec voix consultative.

(3) Le secrétariat du Comité est assuré par la Direction en charge de la normalisation au Ministère chargé du développement industriel et commercial.

(4) Les membres du Comité sont désignés par les Administrations et les organismes socioprofessionnels auxquels ils appartiennent.

(5) La composition du Comité est constatée par arrêté du Ministre chargé de la normalisation.

### **Ghana**

Food and Drugs Law 1992

#### **Section 27 – Establishment of Food and Drugs Board**

(1) There is hereby established a Food and Drugs Board

(2) The Board shall operate under the control and supervision of the Ministry responsible for Health

#### **Section 28 – Functions of the Board**

(1) The Board shall advise the Secretary on all matters relating to the administration and implementation of this Law.

(2) Without prejudice to subsection (1) the Board shall –

- (a) advise the Secretary on measures for the protection of the health of consumers;
- (b) in co-operation with the Ghana Standards Board, ensure adequate and effective standards for food and drugs;
- (c) monitor through the District Assemblies and other agencies of State compliance with this Law;
- (d) advise the Secretary on the preparation of effective regulations for the full implementation of the provisions of this Law;
- (e) perform the functions assigned to it under this Law.

#### **Section 29 – Composition of the Board**

(1) The Board shall consist of the following persons –

- (a) a Chairman appointed by the Council;
- (b) a representative of the Ghana Standards Board;
- (c) a representative of the Food Research Institute

- (d) Director of Fisheries, Department of Fisheries, Ministry of Agriculture;
- (e) a representative of the Ghana Medical Association
- (f) the Registrar of the Pharmacy Board;
- (g) the head of the Nutrition and Food Science Department, University of Ghana;
- (h) a veterinary surgeon nominated by the Secretary for Agriculture;
- (i) the Director, Crop Services Department of the Ministry of Agriculture;
- (j) a representative of the Environmental Protection Council;
- (k) a practitioner of herbal medicine to be appointed by the Council;
- (l) the chief executive of the Board;
- (m) a representative of the Attorney-General or a lawyer of not less than ten years' standing;
- (n) two other persons including at least one woman representing consumer interest appointed by the Council.

(2) All professional specialists on the Board shall be persons in active practice in their professions.

(3) The members of the Board other than the ex officio members shall hold office for a period of three years but shall be eligible for reappointment.

(4) The validity of any proceedings of the Board shall not be affected by any vacancy among its members or by the absence of any one of them.

## **Seychelles**

Food Act 1987

### **Section 12 – Board**

(1) there is established a Board to be known as the Food Control Board, hereafter referred to as the “Board”.

(2) The Board shall consider and advise the Minister on matters necessary for the administration of this Act including the making of regulations under this Act.

(3) The Board shall consist of-

(a) a Chairman to be appointed by the Minister; and

(b) such other members appointed by the Minister as appearing to him to represent –

(i) the Ministry responsible for National Development;

(ii) other Government ministries, departments and public bodies responsible for matters dealing with food;

(iii) food manufacturers, processors, retailers and consumers.

(4) The members appointed under subsection (3)(b) –

(a) shall hold appointment for a period of 3 years and be eligible for reappointment;

(b) may at any time resign by instrument in writing addressed to the Chairman.

(5) Appointments made under subsection (3) shall be notified in the Gazette.

(6) The quorum of the Board shall be such number of members the Minister may the time of appointment determine.

(7) The Board shall meet at such time as the Chairman may determine.

(8) The Board may invite any person to attend any meeting of the Board for the purpose of assisting or advising the Board but such person shall not have any right to vote at such meeting.

(9) Subject to this Act and to any general or specific directions in writing by the Minister, the Board shall regulate its own proceedings.

## **Tanzania**

Food, Drugs and Cosmetics Act 2003

### **Section 4**

(1) There is hereby established the Tanzania Food and Drugs Authority or by the acronym "TFDA".

(2) The Authority shall be an Executive Agency and shall operate in accordance with the Executive Agencies Act, 1997.

(3) The Authority shall have a common seal and the seal of the Authority shall be authenticated by the signature of the Director General or in his absence any person acting on his behalf authorised by him in writing.

(4) The Authority in discharging its functions under this Act, in addition to the functions and powers conferred under sections 5 and 6 shall, take into account the functions as may be specified under the law relating to the establishment of executive agencies.

### **Section 5**

(1) The Authority shall be the regulatory body for the products regulated under this Act, and shall in particular-

(a) regulate all matters relating to quality, and safety of food, drugs, herbal drugs, medical devices, poisons and cosmetics;

(b) regulate in accordance with this Act, the importation, manufacture, labelling, marking or identification, storages promotion, sell and distribution of food, drugs, cosmetics, herbal drugs and medical devices or any materials or substances used in the manufacture of products regulated under this Act;



- (c) ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored globally, are analysed and acted upon;
- (d) ensure that, clinical trials on drugs, medical devices and herbal drugs are being conducted in accordance with prescribed standards;
- (e) foster co-operation between the Authority and other institutions or organizations and other stakeholders;
- (f) approve and register products regulated under this Act, manufactured within or imported into, and intended for use in the United Republic;
- (g) examine, grant, issue, suspend, cancel and revoke certificates and licences or permits issued under this Act;
- (h) appoint inspectors and order inspection of any premises;
- (i) promote rational use of drugs, medical devices and herbal drug;
- (j) establish and maintain the Tanzania National Formulary and Tanzania Pharmacopoeia;
- (k) provide the public with unbiased information on products regulated under this Act;
- (l) prescribe standards of quality in respect of products regulated under this Act, manufactured or intended to be manufactured or imported into or exported from the United Republic;
- (m) maintain registers prescribed under this Act;
- (n) be responsible for its human resource management and development;
- (o) promote, monitor and ensure successful implementation of the provisions of this Act;
- (p) attend to and, where possible, take legal measures on complaints made by consumers against manufacturers of products regulated under this Act;
- (q) carry out such other functions as may be conferred upon the Authority by any written law or as are incidental to the performance of its functions under this Act;
- (r) do such acts or take such measures as are, in the opinion of the Authority, necessary or expedient for the prevention of health hazards to consumers which may result from the consumption or use of low or bad quality products regulated under this Act.

## 5.4 Enforcement Provisions

Because no penalty may be imposed except by virtue of legal authority, food laws contain provisions delegating to an executive authority the power to sanction as well as to take preventive measures in the public interest. It goes without saying that the limits of such powers and the conditions governing their exercise must be laid down with precision in the basic law. Offences must be defined, along with the nature and limits of the penalties that may be imposed, together with the procedures for such imposition once the commission of an offence has been duly established. The law may also outline other necessary measures for the protection of the public, such as the seizure and confiscation of suspect food or the recall of products. It should be noted, however, that in some countries, specific offences and penalties are not elaborated, but instead the food law simply refers to the general provisions of the Criminal Code and the Code of Criminal Procedure (6).

With the trend away from an enforcement-oriented approach in food control, some countries have incorporated concepts from food control, such as HACCP, into their food laws. In general this may be achieved through the subsidiary regulations more than through the law, as the regulations may consist of elements such as guidelines for the inspection service. Under a purely enforcement-oriented approach, improper activities (packaging, transportation, etc.) would be described in the law, and any violation would be perceived and acted upon by an inspector so charged by the law. With a more collaborative and preventive approach, the inspectors might instead be charged with simply controlling the fact that a food enterprise is exercising its own controls on its production systems (6).

### 5.4.1 Enforcement Officers and their Powers

For the effective application of the law, it is necessary to provide for appropriate qualified officials to be given powers to monitor compliance with the law and to take action in the event of a failure to comply. Although the aspects mentioned below need consideration in the

drafting of the legislation, it is well recognised that enforcement is most effective when carried out by highly motivated individuals who are well trained, well rewarded and whose work is highly valued by their superiors.

### *Qualifications and Employment*

There are two main issues with regard to enforcement officers – first is the issue of the appropriate qualifications and second is the issue of who employs them.

There are many different types of officers and the decision to allocate food law enforcement responsibility to a particular type will depend upon many factors associated with the history, resources and legal system in a country. Officers can be trained in the enforcement of many different pieces of legislation (including environmental health, food safety, weights and measures, advertising standards or housing) or they may be specialists (for example food technologists, food microbiologists or food scientists). The precise nature is less important than their ability to act effectively in monitoring compliance with the food law. Many aspects of food law are simple issues of hygiene or temperature control and it does not need a specialist to identify failure. However, the increasingly sophisticated requirements of the food manufacturing industry, with the application of quality management systems such as HACCP, may require a more detailed analysis of food safety issues requiring training to degree level.

There are also aspects of food law which may require specialists. The most obvious example is in the control of animal-based products (for example, meat and milk and their products) where qualified veterinary surgeons are frequently used to monitor compliance, to undertake ante- and post-mortem inspections and to ensure hygienic practices in the handling of animal-based products. Some countries may also establish specialists for products or commodities of particular national importance (wine, coffee or cocoa might be examples). Where available, international guidance should be used to identify best practice. Guidance from the Codex Alimentarius Commission would be the best source of guidance. An example would be the ‘Draft Code of Hygienic Practice for Meat’ (ALINORM 05/28/16)

The employer of the officers will vary greatly depending upon the nature of the administrative structure within a country. Some countries provide for local authorities to undertake enforcement duties within their locality whilst others have established a national food control authority who employs the officers directly. Other countries may have established specialist units or may have given power to inspectors of a standards institute.

The legislation needs to be worded so to ensure that all officers are given the necessary authority under the legislation. This might be given in the main Act or in secondary legislation or in a combination of the two. It may also be considered necessary to ensure that no conflict of interest arises with the work of an authorised officer and any other work that they undertake or are involved with.

### *Powers*

Careful consideration needs to be given to ensuring a balanced approach to the powers allocated to enforcement officers and the rights of the food businesses to carry on their business. Important powers will obviously include the right to enter premises and to inspect food being offered for sale. However it is frequently stated that the access must be at reasonable times (for example, the food law for Ghana includes the phrase ‘any hour reasonable for the proper performance of his duty’).

It may be necessary to be more specific about the powers of inspectors and there could be arguments as to whether looking at recipes, accessing computer data or copying quality records are permitted under the legislation. This might be covered by other aspects of national legislation or it may be necessary to specify it in the food law itself.

Beyond the limited power of inspection, it is likely that legislation will also give powers to enforcement officers to take action. This is usually designed to prevent food which is unfit for human consumption from staying in the food supply. It is usual to allow officers to 'seize' suspect food and prevent it from being removed from premises. Other possible powers include the closure of food premises or the issuing of instructions to carry out improvements to a building or to equipment. Where an enforcement action is permitted under the legislation, careful consideration needs to be given to the possibility of providing the owner with access to an appeals procedure either to a higher official or to an independent body such as the courts. This might be included in the food law or it may already be part of the national legal processes in which case additional clauses may not be needed.

### **Box 12: Examples of enforcement provisions**

#### **Ghana**

Food and Drugs Law 1992

*Note: In this Law, an 'authorised officer' is defined in Section 51 as:*

*a medical officer of health, a health inspector or any person authorised in writing by the Board, the Secretary or a District Assembly.*

#### **Section 36 – Powers of authorised officers**

(1) An authorised officer may any hour reasonable for the proper performance of his duty –

(a) enter any premises where he believes any article to which this Law applies is prepared, preserved, packed, stored or conveyed, examine the article and take samples and examine anything that he believes is used or is capable of being used for the preparation, preservation, packaging, storing or conveying of the article;

(b) open and examine any receptacle or package which he believes contains any article to which this Law applies;

(c) examine any books, documents, or other records found in any place mentioned in paragraph (a) of subsection (1) of this section which he believes contains any information relevant to the enforcement of this Law and make copies of them or take extracts from them;

(d) seize and detain for such time as may be necessary any article by means of or in relation to which he believes any provision of this Law has been contravened.

(2) An authorised officer acting under this section shall, if required, produce his authority.

(3) An authorised officer may by a warrant break open a container or door of premises where food may be kept for storage or sale; except that this power shall be exercised only after the owner or any responsible person in occupation of that premises present, refuses to open the container or door on being asked to do so.

(4) Any person who obstructs or impedes any authorised officer in the course of his duties or by any gratuity, bribe, promise or other inducement prevents, or attempts to prevent the due execution by the authorised officer of his duties under this Law or any regulations made thereunder shall be guilty of an offence.

(5) Where an authorised officer has seized an article under this Law the article may be destroyed or otherwise disposed of as the authorised officer may direct.

#### **Tanzania**

Food, Drugs and Cosmetics 2003

#### **Section 105 – Appointment, authorisation and recognition of inspectors**

(1) For the Purpose of this Act, the Authority may-

(a) appoint any pharmacist, medical Practitioner, health officer, food technologist, pharmaceutical technicians or any public officer as an inspector;

(b) authorise any inspector or officers appointed under any written laws whose functions relate to the functions of the Authority to perform specific functions as inspectors under this Act; and

(c) publish in the *Gazette* inspectors appointed under this Act.

(2) The inspectors or officers referred to under Paragraph (b) of subsection (1) shall be recognised as authorised officers under this Act

(3) When appointing or authorizing inspectors, the Authority shall take into account not to appoint or authorize an inspector who has interest in the manufacture, importation or sale of any product regulated under this Act.

#### **Section 106 – Powers of inspectors**

(1) For the purposes of ensuring compliance under this Act, an inspector or inspectors may-

(a) at all reasonable times, enter –

(i) any set of premises which is on the register of premises;

(ii) any premises in which any person whose name is entered in any register under this Act, carries on any business; and

(iii) any premises in respect of which any person is licensed under this Act;

(b) at any time enter any premises, stall, vehicle, vessel, or conveyance, any premises suspected to be dealing with products regulated under this Act for the purposes of ensuring compliance with this Act;

(c) examine or inspect any certificate of registration, licence, book, electronic information storage system or other document in the premises and, for that purpose, he may do such other things, including the taking of extracts from documents in the possession of the person, as may be necessary to effectual the examination or inspection;

(d) seize and detain any food, drug, cosmetics, medical device, herbal drug, substance or article consisting of, or containing any poison which he has reasonable cause to suspect is liable to forfeiture under this Act;

(e) seize and detain any drug, product, foods, cosmetics, medical device, herbal drug, article, record or other thing which appears to him to constitute or contain evidence of a contravention of any provision of this Act;

(f) close the premises found to contravene the law and institute criminal proceedings;

(g) order the return to the country of origin of any product regulated under this Act imported into the country in contravention of the provisions of this Act.

### **Mauritius**

Food Act 1998

#### **Section 8 – Improvement notice**

(1) Where the Permanent Secretary has reasonable grounds to believe that the owner, occupier or licensee of any premises has failed to comply with any regulations made under this Act, the Permanent Secretary may serve on the owner, occupier or licensee, as the case may be, an improvement notice in the form specified in the Seventh Schedule, specifying -

(a) the matters which constitute any failure on the part of the owner, occupier or licensee to comply with the regulations;

(b) the measures that shall be taken to secure compliance;

(c) the period granted to secure compliance, which shall –

(i) not be less than 14 days; or

(ii) where the non-compliance related to matters constituting, in the opinion of the Permanent Secretary an imminent danger to public health, not be more than 14 days.

(2) The period granted to secure compliance with a notice under this section may, at the discretion of the Permanent Secretary, be extended by 2 further periods of 14 days each.

#### **Section 9 - Prohibition order**

(1) Where the authorised officer is of opinion that the preparation, cooking or selling of food at any premises, or the addition of any ingredient to any food constitute a hazard to health, the authorised officer may serve a prohibition order in the form specified in the Eighth Schedule on the person conducting the trade or business to cause the activity to be discontinued forthwith.

(2) Any person dissatisfied with an order issued under subsection(1) may, within 7 days of the date of service of the order on him, appeal to the Permanent Secretary who may, on appeal, uphold or discharge the order.

(3) An order issued under subsection (1) shall remain in force pending the determination of the appeal by the Permanent Secretary.

#### **Section 10 - Emergency closing order**

(1) Where the authorised officer is of the opinion that any food premises is in such condition that the manufacture, production, packaging, preparing, storing, or selling of food therein or product prepared therein constitutes an imminent hazard to health, he may serve on the owner, occupier or licensee, as the case may be, a notice in the form specified in the Ninth Schedule.

(2) A notice under subsection (1) shall –

(a) give particulars of the condition of the premises which constitute the hazard to health;

(b) explicitly specify the work to be executed or measures to be taken to remedy the situation; and

(c) fix a reasonable time for compliance.

(3) Where a person to whom notice is given under this section fails to comply with the notice, the Permanent Secretary may, after the expiration of the time fixed in the notice and where he has reasonable ground to believe that it constitutes an imminent hazard to health, issue an emergency closing order in the form specified in the Tenth Schedule.

- (4) (a) The owner, occupier or licensee of the premises, as the case may be, may apply by way of pliant with summons to the District Magistrate for the discharge of the order.
- (b) The pliant shall state the grounds on which the discharge of the order is being sought and the matter shall be heard and determined according to the procedure prescribed by the District and Intermediate Courts (Civil Jurisdiction) Act.
- (c) Pending the decision of the District Magistrate upon a pliant under this section, the emergency closing order shall remain in force, or may be amended or stayed in such manner as the District Magistrate considers necessary.
- (d) The Magistrate may dismiss the complaint or discharge the order or amend the order, alter its duration or impose such conditions as he considers expedient and proper for the purposes of the Act.
- (e) Any party aggrieved by the decision of the District Magistrate may appeal to the Supreme Court according to the procedure prescribed by sections 36 and 37 of the District and Intermediate Courts (Civil Jurisdiction) Act.
- (5) Notwithstanding the other provisions of this section, no person shall be relieved from any other liability arising from his failure to comply with the Act, or any regulations made under this Act.
- (6) (a) A copy of an order under this section, signed by the District Clerk, shall be a sufficient warrant for its enforcement by the Commissioner of Police.
- (b) A copy of an order under this section shall be affixed on the main door of the establishment where the offence was committed.
- (7) The Permanent Secretary may, in writing, withdraw the emergency closing order issued under subsection (3) where he is satisfied that the manufacture, production, packaging, preparing, storing or selling of food on the premises does not, any more, constitute a hazard to health.

#### **5.4.2 Sampling and Analysis**

Food law frequently includes provisions defining the legal procedures for sampling, for the analysis of samples and for the subsequent use of any official certificate in any legal proceedings. The provision in the main food law should be limited to ensuring the legality of the sampling and analysis process. For many foods, more detailed legal requirements may be necessary but these would normally be incorporated into secondary legislation.

Countries vary in the way they require evidence to be prepared prior to court proceedings. By incorporating a defined procedure in the legislation, any subsequent argument can be avoided so long as the defined procedure has been followed by the enforcement officer and the analyst. It is common practice to appoint suitably qualified scientists as 'analysts' who are capable of issuing certificates which can be used as evidence in court proceedings. This minimises the risk that the evidence will be successfully challenged in the court. Appropriate provisions to cover this aspect are therefore frequently included in the legislation. Box 13 provides examples of legal procedures for sampling

## **Box 13: Examples of legal procedures for sampling**

### **Mauritius**

Food Act 1998

#### **Section 6 - Procurement of samples**

- (1) Any authorised officer may for the purpose of analysis or examination –
- (a) purchase, at the current market value, a sample of any food or any substance found on any premises capable of being sold as or used in the preparation of food for human consumption;
  - (b) take or obtain without payment-
    - (i) from any premises, samples of any food intended for human consumption;
    - (ii) from any premises where imported food is stored, samples of any food intended for human consumption;
    - (iii) a sample of any article or substance or contact material on any food premises and which he has reason to believe is likely to be used for or in the preparation of foodstuffs for human consumption.
- (2) The purchase, sale or taking of sample of food for analysis or examination under this Act or any regulations made under this Act, shall be deemed to be a purchase, sale or taking of food for human consumption.

#### **Section 7 - Analysis of samples**

- (1) An authorised officer who has procured a sample under section 6 shall submit it –
- (a) to be analysed by a Government Analyst; or
  - (b) to be examined by a food microbiologist,
- or perform a physical examination therewith to determine its fitness for human consumption.
- (2) A person, other than an authorised officer, may purchase any food product or any substance capable of being used in the preparation of food, and submit a sample of the product or of the substance –
- (a) to be analysed by a Government Analyst; or
  - (b) to be examined by a food microbiologist,
- as the case may be.
- (3) Any Government Analyst or Food Microbiologist may demand in advance the payment of a fee specified in the Sixth Schedule for the purpose of any analysis or examination under subsection (2).
- (4) The Government Analyst or the Food Microbiologist, as the case may be, shall analyse or examine as soon as practicable any sample submitted or sent to him under this section and shall give to the person by whom it was submitted a certificate specifying the result of the analysis or examination.
- (5) The certificate issued under subsection (4) shall be signed by the Government Analyst or the food microbiologist conducting the analysis or examination, as the case may be.
- (6) In any proceedings under this Act, the production by an authorised officer of a document purporting to be a certificate issued under subsection (4) shall be sufficient evidence of the facts stated in it.
- (7) No copy of the result of any analysis made under this Act nor any reproduction thereof shall be displayed, published, or used by way of advertisement for any food.

### **Seychelles**

Food Act 1987

#### **Section 18 – Samples and analysis**

- (1) An authorised officer who takes a sample of any article pursuant to his powers under section 14 shall divide the sample into 3 parts (provided that division of the procured quantity of the sample would not interfere with analysis or examination), each part to be marked and sealed or fastened in such manner as its nature permits and shall –
- (a) give one part to the person appearing to him to be the owner or the person in possession of the article of which the sample is taken;
  - (b) submit the second part to an official laboratory for analysis; and
  - (c) keep the third part in the custody of the official laboratory for future comparison
- (2) The person in charge of the official laboratory shall cause the sample submitted for analysis under subsection (1)(b) to be analysed as soon as practicable and shall give to the authorised officer who requested the analysis a report specifying the result of the analysis.

### **Tanzania**

Food, Drugs and Cosmetics 2003

#### **Section 101 - Power to take samples**

- (1) Subject to the provisions of this section and any regulations made under section 122, any inspector may take samples for analysis, or for other examination of any food, drugs or medical devices, cosmetics, and herbal drug or of any substance capable of being used in the manufacture of food, drugs, cosmetics' herbal drug, medical devices which appears to him to be intended for sell or to have been sold for use by man or animal which is found by him

on or in any premises, stall, vehicle, vessel, conveyance, aircraft or place which he is authorized to enter for the purposes of ensuring compliance with this Act.

(2) Where the food, drugs, cosmetics, medical devices or herbal drugs which the inspector intends to take, is kept for retail sale in unopened packages, the sample shall consist of the whole of any one package.

(3) When taking any sample under this section, the inspector shall take any necessary measures to satisfy himself that the sample taken is a representative sample of the bulk of the food, drugs, cosmetics, medical devices and herbal drugs.

(4) Any person who fails to comply with any demand made by an inspector under this section, commits an offence and upon conviction is liable to a fine of not less than one hundred thousand shillings or to imprisonment for a term of not less than two weeks or to both such fine and imprisonment.

#### **Section 102. Right to submit sample to an analyst**

Any inspector who has procured any food, drugs, cosmetics, medical devices and herbal drugs or other substance for use in the manufacture of food, drugs, cosmetics, medical devices and herbal drugs may submit a sample of it to an analyst for analysis.

#### **Section 103 – Provisions regarding the taking of samples for analysis**

(1) Where an inspector who has taken a sample of any food or substance under the provisions of section 102 considers that it should be analysed, he shall forthwith divide that sample into at least three parts, each part to be marked and sealed or secured in the manner permitted by its nature and shall -

(a) with respect to one part of the sample, comply with the provisions of subsection (2); and

(b) with respect to the remaining parts of the sample, comply with the provisions of subsection (3).

(2) (a) if the sample was obtained by purchase from a dealer in the food or substance concerned, the inspector shall permit the vendor to select and take one part from the three parts;

(b) if the sample was obtained by purchase from an automatic machine:

(i) if there appears on the machine the name and address, within the United Republic, of its proprietor, the inspector shall give one part of the sample to that person;

(ii) in any other case, the inspector shall give one part to the occupier of the premises on which the machine stands or to which it is affixed;

(c) if the sample is of any food or substance consigned from outside the United Republic and was taken by that officer before delivery to the consignee, he shall give the one part of the sample to the consignee;

(d) if the sample is of any food or substance in transit from a consignor within the United Republic to a consignee within or outside the United Republic, the inspector shall give the one part of the sample to that consignor;

(e) if none of the preceding paragraphs of this subsection apply, the inspector shall give one part of the sample to the person appearing to him to be the owner of the food or substance from which the sample was taken.

(3) The inspector shall, unless he subsequently decides not to have an analysis made, personally submit to the analyst one of the remaining parts of the sample and retain the other or others for future comparison.

(4) In every case to which subsection (2), applies, the inspector shall inform the person to whom the part of the sample is given that the sample was taken for analysis by the analyst.

(5) Where any sample taken for analysis consist of the contents of an unopened package, the inspector may retain the packing material and, if he decides to have an analysis made, deliver the sample to an analyst.

(6) Any part of a sample which is to be given to any person under this section may be given either by delivering it to him or to his agent, or by sending it to him by post in a registered packet, but if after reasonable inquiry the inspector is unable to find the person to whom the part of the sample is to be given or ascertain his name and address, he may, in lieu of giving that part to that person, retain it.

(7) If it appears to the inspector that any food or substance a sample of which he has taken for analysis was manufactured or put into its wrapper or container by a person, other than one to whom any part of the sample required to be given, having his name and an address in the United Republic displayed on the wrapper or container, the inspector shall, unless he subsequently decides not to have an analysis made, within three days after taking that sample, send to that person a notice informing him that the sample has been taken by him and where the sample was taken or, as the case may be from whom it was purchased.

#### **Section 104 – Where division of sample into parts impracticable**

Where an inspector procures a sample consisting of food or substance contained in unopened packages, and the division into parts of the food or substance in the packages:

(a) is not reasonably Practicable; or

(b) might affect the composition or impede the proper analysis of the contents,

the inspector shall be deemed to have complied with the provisions of section 103(2) if he divides the containers into the requisite number of lots and deals with each lot as if it were a part in the manner Provided by that section, and references in this Act to a part of a sample shall be construed accordingly.

## 5.5 Regulations

In most legal systems, the food law contains a provision or provisions listing the many subject matters that the Minister may address through regulations in order to carry out the purposes of the law. The main advantage of the regulations is that they can be easily changed. The list of regulations may be extremely detailed or it may simply give broad outlines to the kinds of topics that the Minister may address. In either case, the Minister's powers are rarely limited, as in almost all cases the food law will contain a general statement that the Minister may "make all regulations he or she deems necessary to achieve the purposes of this law."

Most legal systems recognise that it is appropriate to have at least two routes for the adoption of legislation. Primary legislation provides for the general principles of a legal power and will establish major offences. This type of legislation is normally adopted using the full legislation-making process (for example, with lengthy debate and consideration in the parliament). The primary legislation is likely to contain a provision which allows for the adoption of secondary legislation (frequently called regulations or decrees) by a shortened route. This secondary legislation is therefore easier to change and can respond quickly to new developments.

The main food law itself is unlikely to specify the precise legislation-making process but it will contain provisions which make use of the appropriate national procedure for the adoption of secondary legislation. In drafting the main food law, it will be necessary to consider carefully which provisions are appropriate for the food law itself and which can be left to secondary legislation. As an example, it might be necessary to consider what aspects of labelling should be covered in the main law and what is left to regulations. Fundamental issues can be included in the act since these are unlikely to need changing (sale of food with a misleading label for example); details of the content of a label (nutrition labelling for example) are best left to regulations. Another area where there can be a need for caution is in the area of licensing of food businesses. Countries vary as to their approach to licensing as in some countries it might be seen as an important part of the control system whilst in others it might seem as a restriction on the freedom to develop a business. National considerations will need to be taken into account in drafting the appropriate system of control.

As indicated, the primary legislation should ensure that the power to issue regulations is allocated appropriately. It is frequently the case that the legislation will list areas where regulations are considered likely (e.g. labelling, hygiene, additives, contaminants) but may contain a phrase which ensures that other aspects can still be subject to regulation.



## **Box 14: Examples of Regulations**

### **Mauritius**

Food Act 1998

#### **Section 18 – Regulations**

- (1) The Minister may make such regulations as he thinks fit for the purposes of this Act and in particular but without prejudice to the generality of his power he may make regulations for-
- (a) prescribing the standard, composition, strength, potency, quality, weight, quantity, shelf-life or other property of any food or ingredient or component thereof;
  - (b) prohibiting the addition of any specified substance to food;
  - (c) prohibiting the addition of more than the specified quantity of a permissible substance to food;
  - (d) the use of any substance as an ingredient of any food so as to prevent the consumer or purchaser from being deceived or misled as to its quality, quantity, character, value, composition, effect or safety, or to prevent damage to the health of the consumer or purchaser;
  - (e) the carriage of food by motorised vehicles or non-motorised vehicles;
  - (f) the mode of labelling of packaged foods;
  - (g) prohibiting or regulating the sale, advertisement or importation of any food or any novel food;
  - (h) prescribing requirements respecting the package of any food and the placing in food for sale or in packages of the food, any toy, coin or other article;
  - (i) securing the observance of hygienic conditions and practices in connection with the carrying out of food business;
  - (j) securing that food is fit for human consumption and meets such microbiological standards as may be specified by any regulations;
  - (k) protecting and promoting the interest of consumers;
  - (l) prescribing fees; or
  - (m) prescribing anything which may be in the interest of public health and safety in carrying out the provisions of this Act.

### **Tanzania**

Food, Drugs and Cosmetics Act 2003

#### **Section 29 – Regulations regarding the composition of food**

- (1) The Minister may, after consultation with the Authority, make regulations prescribing standards to be complied with by manufacturers with regard to the composition of food or its microbiological or chemical or physical standards.
- (2) Without prejudice to the generality of the power conferred by subsection (1), the Minister may in those regulations -
- (a) require, prohibit or regulate the addition to food or extraction from it of any specified substance or any substance of any specified category, or the use of any substance as an ingredient in the manufacture or preservation of that food;
  - (b) prohibit, restrict or regulate the importation, manufacture or sale, possession for sale, offer or exposure for sale or the consignment or delivery, of food or any of its ingredients which do not comply with those regulations;
  - (c) Prohibit or regulate the importation of any food which, in his opinion, is or may be prejudicial to public health;
  - (d) prohibit, restrict or regulate the importation, exportation or use of any specified materials, or materials of any specified category, in the manufacture of apparatus or utensils intended for use in the manufacture or preservation of food;
  - (e) prescribe or provide for methods of analysis for the purpose of ascertaining the presence in any food, or the absence from it, of any specified substance, or the quantity of any substance present in any food.
- (3) In making regulations under this section, the Minister shall have regard to the desirability of restricting, so far as is practicable, the use in the manufacture of food or substances of no nutritional value as foods.

## 5.6 Repeal and Saving

Where a new food law makes significant changes to the food control system, existing laws or regulations may have to be amended or repealed. In such cases the food law will have to list which provisions in which other laws are to be repealed or altered. However, in order not to dismantle the food control system entirely, many laws contain a provision stating that any regulations made under any provision repealed under the new law remain effective, just as if they had been issued under the new food law itself.

New laws must contain provisions which will remove old laws from the legislative structure. Failure to do this can result in confusion over the precise legal requirement. For example, a new law may contain a new definition of 'food'. Another legal document, a drugs law for example, might refer to food by reference to the definition in the earlier legislation. If the earlier definition is not repealed and/or if the drugs law is not amended, then there will be uncertainty over the interpretation of the word 'food' in the drugs law.

Whenever possible, the opportunity should be taken to simplify legislation and remove unnecessary provisions. This will make it easier for both the enforcers and for the food businesses who are seeking to comply with the new legislation. There are though three issues which may need to be included in the legislation:

- (i) The first is that secondary legislation prepared under the authority of the old legislation should remain in force even though the old legislation has been repealed. For example, detailed labelling rules may be in secondary legislation and it may not be revised at the same time as the main food law. The law therefore needs to include reference to this indicating that such secondary legislation will remain in force.
- (ii) Secondly, if some legal proceedings are taking place at the time of the repeal of the old legislation, it maybe necessary to include some statement to the effect that these legal proceeding may continue despite the repeal of the legislation itself.
- (iii) Finally, it may not be possible to transfer all administrative provisions from the old legislation to the new at the exact time that it enters into force. For example, enforcement officers may have been issued with documents giving them authority to inspect premises. Such authorisation may need to be accepted as authorisation for the purposes of the new legislation. Also food businesses may have been issued with licences under the old legislation – these may need to be carried forward until they are next subject to renewal. Box 15 provides some examples of instruments for repeal and saving of old legislation.

**Box 15: Examples of instruments on Repeal and saving old legislation****Tanzania**

Food, Drugs and Cosmetics Act 2003

**Section 125**

The Pharmaceuticals and Poisons Act, 1978 and the Food (Control of Quality) Act, 1978 are hereby repealed.

**Section 126**

(1) Notwithstanding the repeal of the Pharmaceuticals and Poisons Act, 1978 and the Food (Control of Quality) Act, 1978, any subsidiary legislation, licence, certificate and any other administrative order, direction or instruction made, given or issued under or in pursuance of the provisions of the respective Acts which are in force on the commencement of this Act, shall be deemed to have been made, given or issued under or in pursuance of the provisions of this Act, and shall remain in force until revoked, replaced or rescinded by subsidiary legislation, licence, certificate or any administrative order, directions or instruction made or issued under this Act.

(2) All officers appointed pursuant to the Food (Control of Quality) Act, 1978 or the Pharmaceuticals and Poisons Act, 1978 to perform functions in relation to food and drugs, shall continue to perform those functions in so far as this Act relates to them, unless their appointments are revoked or their appointment cancelled and shall for that purpose, be deemed to be inspector appointed under this Act..

## Chapter 6: Conclusion

Ensuring the safety of the food supply require formalized policies and legislative instruments that will provide a coherent framework for national strategies and action. A food safety policy sets out the principles, values, priorities and strategies necessary to enable the development of action to address the main concerns of the sector. Food legislation provides the legal framework for establishing an effective food safety control infrastructure. These Guidelines are aimed at supporting countries to recognize the limitations on the present food control system and build a new system around drafting of a modern food law.

The development and implementation of Food safety Policies and Legislation is a complex process that should be underpinned by the following concepts *inter alia*:

- Early involvement of the public and stakeholders, incorporating a multi-stakeholder consensus approach;
- Openness and transparency;
- Deliberative and accessible process, involving a truly participative approach and;
- Sustained political support and commitment at the highest level throughout the process.

A number of interrelated factors affect food safety so a vital role for those involved in formulating food safety policies is encouraging collaboration, cooperation and coordination of the various sectors so as to facilitate concerted actions and broad-based commitment at addressing concerns. One of the main challenges is to develop skills and a fora that provide all groups concerned with the capacity to effectively participate in policy formulation and implementation processes.

## References

1. National Food Safety Systems in Africa – A Situation Analysis. Paper prepared by FAO Regional Office for Africa for the FAO/WHO Regional Conference on Food Safety for Africa, October 2005. CAF 05/2
2. Second FAO/WHO Global Forum of Food Safety Regulators, Bangkok, Thailand 12-14 October 2004. Legal Basis for Food Safety Official and Non-official Control: Strengthening Official in Health and Development: Report of a Joint FAO/WHO Expert Committee on Food Safety. Geneva, World Health Organization, 1984.
3. Report of the Sixteenth Session of the FAO/WHO Coordinating Committee for Africa. ALINORM 05/28/28.
4. Carnevale. C. W. Regulating Food Safety. Working Paper for the Strategic Planning Meeting on Food Safety. WHO. Geneva. February 2001.
5. Conference on International Food Trade Beyond 2000: Science-Based Decisions, harmonization, Equivalence and Mutual Recognition Melbourne, Australia, 11-15 October 1999. Assuring Food Quality and Safety: Back to the Basics – Quality Control throughout the Food Chain. The Role of Consumers.
6. Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems. FAO Food and Nutrition Paper 76, FAO/WHO Rome 2003.
7. Environmental Policy Implementation: Lessons Learned II. Environmental Policy and Institutional Strengthening Indefinite Quantity Contract (EPIQ) Technical Advisory Group. USAID Global Environment Center. 2001.
8. Paper presented by Uganda on the Second FAO/WHO Global Forum of Food Safety Regulators. CRD 61. Building a Food Safety System in Uganda. Bangkok, Thailand, 12-14 October 2004.
9. World Health Organization (1984). The Role of Food Safety in Health and Development: Report of a Joint FAO/WHO Expert Committee on Food Safety.
10. World Health Organization (1989). Evaluation of programmes to ensure food safety – Guiding principles.
11. Assuring Food Quality and Safety: Back to the Basics – Quality Control throughout the Food Chain. The Role of Governments. Food and Agricultural Organization (FAO). ALICOM 99/10. 1999.
12. 10-Point Regional Strategy for Food Safety in the South-East Asia Region. 1998. World Health Organization Regional Office for South – East Asia.
13. FAO/WHO Model Food Law. FAO and WHO
14. Uruguay Round Agreement: Agreement on the Application of Sanitary and Phytosanitary Measures. [www.wto/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto/english/tratop_e/sps_e/spsagr_e.htm)

15. Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. Procedural Manual; 14<sup>th</sup> Edition/Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme. Rome. FAO. 2004.

## Annex 1

### Basic Food Laws and Enabling Regulations and the Ministries, Department and Agencies Involved

Adapted from Table 1 contained in the paper 'National Food Safety Systems in Africa – A Situation Analysis' prepared for the FAO/WHO Regional Conference of Food Safety for Africa, October 2005 (CAF 05/2)

Country	Legislation	Ministries, Departments and Agencies involved in enforcement and monitoring <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Algeria	Presidential Decree n° 05-118 on iodisation food Executive Decree n° 04-320 of October 2004 on the transparency of the sanitary and phytosanitary measures and obstacles on trade Law on veterinary public health Law on Standardization	Ministry of Commerce Ministry of Trade  Ministry of Agriculture Ministry of Industry
Angola	Law No. 5/87 approving the Sanitary Regulation	Ministry of Health
Benin	Law 84-009. Basic Law governing the control of staple food Regulations on food imports and exports, Street food, food hygiene and labelling	Ministry of Agriculture Ministry of Health and Food, Applied Nutrition Directorate
Botswana	Food Control Act, 1993 (No. 11 of 1993) Disease and Pest Act Permit licensing and Registration of Food Establishments Botswana Agricultural Marketing Board Act, 1974 (No. 2 of 1974) Control of Goods Act, 1973 (No. 23 of 1973) Livestock and Meat Industries Act ( No. 32 of 1962 ) Livestock and Meat Industries (Producers' Agents) Regulations ( No. 8 of 1968)	Ministries of Agriculture, Health, Trade, Tourism Food Control Unit National Food Control Board Ministry of Agriculture  Ministry of Agriculture - Permanent Secretary Ministry of Agriculture
Burkina Faso	Food Hygiene Law 23-94/ADP Law no. 022-2005/AN regarding a Code on public Health Decree n° 2003-670 on the establishment of a general cooperation framework on food safety between the government/partnerships  Control of Pesticide Law 041-96 Standards Decree 98-296	Standardization & Quality Promotion Dir. & National Public Health Lab Ministry of Health   Ministries of Agriculture and Health
Burundi	Decree-law No. 1/036 of December 1989 providing general rules on control quality Decree-law No. 1/16 of May 1982 regarding a code on public health	Ministry of Trade & Industry Ministry of Health
Cameroon	Law No. 64/LF/123 of November 1964 regarding the public health protection Decree no. 011 /CAB/PM of March 2004 on the establishment of an ad hoc committee on food safety	Ministry of Health

Country	Legislation	Ministries, Departments and Agencies involved in enforcement and monitoring <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Cape Verde	<p>Decree-Law No. 100/92 of 17 August 1992 regulating the export of bananas</p> <p>Government Decree no. 1/2005 on infant food public information campaigns, labelling requirements and the related information</p> <p>Government Resolution No. 6/2004 on the National Food Security Sustainable Strategy</p> <p>Decree no. 1/2005 on infant food public information campaigns, labelling requirements and the related information.</p> <p>Decree-Law No. 89/92 providing general rules for the quality control of nationally produced, imported or exported food</p> <p>Decree-Law No. 32/2003 ruling on rice used for human consumption</p> <p>Order No. 6/2001 approving the Regulation of sanitary measures to be applied on fish products</p> <p>Resolution No. 72/98 creating the National Agency for Food Safety - ANSA</p> <p>Decree-Law No. 12/2004 ruling on production, import, export, commercialisation and use of iodated salt</p> <p>Order No. 10/2001 prohibiting bovine importation from areas infected by BSE disease</p> <p>Decree 95030,1995 on Salt Iodization</p>	
Central African Republic	Decree 040-1984 on import and exports	Ministries of Agriculture, Health and Trade and National Animal Husbandry
Chad	<p>Decree 94/499 ruling on production, import, export, commercialisation and use of iodated salt in the Chad Republic</p> <p>Law n° 95-3 1995-02-18/PR on the restructuring of the national office on cereals</p>	
Comoros	Decree n° 82-001/PR on the establishment of a national bureau import and trade of rice	Ministry of Trade
Congo, Rep	Decree n° 86-121 on the commercialisation of dry and salty fish	
Congo, DR	Decree no.364 of September 2000 establishing the list of the authorized additives in the fishery sector	
Cote d'Ivoire	Decree No. 86-454 establishing the power of the government to the municipalities and to the city of Abidjan on veterinary public hygiene measures	Ministries of Finance, Rural Development



Country	Legislation	Ministries, Departments and Agencies involved in enforcement and monitoring <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Eritrea	Fisheries Product Regulations (L.N. No. 40, 41, 105/1998) Fishery Products Additives/Import and Export Regulations (L.N. No. 65/69 of 2003) Heavy Metals Regulations (L.N. No. 66 of 2003) Potable Water Regulations (L.N. No. 68/2003) Regulations regarding Import Permits and Declared Goods (L.N. No. 78 of 2003) Fishery Products Importation and Exportation Regulations (L.N. No. 69 of 2003)	
Ethiopia	Quality & Standards Authority of Ethiopia Establishment Proclamation (No. 102/1998) Emergency Food Security Reserve Administration Establishment Council of Ministers Regulations (No. 67/2000)	Emergency food security reserve administration
Gabon	Decree 00766,1963 on Public Health Ministries of Trade, Agric and Health Decree 01574 on import and exports Decree n° 834/PR/MAEDR establishing a national Codex Alimentarius Committee	Dir. of Competition & Fraud Control Ministry of Agriculture
Gambia	Public Health Act, 1989 (Act No. 1 of 1989) Public Health and Fisheries Acts Regulations on Imports/Exports, Food Establishment, Food Labelling & Certification of Fish Processing Plants	National Nutrition Agency (NaNA) Dept of State for Agriculture, Health & Trade National Nutrition Agency (NaNA)
Ghana	Food and Drugs Law (P.N.D.C.L. 305B, 1992) Standards Decree (N.R.C.D. 173, 1973) General Labelling Rules, 1992 (L.I. No. 1541, 1992) Ghana Standards Board Certification Mark Rule, LI 662,1970 Pest and Plant Disease Act 307, 1965 (L.I. No. 1541, 1992) Pesticides Act 528, 1997	Food and Drugs Board Ghana Standards Board Food and Drugs Board Ghana Standards Board Plant Protection and Regulatory Services Ministries of Health, Food & Agriculture & Trade
Guinea	Decree D/2003/4/PRG/SGG on the establishment of a national commission on food safety and quality (CNSSA)	CNSSA
Guinea Bissau	Decree No. 62-E/92 establishing sanitary food protection	

Country	Legislation	Ministries, Departments and Agencies involved in enforcement and monitoring <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Kenya	<p>Use of Poisonous Substances Act</p> <p>Fertilizer and Animal Foodstuffs (Importation and Use of Meat Animal Bone Meal) (Prohibition) Regulations 2001 (L.N. No. 19 of 2001). Meat Control (Importation of Meat and Meat Products) Regulations, 2001 (L.N. No. 28 of 2001) Sugar (Imports, Exports and By-products) Regulations, 2003 (L.N. No. 39 of 2003) Tea (Packing) Regulations, 1999 (L.N. No. 41 of 1999) Food, Drugs and Chemical Substances Act Cap 254 Public Health Act Cap 242 Standards Act Cap 496 Meat Control Act Cap 356</p> <p>Import Inspection Directive Radiation Protection Act Cap 243 Liquor Licensing Act Cap 121 Meat Control Act 356</p> <p>Pharmacy and Poisons Act Cap 244 Animal Health Act Cap 364</p> <p>Fertilizer and Animal Feedstuff Act Cap 345</p> <p>Dairy Act Cap 336</p> <p>Fisheries Act Cap 378 Pest Control Products Act Cap 346 Seed Act Cap 326 Noxious Seed Act Cap 325 Plant Protection Act Cap 324 Legal notice under Cap 318 Science and Technology Act Cap 256 Agric. produce Act Cap 319</p>	<p>Ministries of Health, Agriculture, Trade &amp; Industry</p> <p>Dept. of Veterinary Services</p> <p>Fish Quality and Safety Unit</p> <p>Kenya Plant Health Inspectorate Service Customs and Excise Dept., KEBS Ministry of Health Ministry of Health Ministry of Trade and Industry Ministry of Health</p> <p>Customs and Excise Dept., KEBS Ministries of Health, Department of Public Health Ministries of Health, Department of Public Health Ministries of Health, Livestock, development and fisheries, Department of Public Health Ministries of Health, Pharmacy and poisons Board Livestock, development and fisheries, Department of Veterinary Services Livestock, development and fisheries, Department of Veterinary Services Livestock, development and fisheries, Agric., Department of Veterinary Services Livestock, development and fisheries, Agric., Department of Fisheries Ministry of Agriculture, Pest Control and Products Board Ministry of Agriculture, Kenya Plant Health Inspectorate Services Ministry of Agriculture, Kenya Plant Health Inspectorate Services Ministry of Agriculture, Kenya Plant Health Inspectorate Services Ministry of Agriculture, Horticultural Crops Development Authority Ministry of Education, Science and Technology, National Council for Science and Technology Ministry of Agric.,</p>

<b>Country</b>	<b>Legislation</b>	<b>Ministries, Departments and Agencies involved in enforcement and monitoring</b> <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Lesotho	Public Health Order 12, 1970 Agricultural Marketing (Import of Sugar) Regulations (L. N. No. 176 of 1989). Marketing Registration 23, 1971 Food Establishment Act 13, 1997 Milk Hygiene Regulation 28, 2000 Street Food Legal Notice 13, 1971	Ministry of Health and Social Welfare Minister of Agriculture Ministry of Industry, Trade & Marketing Ministry of Agriculture Dept. of Chem. - University of Lesotho Dept. of Chem. - University of Lesotho
Madagascar	Food Law, 1st August 1905 Ordinance 73-054 and 73-055 Ordinance 88-015, 1st September 1988 (Facilitate food product import and export)	Ministry of Trade & Industry
Malawi	Meat and Meat Products Act Malawi Dairy Industries Corporation (Establishment) Order, 1987. Milk and Milk Products Act Public Health Act Meat Inspection Regulations Meat Marketing Regulations Pig Grading Regulations Public Health (Condensed Milk) Rules	Depts of Fisheries, Animal Health & Industry  Veterinary Labs, MBS Ministry of Health and Population Ministry of Commerce and Industry Ministry of Agriculture and Irrigation National Quality Control Lab Veterinary Labs, MBS
Mali	Decree n°01-175/pm-rm on capacity building against poverty Decree n°00-183/p-rm on the ruling of the public services of the water for consumers	Ministry of Agriculture, Ministries of Health, Trade Ministry of Public Health
Mauritania	Food Regulations made under the Food Act 1998 Decree n° R-0017 on the definition of the elaborate product of fishing Sale of Frozen Foods Regulations 1985 (G.N. No. 113 of 1985)	Ministries of Health and Trade Ministry of Fisheries Food Hygiene Lab and Cen. for Animal Husbandry & Vet. Research
Mauritius	Environment protection (Polyethylene Terephthalate) (PET) bottle Permit) Regulations 2001 (G.N. No. 33 of 2001). Food Act 1998 (Act No. 1 of 1998) Food and Drugs Act 25 May 1940 Meat Act 3/665 November 1974 Food Regulations made under the Food Act 1998	Ministry of Health & Quality of Life Ministry of Health & Quality of Life Mauritius Meat Authority Ministry of Health & Quality of Life

Country	Legislation	<b>Ministries, Departments and Agencies involved in enforcement and monitoring</b> <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Mozambique	Order No. 56/2001 approving the Customs regime applicable to sugar import. Decree No. 72/98, implementing the water supply policy Public Health Act 11, Fisheries Law 3, 1990  Standards Decree 2, 1993 Ministerial Order No. 120/87 approving quality standards for wheat, corn and their flours Ministerial Order No. 51/84 approving hygiene regulations for food handling establishments Ministerial Order No. 80/87 approving the hygiene Regulation on food imports Order No. 184/75 establishing copra oil as edible oil and defining its characteristics Order No. 23.964 defining sunflower seed oil as an edible oil and establishing quality standards	Ministries of Development, Agriculture, Trade & Industry Ministries of Fisheries, Trade and Agriculture National Inst. of Standards and Quality  National Food Lab Ministry of Trade Ministry of Health  Ministry of Health
Namibia	Public Health Act No. 36 of 1919 Standards Act No. 33 of 1962, Export/Registration of Foodstuffs Cosmetics and Disinfectants Order No. 18 of 1979 General Registration GN 121 of 1969 Prevention of Undesirable Residue in Meat Amendment Act, 1994 (Act No. 11 of 1994) Meat Act, 1991 (G.N. No. 220 of 1994) Amendment of Regulations relating to the standards of food, drugs and disinfectants (No. 124 of 1994). Regulations Relating to Grading and Classification of Maize (No. 71 of 1994) Standards of Composition of Maize Products: Agronomy Industry Act, 1992 (No. 72 of 1994)	Ministry of Health Ministry of Agriculture, Water & Rural Development University of Namibia (Dept of FS & Tech) SABS Customs & Excise Prime Minister  Meat Board of Namibian Agronomic Board Ministry of Health & Social Services  Ministry of Agriculture, Water, Rural Development Ministry of Agriculture
Niger	Decree 98-108, 1998 on Food Imports/exports Decree n° 76/MDR/CAB on the promotion and organization of agricultural exportation projects implemented by decree n° 77/MDR/CAB and decree n° 78/MDR/CAB Order n° 35/MDR/CAB, 2001 on the establishment of a Committee on food safety implements decree n. 2000-147 ruling the rural development ministry assignments Order n° 09/CAB/PM/2001 establishing a committee for food safety policies  Laws on fraud control 1905  Gen Order 131, 1941 on the preparation of meat  Order 3278, 1942 on imports/exportation of animals, Meat and other animal products	Ministry of Agricultural Development Ministry of Rural Development      Ministry of Public Health Ministry of Trade & Industry National Public Health Lab

Country	Legislation	Ministries, Departments and Agencies involved in enforcement and monitoring <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Nigeria	Counterfeit and Fake Drugs and Unwholesome Processed Food Decree, (Act No. 25 of 1999) National Agency for Food and Drug Administration and Control (Amendment) Decree 1999 (No. 19 of 1999) Food and Drugs (Amendment) Decree 1999 (No. 21 of 1999) National Agency for Food and Drug Administration and Control Decree 1993 (No. 15 of 1993) Public Health Ordinance Cap 164 of 1958 The Standards Organisation of Nigeria Decree, No. 56 of 1971 The Animal Disease Control Decree, No. 10 of 1988 The Marketing of Breast Milk substitute Decree, No. 41 of 1990	Federal Ministry of Health Food and Drug Agency  Food & Drug Administration & Control (NAFDAC) Standards Organization of Nigeria (SON) National Codex Committee Standards Organization of Nigeria (SON) Federal Ministry of Agriculture
Rwanda	Order no. 74/453 of December 1952 ruling the sanitary procedure on food amended by order 74/416 of December 1953 Order n° 41-38 of March 1956 ruling the commercialization of Wheat	
Senegal	Decree n° 99-259 on horticultural products quality and control Decree n° 98-554 on the establishment of a national food safety Counsel	Ministry of Agriculture Ministry of Agriculture
Seychelles	Food Act 1987 (Act No. 14 of 1987)	
Sierra Leone	Public Health Act 23, 1960 Fisheries Management Act, 1994 Standards Act 12, 1996, Registration on Food Establishment, Street Foods, Export & Imports	Ministry of Health & Sanitation Ministry of Agriculture, Forestry & Marine Resources Sierra Leone Standards Bureau (SLSB)
South Africa	Regulations relating to labelling of alcoholic beverages (No. 109 of 2005) Regulations governing general hygiene requirements for food premises and the transport of food of 12 July 2002 Agreement between the European Community and the Republic of South Africa on trade in spirits - November 2002 Meat Safety Act, 2000 Foodstuffs, cosmetics & Disinfectant, Act No. 54 of 1972 Health Act No. 63 of 1977 Standards Act No. 29 of 1993 Food, Drugs & Disinfectant Act No. 13 of 1929 Trade Metrology Act No. 77 of 1973 Regulations on Food Establish & Export/Import The International Health Regulations Act, 1974 (Act 28 of 1974) The Medicines and Related Substances Act, 1965 (Act 101 of 1965) Wine and Spirits Control Act Regulations governing general hygiene requirements for food premises and the transport of food (G. N. No. R.918 of 1999)	Ministry of Health Ministry of Health  Dept. of Health & SABS Dept. of Agriculture Ministry of Health SABS Dept. of Trade & Industry Dept. of Trade & Industry Customs & Excise Division Ministry of Health Ministry of Health

Country	Legislation	<b>Ministries, Departments and Agencies involved in enforcement and monitoring</b> <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Swaziland	Public Health Act No. 5 of 1969 Slaughter House Act. No. 10, 1964 Sale of Adulterated Food Act No. 25, 1968 Food Hygiene Regulation 1973 Bakery Regulation, 1974	Ministry of Health & Social Services (MOHSS) Vet. Services Laboratory & Swaziland Meat Industries University of Swaziland (Lect. of Health Sev.) Ministry of Enterprises & Employment Ministry of Enterprises & Employment
Tanzania	Coffee Industry Act, 2001 (Act No. 23 of 2001) Food (Control of Quality) Act, 1978 (Act No. 10 of 1978) Sugar Industry Act, 2001 (Act No. 26 of 2001) Produce Export Ordinance Adulteration of Produce Decree (Cap. 109) Cashew Nut (Marketing) Regulations, 1996 (G.N. No. 369 of 1996) Fish (Quality Control and Standards) Regulations, 2000 (L.N. No. 300 of 2000) Tea Regulations (S.I. No. 92 of 1999) Plant Protection Act 13, 1975 Public Health Act Fisheries Act 6, 1970 Vet. Act Standard Act 3, 1975	Ministry Agric & Food Security Government Chemist Lab, Agency Ministry of Industry & Trade  National Food Control Commission Ministry of Health Ministry of Agriculture & Food Security Tanzania Bureau of Standards (TBS) Ministry of Natural Resources & Tourism Ministry of Health Ministry of Fisheries
Togo	Law n° 57-16 on the commercialization of local fishing	Ministry of Commerce and Industry, Finance
Uganda	Public Health Act, 1964 Plant Protection Act 1962 Fish Quality Assurance Rule Import/Inspection of Clearance Rules, 2002 Standard Act, 1983, Registration on Food Establishment	Ministry of Health, Tourism, Trade & Industry Ministry of Agriculture, Animal Industry & Fisheries Uganda National Bureau of Standards Uganda Revenue Authority (Chemist) Ministry of Agriculture
Zambia	Dairies and Dairy Produce Act (Chapter 342) Food Reserve (Designated Commodities) Standard of Conduct (Amendment) Regulations (S.I. No. 41 of 2004) amending Regulations S.I. No. 94 of 1996 Dairy Produce Board (Establishment) Act (Cap. 350) Dairies and Dairy Produce Regulations (Chapter 342) Grain Marketing (Acceptance Standards) Regulations. (S.I. No. 296 of 1969) Food & Drugs Acts, Cap 303 Food/Drug Registration SI 90/2001 Public Health Act, Cap 295 Plant Pesticides Act Cap 252 Standard Act Cap 416, Registration on Exports/Imports and Food Establishments	Ministry of Agriculture & Cooperation Ministry of Agriculture  Central Board of Health Central Vet. Research Institute Customs & Excise Division Food & Drugs Laboratory Ministries of Health, Commerce, Trade & Industry ZBS National Food & Nut Commission

Country	Legislation	<b>Ministries, Departments and Agencies involved in enforcement and monitoring</b> <i>(MDAs not in any particular or specific order in relation to the enforcement of food laws for each country. Mandates and functions overlap)</i>
Zimbabwe	Dairy Act Food and Food Standards Act Fruit Marketing Act (No. 55 of 1966) Public Health Act (Chapter 15:09)  Animal Health (Import) Regulations (S.I. No. 57 of 1989) Produce Export Act	Ministry of Agriculture Minister of Health and Child Welfare Ministry of Agriculture Minister of Health and Child Welfare Advisory Board for Public Health  Ministry of Agriculture Ministry of Agriculture

## **Box 16: Food Safety Country Situation Analysis**

The food safety situation analysis should include information, as appropriate, on:

### **Status of food and agriculture**

- Primary food and agriculture production; food processing industry (types and number of establishments, processing capacity, value of production etc); food distribution and marketing.
- Formal and informal industry
- Potential for industry development.
- Food chain, and identification of key intermediaries who may influence quality and safety of foods.
- Market infrastructure including assets and deficiencies.
- Safety and quality management programmes including level of HACCP implementation in the industry.
- Food consumption data. Information on consumers will include data on energy/protein intake, percentage of the population dependent upon subsistence economy, per capita income etc.
- Cultural, anthropological, and sociological data is also important, including information on food habits and food preferences.

### **Food security, food imports and nutritional objectives**

- Food demand for nutritional requirements; post-harvest food losses; type and quantities of food imports.

### **Consumer concerns or demand**

- Consumer demand on safety, quality and information (labeling) issues.

### **Food Exports**

- Quantity and value of food exports and potential for growth in export trade.
- Data on detentions or rejections of food exported.
- Number and types of complaints from buyers and remedial action.
- Identification of foods with potential for export and target countries for export.

### **Epidemiological information**

- Prevalence and incidence of food borne disease; procedures used for investigating and notifying food borne diseases; information on food incriminated; suitability of collected data for risk assessment purpose.

### **Food contaminants data**

- Prevalence and level of contamination of food; monitoring programmes for biological and chemical contamination of food; suitability of collected data for risk assessment purpose.

### **Human resources and training requirements**

- Number and qualification of personnel involved in food control i.e. staff engaged in inspection, analysis and epidemiological services; information regarding on-going training, and educational activities; projections on future staffing and training needs.

### **Extension and advisory services**

- Existing extension and advisory services for the food sector as provided by the government, industry, trade associations, non-governmental organizations, and educational institutions; train-the-trainer type of activities; training needs analysis.



### **Public education and participation**

- Consumer education initiatives in food hygiene; potential for increased involvement and interaction between government, consumer associations, non-governmental organizations, and educational institutions in risk communication activities; risk communication to prevent food borne diseases and possible improvements.

### **Government organization of food control systems**

- Listing of government departments and authorities concerned with food safety and food control activities.
- Description of the food control system and an overview of the resources, responsibilities, functions, and coordination between the entities; methods of determining priorities for action; options for raising resources.

### **Food legislation**

- Current food legislative arrangements, including regulations, standards, and codes of practice.
- Authorities empowered to prepare regulations and standards, and how they coordinate their activities and consult with industry and consumer organizations.
- Capacity to carry out risk assessment.

### **Food control infrastructure and resources**

- Organization of inspection, surveillance, and enforcement activities (national, provincial, and local levels).
- Number and qualifications of inspection personnel.
- Resources within inspection agency, and assessment of strengths and weaknesses. Analytical support facilities (number of laboratories, facilities and equipment, monitoring programmes, etc).
- Codes of hygienic practice.
- Licensing arrangements for food premises.

From 'Assuring food safety and quality: Guidelines for Strengthening National Food Control Systems'.  
FAO/WHO. 2003

## Annex 2

# Food Law Examples from outside the African Region

### A Scope and Definitions (*see 5.1*)

#### A.1 Scope (*see 5.1.1*)

##### **Box 17: Example of details to be included in the section on scope of Food Law**

###### **European Union**

Regulation 178/2002

###### **Article 1 - Aim and scope**

1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.

It establishes the European Food Safety Authority.

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

#### A.2 Definitions (*See 5.1.2*)

##### ***Definition of Food***

Note that the recent definition adopted by the European Union (given below) is an example of the use of the Codex Alimentarius Commission's definition of 'food'. The initial sentence is clearly based on the Codex definition but it then provides clarification for a number of situations where more precision is needed at the interface with other legislation. As an example, it was considered necessary to clarify the circumstances under which 'water' is considered as a food item and when it is covered by water supply requirements. The sale of bottled water is considered as a sale of food but when the water is in pipes it is subject to different legislation.

## **Box 18: Examples of Definitions of Food from the European Union**

### **European Union**

Regulation 178/2002

#### **Food**

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' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;
- (e) cosmetics within the meaning of Council Directive 76/768/EEC;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants.

### **United States of America**

Food, Drug and Cosmetic Act 1938 (as amended)

#### **Food** – means

- (1) articles used for food or drink for man or other animals,
- (2) chewing gum, and
- (3) articles used for components of any such article.

### ***Other Definitions***

In the example below, it can be noted that the European Union has included definitions linked to risk analysis and its components. These are based on those adopted by the Codex Alimentarius Commission. Within the European Union food law Regulation there is great emphasis put on the allocation of responsibilities between the different bodies within the European Union (for example, the Commission, the Member States and the European Food Safety Authority). This allocation uses the components of risk analysis and therefore it is appropriate to include the definitions in the Regulation.

## **Box 19: Examples of definitions of other terms from the European Union and the United States of America**

### **European Union**

Regulation 178/2002

**Food law** - the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals.

**Food business** - 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.

**Food business operator** - the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

**Feed (or Feedingstuff)** - any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

**Feed business** - any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding.

**Feed business operator** - the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control.

**Retail** - the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets.

**Placing on the market** - the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.

**Risk** - a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

**Risk analysis** - a process consisting of three interconnected components: risk assessment, risk management and risk communication.

**Risk assessment** - a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

**Risk management** - the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

**Risk communication** - the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

**Hazard** - a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.

**Traceability** - the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

**Stages of production, processing and distribution** - any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed.

**Primary production** - the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.

**Final consumer** - the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

### **United States of America**

Food, Drug and Cosmetic Act 1938 (as amended)

**Food additive** - means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include -

- (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
- (2) a pesticide chemical; or
- (3) a color additive; or
- (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];
- (5) a new animal drug; or
- (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement

**Label** - means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

**Labeling** - means all labels and other written, printed, or graphic matter

- (1) upon any article or any of its containers or wrappers, or
- (2) accompanying such article.

**Infant formula** - means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

**Processed food** - means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling

## **B General Principles** (*see* 5.2)

### **B.1 Key Offences** (*see* 5.2.1)

#### **Box 20: Examples of Offences from the European Union and the United States of America**

##### **European Union**

Regulation 128/2002

##### **Article 14 - Food safety requirements**

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
  - (a) injurious to health;
  - (b) unfit for human consumption.
3. In determining whether any food is unsafe, regard shall be had:
  - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
  - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.
4. In determining whether any food is injurious to health, regard shall be had:
  - (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
  - (b) to the probable cumulative toxic effects;
  - (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.
5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.
8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.
9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

##### **Article 16 – Presentation**

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

## United States of America

Food, Drug and Cosmetic Act 1938 (as amended)

### Section 331:

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

... continues ...

*The above prohibitions can only full understood by reference to Sections 342 and 343 which define the terms 'adulterated' and 'misbranded':*

### Section 342

A food shall be deemed to be **adulterated**—

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.[1]

(2)

(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a (a) of this title; or

(C) if it is or if it bears or contains

(i) any food additive that is unsafe within the meaning of section 348 of this title; or

(ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

... continues ...

### Section 343

A food shall be deemed to be **misbranded**—

(a) *False or misleading label*

If

(1) its labeling is false or misleading in any particular, or

(2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350 (b)(2) of this title.

(b) *Offer for sale under another name*

If it is offered for sale under the name of another food.

(c) *Imitation of another food*

If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) *Misleading container*

If its container is so made, formed, or filled as to be misleading.

... continues ...

## B.2 Defences (see 5.2.2)

An interesting form of defence, known as ‘due diligence’ has been introduced in the United Kingdom and can be seen in Section 21 of the Food Safety Act quoted in Box 57 below. Here the expectation is that all food businesses will need to consider the legal position of the food they are selling. Here they are required to show that

*“he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.”*

In this defence it is expected that all food businesses will need to consider the implications of what they are doing. They will need to take appropriate precautions to avoid breaking the law. However, the word ‘reasonable’ is used to indicate that small business will not be expected to undertake as many checks as large business. Businesses will have to be diligent – they will need to check that their procedures are working and effective. It is not acceptable simply to say that a system of checks was established, for temperature controls for example, without demonstrating to the court that the thermometers were also subject to calibration. Additional provisions are provided to cover various different uses of the defence (see subsection (2)-(4)).

The UK defence is based on a significant amount of case law and is unlikely to be suitable for many countries without detailed guidance and preparation. For this reason, the warranty defence is still likely to be important as a means of providing some protection for honest traders who have themselves purchased illegal food items.

### **Box 21: Examples of defences from the United Kingdom**

#### **United Kingdom**

##### **Food Safety Act 1990**

##### **Section 20 - Offences due to fault of another person.**

Where the commission by any person of an offence under any of the preceding provisions of this Part is due to an act or default of some other person, that other person shall be guilty of the offence; and a person may be charged with and convicted of the offence by virtue of this section whether or not proceedings are taken against the first-mentioned person.

##### **Section 21 - Defence of due diligence.**

(1) In any proceedings for an offence under any of the preceding provisions of this Part (in this section referred to as "the relevant provision" ), it shall, subject to subsection (5) below, be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.

(2) Without prejudice to the generality of subsection (1) above, a person charged with an offence under section 8, 14 or 15 above who neither—

- (a) prepared the food in respect of which the offence is alleged to have been committed; nor
- (b) imported it into Great Britain,

shall be taken to have established the defence provided by that subsection if he satisfies the requirements of subsection (3) or (4) below.

(3) A person satisfies the requirements of this subsection if he proves—

- (a) that the commission of the offence was due to an act or default of another person who was not under his control, or to reliance on information supplied by such a person;
- (b) that he carried out all such checks of the food in question as were reasonable in all the circumstances, or that it was reasonable in all the circumstances for him to rely on checks carried out by the person who supplied the food to him; and

(c) that he did not know and had no reason to suspect at the time of the commission of the alleged offence that his act or omission would amount to an offence under the relevant provision.

(4) A person satisfies the requirements of this subsection if he proves—

- (a) that the commission of the offence was due to an act or default of another person who was not under his control, or to reliance on information supplied by such a person;
- (b) that the sale or intended sale of which the alleged offence consisted was not a sale or intended sale under his name or mark; and



(c) that he did not know, and could not reasonably have been expected to know, at the time of the commission of the alleged offence that his act or omission would amount to an offence under the relevant provision.

(5) If in any case the defence provided by subsection (1) above involves the allegation that the commission of the offence was due to an act or default of another person, or to reliance on information supplied by another person, the person charged shall not, without leave of the court, be entitled to rely on that defence unless—

(a) at least seven clear days before the hearing; and

(b) where he has previously appeared before a court in connection with the alleged offence, within one month of his first such appearance,

he has served on the prosecutor a notice in writing giving such information identifying or assisting in the identification of that other person as was then in his possession.

(6) In subsection (5) above any reference to appearing before a court shall be construed as including a reference to being brought before a court.

### **Section 22 - Defence of publication in the course of business.**

In proceedings for an offence under any of the preceding provisions of this Part consisting of the advertisement for sale of any food, it shall be a defence for the person charged to prove—

(a) that he is a person whose business it is to publish or arrange for the publication of advertisements; and

(b) that he received the advertisement in the ordinary course of business and did not know and had no reason to suspect that its publication would amount to an offence under that provision.

## **C Enforcement Provisions (see 5.4)**

### **C.1 Enforcement Officers and their Powers (see 5.4.1)**

#### **Box 22: Examples of enforcement provisions from the European Union and the United Kingdom**

##### **European Union**

Regulation (EC) No 882/2004

##### **Article 6 Staff performing official controls**

The competent authority shall ensure that all of its staff performing official controls:

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. This training shall cover as appropriate the areas referred to in Annex II, Chapter I;

(b) keep up to date in their area of competence and receive regular additional training as necessary; and

(c) have aptitude for multidisciplinary cooperation.

##### **Annex II, Chapter I - Subject matter for the training of staff performing official controls**

1. Different control techniques, such as auditing, sampling and inspection

2. Control procedures

3. Feed and food law

4. 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

5. Assessment of non-compliance with feed and food law

6. Hazards in animal feed and food production

7. The evaluation of the application of HACCP procedures

8. 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

9. Official certification systems

10. Contingency arrangements for emergencies, including communication between Member States and the Commission

11. Legal proceedings and implications of official controls

12. 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

13. Any other area, including animal health and animal welfare, necessary to ensure that official controls are carried out in accordance with this Regulation.

##### **Article 10 - Control activities, methods and techniques**

1. Tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.
2. Official controls on feed and food shall include, *inter alia*, the following activities:
  - (a) examination of any control systems that feed and food business operators have put in place and the results obtained;
  - (b) inspection of:
    - (i) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;
    - (ii) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;
    - (iii) semi-finished products;
    - (iv) materials and articles intended to come into contact with food;
    - (v) cleaning and maintenance products and processes, and pesticides;
    - (vi) labelling, presentation and advertising;
  - (c) checks on the hygiene conditions in feed and food businesses;
  - (d) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation;
  - (e) examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;
  - (f) interviews with feed and food business operators and with their staff;
  - (g) the reading of values recorded by feed or food business measuring instruments;
  - (h) controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;
  - (i) any other activity required to ensure that the objectives of this Regulation are met.

## **United Kingdom**

Food Safety Act 1990, Section 5

### **Section 5**

(6) In this Act "authorised officer", in relation to a food authority, means any person (whether or not an officer of the authority) who is authorised by them in writing, either generally or specially, to act in matters arising under this Act; but if regulations made by the Ministers so provide, no person shall be so authorised unless he has such qualifications as may be prescribed by the regulations.

### **Section 9 - Inspection and seizure of suspected food.**

(1) An authorised officer of a food authority may at all reasonable times inspect any food intended for human consumption which—

(a) has been sold or is offered or exposed for sale; or

(b) is in the possession of, or has been deposited with or consigned to, any person for the purpose of sale or of preparation for sale;

and subsections (3) to (9) below shall apply where, on such an inspection, it appears to the authorised officer that any food fails to comply with food safety requirements.

(2) The following provisions shall also apply where, otherwise than on such an inspection, it appears to an authorised officer of a food authority that any food is likely to cause food poisoning or any disease communicable to human beings.

(3) The authorised officer may either—

(a) give notice to the person in charge of the food that, until the notice is withdrawn, the food or any specified portion of it—

(i) is not to be used for human consumption; and

(ii) either is not to be removed or is not to be removed except to some place specified in the notice; or

(b) seize the food and remove it in order to have it dealt with by a justice of the peace;

and any person who knowingly contravenes the requirements of a notice under paragraph (a) above shall be guilty of an offence.

(4) Where the authorised officer exercises the powers conferred by subsection (3)(a) above, he shall, as soon as is reasonably practicable and in any event within 21 days, determine whether or not he is satisfied that the food complies with food safety requirements and—

(a) if he is so satisfied, shall forthwith withdraw the notice;

(b) if he is not so satisfied, shall seize the food and remove it in order to have it dealt with by a justice of the peace.

(5) Where an authorised officer exercises the powers conferred by subsection (3)(b) or (4)(b) above, he shall inform the person in charge of the food of his intention to have it dealt with by a justice of the peace and—

(a) any person who under section 7 or 8 above might be liable to a prosecution in respect of the food shall, if he attends before the justice of the peace by whom the food falls to be dealt with, be entitled to be heard and to call witnesses; and

(b) that justice of the peace may, but need not, be a member of the court before which any person is charged with an offence under that section in relation to that food.

(6) If it appears to a justice of the peace, on the basis of such evidence as he considers appropriate in the circumstances, that any food falling to be dealt with by him under this section fails to comply with food safety requirements, he shall condemn the food and order—

(a) the food to be destroyed or to be so disposed of as to prevent it from being used for human consumption; and

(b) any expenses reasonably incurred in connection with the destruction or disposal to be defrayed by the owner of the food.

(7) If a notice under subsection (3)(a) above is withdrawn, or the justice of the peace by whom any food falls to be dealt with under this section refuses to condemn it, the food authority shall compensate the owner of the food for any depreciation in its value resulting from the action taken by the authorised officer.

(8) Any disputed question as to the right to or the amount of any compensation payable under subsection (7) above shall be determined by arbitration.

(9) In the application of this section to Scotland—

(a) any reference to a justice of the peace includes a reference to the sheriff and to a magistrate;

(b) paragraph (b) of subsection (5) above shall not apply;

(c) any order made under subsection (6) above shall be sufficient evidence in any proceedings under this Act of the failure of the food in question to comply with food safety requirements; and

(d) the reference in subsection (8) above to determination by arbitration shall be construed as a reference to determination by a single arbiter appointed, failing agreement between the parties, by the sheriff.

#### **Section 10 - Improvement notices**

(1) If an authorised officer of an enforcement authority has reasonable grounds for believing that the proprietor of a food business is failing to comply with any regulations to which this section applies, he may, by a notice served on that proprietor (in this Act referred to as an "improvement notice")—

(a) state the officer's grounds for believing that the proprietor is failing to comply with the regulations;

(b) specify the matters which constitute the proprietor's failure so to comply;

(c) specify the measures which, in the officer's opinion, the proprietor must take in order to secure compliance; and

(d) require the proprietor to take those measures, or measures which are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.

(2) Any person who fails to comply with an improvement notice shall be guilty of an offence.

(3) This section and section 11 below apply to any regulations under this Part which make provision—

(a) for requiring, prohibiting or regulating the use of any process or treatment in the preparation of food;

or

(b) for securing the observance of hygienic conditions and practices in connection with the carrying out of commercial operations with respect to food or food sources.

## C.2 Sampling and Analysis (see 5.4.2)

### Box 23: Examples of Legal Procedures for Sampling from the European Union

#### European Union

Regulation 882/2004

#### Article 11 - Methods of sampling and analysis

1. Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or,
  - (a) if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation;or,
  - (b) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.
2. Where paragraph 1 does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.
3. Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III.
4. The following implementing measures may be taken in accordance with the procedure referred to in Article 62(3):
  - (a) methods of sampling and analysis, including the confirmatory or reference methods to be used in the event of a dispute;
  - (b) performance criteria, analysis parameters, measurement uncertainty and procedures for the validation of the methods referred to in (a);and
  - (c) rules on the interpretation of results.
5. The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of competent authorities to take prompt action in case of emergency.
6. In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.
7. Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.

#### Article 12 - Official laboratories

1. The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls.
2. However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:
  - (a) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
  - (b) EN 45002 on 'General criteria for the assessment of testing laboratories';
  - (c) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition',taking into account criteria for different testing methods laid down in Community feed and food law.
3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.
4. The competent authority may cancel the designation referred to in paragraph 1 when the conditions referred to in paragraph 2 are no longer fulfilled.