CHAPTER

2

Development of Food Legislation Around the World[1]

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2.1 INTRODUCTION

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2.1.1 We Always Eat

Eating and drinking are among the few things that, without a single exception, everyone does. A custom we share with all our contemporaries and ancestors. It is obvious that where a concept of law is developed it will quickly lead to rules related to the acquiring and distributing of food. German introductory literature (for example, Lips & Beutner, 2000) on food law likes to refer to the discovery of a Phoenician inscription that dates back to 1000 BC. Some believe this the oldest food regulation still in our possession.[2] It reads: 'Thou shall not cast a spell on thy neighbor's wine'.

There is, however, much more law than just statutory regulations. Echoes of food law resound from an even more distant past. The oldest pieces of writing, for instance, that remain of Pharaonic Egypt are food labels (Seidlmayer, 1998). They date back to the first dynasty, i.e. 3000 BC. Archaeologists are very fond of labels as they provide a wealth of information on many different aspects of a culture. They contain at least three types of texts: names of products,[3] specifications of quantities[4] and dates.[5] For lawyers it is just a small step to suspect a general rule behind the label stipulating that the product, quantity and date stated must be correct. It does not matter whether that general rule has been issued by a ruler, has a religious origin or is rooted in the conviction of the parties concerned that this is as it should be. All constitute a source of law and thus a rule of law. Of course we do not know what the consequences were of violation of that rule of law. Were there sanctions? Could a buyer return an improperly labeled product?

The role of the authorities in ancient Egyptian food law is also unknown. The Bible-book of Genesis[6] shows that a vice-pharaoh who in times of plenty had stores laid up to feed his people in the years of famine was regarded as extremely wise. It seems that concern for his people, although appreciated, was not one of the standard responsibilities of a ruler.

2.1.2 Food and Values

In modern time food is recognized as a human right. The right to adequate food is mentioned in the Universal Declaration on Human Rights (Article 25) and laid down in several international treaties of which the International Covenant on Economic, Social and Cultural Rights (Article 11) is probably the most important. International organizations such as the Food and Agriculture Organization (FAO) and the UN Committee on Economic, Social and Cultural Rights have further elaborated this right.[7] The right to adequate food is realized if people have access to food that:

- provides sufficient nutritional value and micronutrients for a person to lead a healthy and active life;
- is free of hazardous substances;
- is acceptable within a given culture.

[2]This is debatable, however. The famous Babylonian Code of Hammurabi is about a millennium older and also holds provisions that may be understood to relate to the adulteration of food.
[3]They provide information on language.
[4]They provide information on measurements and weights.
[5]They provide information on chronology—crucial to archaeologists.
[6]Genesis 41: 37–57.
[7]See for example the Voluntary Guidelines to support the progressive realisation of the right to adequate food in the context of national food security: <http://www.fao.org/docrep/meeting/009/y9825e/y9825e00.htm>.

Rights always go hand in hand with obligations. Human rights go hand in hand with state obligations. Regarding the right to food three types of obligations are distinguished:

1. The obligation *to respect*. In general people are able to care for themselves and their families. This ability may not be curbed without sound legal justification; this is in line with other fundamental rights such as the freedom of expression for instance.
2. The obligation *to protect*. If the ability of citizens to provide for themselves is threatened by other citizens the government must do its best to protect these citizens from the others.
3. The obligation *to fulfill*. This obligation is composed of a policy obligation and a relief obligation. On the one hand a prudent government is expected to adopt policy geared towards supporting and promoting the ability of the population to provide for itself, on the other hand it must do its best to provide assistance if people find themselves in a situation in which they cannot provide for themselves through no fault of their own.

Here below we will see that it is mainly the second aspect of adequate food (safety) and the second state obligation (to protect) that is taken up in the food regulatory systems as we find them today in all over the world.

2.1.3 This Chapter

Legislation on food is not only widely distributed in time, but also in space. We may expect to find law relating to food in all corners of the globe. This book is not a place to attempt a systematic overview. In this chapter a variety of systems are presented (International, India, South Africa, Eastern Africa, Australia and New Zealand, United States of America, Canada, Latin America, the EU, the Near East, Northeast Asia, China and the Russian Federation) in the perspective of their development to give an impression of the features found in food law and the reasons why they have taken certain forms. Each section has its own separate author or authors, indicated at its beginning. The authors have based their contributions on an open question to present highlights in development, not on strict guidelines. Personal differences in style and approach of the subject matter have been respected.

In the systems presented we repeatedly find a complex situation due in part to the distribution of the subject matter over different competent authorities. We find product specific provisions alongside legislation of a more general nature. In all systems presented here, safety is an important consideration for the legislators concerned who increasingly rely on science. Repeatedly reference is made to international developments and standards such as the *Codex Alimentarius*. For this reason this chapter opens with a section introducing international food law as a background to the national and regional systems discussed thereafter.

2.2 INTERNATIONAL FOOD LAW

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2.2.1 *Codex Alimentarius*

In 1961 the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) established the Codex Alimentarius Commission (CAC). Over the years the CAC has established specialized committees. These committees are hosted by member states all over the world. Some 175 countries, representing about 98% of the world's population, participate in the work of *Codex Alimentarius*.

Food standards are established through an elaborate procedure of international negotiations (FAO/WHO, 2006). All standards taken together are called '*Codex Alimentarius*'. In Latin

this means 'food code'. It can be seen as a virtual book filled with food standards. The food standards represent models for national legislation on food.

Beside the food standards, *Codex Alimentarius* includes advisory provisions called codes of practice or guidelines. These codes of practice and guidelines mainly address food businesses.

At present the Codex comprises more than 200 standards, close to 50 food hygiene and technological codes of practice, some 60 guidelines, over 1,000 food additives and contaminants evaluations and over 3,200 maximum residue limits for pesticides and veterinary drugs. Finally, the *Codex Alimentarius* includes requirements of a horizontal nature on labeling and presentation and on methods of analysis and sampling (FAO/WHO, 2002, 2006; Masson-Matthee, 2007).

TABLE 2.1 Some definitions in the *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.
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.

TABLE 2.2 Some principles in the *Codex Alimentarius* Procedural Manual

Statements of Principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account
1. The food standards, guidelines and other recommendations of *Codex Alimentarius* shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards *Codex Alimentarius* will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

2.2.2 Procedural Manual

The 'constitution' of the *Codex Alimentarius* is the Procedural Manual. The Procedural Manual not only gives the procedures and format for setting Codex Standards and Guidelines, but also some general principles and definitions (Table 2.1). The principles relate among other things to the scientific substantiation of the work of *Codex Alimentarius* and the use of risk analysis for food safety (Table 2.2).

2.2.3 Standards

The work of the CAC has resulted in a vast collection of internationally agreed food standards that are presented in a uniform format. Most of these standards are of a vertical (product specific) nature. They address all principal foods, whether processed, semi-processed or raw. Standards of a horizontal nature are often called 'general standards', like the General Standard for the Labeling of Pre-packaged Foods.[8]

[8]CODEX STAN 1-1985 (Rev. 1-1991).

According to this general standard, the following information shall appear on the labeling of pre-packaged foods:

- the name of the food; this name shall indicate the true nature of the food;
- list of ingredients (in particular if one of a list of 8 allergens is present);
- net contents;
- name and address of the business;
- country of origin where omission could mislead the consumer;
- lot identification;
- date marking and storage instructions;
- instructions for use.

2.2.4 Codes

In addition to the formally accepted standards the Codex includes recommended provisions called codes of practice or guidelines. There is, for example, a 'Code of Ethics for International Trade in Food',[9] and a set of hygiene codes like the 'Recommended International Code of Practice General Principles of Food Hygiene' and the 'Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application' (Table 2.3).

TABLE 2.3 The principles of HACCP according to *Codex Alimentarius*

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

2.2.5 Legal Force

The Codex standards do not represent legally binding norms. They present models for national legislation. Member states undertake to transform the Codex standards into national legislation. However, no sanctions apply if they do not honor this undertaking.

By agreeing on non-binding standards, the participating states develop a common language. All states and other subjects of international law will mean the same thing; for example, when they meet to negotiate about food, they mean 'food' as defined in the Codex. The same holds true for 'milk' and 'honey' and all the standards that have been agreed upon. The notion of HACCP has been developed—and is understood—within the framework of *Codex Alimentarius*.[10] In this way the *Codex Alimentarius* provides a common frame of reference, but there is more.

The mere fact that national specialists on food law enter into discussion on these standards will influence them in their work at home. A civil servant drafting a piece of legislation will look for examples. As regards food s/he will find examples in abundance in the Codex. In these subtle ways the *Codex Alimentarius* is likely to have a major impact on the development of food law in many countries even without a strict legal obligation to implement.

It turns out more than once that soft law has a tendency to solidify. Once agreements are reached, parties tend to put more weight on them than was initially intended. This is true for Codex standards as well. Due to several

[9]CAC/RCP 20-1979 (Rev. 1-1985).
[10]Recommended International Code Of Practice General Principles Of Food Hygiene CAC/RCP 1-1969, Rev. 3-1997, Amd. (1999).

developments they are well on their way to acquiring at least a quasi-binding force.

2.2.6 World Trade Organization/Sanitary and Phytosanitary Agreement

The World Trade Organization[11] (WTO) tries to remove barriers to trade. To achieve this, several measures have been taken. Tariff barriers were reduced and to the extent that this was successful non-tariff barriers became more of a concern. The basic treaty addressing trade in goods is the General Agreement on Tariffs and Trade (GATT). The GATT recognizes that certain exceptions to free trade can be necessary to protect higher values like health and (food) safety.

In the food trade, differences in technical standards like packaging requirements may cause problems. However, it is mostly concerns about food safety, human health, animal and plant health that induce national authorities to take measures which may frustrate the free flow of trade. To address these concerns two WTO treaties were concluded: the Agreement on Technical Barriers to Trade (the TBT Agreement) and the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

The SPS Agreement was drawn up to ensure that countries only apply measures to protect human and animal health (sanitary measures) and plant health (phytosanitary measures) based on the assessment of risk, or in other words, based on science. The SPS Agreement incorporates, therefore, safety aspects of foods in trade. The TBT Agreement covers all technical requirements and standards (applied to all commodities), such as labeling, that are not covered by the SPS Agreement. Therefore, the SPS and TBT Agreements can be seen as complementing each other.

To a certain extent the WTO is a supranational organization. The treaties concluded between its members are binding. There is the Dispute Settlement Understanding, providing an arbitration procedure to resolve conflicts. If a party wants to present a conflict, a Dispute Settlement Body (DSB) is formed to arbitrate on the basis of WTO law. If a party does not agree with the decision of the DSB, it can take the case to an Appellate Body (AB). The WTO does not have powers to enforce decisions taken in this arbitration procedure. It can condone, however, that if the decision reached is not implemented by the party found at fault, the winning party may implement economic sanctions. These sanctions usually take the form of additional import levies on goods from the state found at fault. If the levies are condoned by the DSB (or the AB), setting them does not in itself constitute an infringement of WTO obligations.

As follows from the above, the SPS Agreement is very important from a food safety point of view. The SPS Agreement recognizes and further elaborates on the right of the parties to this agreement to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health. The measures must be scientifically justified and they may not be discriminating, nor constitute disguised barriers to international trade.

If the measures are in conformity with international standards, no scientific proof of their necessity is required. These measures are by definition considered to be necessary. The most important international standards regarding SPS are set by the so-called three sisters of the SPS Agreement: the Codex Alimentarius Commission, the International Office of Epizootics (OIE[12]) and the Secretariat of the International Plant Protection

[11]Established 1 January 1995 by the Agreement Establishing the World Trade Organization as the result of the so-called Uruguay round of trade negotiations and signed in Marrakesh on 15 April 1994 (WTO Agreement). The WTO is the institutional continuation of the General Agreement on Tariffs and Trade 1947 (GATT).

[12]The abbreviation follows the French spelling. In 2003, the International Office of Epizootics became the World Organisation for Animal Health, but kept its historical acronym.

Convention (IPPC). The standards on food and on food safety are mainly to be found in the *Codex Alimentarius*.[13]

2.2.7 Conclusion

The inclusion of the *Codex Alimentarius* in the SPS Agreement, greatly enhances its significance. WTO members who follow Codex standards are liberated from the burden to prove the necessity of the sanitary and phytosanitary measures they take. If they cannot base their measures on Codex, they have to prove that their measures are science-based.

2.3 INDIA

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2.3.1 Introduction

Adequate, nutritious and safe food is essential to human survival and it is the duty of the government to see that the consumers are provided with such safe food. The assurance of safe food production is a multidisciplinary task involving food producers, processors, food scientists, technologists, toxicologists and food regulators. The general public may consider that 'safe food' means food with zero risk. But from a regulatory point of view, safe food means food that has an appropriate level of protection (ALOP). Today, globalization of food trade and increasing problems worldwide with emerging and re-emerging foodborne pathogens have increased the risk of cross-border transmission of infectious diseases. The standards, guidelines of hygienic practices and recommendations established by the Codex Alimentarius Commission are recognized as the basis for harmonization by the World Trade Organization. India, being a signatory to WTO agreements, has taken adequate steps to harmonize the laws based on risk analysis. Furthermore, food safety is not limited to concerns related to foodborne pathogens, physical hazards or toxicity due to contaminants—in today's context it is extended to include nutrition, food quality, labeling and awareness. The food control system in India is geared to meet these additional requirements.

In this context, it is fascinating to see the evolution of Indian Food Legislation which has evolved over the last fifty years or so with a paradigm shift from gross adulteration to subtle contamination in foods. This has reflected a blend of social, economical, political and scientific factors, which is sometimes marked by little coherence in its development resulting into over-complexity with fragmented measures, contradictions and sometimes lack of consistency. However, these shortcomings are being addressed in the New Food Safety and Standards Act 2006.

2.3.2 Food Legislation in India

Food laws and regulations existed in some forms in most ancient cultures to deal with food safety and consumer concerns. In Charak Samhita, there are references about the quality of food articles for maintaining a good health. The great economist Chanakya in his 'Arthashastra' written in 375 BC, was mentioning food adulteration and punishments to be given to traders indulging in such anti-social activities. People in pre-historic times knew about the benefits and safety of various foods and the sale of adulterated food was dealt with by Criminal Acts that existed during those periods.

It is possible that Food Legislation in India dates back to 1860 with certain sections of the Indian Penal Code dealing with food adulteration. However, the exclusive food laws were enacted

[13] The Agreement on Technical Barriers To Trade (TBT Treaty) has similar articles.

only early in the twentieth century. Before independence in 1947, Indian provinces under British rule, had their own acts and rules to deal with prevention of food adulteration (e.g., The Bengal Food Adulteration Act 1919, The Bombay Prevention of Food Adulteration Act 1925, The Calcutta Municipal Act 1923, The Madras Prevention of Food Adulteration Act 1918, The Punjab Pure Food Act, 1929, etc.).

These laws were based largely on the British Food and Drug Act, 1872 and generally dealt with gross adulteration of cereals and pulses with extraneous matter, spices with colors, milk with water etc. These laws had the provisions for seizure of such foods followed by prosecution in the courts of law. In 1943, a Central Advisory Committee was appointed, which recommended establishment of Central Legislation to bring about uniformity in food legislation throughout the country.

Consequently, the national food law, namely the Prevention of Food Adulteration Act (PFA Act), was enacted in 1954 (Act 37), which came into force from 1 June 1955, vide Notification No. SRO 1085, dated 10 May 1955, Gazette of India (MoHFW, 1954). The objective of the PFA Act is to protect the consumers against impure, unsafe and fraudulently labeled foods. The PFA covers food production, processing, formulation, packaging, labeling and distribution. Furthermore, limits for additives and contaminants in foods have been specified. These standards and regulations apply to both domestic and imported foods.

The Directorate General of Health Services, through the Central Committee for Food Standards, under the Ministry of Health and Family Welfare, Government of India, lays down food standards and has the power to amend the rules as and when necessary. The implementation of the rules goes through the State governments and local bodies. Till this day, the rules have been amended more than 200 times to meet the current requirements of safety as enunciated in SPS, TBT and other agreements of WTO. Some of the major amendments till this date are listed in Table 2.4.

2.3.3 Aspects of India's Food Legislation

The evolution of Indian Food Legislation involves three aspects, namely: 1) legislation; 2) administration; and 3) participation of stakeholders. These are briefly discussed here.

2.3.3.1 Legislation Aspects

Apart from amendments in PFA, the following important statutory quality legislation and orders have been promulgated to regulate different categories of processed foods such as processed fruit and vegetable products, meat and meat products, milk and milk products, vegetable oils etc. Some of the important acts/

TABLE 2.4 Highlights of the development of food legislation in India

1976	Minimum of six month jail for the persons indulged in food adulteration.
1986	Introduction of Consumer Protection Act under which the consumer is eligible to submit a food product for testing to the state laboratory.
1998	Vegetable oils to be sold only in packed conditions to avoid adulteration.
2004	Harmonization of food laws with reference to food additives such as Synthetic sweeteners, bulk sweeteners, preservatives antioxidants, etc. in traditional sweets, snacks, instant mixes, confectionery products, etc. Limits for pesticide residues, antibiotic residues, toxic metals and aflatoxins have been laid down for various products based on risk analysis.
2004 & 2006	Microbiological requirements for sea foods, fruit and vegetable products and milk products have been introduced.
2008	Nutritional labeling covering nutrients such as protein, fat, carbohydrates, calories, added vitamins and minerals and trans-fats (for products containing hydrogenated vegetable oil) for the prepackaged foods is made compulsory; health claims are permitted.

orders and the year in which they were promulgated are given below:

(a) Essential Commodities Act, 1955 A number of Orders have been formulated under the provisions of the Essential Commodities Act in 1955 with the objectives to regulate the production, supply, distribution and trade and commerce of essential commodities, including foods.

These orders include:

(i) *Fruit Product Order, 1955* The order is administered by the Ministry of Food Processing Industries. It lays down standards for processed fruit and vegetable products, hygienic and sanitary requirements, food additives and contaminants (MoFPI, 1955).

(ii) *Meat Food Products Order, 1973* This order, laying down conditions for licensing and hygienic requirements, is implemented by the Directorate of Marketing and Inspection, Ministry of Agriculture (MoA, 1973).

(iii) *Solvent Extracted Oil, De-oiled Meal and Edible Flour (control) Order, 1967* Standards, packing and labeling requirements for the solvent extracted products have been laid down in this order, which is regulated by the Department of Consumer Affairs, Ministry of Consumer Affairs (MoCA, 1967).

(iv) *Vegetable Oil Products (Regulation) Order, 1998* This order is implemented by the Directorate of Vanaspati, Vegetable Oils and Fats under the Ministry of Consumer Affairs. It provides for compulsory licensing for manufacturing units and lays down standards for these products (MoCA, 1998).

(v) *Milk and Milk Products Order 1992* The order is implemented by the Ministry of Agriculture. It provides for compulsory registration of the units and lays down hygienic and sanitary requirements (MoA, 1992).

(b) Export (Quality Control and Inspection) Act, 1963 (Amended in 1984) The government has established the Export Inspection Council under the Ministry of Commerce to ensure the safety and quality of foods meant for export through consignment testing, premise inspection and implementation of Quality Assurance systems such as GMP,[14] GHP[15] and/or HACCP in the processing units (MoC, 1963).

(c) Standard of Weights and Measures Act, 1976 Under this act, rules were laid down in 1977 for prepackaged products to regulate interstate trade. It is regulated by the Ministry of Consumer Affairs. As per the act every package shall have: (a) Name of the product, (b) Net quantity in standard units of weight and measures, (c) Unit sale price and (d) Name of Manufacturer, packer or distributor (MoCA, 1976).

(d) Voluntary Based Product Certifications

(i) *Bureau of Indian Standards Act, 1986* In 1947, the government, recognizing the role of standardization in the industry to promote competitive efficiency and quality production, set up the "Indian Standards Institution (ISI)", as a registered society. In 1986 the government gave ISI a Statutory status through the Bureau of Indian Standards (BIS) Act 1986. The organization runs a voluntary certification scheme known as the "ISI" Mark for certification of consumer goods, including processed food products (BIS, 1986). Under the provisions of the PFA Act, it is compulsory to have BIS certification for food additives, condensed milk, milk powder, Infant Milk substitutes and packaged drinking/mineral water.

(ii) *Agmark Grading and Marking Act and Rules,1937* Under the Directorate of Marketing and Inspection under the

[14] Good Manufacturing Practices.
[15] Good Hygiene Practices.

Ministry of Agriculture, operates a voluntary scheme of certification of raw and processed agricultural commodities (AGMARK, 1937).

2.3.3.2 *Administrative Aspects*

A closer look at the PFA Act and rules reveals that the enforcement of the act rests with the Food (Health) Authority of the States. Norms have been laid down by the authority for the appointment of qualified Food Safety Officers (Food Inspectors) with requirements of adequate training and awareness and provision for accreditation of the central /state testing laboratories to establish competence of the analysts/chemists.

2.3.3.3 *Participation of Stakeholders*

As food safety involves major stakeholders such as government, food industry and consumers, provisions have been made for adequately representing these stakeholders in various scientific panels /committees.

2.3.4 Development of Integrated Food Laws

It is evident from the above evolution of Indian Food Laws that India has a multiplicity of food laws, that are implemented through different ministries and departments. To avoid inter-ministerial confusions and contradictions, a Task Force was appointed in 2002 to review the Food and Agro Industries Management Policy (TASK FORCE, 2002).

One of the major recommendations was the consolidation of various food laws under one umbrella so that a single authority could formulate laws and supervise effective implementation of various food laws. The Ministry of Food Processing Industries (MoFPI) drafted a new Food Bill in 2002. The government constituted a group of Ministers to formalize the new legislation. The group drafted the Food Safety and Standards Bill 2005. On further review by the Parliamentary Standing Committee on Agriculture, the Bill was passed by the parliament and the Food Safety and Standards Act 2006 came into effect from 24 August 2006. Once the rules are framed under this Act, the PFA Act and orders under Essential Commodities Act will stand repealed.

Under the new act, the Central Government has constituted the Food Safety and Standards Authority of India (FSSAI) headed by a chairman with twenty-two members drawn from ministries, foods industry and food technologists. Scientific Panels for Food Additives, Contaminants, Labeling, GM Foods, Nutraceuticals, etc. are being constituted. The act is expected to boost the food processing sector by providing a single window for all regulatory issues as it is considered to be industry friendly, transparent, and science based (FSSAI, 2006).

2.4 SOUTH AFRICA

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2.4.1 Introduction

South Africa had its own Public Health Act in 1919, followed by the Food, Drugs and Disinfectants Act in 1929. These Acts have since been replaced with others as indicated below. Since democracy in 1994, South Africa became a member of the *Codex Alimentarius*, the IPPC[17] (plant health) and the OIE[18] (animal health). In

[16]Sincere acknowledgement goes to Dr Theo van de Venter, former Director: Food Control, Department of Health, and to Mr Andries Pretorius, current Director: Food Control, Department of Health.

[17]International Plant Protection Convention.

[18]World Organisation for Animal Health (formerly Office International des Epizooties).

1995, South Africa became a signatory to the WTO as well.

In South Africa the control over foodstuffs is fragmented between a number of authorities and components at national, provincial and local level. Typically, national government departments governing food safety, are responsible for writing policies and regulations, whilst local authorities are responsible for enforcement. Foodstuffs are not always regulated as foodstuffs but also as animals, animal products, plants, plant products or reproductive material. The objectives of such control relate to human health concerns such as food safety and nutrition, as well as to quality and to animal and plant health. Economic and environmental considerations also play a role. The relevant South African legislation and the authorities that are involved in the administration and enforcement of such legislation are discussed here below.

2.4.2 Foodstuffs, Cosmetics and Disinfectants Act

The Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) (FCD Act) is the most important set of legislation related to foodstuffs within the health sector in South Africa. Those aspects of this Act that relate to foodstuffs are administered by the Directorate: Food Control of the Department of Health and are enforced by local authorities in their areas of jurisdiction. Food imports are controlled by the provincial health departments on behalf of the national Department.

According to its long title, the Act is there "to control the sale manufacture and importation of foodstuffs, cosmetics and disinfectants; and to provide for incidental matters". Its objectives can however be summarized more clearly as follows:

1. It forbids the sale of foodstuffs, cosmetics and disinfectants that may be detrimental or harmful to human health.
2. It endeavors to protect the consumer from exploitation by false or misleading claims.
3. It attempts to provide the consumer with such information as is necessary to make informed choices according to individual needs and wishes.

The second and third objectives obviously refer to labeling.

The philosophy of the Act is that it is reactive as well as prohibitive:

- *Reactive* because no provision is made for the registration or approval of foodstuffs, or for the labels on such commodities. The onus also rests on the law enforcer to establish whether the product being manufactured, imported or sold, does in fact comply with the legal requirements. The law enforcer therefore reacts to a particular situation and cannot take recourse to any registration or approval to ensure the safety of a product. The Act does, however, make provision for approval by means of regulation for the use of certain *ingredients* in these commodities. A good example is the listing of permissible food additives, as well as the stipulation of the maximum permissible levels of specific substances that a foodstuff may contain.
- *Prohibitive* because nothing may be added to or removed from a foodstuff unless permitted by regulation or unless necessary for the manufacture of such foodstuff, or unavoidably present as a result of the process of its collection or manufacture.

Table 2.5 lists some regulations that, among others, have been published in terms of the Act by the Minister of Health.

The FCD Act (as for other Acts) is amended from time to time to include any significant changes as required.

2.4.3 Other Legislation on Food

2.4.3.1 Health Act

The Health Act, 1977 (Act 63 of 1977). Regulations under this Act govern the hygiene

TABLE 2.5 South African regulations on food under the FCD Act (Act 54 of 1972)

Anti-caking agents—Amounts that may be used in foodstuff
Baking powder and chemical leavening substances
Preservatives and antioxidants
Irradiated foodstuffs
Emulsifiers, stabilizers and thickeners and the amounts that foodstuffs may contain
Labelling and advertising of foodstuffs
Guar Gum—Prohibiting as a foodstuff
Colourants—Food
Soft drinks
Herbs and spices
Milk and dairy products
Metals in foodstuffs
Food fortification
Microbiological standards for foodstuffs and related matters
Mineral hydrocarbons in foodstuffs
Pesticide residues that may be present—Maximum levels in foodstuffs
Radio activity in foodstuffs
Marine food
Certain seeds in certain agricultural products—Tolerances for
Certain food additives in certain wheaten and rye products—Use of
Salt
Substances in wine, other fermented beverages and spirits—Additives, amounts, tolerances
Acids bases and salts—The amounts thereof that foodstuffs may contain
Fungus-produced toxins in foodstuffs—Tolerances for
Food additives containing nitrite and/or nitrate and other substances
Sweeteners in foodstuffs—Relating to the use of
Veterinary medicine and stock remedy residues—Regulations governing the maximum limits
Fats and oils—Edible
Foodstuffs for infants, young children and children
Certain solvents
Articles imported in transit and addressed to or intended for transmission to Botswana, Lesotho and Swaziland
Perishable foodstuffs
Inspectors and analysts—Duties of
Jam, conserve, marmalade and jelly
Mayonnaise and other salad dressings
Raw boerewors (a unique type of South African sausage), raw species sausage and raw mixed species sausage—Composition and labeling of
Manufactured or processed foodstuffs
Hazard Analysis and Critical Control Point
Labeling of foods produced by certain techniques of genetic modification.

aspects of food premises (including milking sheds) and the transport of food. These are also administered by the Directorate: Food Control of the Department of Health and enforced by local authorities in their areas of jurisdiction.

2.4.3.2 IHR

The International Health Regulations (IHR). These regulations of the World Health Organization, as adopted by South Africa, have certain provisions that relate to the provision and handling of food, as well as the control of foodborne diseases of global concern. The Department of Health is responsible for the approval of the source of food for consumption on the premises of ports and airports as well as on vessels and aircraft. Currently the provincial health authorities are conducting these approvals on behalf of the national Department. The Act also tasks local authorities to inspect the premises and to take food samples for analysis.

2.4.3.3 Agricultural Product Standards Act

The Agricultural Product Standards Act, 1990 (Act 119 of 1990). This Act controls and promotes specific product standards (e.g. meat, dairy products, cereals, certain canned products, fruit and vegetables) for local and for export purposes. It is administered and enforced by the Division: Food Safety and Quality Assurance of the Department of Agriculture.* Various assignees such as the Perishable Products Export Control Board are appointed and authorized as assignees to do physical inspections under the Act.

2.4.3.4 The Liquor Products Act

The Liquor Products Act, 1989 (Act 60 of 1989). Addresses requirements for wines and spirits. It is also administered and enforced by the Division: Food Safety and Quality Assurance of the Department of Agriculture, Forestry and Fisheries.

2.4.3.5 The Liquor Act

The Liquor Act, 1989 (Act 27 of 1989). This Act is administered by the Department of Justice and controls aspects such as liquor licenses and selling hours.

2.4.3.6 The Meat Safety Act

The Meat Safety Act, 2000 (Act 40 of 2000). Administered by the Division: Food and Veterinary Services of the Department of Agriculture, Forestry and Fisheries. It addresses food safety and hygiene standards in abattoirs. These regulations are enforced mainly by the provincial agriculture departments. The import and export of unprocessed meat is also controlled by this Act. This aspect is enforced by the national Department.

2.4.3.7 The Animal Diseases Act

The Animal Diseases Act, 1984 (Act 35 of 1984). Administered by the Division: Food and Veterinary Services of the Department of Agriculture, Forestry and Fisheries and enforced by the provincial components, except for import control which is a national responsibility. The Act controls animals as well as animal products, including meat, eggs and their products from an animal disease point of view.

2.4.3.8 The Genetically Modified Organisms Act

The Genetically Modified Organisms Act, 1997 (Act 15 of 1997). Administered and enforced by the Division: Biosafety of the Department of Agriculture, Forestry and Fisheries. This Act controls issues such as the licensing and importation of live genetically modified organisms. These may currently include foods such as maize, soy beans and tomatoes.

*Department of Agriculture, Forestry and Fisheries (www.daff.gov.za).

2.4.3.9 The National Regulator for Compulsory Specifications Act

The National Regulator for Compulsory Specifications Act, 2008 (Act 5 of 2008). Administered by the National Regulator for Compulsory Specifications (NRCS) (www.nrcs.org.za), (formerly known as the regulatory division of the South African Bureau of Standards). The NRCS is a public entity within the Department of Trade and Industry and is responsible for the administration of technical regulations, including compulsory specifications based on standards that protect human health and safety, and the environment. The NRCS was launched as recently as October 2008. It typically administers compulsory specifications for:

1. Canned meat and canned meat products;
2. Canned fish, marine mollusks and crustaceans;
3. Frozen fish and marine mollusks;
4. Frozen rock lobster;
5. Frozen shrimp, langoustines and crab;
6. Smoked snoek.

The NRCS exercises import and export control over these products, and is recognized by the European Union and other countries as the competent authority for certifying exports of fish and fishery products.

2.4.3.10 The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act

The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). Administered by the Division: Feeds, Stock Remedies, Pesticides and Fertilizers of the Department of Agriculture, Forestry and Fisheries. Animal feeds, stock remedies and agricultural remedies are registered in terms of this Act, which therefore has indirect implications for food safety.

2.4.3.11 The Medicines and Related Substances Act

The Medicines and Related Substances Act, 1965 (Act 101 of 1965). Administered and enforced by the Chief Directorate: Medicines Administration of the Department of Health. This Act *inter alia* provides for the registration of veterinary drugs as well as for the registration of foodstuffs and food supplements with medicinal effects or in respect of which medicinal claims are made.

2.4.3.12 Agricultural Legislation

The Plant Breeders Rights Act, 1976 (Act 15 of 1976), the Plant Improvement Act, 1976 (Act 53 of 1976), and the Agricultural Pests Act, 1983 (Act 36 of 1983), are all administered by various divisions in the Department of Agriculture, Forestry and Fisheries. The regulations made in terms of these Acts have implications for certain foodstuffs. The Agricultural Pests Act, 1983, for example regulates the importation of certain controlled goods such as plants, plant products, honey, used apiary equipment, exotic animals, etc.

2.4.3.13 Industrial Legislation

The Trade Metrology Act, 1973 (Act 77 of 1973), and the Trade Marks Act, 1963 (Act 62 of 1963). Both have certain implications for food labeling. The Trade Metrology Act is administered by the NRCS whilst the Trade Marks Act is administered by the South African Bureau of Standards (SABS).

2.4.4 Food Legislation Advisory Group (FLAG)

The Director: Food Control created the Food Legislation Advisory Group (FLAG) some years ago by inviting a number of stakeholders to nominate persons to advise him on matters that relate to his regulatory responsibilities. FLAG is non-statutory by nature, and members attend meetings (biannually) in their own time and

TABLE 2.6 Members of the Food Legislation Advisory Group in South Africa

Government:	Department of Health (various national and provincial components)
	Department of Agriculture (Food Safety and Quality Assurance)
	Department of Trade and Industry
Statutory:	South African Bureau of Standards
	Council for Scientific and Industrial Research
	Agricultural Research Council
	National Regulator for Compulsory Specifications
Other:	Allergy Society of South Africa
	Association for Dietetics in Southern Africa
	Consumer Goods Council of South Africa
	South African Association for Food Science and Technology
	South African Association for Flavor and Fragrance Manufacturers
	South African Milk Chamber of Milling/Chamber of Baking
	South African Soft Drinks Federation
	University of Stellenbosch
	Botswana Ministry of Health
	National Consumer Forum
	International Life Sciences Institute of South Africa

at own cost. In spite of being only an advisory body, most of its members are experts in the various fields of food control, and play an important role in the preparation and revision of regulations. The objective is to obtain as much consensus as possible on draft regulations even before they are published for comment. Table 2.6 lists the organizations that are represented on FLAG.

2.5 EASTERN AFRICA

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2.5.1 Introduction

The global regulation of food safety has a great impact on developing countries, such as those in Africa. Food supplies in many African countries are inadequate in quantity and quality. This contributes to widespread malnutrition on the continent. It has been found that at least 60% of the food supply is imported to supplement the local production.[19] With such a trend, there is the need for a local food safety system that ensures food for better health and agricultural trade opportunities.

Many African countries do not currently have effective food safety regimes and hence the safety of imported food cannot be assured, thus adding the risk of widespread contamination of

[19]See <http://www.fao.orgnewsroom/en/news/2005/2005/107908/index.html>. See also FAO/WHO Regional Conference on Food Safety for Africa Harare, Zimbabwe, 3–6 October 2005, final report, p 121.
[20]<http://www.fao.org/newsroom/en/news/2005/107908/index.html>.

food.[20] In this section, the situation in Tanzania is presented as an example.

In Tanzania and other African countries to achieve high food safety standards, a need is recognized to revise legislation relating to food safety in order to harmonize it with international standards such as the SPS Agreement, *Codex Alimentarius*, IPPC and importing country or regional regulations such as EU legislation.[21]

The importance of food safety does not lie in health and international trade alone. Firstly, Food *safety* is a critical element of food *security*. Secondly, lack of food safety has a high cost. Each outbreak of foodborne illness causes not only human suffering, but also direct and indirect costs. Thirdly, improving food safety has the added advantage of helping reduce food losses or even avoid them. In short, the improved safety of food can contribute to increased availability of food.[22] To meet all these, African countries are challenged to improve the food safety situation by improving their basic infrastructures such as regular access to electricity, safe water, transportation and storage.[23] These countries also need capacity building in food safety planning. Donors should provide technical assistance and traffic through national borders should also be monitored to prevent the importation of sub-standard foodstuff.[24]

So far, African food safety does not progress at the required pace, in its socio-economic and political aspects, as the failure of many African produced food products to meet international food safety and quality standards hampers the continent's efforts to increase agricultural trade both intra-regionally and internationally. The repercussion is that many African farmers miss out on another chance to improve their economic well-being.[25]

After discussing Tanzania, this section will turn its attention to the African Union.

2.5.2 Tanzania

2.5.2.1 Situation

The economy of Tanzania is based on agriculture (including animal production and fisheries) which accounts for more than 60% of the GDP. More than 80% of the population is rural based and depends entirely on agriculture for food and cash earnings.

The food safety situation in Tanzania as in many African countries is problematic. Illustrations from the press are disturbing. In 2008, there were people in Dar es Salaam (Tabata Dampo) whose houses were demolished owing to a court decree. These people have been provided with some foodstuff, some of which has been discovered to be unfit for human consumption.[26] Imported foods in Tanzania seem to have difficulties in meeting the standard food safety qualities. For instance, Zanzibar's Pharmaceutical and Cosmetics Board declared 70 tons of rice and wheat flour imported into the Isles from Dubai unfit for human consumption and to be destroyed.[27] This is evidenced by the Government act of destroying foodstuff

[21]United Nations Conference on Trade and Development, Geneva: Costs of Agri-Food Safety and SPS Compliance: United Republic of Tanzania, Mozambique and Guinea: Tropical Fruits Selected Commodity Issues, in the Context of Trade and Development, Unctad/Ditc/Com/2005/2, at 9.

[22]FAO/WHO Regional Conference on Food Safety for Africa: Harare, Zimbabwe, 3–6 October 2005 Final Report, p 34.

[23]*Ibid*, Challenges of food Safety, 35.

[24]*Ibid*.

[25]<http://www.fao.org/newsroom/en/news/2005/107908/index.html>.

[26]Makamba Atoa Msaada Wa Mchele Mbovu Kwa Waliobomolewa Nyumba Tabata, www.jamboforums.comshowthread.phpt=11173KwaWaliobomolewaNyumbaTabata-JamboForums_com.htm (visited on 24 March 2008).

[27]Tanzania Standard NewspapersHome www.dailynews.habarileo.co.tzsportsindex.phpid=2950.htm (visited on 24 March 2008).

that was found to be unfit for human consumption.[28] Such acts of destruction have been made several times while the food concerned was already on the market.[29] Such foodstuffs are imported through the Tanzanian harbors. This brings more questions than answers. That is: how did such food pass through the port? Are the legally established agencies not working? Is the foodstuff destroyed tantamount to the whole food imported? If this foodstuff was discovered to be unfit for human consumption how many times has it passed through the ports thereby affecting the health of the citizens?

Unfortunately, it was also revealed that in the case of the rice and wheat flour imported from Dubai, both products were covered with green fungus and the consignments lacked indications for both the expiry and manufacturing dates. This apart from being dangerous to health, infringes the public/consumer right to know important information about the product before making the decision whether to buy or not.[30] This right is irrespective of the health situation of the food. According to FAO, Tanzania should indulge in building an effective food safety regime as an urgent necessity to save lives and create economic opportunity across the continent.[31]

All these examples show that it is a necessity to create the conditions for a "bottom up" democracy, where the citizens raise their awareness in considering Food Safety as another way to give their needs the right voice.[32]

In the Annual Report of the Commission on the Social Dimensions of Globalization T. Halonen, President of Finland and B.W. Mkapa, former President of the United Republic of Tanzania, expressed this opinion with the following words:

> "[t]here is a wide international agreement on the essentials which we must urgently strive for: […] a vibrant civil society, empowered by freedom of association and expression, that reflects and voices the full diversity of views and interests. Organizations representing public interest, the poor and other disadvantaged groups are also essentials for ensuring participatory and socially just governance."

This idea is linked to the recognition of two sources for the challenges facing developing countries, Africa in particular, in the global system.

> "One is domestic; the other one is systemic. […] [S]olutions to the difficulties will have to come from these two sources. African countries will hardly make any impact in global trade negotiations if they fail to take trade issues and trade rules seriously at home. It is becoming crystal that participation and strategic and clever moves at International negotiations can make a difference to what a country gets from such negotiations."

This discourse referred to global trade law, but it can easily apply to food safety law. The idea is that the problem has to be faced both at an international and national level, through an aware participation with the intention at least to temper the abuse of the stronger interlocutor.

[28] *Ibid*.

[29] *Ibid*.

[30] Pacific Law Journal, 1988–1989, 969.

[31] <http://www.fao.org/newsroom/en/news/2005/107908/index.html>.

[32] It is worth noting that, despite the mentioned remarkable attempts, public opinion still underestimates the importance of reaching high standards in food safety as part of the protection of human health. See the key points summed up in the report of The African Food Safety and Traceability Conference. The African Food Safety and Traceability conference 2007 that took place from 11th to 13th April 2007 welcomed more than 120 participants. The conference was organized by GS1 Kenya and Insysnc Ltd. under the auspices of the Ministry of Trade and Industry and sponsored by Syngenta. Speakers included policymakers, academics industry leaders and solution providers.

For the last two decades, Tanzania has been carrying out micro- and macro-economic adjustments in line with globalization and market liberalization forces in the world. Such adjustments have recognized food safety as a prerequisite for national food security and for both regional and international trade in food. It is in view of this recognition that food function in the country is in the process of re-organization to ensure food safety and food security.[33]

2.5.2.2 Law

In line with the idea of food safety as a prerequisite of food security, and considering the two regimes deeply interconnected, the Ministries of Health, Agriculture and Food Security, Natural Resources and Tourism, and Ministry of Industries and Trade carry out food safety and quality control functions in Tanzania. Laws empowering these ministries had been considered to be adequate for the monitoring and control of transboundary safety emergencies. Among these laws are notably the Tanzania Food, Drugs and Cosmetics Act and Food Security Act .

Within this law, there is also a provision concerning the necessity for the exchange of information. In particular, Article 12 states that

> "(1) [f]or the purposes of securing the proper performance of its functions under this Act, the Department may require in writing any department, organization, authority or body of persons, to furnish it with such information required for the purpose of food security planning and operations as the Board or the Director may deem necessary; (2) [a]ny person who is required to furnish information under subsection (1) of this section shall comply with that requirement and any person who refuses or fails to comply with that requirement shall be guilty of an offence and be liable on conviction to a fine not exceeding ten thousand shillings, or a jail term not exceeding six months, and he shall be ordered by the trial court to furnish the information required."

The mentioned provision seems to be unidirectional, referring to the possibility of information transfer only from the Authority to the citizens and not *vice versa*. The expected goal should be a cross cooperation between authority and citizens, through the provision of an asset of "participatory rights" for the citizens and all the actors belonging to civil society in general (non governmental organizations, international organizations and so on).

The Tanzania Food, Drug and Cosmetics Act establishes the Tanzania Food and Drugs Authority (TFDA). This is the main agency for the control of food safety in Tanzania. To achieve food safety the Act vests the TFDA with the following objective, *inter alia* (a) to regulate all matters relating to quality, and safety of food, drugs, herbal drugs, medical devices, poisons and cosmetics; (b) to regulate the importation, manufacture, labeling, marking or identification, storage promotion, selling and distribution of food, drugs, cosmetics, herbal drugs and medical devices or any materials or substances used in the manufacture of products regulated under the Act.

Actually, the development of the matter seems to be an ongoing process. Even from the

[33] In Tanzania, the institutions involved in the regulatory system and standard-setting system are the Tanzania Bureau of Standards (TBS), under the authority of the Ministry of Industry and Trade, the Plant Health Services (PHS) in the Ministry of Agriculture and the Tanzania Food and Drugs Authority (TFDA), under the Ministry of Health. See the Workshop of the United Nations Conference on Trade and Development, *Costs of Agri-Food Safety and SPS Compliance: United Republic of Tanzania, Mozambique and Guinea: Tropical Fruits, Selected Commodity Issues in the Context of Trade and Development*, New York and Geneva, 2005.

point of view of access to information it seems to be a work in progress. Most importantly, the awareness of the need to participate in the same network as the Food Safety agencies is still feeble, if not non-existent. However, the main objective of the Authority is to become the best agency in regulating food, drugs, cosmetics and medical devices by 2015.

2.5.3 African Union and the Harmonization of Food Law

2.5.3.1 African Model Law on Safety in Biotechnology

One of the most remarkable attempts to create a network of interlocutors in food safety is the development of the African Union (AU). The African Union may be considered an example of the desegregation of the barriers between international and national domains. It is an actor of the network, contributing to the building of linkages between international institutions and civil society.

The African Union shall play this role of interlocutor between the International Organizations, the various African States and civil society, cooperating with the WTO and with International Organizations in general.

The AU Assembly of Heads of State and Government in July 2003 in anticipation of the entry into force of the Cartagena Protocol endorsed the draft African Model Law on Safety in Biotechnology, finalized in May 2001. The Model Law is an attempt to harmonize existing and future biosafety legislation in Africa. It provides a comprehensive framework of biosafety regulations designed to protect Africa's biodiversity, environment and health. Deeply connected with the compliance of the African Model Law is the creation of a competent authority.

The African Model Law provides (in Article 3) that the Government shall designate or establish a competent authority to follow up, supervise and control the implementation of this law. The powers and duties of the Competent Authority shall include: prescribing criteria, standards, guidelines and regulations as may be necessary for the fulfillment of the objective of this law; taking into account the policy recommendations and other guidelines of the National Biosafety Committee in making decisions on the import, transit, contained use, release or placing on the market of a genetically modified organism; establishing of Institutional Biosafety Committees at relevant institutions or nominating independent panels or any other body of experts, as appropriate, as technical and scientific advisors on issues of biosafety; keeping genetically modified organisms globally under constant review and when any one of them is suspected of posing a serious risk to human health or to the environment, banning its transit through the country's territories and notify the Clearing-House, the customs and trade officials accordingly; informing the Secretariat of the Cartagena Protocol, if appropriate, that it has no access to the Clearing-House; maintaining and making available to the public on request, a database on genetically modified organisms and products of genetically modified organisms intended for direct use as food or feed, or for processing.

The Law also provides that a National Biosafety Committee comprising of representatives of governmental and non-governmental organizations, and the private sector that are relevant to the issues of biotechnology and biosafety shall be established by the government to provide, as appropriate, policy recommendations and guidelines to the competent authority. The National Biosafety Committee will further develop based on its general responsibility, its terms of reference and may draw up its own rules of procedure.

A member of the National Biosafety committee who finds a conflict of interest in the case at hand must declare it and withdraw from the Committee in so far as that case of conflict of interest is concerned. Institutional Biosafety

Committee Institutions that are involved in the import, export, handling, contained use, release or placing on the market of genetically modified organisms or products of genetically modified organisms will establish Institutional Biosafety Committees to institute and control safety mechanisms and approval procedures at the institution level.

2.5.3.2 Risk Assessment

A workshop was held in Addis Ababa from 23 to 25 August 2007,[34] organized by the African Union Experts Meeting on the revised African Model Law on Safety in Biotechnology. This was the first attempt to comply with international standards concerning the risk assessment settled upon in the mentioned Cartagena Protocol.

The objectives were to enable participants to learn about risk assessment and risk management in the context of the Biosafety Protocol;[35] to review the general concepts, principles and methodologies; to exchange practical experience; to review the existing guidance materials on risk assessment and risk management; to consider the need for further guidance; to review the format and key elements of risk assessment reports; and to identify mechanisms for promoting cooperation and networking between experts and agencies.

The efforts undertaken by the African Union are likely to be the first achievements in harmonization of food safety regulation in Africa. It is worth mentioning the recent goals reached by the African Union Commission, together with many other actors, with respect to the Capacity building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms.

The FAO/WHO Regional Conference on Food Safety for Africa in Harare, Zimbabwe, from 3 to 6 October 2005, is another cooperative attempt in the promotion of food safety situation in Africa. The participants of the meeting were nearly all the African countries, as well as some international organizations in the area of food safety and observer countries such as Italy and the USA.[36]

The important issues discussed were National Food Safety Systems in Africa—A Situation Analysis,[37] Prioritization and Coordination of Capacity Building Activities,[38] Informal Food Distribution Sector in Africa (Street foods): Importance and challenges,[39]Assuring Food

[34] The workshop was attended by fifty seven participants from twenty five countries and sixteen organizations involved in risk assessment and risk management. Amongst the organizations represented, there were Addis Ababa University, AfricaBio, African Biodiversity Network, African Union Commission, United Nations Economic Commission for Africa (UNECA) and University of Rome 'La Sapienza'. For the official documents concerning the meeting, see <http://www.cbd.int/doc/meetings/bs/rwcbafr-01/official/rwcbafr-01-02-en.pdf>. The meeting is one of the most recent attempts of the global actors to settle a 'corpus' of standards in Food Safety. For further examples, see the African food safety meeting held on the 6 October 2005 in Geneva/Rome—The first pan-African food safety meeting attended by 147 food regulation officials and experts from some 50 countries, unanimously recommended a Strategic Plan for Food Safety in Africa for adoption by UN food and health agencies and the African Union. See <ftp://ftp.fao.org/es/esn/foodsafetyforum/caf/CAF_foodsafetyclose.pdf>. To consult the list of the main meetings on this topic see: <http://www.who.int/foodsafety/publications/newsletter/18/en/index.html>.

[35] For the text of the Protocol see <http://www.cbd.int/biosafety/>.

[36] FAO/WHO Regional Conference on Food Safety for Africa: Harare, Zimbabwe, 3–6 October 2005Final Report See the list of participants, at 13–30.

[37] Paper prepared by FAO Regional Office for Africa, Accra, Ghana, *ibid* pp 47–87.

[38] Paper prepared by the FAO/WHO secretariat, *ibid* pp 88–97.

[39] Paper prepared by Zimbabwe *ibid*, 98–107.

Safety And Quality In Small and Medium Size Food Enterprises[40] and International, Regional, Sub-regional and National Cooperation In Food Safety in Africa.[41] This meeting, apart from other things, formulated a resolution to ensure the eradication of problems associated with food safety in Africa.[42]

The increasing globalization of the food trade has notably resulted in shifting food consumption patterns, new production methods and technologies, faster trans-boundary transfer of microbiological and chemical hazards between regions.[43] With this, there can be no successful food safety without dealing holistically with the concerns of the main players in the food industry.[44] This, in fact, underlines the importance of cooperation. Cooperation at national, sub-regional, regional and international levels provides opportunities in synergy and maximized benefits for improved human health and economic development.[45]

These are good examples of cooperation to implement the standards and develop the exchange of information amongst the actors in the global arena. The mentioned examples testify to the progress towards cooperation between authorities to reach the goal of Food Safety in Africa and to assure the respect of a fundamental human right, the right to safe food.

2.5.4 Conclusion

In Eastern Africa developments in food take place both at national and at international level. Tanzania has established a food safety authority. A small step, such as the implementation of the Tanzanian Food Safety legislation with the provision of participatory rights, can consolidate the edification of a "common core" of global standards. The regulation of a transparent procedure, where citizens can participate in the decision-making processes, helps reach a more efficient distribution of information.

It was further observed that, establishing pan-African food safety standards will not only save lives and improve the health of African people but will also go a long way towards helping Africans to join international trade and raise African living standards. This is particularly true in rural areas where the most poor are subsisting.[46]

The African Union, confronted with the challenges created by biotechnology and the issue of biosafety, has moved to formulate an African Model Law on Safety in Biotechnology. It contributes to establish the concept of risk assessment in African food law.

2.6 AUSTRALIA AND NEW ZEALAND

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2.6.1 International Development of Food Law and its Application in Australia

The development of food law internationally is well documented. O'Keefe (1968) identifies six centuries of adulteration in a wide range of

[40] Paper prepared by Botswana *ibid*, 108–120.
[41] Prepared by the WHO Regional Office for Africa, BP 06, Brazzaville, Republic of Congo *ibid* ,121–131.
[42] On the resolution see *ibid*, 134–135.
[43] *Ibid*, 45.
[44] *Ibid*.
[45] *Ibid*,121.
[46] *Ibid*.

foodstuffs, the ineffectiveness of officials and the ad hoc statutory provisions to remedy the matter in the UK as significant factors. Add to that the rise of analytical chemistry and the increased awareness of the level of food adulteration and particularly a series of articles published by the Lancet, and the findings of a Select Parliamentary Commission (1855). These resulted in the passage of the UK Adulteration of Food and Drink Act 1860.

At the time of white settlement in Australia, the laws then in place in Britain were considered to apply in the new colony of New South Wales. However, legislation subsequently passed by the British Parliament had no application in the colonies unless expressly provided. Consequently the 1860 UK Act did not apply.

2.6.2 Federal and State Responsibility

Australia is a federation of six States and two Commonwealth Territories. From 1788 there was just the colony of New South Wales; New Zealand was first to split away, then Victoria and Queensland, followed by the proclamation of the other Australian colonies. Prior to federation in 1901, each State was an independent colony of Great Britain with its own legislative system including matters relating to food.

Laws regulating food were first introduced in the State of Victoria in the mid-nineteenth century as a response to concern over adulterated food. The Victorian Public Health Act of 1854 empowered the Board of Health to inspect, seize and destroy unwholesome food (Anon, 1988). Specific legislation followed as analytical techniques developed to permit a closer examination of what was being added to food. In 1838, the New South Wales government passed an Adulteration of Bread Act, and in 1879 the first general legislation, the Adulteration of Food Prevention Act. The Act appears to have had little or no use (Madgwick, unpublished material).

When Australia became a Federation, domestic food legislation was not among the powers vested in the Commonwealth and each State individually introduced specific legislation to control manufacture and sale of food. This activity was led by Victoria, which introduced its Pure Food Act in 1905 and by 1912 most of the other States had followed with similar, but not identical, legislation aimed primarily at preventing the sale of adulterated food. New Zealand had eliminated its provincial governments in 1876 and as a consequence its Sale of Food and Drugs Act of 1877 applied throughout the country (Farrer, 1983).

Regulations were progressively made under the State Food Acts to set standards for foods, including labeling requirements. In NSW the Pure Food Advisory Committee established by the Act consulted extensively with the food industry and took evidence as part of their regulation-making process (PFAC minutes).

The non-uniformity of food regulations in Australia created real difficulties for the burgeoning interstate trade and a series of Commonwealth/State conferences were held in 1910, 1913, 1922 and 1927 to set uniform standards for foods. Many of these were adopted under State Food Acts and remained unchanged through to the 1950s. Nonetheless the need for uniform adoption of these standards was emphasized. A Royal Commission was held in 1925 to endeavor to overcome the problems but without notable success. In particular the Commission made the following recommendation "That the States transfer to the Commonwealth the Constitutional power to legislate for the control of food and drugs" (Downer, 1995).

In 1936, the National Health and Medical Research Council (NHMRC) was established within the Commonwealth Department of Health with responsibility for advising both Commonwealth and State Governments on matters of public health. Food was considered part of its interest because food was seen as a public health matter.

The initial concern of the NHMRC on food was primarily the nutritional value of the Australian food supply. No reference was made

in the NHMRC report to food legislation until November 1952 when the NHMRC adopted recommendations from its Public Health Committee (made up of representatives of the States as well as Commonwealth officers) concerning the need for national uniformity of food and drug regulations. The NHMRC noted the need for closer liaison between the Commonwealth, the State Food Advisory Committees and industry organization, viz., the Chamber of Manufacturers and the Council of Food Technology Associations (CAFTA) to achieve this end. This led to the formation of the Food Standards Committee (FSC) of the NHMRC.

2.6.3 Towards a Model Food Standards Code

The FSC had its first meeting in 1955 when it identified as its purpose to recommend to the NHMRC model food standards that would be adopted without material change in all States so that food legislation might be uniform throughout Australia. It was not concerned with the legal machinery for the policing of these regulations, which remained with the States.

The FSC was made up of senior officers of the State and Federal governments together with an industry representative nominated by CAFTA. A unique feature of this system was that first drafts for any proposed standard or amendment would be supplied by CAFTA, giving the industry body the opportunity to be fully involved in the standard making process. It was the FSC's wish that industry would not communicate with it directly but through CAFTA. This clearly showed that the FSC acknowledged CAFTA's ability to speak for industry in a balanced and ethical manner (Reuter, 1997).

Before the establishment of the FSC, the NHMRC had acted to review existing controls on additives and contaminants in the food supply with particular reference to preservatives and colors. They did this by establishing a Food Additives Committee in 1953. The early work of this committee is described in detail by Farrer (1990). The terms of reference of the Food Additives Committee as enunciated when it subsequently became a subcommittee of the FSC were to enquire into and advise the FSC on matters concerning food science and technology including:

1. the specifications for purity and identity of food additives;
2. the technological need for and safety of food additives;
3. contaminants in food; and
4. the use of coloring substances in cosmetics, pharmaceuticals and food.

Australia provided a representative at the first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1956 and has maintained regular representation since that time.

While the major food safety concern of the NHMRC and its reference groups in matters of food law were with chemicals in foods, microbiological standards began to appear in product standards, particularly dairy products, on an ad hoc basis in the mid-1960s. Greater recognition of the importance of microorganisms in food safety led in 1965 to the establishment of the Food Microbiology Subcommittee (FMC) to assist the FSC in the preparation of microbiological standards (Smith, 1978).

Faced with a lack of information on the microbiological status of Australian foods, one of the first initiatives of the FMC was to organize a comprehensive survey of the States of a range of ready-to-eat foods using standard laboratory methodology. The FSC proved reluctant to clutter the regulations with microbiological standards of doubtful value, recommending Codes of Practice whenever possible.

Since a major reason given for States being unable to adopt uniformly the model food standards recommended by the NHMRC system

was the inherent differences in the Food Acts, moves were commenced in 1975 to have a uniform Food Act for the States and Commonwealth territories. This so called Model Food Act was eventually adopted at a Health Minister's Conference in 1980. The path to achieving this was by no means straightforward and is described in some detail by the first chairman of the Food Standards Committee (Reuter, 1997). It then took some years for all the States to change their Food Acts so that food standards generated through the NHMRC could be incorporated automatically as regulations under State law.

However this was facilitated by the model food standards being endorsed by all parties and gazetted in whole as the NHMRC's Australian Food Standards Code (AFSC) in 1986.

While some success could be claimed for introducing uniformity between States with regard to food standards this was by no means complete. In addition, the Code and the way it was amended continued to be the subject of criticism by the food industry and by consumer groups who now took a marked interest in food. Industry representatives complained that the Code was overly prescriptive, difficult to have amended and inhibited innovation. Consumer representatives criticized the lack of information on labels.

2.6.4 Winds of Change

In 1989 food standards development was transferred from the NHMRC to the Bureau of Consumer Affairs in the Attorney-General's Department in the Commonwealth Government. While the representation on the former food standards committee was enlarged, the committee system continued to operate with, in the view of the industry, its inherent deficiencies. This view was at least partly shared by three major review committees reporting to the Commonwealth government around this time.

Following further discussion by State Premiers, it was agreed in 1990 that a new body, the National Food Authority (NFA), which later became the Australia New Zealand Food Authority (ANZFA), responsible to the Minister for Health and Human Services should be established. ANZFA was to undertake a number of functions in re-ordering the food regulatory system of which the principal one was to identify more specific objectives for domestic food standards which would:

- protect public health and safety;
- provide sufficient information on food ingredients to allow consumers to make informed choices;
- promote fair trading practice at the national level; and
- promote domestic uniformity and alignment with international requirements to promote trade and commerce in the food industry.

Recommendations of the NFA were referred to the National Food Standards Council that comprised State Health Ministers and the Commonwealth Minister for Consumer Affairs. The National Food Standards Council was supported by the Uniform Food Law Interpretation Committee made up of Commonwealth and State officers, usually Chief Food Inspectors or their equivalent, which had come into being under the previous system. Health officers from the New Zealand Department of Health started attending meetings of the NFA as they had done prior to that of the AFSC. These officers had observer status and contributed to discussions. Under the Act of the Commonwealth Parliament which established the NFA, it was also responsible for developing food inspection policies for imported food.

Under a 1991 Inter Governmental Agreement between the Commonwealth and State and Territory governments, the States and Territories agreed to adopt, without variation, food standards recommended by the National Food Authority. The purpose of the agreement was to consolidate responsibility for developing food standards in one specialist agency and to ensure the uniformity of food standards across all States

and Territories, which continued to have primary responsibility for enforcing food laws.

In 1996 the Australian and New Zealand governments agreed to establish a bi-national regime to develop food standards that were to apply in both countries. This agreement took effect by way of a treaty which outlined four specific aims focused at reducing unnecessary barriers to trade by adopting a joint system for the development of food standards. These were the same as listed above. The treaty applies generally to food standards within the AFSC except for those standards addressing maximum residue limits for agricultural and veterinary chemicals, specifications for food hygiene requirements, which are the responsibility of the New Zealand Food Safety Authority (Winger, 2003) in that country. It also contains provisions that allow New Zealand to opt out of a joint standard for exceptional reasons relating to health, safety, trade, environmental concerns or cultural issues. For example, New Zealand has opted out of the Code's country of origin labeling requirements.

The commitments contained within the treaty were implemented by a new body, the Australia New Zealand Food Authority, which subsequently became Food Standards Australia New Zealand (FSANZ) by virtue of the revised amended Commonwealth, State and Territory Agreement in 2000. The 2000 agreement left standards development as the prime responsibility of FSANZ, but vested policy development as the responsibility of the Food Regulation Ministerial Council, assisted by the Food Regulation Standing Committee. The objectives for developing food standards were reduced to three with the protection of public health and safety retained as the primary objective (Healy, Brooke-Taylor, & Liehne, 2003).

In Australia, additional legislation applies to imported food at the point of entry. Implementation of the Imported Food Control Act of 1992 requires food to be safe and to meet the requirements of the Australian Food Standards Code. In New Zealand, imported food is subject to the New Zealand Customs and Excise Act of 1996. In addition, the Australia/New Zealand treaty does not apply to export requirements relating to third country trade.

There remains another significant area of non-uniformity in the shape of the Trans-Tasman Mutual Recognition Arrangement (TTMRA). This arrangement, which commenced in 1997, allows for the sale in either country of foods which comply with the laws in the other. Thus for example, foods imported from New Zealand can be sold in Australia without country of origin labeling, notwithstanding the application of the Food Standards Code in Australia. New Zealand also has its Dietary Supplements Regulations 1985 which allow the sale in New Zealand of foods and drinks with added vitamins, minerals and other substances not permitted under the Code. Under TTMRA these products may be legally imported from New Zealand and sold in Australia, although it would be an offence to manufacture such products in Australia.

A major review of the Australian Food Standards Code was commenced in 1994 and this review was continued as a vehicle to develop the joint Australia New Zealand Food Standards Code. The basic principle underlying the policy for the review was efficient and effective regulation. The reform of food product standards aimed to reduce the level of prescription and to construct standards that apply across all foods or a range of foods (Healy *et al.*, 2003). The first general or horizontal standard to be completed was the joint standard for food additives and this was also the first standard to be adopted as a joint Australian and New Zealand standard. The process of reviewing food additive regulation at a fundamental level enabled the development of a standard that recognizes the principles of the Codex General Standard for Food Additives (Codex Alimentarius Commission, 1995) as well as the food additive regulations of the major trading partners (Brooke-Taylor, Baines, Goodchap, Gruber, & Hambridge, 2003).

The most notable reforms have occurred in food hygiene requirements. Within Australia,

hygiene requirements for food, with the exception of a small number of microbiological standards, had traditionally been specified within the legislation of each State or Territory with some local municipal councils (the third tier of government in Australia) introducing additional requirements. This resulted in a lack of national consistency and also many prescriptive requirements which were of little or no relevance to food safety. The policy guiding the reform required that food safety standards represent international best practice and particular note was taken of the guidelines for the use of hazard analysis critical control point (HACCP) systems as defined by the Codex Alimentarius Commission (1997),[47] which had already been partially introduced in New Zealand by the New Zealand Food Safety Authority and by State and Territory Primary Production Authorities.

Basic hygienic requirements for food in the Food Standards Code are now in four food safety standards. Three of the four were approved in 2000 as mandatory standards. These are Standard 3.1.1, Interpretation and Application; Standard 3.2.2, Food Safety Practices and General Requirements; and Standard 3.2.3, Food Premises and Equipment. The fourth Standard, 3.2.1, Food Safety Programs, which specifies requirements for HACCP based food safety plans was originally approved as a voluntary standard to provide a model set of requirements for those States and Territories wishing to introduce such requirements. The introduction has to date not been uniform but significant progress has been made. In addition the Food Standards Code now includes a mandatory standard for Food Safety Programs for Food Service to Vulnerable Persons. Standard 3.3.1, which calls up Standard 3.2.1.

2.6.5 Model Food Act, Part 2

Uniformity across State and Territory Food Acts remains the holy grail of food regulators. The 1980 Model Food Act was adopted in a desultory fashion at best by the States and Territories. The second "Model Food Bill" was finalized in October 2000. On 3 November 2000, the Council of Australian Governments (COAG) signed an Inter-Government Agreement agreeing to a new food regulatory system. The Commonwealth of Australia and all the Australian States and Territories are signatories to the Agreement. The new arrangements required a renegotiation of the Treaty with New Zealand prior to full implementation. This Inter-Governmental Agreement is also known as the Food Regulation Agreement.

The Agreement states in part that States and Territories will use their best endeavors to submit to their respective Parliaments, within twelve months of the date of signing this Agreement, legislation which gives effect to the provisions listed at Annex A and Annex B of this Agreement which provide for the effective and consistent administration and enforcement of the Food Standards Code (including the Food Safety Standards). Annex A was to be adopted without change, except in respect of separate legislation governing safe primary food production. Annex B was completely optional.

Some States and Territories honored the agreement without delay. New South Wales fell across the line in 2003. At the time of writing West Australia has yet to enact the model food provisions.

2.6.6 Where To From Here?

At the time of writing, FSANZ is in the process of developing standards for primary production and processing paving the way for a complete food chain approach to food safety. Standards for the seafood and dairy industries have been completed with work being undertaken on the egg, poultry, meat, and dairy (raw

[47] See section 2.2 above.

milk products) industries. Administration of "paddock to plate" standards continues to be problematic with only New Zealand and New South Wales having through chain agencies.

The October 2008 meeting of the Food Regulation Ministerial Council agreed in principle to commission an independent, comprehensive review of food labeling law and policy. The review would be undertaken by an independent expert panel. The expert panel is to comprise prominent individuals appointed by the Ministerial Council who collectively possess knowledge and expertise in the fields of public health, regulatory, economics/public policy, law and consumer behavior and business. The review is to be chaired by an independent public policy expert.

The Australian Government has been active in progressing food regulation reform. Much of the drive for reform has come from the Commonwealth Productivity Commission. In October 2008 the COAG Business Regulation and Competition Working Group agreed that the Commission should benchmark food safety regulation in 2009, "and report by December 2009. In November 2008, the Council of Australian Governments (COAG) agreed to consider options to improve national consistency in the monitoring and enforcement of food standards and options to improve food labeling law and policy in early 2009 (COAG). This could be seen as a move toward the Commonwealth assuming administrative responsibility for certain aspects of food regulation. As mooted in 1925 and many times since.

2.7 THE UNITED STATES AND CANADA

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2.7.1 Introduction

As food trade expands and food processing increases, so does the opportunity and the scope of adulteration. Legislatures have followed rather than led food safety reform. Scientists and analytical methods have played a critical role in increasing awareness of food safety risks. Public outrage has also played a role. The food industry also plays an important leadership role out of enlightened self-interest in improved food safety. However, rarely have any of these factors alone been enough. Major food law revision occurs when all—scientists, the public, and food industry leadership—are galvanized, too often by outrageous tragedy.

2.7.2 The Early Years

> And chalk, and alum and plaster are sold to the poor for bread.
>
> —Alfred Lord Tennyson, *Maud* (1886)

The history of adulteration of food is as old as the trade in food (Hart, 1952). The corresponding history of food law and the efforts to detect adulteration similarly run as far back as commerce itself (*Ibid*.). The earliest adulteration was comparatively simple, in large part because food was mostly unprocessed. Whole coffee beans, for instance, provide less opportunity for adulteration than ground coffee. The more processing, the greater the opportunities for adulteration. Grinding grain into flour provides one opportunity, and the mixing and baking of the flour into bread provides additional opportunities. Therefore, it is no coincidence that the earliest food laws covered the earliest processed foods: bread, wine, and beer (*Ibid*.).

In these earliest years, consumers served as their own food inspectors. They sniffed fish and meat for freshness, squeezed fruit and vegetables to check for soundness, and examined grain for mold (Janssen, 1975). Lack of analytical techniques limited the ability to detect adulteration.

However, most food trade was local, so consumers assessed the reputation of the purveyors of food.

In their colonial years, before the founding of the United States and the confederation of Canada, the British common law applied the earliest food safety law. The essence of the common law was plain and direct: 1) Do not poison food, and 2) Do not cheat (Hutt, 1960). "Adulterated food" in the common law consisted of food that was unfit for human consumption or contained some deleterious substance, whereby rendering it dangerous to health (*Ibid*.). Packaged food with labels was rare, so there was no common-law offense of mislabeling. However, our basic concept of mislabeling existed as the common law offense of falsely representing merchandise for sale (*Ibid*.).

The sixteenth, seventeenth, and eighteenth centuries were an era of colonial expansion in the United States and Canada. This expansion coincided with increased trade in agricultural goods from the New World (Hart, 1952). As demand and value of exported goods rose, so did incentive and the opportunity to adulterate (*Ibid*.). During this same period, food production began shifting from the home to manufacturers. As people moved to the cities, consumers bought more processed and manufactured foods. Reputation weakened as a means of control. Laws were enacted to prohibit adulteration, but without analytical methods of detection, the laws provided only minimal protection (*Ibid*.).

The legislative food laws of this era were largely ones that protected commerce rather than food safety. For instance, seventeenth century colonial bread laws penalized short weight and the failure to identify the maker of the bread (Janssen, 1975). Merchants pushed for the establishment of food inspection laws because they recognized the marketing problems created by inferior goods, and they wished to create a level playing field (*Ibid*.). Honest dealings were important in creating and preserving the export markets, so the colonies created laws on food export.

2.7.3 The State and Local Legislative Era in the United States

The first food safety law in North America is thought to be the Massachusetts "Act against selling unwholesome Provisions" passed on 8 March, 1785 (Hart, 1952; Janssen, 1975). However, not until the latter half of the nineteenth century were major food safety laws enacted. Rapid development of analytical methods began in the early 1800's, and these tools identified adulteration of shocking scope. In 1820 Frederick Accum documented adulteration so widespread that he found it difficult to find a single type of food that was not adulterated; and some foods he scarcely ever found genuine (Accum, 1820; Hutt & Hutt, 1984).

The public was shocked and dismayed, but legislative reform was slow in coming. The early nineteenth century was the height of *laissez faire* capitalism. This economic philosophy called for deregulation of business, not food protection.[48] At the same time, however, the exodus from farms to the cities continued. The development of large cities by the middle of the nineteenth century required increased national commerce in food. More people purchased processed food, and adulteration increased. This degradation of the food supply was increasingly documented as scientists found new ways to detect adulteration[49] (Batrershall, 1887; Beck, 1846; Byrn, 1852; Felker, 1880; Hoskins, 1861; Richards, 1886).

[48]This was not called the era of the "robber barons" for nothing.

[49]For example, in the period around 1880, over 73% of the milk in Buffalo, New York, was watered; 41% of the samples of ground coffee in New York were adulterated; and 71% of the olive oil in New York and Massachusetts were adulterated (Hart, 1952).

The period from 1865 to 1900 was one of increased state legislative activity. The Georgian Code of 1867 provided fines, imprisonment, and whipping up to 39 strokes, or chain gang for up to one year for knowing sale of unwholesome food or drink (Hart, 1952). Massachusetts, New York, Michigan, New Jersey, Rhode Island, and others jurisdictions passed food laws in this period (*Ibid*.).

2.7.4 The Federal Era

Both Canada and the United States are federations. Some powers are assigned to the federal or national government, but other powers are reserved to the individual provinces or states. This division of power from time to time has created questions of the proper role of the federal government in regulating food. However, increasing national and international commerce along with growing magnitude of the problem made national regulation inevitable.

Both federal governments hold authority over commerce. However, unlike the United States, the Canadian Constitution Act, 1867, assigns criminal law power and presumably power over health and safety concerns to the federal government. Therefore, food safety legislation falls naturally under federal authority in the Canadian system.

2.7.4.1 Canada

Canada confederated in 1867. Canada's first federal food law was the Inland Revenue Act of 1875, enacted just seven years after confederation.[50] The act prohibited the adulteration of food and drink and covered alcohol and drugs. The definition of adulterated was nearly the same as in the common law and similar to English statutes of that era (Hutt & Hutt, 1984). Adulterated meant, "all articles of food or drink with which there has been mixed any deleterious ingredient or any material or ingredient of less value than is understood or implied by the name under which the article is offered for sale" (Blakney, 2009).

Adulterated liquor apparently was a great cause of concern and adulterants included ferrous sulfate, opium, hemp, strychnine, and tobacco (Gnirss, 2008). According to a report by the Commissioner of the Inland Revenue Act, 50% of all foods sold in Canada at the time were adulterated (*Ibid*.) Similar to the United States, nearly all coffee and pepper were adulterated, milk was diluted with water, and other high value items, such as tea and chocolate were often adulterated (*Ibid*.).

The Inspection Law, 1874, established a system of quality and grade inspections for staple food commodities, such as butter, flour, and meal (Blakney, 2009). Although the grading was voluntary for domestic product, some grades were mandatory for export goods (*Ibid*.) In 1884, the Inland Revenue Act of 1875 was amended and renamed by the Adulteration Act of 1884. Standards of identity began with a standard for tea in 1894, but standards soon followed for milk, milk products, honey, maple products, and foods (Gnirss, 2008). These standards served as important tools to prevent adulteration and as food safety controls.

2.7.4.2 United States

> We face a new situation in history. Ingenuity, striking hands with cunning trickery, compounds a substance to counterfeit an article of food. It is made to look like something it is not; to taste and smell like something it is not; to sell like something it is not, and so deceive the purchaser.
>
> —US Congressional Record, 49 Congress I Session 1886

[50]37 Vict. c. 8.

Through the late 1800s, nearly all of the early food laws in the United States were state and local. The limited federal activity was largely to regulate imports and exports. For instance, in 1883 the United States Congress enacted a law to prevent the importation of adulterated tea. The oleomargarine statute followed in 1896, which was passed because of the dairy industry's objections to the sale of fats colored to look like butter.[51] In 1890, Congress passed a meat inspection act to facilitate the export sale of meat (Hutt & Hutt, 1984). A live cattle inspection law followed in 1891 (*Ibid*.). In 1899, Congress authorized the Secretary of Agriculture to inspect and analyze any imported food, drug, or liquor when there was reason to believe there was a danger (*Ibid*.).

From the beginning of federal regulation, analytical chemistry played an important role. When the United States Department of Agriculture (USDA) was created in 1862, Congress authorized the agency to employ chemists. This Chemical Division eventually became the US. Food and Drug Administration (FDA) in 1930 (Hutt, 1990). The FDA was transferred from USDA in 1940. In 1883, Dr. Harvey Wiley became the chief chemist of the USDA Bureau of Chemistry. Dr. Wiley expanded research and testing of food and documented the widespread adulteration (FDA, 2002). He helped spur public indignation by his dramatic and highly publicized "Poison Squad." The volunteers in the Poison Squad consumed questionable food additives, such as boric acid and formaldehyde. Observation and documentation of the ill effects and symptoms of the volunteers provided a crude gauge of food additive safety.[52]

2.7.4.3 The 1906 Pure Food and Drug Act

Public support for passage of a federal food and drug law grew as muckraking journalists exposed in shocking detail the frauds and dangers of the food industry, such as the use of poisonous preservatives and dyes in food. A final catalyst for change was the 1905 publication of Upton Sinclair's *The Jungle* (Sinclair, 1905). Sinclair's portrayal of nauseating practices and unsanitary conditions in the meatpacking industry captured the public's attention. On 30 June 1906, President Theodore Roosevelt signed both the Pure Food and Drug Act[53] and the Meat Inspection Act[54] into law.

2.7.4.4 Evolution of the Food Statutes

Not long after passage of the Pure Food and Drug Act, legislative battles began to expand and strengthen the law. For example, leaders in the food industry called for more stringent product quality standards to create a level playing field. Consumers wanted stronger safety standards and fair dealing. However, major revision of the 1906 Act stalled until a precipitous tragedy occurred. The agonizing deaths of more than 100 children from sulfanilamide spurred the passage of the Federal Food, Drug, and Cosmetic Act of 1938.

This pattern for major revision of the national food law repeats itself. A tragedy alone is not enough. Concerns of a few interested parties are not enough. Typically, scientists, the food industry, and the public must all be interested in addressing the issue of the day.

The food laws continued to evolve based upon the concerns and issues of the times. In the 1950s, concerns over synthetic food additives,

[51]Margarine was patented in 1869 (Hutt & Hutt, 1984).
[52]The data is collected in the USDA, Bureau of Chemistry, bulletin no. 84 (1902–1908).
[53]21 U.S.C. § 1 *et seq.*
[54]21 U.S.C. § 601 *et seq*.

pesticides, and cancer were high. Consequently, in 1958, the Food Additives Amendment was enacted, requiring the evaluation of food additives to establish safety. The Delaney Clause forbade the use of any substance in food that was found to cause cancer in laboratory animals.

In 1920, the Canadian Adulteration Act was repealed and replaced with the Food and Drug Act of 1920. While the predecessor acts were significantly influenced by British law, this new statute looked more like the US Pure Food and Drug Act of 1906 (Gnirss, 2008). The Canadian Food and Drug Act of 1920 was revised in 1952-53 to cover cosmetics and therapeutic devices and to increase the regulation over labeling, packaging, and advertising (Blakney, 2009).

2.7.5 Conclusion

Food law is again at a crossroads. Rapid improvement in analysis and technology combines with rising global trade and more processing of food before reaching consumers. These conditions set the stage for increased adulteration, public outrage, unstable markets, and need for greater food safety oversight.

The past decade has been an American experiment with food safety deregulation. The results have left Americans with a growing sense of the failure of their government to ensure food safety. A series of foodborne disease outbreaks—melamine in pet food and then in human food, *E. coli* in spinach, lettuce, *Salmonella* recalls on tomatoes, peppers, and peanut butter—have left the public feeling vulnerable and intensified calls for reform of the food safety system. Firms have lost hundreds of millions of dollars in recalls and lost market share.

The history of adulteration in food reveals that increased processing and globalization will magnify the challenges to ensure pure and safe food. History instructs that the legislatures will follow rather than lead food safety reforms. Scientists play a critical role in increasing awareness of food safety risks. Public outrage also plays a role. The food industry must play a leadership role. Enlightened self-interest points to stringent but fair food safety regulation as necessary to preserve and grow food trade.

Major food law reform usually occurs only when all—scientists, the public, and food industry leadership—are galvanized by current events. Sadly, all too often this has been outrageous tragedy.

2.8 LATIN AMERICA

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2.8.1 Introduction

Latin America is a very complex region that faces diverse challenges due to a disparity of social, economic and cultural conditions. Each country and even each sub-region has its own strengths, weaknesses and challenges, so it is difficult to portray the whole region in just a few pages without making generalizations. Latin American countries are most definitely not strangers to the "globalization processes" and have been quickly gaining a position in global markets with unique products. In addition, Latin America represents a huge market that is very attractive for companies around the world and commercial activities within the region have increased through the participation in several free trade agreements. These new market opportunities have helped shape the region's industry and food regulations and have sparked the interest in actively participating in International Organizations such as the *Codex Alimentarius*.

Latin American countries have only recently sought to promote a policy shift from protecting national industries through openly protectionist policies towards an open market, free commerce system that seeks to foster competition within

the "global market" framework. The shift to free markets has not come without opposition. Of course, there is the responsibility of the state to defend the health and safety of its national consumers. However, most Latin American countries are subject to private sector pressures and are struggling to find the balance between encouraging more open commerce while making sure the products being imported are safe. In primary production, the shift from subsistence agriculture to competitive productive systems has faced a lot of cultural resistance and in many countries land reform has fractionated land to a point where it is almost impossible to compete without proper cooperation. How can small Central American producers compete with the economies of scale? How will they make the transition when the Central American Free Trade Agreement is fully operational? What are their options and their real competitive strengths?

2.8.2 First Steps Towards Harmonization

Harmonization is not new to the region. In fact, long before other regions of the world began to imagine a framework of food standards beyond their national borders, in 1924, in Buenos Aires, at the first Latin American Congress of Chemistry, a Commission composed of two delegates from each country represented in the Congress proposed the development of a *Codex Alimentarius Sudamericanus*. This Commission accomplished their objective and in 1930 at the following Congress in Montevideo they presented a Code that had 154 articles and was considered for adoption by all countries in Latin America. The Code contained definitions of food products and general dispositions. Unfortunately, then, as now, turning a proposal into a reality was not easy. Although many countries in Latin America have adopted "modern" and well thought out food legislation, as a region Latin America did not achieve an early effective regional regulation of food. In the following Latin American Congresses of Chemistry, there was much discussion on the same topic always with the vision of developing a Latin American Code. During the sixth Congress in Caracas in 1955, after much discussion, there was a vote for a new commission that was composed of official representatives of each country. In addition, a group of specialists in Bromatology was formed. This group was charged with the project and after working for three years the Commission presented a new document that was unanimously approved. The Revised Latin American Food Code was published in Spanish in 1960. This document is highly relevant since it represents the regional efforts towards harmonization. In addition, its value is that in combination with European Legislation, it served as a source for the *Codex Alimentarius* (Acosta & Marrero, 1985; Nader & Vitale, 1998). Despite these very valuable efforts, with so much diversity in the region and with the problems Latin America has had to face, it is not surprising that food regulation has also been challenging.

The Codex Alimentarius Coordinating Committee for Latin America (CACCLA) was created in 1976 with the mandate to define the region's challenges and needs for food regulations as well as inspection systems, to strengthen the inspection infrastructure and to recommend the establishment of international standards for products of interest to the region; particularly products that in the Committee's judgment could have commercial potential in international markets; to establish regional regulations for products that are traded almost exclusively in regional markets; to identify important challenges unique to the region; and to promote the coordination of all food regulatory activities promoted by international organizations, local government and non-governmental organizations (Acosta & Marrero, 1985).

2.8.3 Challenges of Regional Food Regulation

A 1988 study of food regulation in Latin America sponsored by the Pan-American Health

Organization (2008) and the Food and Agriculture Organization noted the following deficiencies common in the region:

- Insufficient commitment on a national level to protect food.
- Lack of coordination between responsible agencies.
- Deficiencies in the laws and regulations.
- Problems in the infrastructure of agencies enforcing the laws and regulations.
- Lack of information.
- Insufficient participation in the preparation of international norms and a subsequent difficulty in accepting and applying them.
- Investigation.
- Inadequate sanitation education.

Since 1988 the region has made strides to overcome some of these deficiencies, but there is still a long way to go. According to Pineiro (2004), there are several key problems in the region. These can be grouped into three major areas: 1) inadequate food control systems (FCS); 2) lack of prevention and control policies and strategies coordinated into integrated national plans of action; and 3) insufficient awareness and funding. All these alone or in combination have important health and economic effects. From these issues, the first and foremost problem in the region is a weak FCS. Pineiro defines a FCS as a system of voluntary and mandatory activities carried out by food producers, processors, marketers and national or local authorities to provide consumer protection and ensure that all foods, domestically produced or imported, conform to national requirements of quality and safety. An adequate FCS has several major components that include Food Legislation, Quality Assurance, Food Inspection and Analysis (including infrastructure and human resources), Food Control Management and Information and Cooperation. From a weak FCS the other two major areas of concern inevitably follow and this, obviously complicates any regional efforts.

Harmonization is also complicated by the diversity of food control systems since these are at very different stages of development and are not always organized, developed, comprehensive or effective. In most Latin American countries, the systems are heavily challenged by problems of growing population and lack of resources. In many cases, there are sufficient food regulations but the enforcement capabilities are missing so the control is not always translated into better availability of a safe food supply. Even if there have been many efforts, in many cases, the regulatory framework is not harmonized with international standards.

2.8.4 Regional Intentions for Improvement: The Pan-American Commission for Food Safety (COPAIA 5)

Harmonizing regulatory requirements to assure safe and good quality foods and promote trade is of increasing interest to all countries in the Americas. In general, in the region, there are no structures and processes to achieve these objectives in a harmonized manner. Work towards regional structures and processes in the Americas has been strengthened and promoted via the activities of the Pan American Health Organization (PAHO), which is one of six regional organizations of the World Health Organization, and the Food and Agriculture Organization of the United Nations.

For example, PAHO plans and executes many training activities in the Americas. Recently, PAHO has supported establishment of a hemispheric Commission for Food Safety (COPAIA). Training and research links between the COPAIA and academic institutions in the Americas may be especially useful to promote collaborations and leverage resources (FAO, 2002).

Almost 20 years after the original PAHO study, it seems that, in reality, although the framework has improved and there are now commercial blocks trying to harmonize their regulatory systems, the challenges remain very much the same. During the Fifth Meeting of

the Pan-American Commission for Food Safety (COPAIA-5) celebrated in Rio de Janeiro, on 10 June 2008, the members of the Commission that consisted of delegates from the ministries of health and agriculture and representatives of the consumers and producer sectors of the sub-regions of the Andean Area, the British Caribbean, Central America, the Latin Caribbean, the Southern Cone and North America made the following statement:

'Recognizing that access to safe food and nutritionally adequate diet is a right of each individual, and convinced that:

- *Food safety is an essential public health function, which protects consumers against health risks posed by biological, chemical and physical hazards associated with food;*
- *If uncontrolled, the risks associated with food may become a major cause of diseases and premature death, as well as entailing losses owed to diminished productivity and serious economic damage to the agricultural, livestock and tourist sectors including agri-food industry, food processors, food distribution and retailers;*
- *Effective risk management and communication requires surveillance systems that can link disease outbreaks and illness to specific food supply chains;*
- *Appropriate implementation of food safety measures among and within countries can improve food safety on both a regional and a global scale;*
- *Integrated food safety systems can make possible the management of potential risks throughout the food chain from production to consumption;*
- *Measures aimed at food safety should be based on scientific evidence and on risk analysis principle, and avoid raising unnecessary barriers to food trade;*
- *The production of safe food is a primary responsibility of the food industry;*
- *Consumer education is an essential factor in promoting appropriate measures for ensuring food safety at home; and the sale of foods in general;*
- *Interactive communication with consumers is important for ensuring that society's values and expectations are taken into consideration in decision-making.*

Now therefore, the COPAIA 5 delegates recommend the:

- *Designation of competent food safety authorities as independent entities under a comprehensive legal framework encompassing the entire food chain from production to consumption;*
- *Adoption of regulations and other measures based on risk analysis to ensure food safety along the entire food chain from production to consumption, consistently with the guidelines and norms of the Codex Alimentarius Commission and other relevant organizations that work on the definition of norms and standards;*
- *Ensuring the food legislation's effective enforcement through methodologies based on risk analysis, such as the Hazard Analysis and Critical Control Points (HACCP) whenever possible;*
- *Adoption of programs for the monitoring of food, total diet studies and disease surveillance systems, so as to obtain prompt, reliable information about the prevalence and emergence of food transmitted diseases and biological and chemical hazards in food sources;*
- *Establishment of procedures, such as traceability and alert systems throughout the food industry, to allow the prompt identification and investigation of incidents related to contaminated food, and report to the WHO incidents contemplated in the International Health Regulation (WHO, 2005) through the International Food Safety Authorities Network-INFOSAN and the IHR focal points;*
- *Promotion of communication and effective consultation with consumers, the food industry, and other relevant sectors with a view to the formulation, implementation and review of food safety policies and priorities, including education with a systematic focus along the entire food chain from production to consumption;*
- *Proceeding further with the strengthening of capabilities in respect of food safety by means of effective cooperation between developed and developing countries, as well as among*

developing countries, so as to promote the access to food safety for all; and

- *Establishment of cooperation programs among international and regional technical cooperation organizations involved in food safety in areas of common interests and pursuant to the Member States mandates.'*

This declaration seems to cover the challenges faced by the region. However, the greatest challenge is in the actual implementation of the actions and promotion of true regional harmonization.

2.8.5 General Regulatory Structure

There are many general strategies to group different Latin American countries in blocks. These divisions are made based on geographical location, cultural background, language spoken, level of development, etc. The following statements are based on an informal division based in part on a geographical division as well as common typical regulatory structure. This division is by no means formal. In general, Caribbean countries have individual laws and regulations for consumer products. Some of the islands are associated with the European Union or the US and follow their regulatory structure while others have decided to adopt Codex standards as their own. Central American countries have individual laws and regulations and, again, in many cases have opted for the adoption of Codex standards. Most countries in South America have individual laws and regulations for products. However, five have entered a common market arrangement known as MERCOSUR. In addition, even when countries such as Bolivia, Chile, Colombia, Ecuador, the Falkland Islands, French Guiana, Guyana, Paraguay, Peru, Suriname have existing trade agreements, they maintain individual laws and standards for products. Chile, for example has very specific unprecedented laws for toluene limits in children's products.

2.8.6 Trade Agreements

There are several associations and trade agreements within the region. Each of these agreements varies widely in terms of their scope and the degree of harmonization.

2.8.7 The North American Free Trade Agreement

The North American Free Trade Agreement (NAFTA) between Mexico, the United States and Canada has had a profound effect in Mexican regulations. So, even when technically speaking this is not a Latin American Agreement, it is still of extreme importance to the region. NAFTA includes text on sanitary and phytosanitary measures, modeled after the Uruguay Round Agreement on sanitary and phytosanitary measures. Article 756 of NAFTA recommends that the three countries 'pursue equivalence of their respective sanitary and phytosanitary standards.' This article was drafted to assist in avoiding trade disputes among the three regarding the preparation and processing of food products that are traded. The idea is that the countries pledge to harmonize food production processes to 'the extent feasible' and that measures do not become disguised trade restrictions.

To avoid barriers to trade, the NAFTA agreement encourages countries to use relevant international standards, if existent, when developing their SPS measures. However, each country is permitted to adopt a standard more stringent than international standards to achieve an appropriate level of desired protection of human, animal or plant health if the standard is based upon scientific principles. The NAFTA signatories have agreed to work toward 'equivalent' SPS measures without reducing national levels of desired, appropriate protection. Equivalency recognizes that different methods may be used to reach the same level of protection. Each country agreed to accept the others' SPS measures as

equivalent, provided the exporter shows that its SPS measures meet the importer's desired level of protection as long as it is based on risk assessment techniques (Looney, 1995).

Mexico's inclusion in the NAFTA agreement has permitted it to reach a level of parity with the US that other Latin American trade partners may not reach for several years. But before this could occur, officials in Mexico, the US and Canada, spent years comparing standards in food regulation and making changes that would permit this trade partnership to go forward on a common basis. No other countries in Latin America have attempted, much less achieved, what Mexico has done up to this moment in time to warrant inclusion in a regional trade agreement with the US.

2.8.8 Andean Community

The Andean Community (Peru, Ecuador, Colombia, and Bolivia) is a South American organization that was founded to encourage industrial, agricultural, social and trade cooperation. In 2005, this organization signed an agreement with MERCOSUR. Through this, the Andean Community gained four new associate members, Argentina, Brazil, Paraguay and Uruguay. Among the objectives of this association is to facilitate the participation in the regional integration process, with a view to the gradual formation of a Latin American common market. At the time of writing, the Technical Committees have been able to finalize a few common (harmonized) Andean standards, with several more in the project stage. The Andean Group Member Countries are also working on the harmonization of health and consumer safety requirements for processed foods, pharmaceutical products and cosmetics. Members are considering the creation of Ad Hoc Committees to consider standards-related aspects of security, health, consumer protection, the environment and national defense of Andean Group members. The Andean countries have adopted the ISO/IEC guidelines related to standardization and conformity assessment procedures. With respect to the adoption and/or development of Andean standards, Decision 376 sets out an order of preference from which these should be drawn, proceeding from international standards, to regional standards, to national standards of Member Countries, followed by those of non-member countries and lastly, to those of private standards organizations (OAS, 1998).

2.8.9 Caribbean Community and Common Market

The Caribbean Community and Common Market (CARICOM) is an organization that aims at the eventual integration of its members and economies and the creation of a common market. Its members include: Antigua and Barbuda, Belize, Grenada, Montserrat, St. Vincent and the Grenadines, Turks and Caicos Islands, The Bahamas, British Virgin Islands, Guyana, St. Kitts and Nevis, Suriname, Barbados, Dominica, Jamaica, Saint Lucia, and Trinidad and Tobago. As signatories to the WTO, CARICOM countries are expected to harmonize national and regional food safety standards with Codex standards in the import and export of food products, and to adopt the WTO approach to food safety.

The Caribbean Food Safety Initiative (CFSI) was designed by the CARICOM Secretariat, the US Department of Agriculture (USDA), the Food and Drug Administration (FDA) and the Interamerican Development Bank (IDB). The purpose of this initiative was to develop a model approach to assist countries in meeting their WTO Sanitary and Phytosanitary obligations. The outcome of the first mission of specialists was used by the CARICOM Members to achieve greater harmony among national and regional food safety policies and infrastructures; promote technical cooperation among developing countries, and leverage financial support from international donor groups (FAO, 2002).

2.8.10 Central American Common Market

The Central American Common Market (CACM), is a well integrated group of five Central American economies (Guatemala, Honduras, El Salvador, Nicaragua and Costa Rica). The progress in this regional integration has been the consequence of forty years under the CACM, this is a far-reaching trade agreement that, among other things, ensures tariff-free exchange for 99.9% of the native products within the region. The CACM also provides common regulation in many areas from services to product registry to dispute resolution. The region has now been working for a few years in upgrading the common market into a Central American Customs Union. This means extending the integration process to a point in which internal customs procedures for trade within the isthmus become redundant and are eliminated, while customs procedures for trade with non-regional partners are homogenized and administrated jointly. However, at the time of writing, although Central American Countries have adopted Codex Standards as their own, in practice, each country still follows their own individual rules.

2.8.11 MERCOSUR

Argentina, Brazil, Paraguay, and Uruguay created MERCOSUR in March 1991 with the signing of the Treaty of Asuncion. MERCOSUR was originally created with the ambitious goal of creating a common market similar to the European Union. Venezuela became a full member in 2006. Similar to the EU, MERCOSUR has different legislative and technical organizations that create legislation and standards that are voted on and if passed are supposed to be adopted into national law. Although many hundreds of standards have been created and adopted by MERCOSUR, individual country adoption is still lagging. Food law harmonization has been conducted by the SGT-3 (Technical Regulations Work Subgroup) under the responsibilities of the Food Committee. Originally, the objective was to have all food law harmonized in time for the start of the single market. However, not only were few MERCOSUR resolutions adopted by 1 January 1995, but of those, very few were actually implemented by the member countries at that time. In general, the process as followed before the adoption of a MERCOSUR initiative by the member countries is (De Figuereido Toledo, 2000):

1. Elaboration of the proposals to be discussed jointly by governmental and private institutions.
2. Submission of the proposals to all member countries during an ordinary meeting of the SGT-3 Food Commission.
3. Discussion of the proposal by the specific ad hoc group.
4. Approval of the proposal by consensus.
5. Elaboration of a MERCOSUR project of technical regulation.
6. Internal discussion of the project within each member state by all interested parties
7. Approval of the project by the SGT-3
8. Submission of the harmonized project to the GMC for approval as a resolution.

In order to supplement the scientific knowledge required to set food standards, *Codex Alimentarius* standards, guidelines and recommendations as well as EU directives and the US FDA regulations are consulted. The process is well established. However, with the participation of four (now five) countries with different laws, habits, idiosyncrasies and interests, harmonization has not progressed as originally planned.

2.8.12 Conclusion

Although food law harmonization is highly desirable to set a level playing field for global food trade, its implementation, in reality, may be hampered by many challenges. In the Latin

American region, these challenges are further complicated by the diverse level of development of national food control systems. Each country must first face the challenges of their own internal system before participating in a more regional approach. This development could be facilitated by the adoption of already internationally recognized standards such as the *Codex Alimentarius*. However, it is important to consider that each country has its own idiosyncrasies and needs and thus, the level of adoption and the activities for implementation may still be very different. The process of regional harmonization will still take some time and will depend on technical assistance and the use of sound risk assessment activities that are already available through international organizations. In some cases, harmonization activities may already be well-defined on paper. However, the challenge still resides in making them a reality.

2.9 EUROPEAN UNION

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2.9.1 Introduction

From its beginning in 1958 the European Economic Community devoted much of its attention to agriculture. Initial motivators where the desire to gain self sufficiency and to support the rural areas and their agricultural population. Almost immediately legislation started to develop addressing food as a commodity in its own right.[55] At first this legislation originated from the directorate general (DG) responsible for agriculture, but emphasis shifted to the DGs responsible for industry, enterprises and the internal market.

From the early 1960s until the eruption of the BSE crisis in the mid-1990s, European food law was principally directed at the creation of an internal market for food products in the EU.

This market-oriented phase can be divided into two stages. During the first, emphasis was on harmonization through vertical directives. This stage ended with the 'Cassis de Dijon' case law. During the second stage emphasis shifted to harmonization through horizontal directives.[56]

The BSE crisis and other food scares in the 1990s brought to light many serious shortcomings in the existing body of European food law. It became evident that fundamental reforms would be needed. In January 2000 the European Commission announced its vision for the future development of European food law in a "White Paper on Food Safety".[57]

The "White Paper on Food Safety" emphasized the Commission's intent to change its focus in the area of food law from the development of a common market to assuring high levels of food safety. In the years since its publication, a complete overhaul of European food legislation has taken place.

2.9.2 Creating an Internal Market for Food in Europe

When the six original members of what is today the European Union signed the Treaty of Rome in 1957, they created a community with an economic character. This was reflected

[55] It took some decades, however, before food law developed as an academic specialization. The European Council for Agricultural Law (CEDR: Comité Europeèn de Droit Rural: <www.cedr.org>) for example was established in 1957. The European Food Law Association (EFLA: <www.efla-aeda.org>) in 1973.

[56] The distinction between horizontal and vertical directives will be discussed hereafter.

[57] COM(1999) 719 def. Commission White Papers traditionally contain numerous proposals for Community action in specific areas, and are developed in order to launch consultation processes at the European level. If White Papers are favorably received by the Council, they often form the basis of later "Action Programs" to implement their recommendations.

not only in its original name—the European Economic Community—but also in the original objective to create a common market.

At the heart of the instruments to achieve this objective are the so-called four freedoms of the European Union: the free movement of labor, the free movement of services, the free movement of capital and the free movement of goods. The free movement of goods[58] has been vital to the development of food law.

During the first years of implementing the ambitious idea of trade without frontiers, Community legislation aimed primarily at facilitating the internal market through the harmonization of national standards. Agreement about the quality and identity of food products was considered necessary. To reach such agreement directives were issued on the composition of certain specific food products. This is called vertical (recipe, compositional or technical standards) legislation. Vertical legislation resembles the product standards of the *Codex Alimentarius*.

Early attempts to establish a common market for food products in Europe by prescribing harmonized product compositions faced two substantial obstacles. Firstly, at that time all legislation required unanimity in the Council, which gave each member state a virtual right of veto over new legislation. Secondly, there was the sheer scale of the task. Browse through a supermarket in any EU member state and consider the variety of products on the shelves. There are, as the Community institutions soon realized, simply too many food products to deal with. Creating compositional standards for each product would have been a mission impossible, and the Commission wisely chose to seek alternatives. Nevertheless quite a few products remain subject to European rules on compositional standards.[59] These compositional standards form the legacy of the first phase of EU food law. They are being updated or replaced when necessary but no new products are being added.

2.9.3 Advancement Through Case Law

It was the Court of Justice of the European Communities that showed the way out of the deadlock through new, broad, interpretations of the key provision on the free movement of goods in the common market: Article 28 of the EC Treaty.[60] This Article prohibits quantitative restrictions on imports and all measures having equivalent effect.[61]

This article should be read in connection with Article 30 of the EC Treaty which lists possible exceptions to the free movement of goods, such as the protection of health and life of humans, animals or plants.

The landmark decision in this context was Cassis de Dijon.[62] A German chain of supermarkets sought to import Cassis de Dijon, a fruit liqueur, from France. The German authorities, however, refused to authorize the import because the alcohol content was lower than allowed by German national law, which stipulated that such liqueurs should contain at least 25% alcohol. Cassis de Dijon contained just 20% alcohol.

The German authorities acknowledged that this was a restriction on trade, but sought to justify it on the basis that beverages with too little alcohol pose several risks. The German

[58] Now Article 3 (1)(c) and Article 23–31 EC Treaty.

[59] E.g. sugar, honey, fruit juices, milk, spreadable fats, jams, jellies, marmalade, chestnut puree, coffee, chocolate, natural mineral waters, minced meat, eggs, fish. Wine legislation is a body of law in itself. For legislation on fresh fruit and vegetables. Compositional standards still figure prominently in the *Codex Alimentarius*.

[60] At that time numbered Article 30.

[61] On the relevance of Article 25 EC Treaty banning customs duties and charges having equivalent effect, see Broberg (2008), sections 2.3 and 2.4.

[62] EC Court of Justice 20 February 1979, Case 120/78 (Cassis de Dijon), ECR 1979, page 649.

authorities argued that alcoholic beverages with low alcohol content could induce people to develop tolerances for alcohol more quickly than beverages with higher alcohol content, and that consumers trusting the (German) law might feel cheated if they purchased such products with the expectation of higher alcohol content. Finally, Germany submitted that in the absence of such a law, beverages with low alcohol content would benefit from an unfair competitive advantage because taxes on alcohol are high, and beverages with lower alcoholic content would be saleable at significantly lower prices than products produced in Germany according to German law.

The Court held that the *type* of arguments presented by the German authorities would be relevant, even where they did not come under the specific exceptions contained in the EC Treaty, provided that those arguments met an urgent need. This is known as the rule of reason.

The Court found that Germany's public health argument did not meet this standard of urgency. The Court specifically cited the availability of a wide range of alcoholic beverages on the German market with alcohol content of less than 25%. As to the risk of consumers feeling cheated by lower than expected alcohol content, the Court suggested that such a risk could be eliminated with less effect on the common market by displaying the alcohol content on the beverages label.

For cases such as this one, in which there are no specific justifications for restrictions on the trade between Member States, the Court introduced a general rule: products that have been lawfully produced and marketed in one of the member states, may not be kept out of other member states on the grounds that they do not comply with the national rules. This is called the *principle of mutual recognition*.

With its ruling the Court in Luxemburg laid the legal foundation for a well-functioning common market. Food products that comply with the statutory requirements of the member state where they are brought on the market must, in principle,[63] be admitted to the markets of all other member states.

Several commentators expressed concern that the Cassis de Dijon decision would lead to product standards based on the lowest common denominator. It is clear that manufacturers established in member states with the most lenient safety or technical requirements or legal procedures do gain a competitive advantage.

The limitations and drawbacks of the principle of mutual recognition highlighted the need for further harmonization of food requirements at the European level. For member states with more stringent national standards, European-level legislation became the best hope for raising neighbors' standards. The Cassis de Dijon ruling marked a significant change in the perception of the benefits of harmonization. Before Cassis, harmonization was seen merely as a condition for the functioning of the internal market. Afterwards, emphasis shifted to the need to alleviate the consequences of the internal market. In legal terms, too, the wave of harmonization that followed Cassis differed from earlier efforts. Emphasis shifted from product-specific legislation, to horizontal legislation, meaning general rules addressing common aspects for a broad range of foodstuffs.

Mutual recognition remains the rule up to this day. Food products that have legally come to the market in any member state, may in principle be sold without restrictions across the whole territory of the European Union.

2.9.4 Breakdown

The heyday of market-oriented food law based on mutual recognition ended in tears. The food and agricultural sectors in the European Union emerged deeply traumatized from the

[63] Exceptions can be based only on Article 30 of the EC Treaty or the rule of reason.

1990s. A series of crises resulted in a breakdown of consumer confidence in public authorities, industry and science. The current third phase of EU food law can only be truly fathomed if the trauma to which it responds is understood.

Although the bovine spongiform encephalopathy (BSE) crisis was not the first and, in terms of death toll, not the worst[64] food safety crisis in the EU it caused an earthquake in the legal and regulatory landscape of Europe. Subsequent food safety scares,[65] outbreaks of animal diseases[66] and scandals over fraudulent practices, added to a sense of urgency to take protective measures. These fraudulent practices included the discharge of waste in animal feed[67] and the underworld involvement in the supply and employment of growth hormones[68] mounting to the murder of the veterinarian who brought the use of these illegal substances to the attention of the authorities and the public (Butler, 2002).

Public awareness of the BSE-epidemic, and the time it had taken British and European authorities to address it, presented a major challenge to European cooperation in the area of food safety. When the extent of the crisis became public, the European Union issued a blanket ban on British beef exports. In response, Britain adopted a policy of non-cooperation with the European institutions, and sought to deny the extent and seriousness of the BSE problem.[69]

The European Parliament played a crucial role in defusing this crisis. A temporary Enquiry Committee was instituted to investigate the actions of the national and European agencies involved in the crisis.[70] The Enquiry Committee presented its report in early 1997 (Ortega Medina Report, 1997). The report strongly criticized the British government as well as the European Commission. The Commission was accused of wrongly putting industry interests ahead of public health and consumer safety, science had been biased and transparency had been lacking.

Paradoxically, this reproachful report followed by a motion of censure proposed to the

[64] *See* Abaitua Borda *et al*. (1998); Gelpí *et al*. (2002) (finding that the toxic oil syndrome (TOS) epidemic that occurred in Spain in the spring of 1981 caused approximately 20,000 cases of a new illness. Researchers identified 1,663 deaths between 1 May 1981 and 31 December 1994 among 19,754 TOS cohort members. Mortality was highest during 1981). The poisoning was caused by fraud consisting of mixing vehicle oil with consumption oil.

[65] One example is the Belgian dioxin crises. It was caused by industry oil that had found its way into animal feed and subsequently into the food chain (Whitney, 1999). Another example is the introduction of medroxyprogesterone acetate (MPA) into pig feed in 2002 (Graff, 2002). Sugar discharges from the production of MPA, a hormone used in contraceptive and hormone replacement pills, were used in pigs feed and by that route MPA entered the food chain. In 2004 a dioxin crisis broke out in the Netherlands.

[66] Like Food and Mouth Disease, SARS and Avian Influenza.

[67] Probably the cause of the first dioxin crisis (Whitney, 1999).

[68] Community and national legislatures in the EU have been battling the use of artificial hormones—DES (diethylstilbestrol) in particular—for years. When it turned out to be impossible to separate their use from body-proper hormones and to get them under control, finally all hormones were banned. The legislation on the use and application of hormones started with Directive 81/602 (prohibiting certain matters with hormonal effects and of stuffs with thyrostatic effects). Directive 81/602 has been supplemented by Directive 85/358/EEC and replaced by Directive 88/146/EEC (prohibition of applications of certain stuffs with hormonal effect in the cattle breeding sector). A next one, Directive 88/299 is aiming at the trade in animals and meat treated with stuffs with hormonal effect referred to in Directive 88/146.

[69] A symbolic event was shown on TV where the responsible Secretary of State, John Gummer is shown feeding his little daughter a hamburger, to convince the public that nothing was wrong with British beef (16 May 1990, BBC). Text, picture and video available at BBC (16 May 1990).

[70] OJ 1996 C 261/132.

European Parliament provided the Commission with the impetus it had hitherto lacked; indeed with a window of opportunity, to take the initiative for restructuring European food law in a way that considerably strengthened its own powers. The Commission undertook far-reaching commitments to implement the Committee's recommendations.

Progress was made along institutional lines as well as policy lines. The Directorate General (DG) XXIV "Consumer Policy" created two years earlier, was reinforced and renamed "Consumer and Health Protection Policy" and included the scientific advisory committees from the DGs for Industry and Agriculture.[71] A Scientific Steering Committee was created to bring wider scientific experience and overview to consumer health questions. The internal market "product warning system" was also transferred from DGIII (Agriculture) to DGXXIV. As of 1997, the centre of gravity in food legislation moved from DG Agriculture to DGXXIV, now called "SANCO."

As early as May 1997, the Commission[72] published a Green Paper on the general principles of food law in the EU.[73] It set out the structure of a legal system capable of getting a firm grip on food production. Consumer protection was made the main priority. The Commission committed to strengthening its food safety control function. This led directly to the establishment of the Food and Veterinary Office (FVO) in Dublin in 1997.[74] The FVO was charged with carrying out the Commission's control responsibilities in the food safety sector, to include controlling animal health and welfare and auditing third countries that wish to export to the EU. Furthermore, the Commission announced the establishment of an independent food safety authority.[75]

The Commission kept the pressure on beyond 1997, eventually gaining the support of the European Court of Justice for the measures that had been taken against Great Britain at the climax of the crisis.[76]

On 12 January 2000 the Commission published its famous White Paper on Food Safety.[77]

2.9.5 The White Paper: A New Vision on Food Law

The Commission's vision on the future shape of EU food law, its blueprint so to speak, was laid down in the White Paper on Food Safety. Before the BSE crisis, European food safety law was subordinated to the development of the internal market. The shortcomings in the handling of the crisis clearly revealed a need for a new, integrated approach to food safety.

The Commission aimed to restore and maintain consumer confidence.

The White Paper focused on a review of food legislation in order to make it more coherent, comprehensive and up-to-date, and to strengthen enforcement.

[71]Knudsen & Matikainen-Kallström (1999); European Parliament Fact Sheets 4.10.1. Consumer Policy: principles and instruments, chapter 3 Reform in the wake of the BSE crisis, Green Paper on general principles of food law.
[72]Interestingly, DG Industry was the instigator.
[73]*Commission Green Paper on the General Principles of Food Law in the European Union*, COM(1997) 176.
[74]*See generally* DG Sanco (2002 and 2007).
[75]Communication of the European Commission, Consumer Health and Food Safety COM(97) 183 fin. of 30 April 1997. See also: James, Kemper, & Pascal (1999).
[76]*See* Case C-157/96, The Queen v. Ministry of Agric., Fisheries and Food, 1998 ECR I-02211; Case C-180/96, United Kingdom of Great Britain and Northern Ireland v. Commission, 1996 ECR I-03903; Case C-209/96 UK vs. Commission.
[77]COM(1999) 719 final. Unlike a Green Paper that is intended mostly as a basis for public discussion, a White Paper contains concrete policy intentions.

Furthermore, the Commission backed the establishment of a new European Food Safety[78] Authority, to serve as the scientific point of reference for the whole Union, and thereby contribute to a high level of consumer health protection.

2.9.6 Implementing the Vision

The Annex to the aforementioned White Paper is the Action Plan on Food Safety, a list of 84 legislative steps that the Commission deemed necessary to create a regulatory framework capable of ensuring a high level of protection of consumers and public health.

The turn of the millennium saw the beginning of the planned overhaul of European food law. The first new regulation took effect in 2002 and at the time of writing most of the 84 steps have been taken.[79] The new regulatory framework is based on regulations rather than directives.

Only two years after the White Paper was published, the cornerstone of new European food law was laid: 'Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety'.[80] This regulation is often referred to in English as the 'General Food Law' ('GFL'). The Germans speak of it as a 'Basisverordnung'—perhaps a more precise phrase given that the regulation is in fact the basis upon which European and national food laws are now being reconstructed.[81] The main objective of the General Food Law is to secure a high level of protection of public health and consumer interests with regard to food products. It does so by stating general principles, establishing the European Food Safety Authority and giving procedures to deal with emergencies.

TABLE 2.7 Highlights in the overhaul of EU food law

2002	Regulation 178/2002 (GFL)
2003	Regulations 1829/2003 and 1830/2003 GMO package
2004/2005	Regulations 852-854/2004 Hygiene package
	Regulation 882/2004 Official controls
	Regulation 1935/2004 Food contact materials
2006/2007	Regulation 1924/2006 nutrition & health claims
2007	White Paper A Strategy for Europe on Nutrition, Overweight and Obesity related health issues
Ongoing	Obesity policy
	Modernization pesticides legislation
	Modernization legislation on additives, flavorings, enzymes and novel foods
	Modernization of labeling legislation

After the General Food Law, whole packages of new legislation followed (Table 2.7).

It is next to impossible to predict how long we will remain in the third phase of EU food law and what will come afterwards.

The window of opportunity for large-scale legislative projects on food that opened after the animal health and food safety scares of the 1990s seems to be closing. Some finalising proposals are underway. If no major crisis sparks new

[78]In the White Paper the Commission speaks of a European Food Authority. The word 'safety' was inserted later.
[79]*See* Knipschild (2003), Nöhle (2005), and Berends & Carreno (2005).
[80]OJ 1.2.2002 L 31/1.
[81]New European food law displays several characteristics in which it is different from its predecessor: more emphasis on horizontal regulations (than on vertical legislation), more emphasis on regulations that formulate the goals that have to be achieved, so-called objective regulations, than on means regulations; increased use of regulations (rather than directives) and thus increasing centralization.

action, it seems unlikely that more legislation of fundamental nature will be undertaken in the near future. The EU legislator will probably feel prompted to make an attempt at simplification and reduction of burdens for the food sector.

The most pressing issue on the agenda for the years to come is probably overweight and obesity. So far the EU legislator has not found suitable instruments to deal with this problem. Measures are currently limited to providing consumers with information directly and on food product labels.

2.9.7 Analysis

The quantity of European legislation regarding food is overwhelming. The food sector has become the third most regulated sector in the EU (after automobiles and chemicals). At closer look, however, the structure turns out to be rather straightforward. There are public powers of law enforcement[82] and incident management and legislation addressing food businesses.

Legislation addressing food businesses usually can be grouped in one of three categories: legislation on the product, legislation on the process and legislation on presentation.

The whole structure is embedded in general principles.

2.9.7.1 Principles of EU Food Law

The General Food Law provides some general concepts, obligations, requirements and principles of food law. Food law should aim at the protection of human life and health and (other) consumers' interests (Article 5). In protecting life and health it should be science based, that is to say based on risk analysis (Article 6). When scientific risk assessment is inconclusive the precautionary principle justifies temporary measures to be taken to protect from possible risks (Article 7). The authority responsible for risk assessment is the European Food Safety Authority—EFSA (Article 22).

Where international standards—like the *Codex Alimentarius* exist—or their completion is imminent, they shall in general be taken into consideration in the development or adaptation of food law (Article 5(3) GFL). The definition of food for example is tailored to the Codex and also the principle of HACCP as elaborated in the Codex is incorporated in EU food law (see hereafter). The legion of product standards that is available in the Codex has less influence on EU legislation as product specific legislation has been largely abandoned in the EU (see above).

Food businesses are responsible for ensuring compliance. Member states are responsible for enforcement (Article 17).

2.9.7.2 Product

Legislation addressing the product can be further subdivided in three categories: 1) compositional standards, 2) market access requirements, 3) restrictions.

Above we have encountered (vertical) legislation about the composition or quality of products. This type loses in relevance.

The general rule is that producers are free in their choice of ingredients. Increasingly exceptions to this rule are made in the sense that approval is required of certain products. Approved products are included in so-called positive lists (lists of products that may be used).

The most important categories for which approval is required are food additives,[83] genetically modified foods[84] and novel foods.[85] Food additives are synthetic substances that are not foods by themselves but are added to foods for

[82] Regulation 882/2004.

[83] *See* Additives Framework Directive 89/107; Sweeteners Directive 94/35; Colours Directive 94/36 and Miscellaneous Additives Directive 95/2. A proposal for a modernization of this legislation is currently in procedure.

[84] Regulations 1829/2003 and 1830/2003.

[85] Regulation 258/97. A proposal for a modernization of this legislation is currently in procedure.

technological reasons like preservatives, gelling agents and colors. Genetically modified foods are foods consisting of, made from or made with organisms to which gene technology has been applied. Novel foods are all (other) foods that have not been consumed to a significant degree in the EU prior to 1997.

The most important criterion for approval is scientific risk assessment.

Finally, there is legislation setting limits to the presence of undesirable substances (contaminants) or organisms in food.[86] The limits are set on the basis of scientific risk assessment. To products that have not been approved or for which no lowest safety level can be established, a zero tolerance may apply.

2.9.7.3 Process

It has been recognized that in order to ensure food safety processes must be under control in production as well as in trade. Practices aimed at the prevention of food safety risks are known as 'hygiene'. At the heart of EU legislation on food hygiene is the so-called HACCP-system: Hazard Analysis and Critical Control Points.[87] This system requires food businesses to make such an analysis of their processes that they know where hazards may occur, how to recognize them and how to deal with them in order to maintain food safety. Application of the system must be well documented.

In trade a requirement of traceability applies (Article 18 GFL). Food businesses must record where their inputs come from and where their products go. If a food safety incident occurs this information must enable the authorities to swiftly identify the origin of the problem and its dispersal in order to eliminate the cause and take care of the consequences.

Finally, businesses that have reason to believe that a food they have brought to the market may not be in conformity with food safety requirements, are under obligation to withdraw it from the food chain and recall it from consumers (Article 19 GFL).

2.9.7.4 Presentation

A large part of food legislation addresses the information food businesses provide to consumers regarding their product through advertising and—mainly—labeling. The most important codification of these rules is to be found in Directive 2000/13 of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs: the so-called 'Labeling directive'.[88] Labeling means 'any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff'. Labeling may not be misleading.

All pre-packaged food products must be labeled in a language that is easily understood. Usually this means in the national language of the member state. Other information is mandatory, restricted or forbidden.

There are about twelve required (mandatory) pieces of information, the most important of which are: the name under which the product is sold; the list of ingredients; the quantity of certain ingredients or categories of ingredients; the presence of allergens; in the case of pre-packaged

[86] *See* Framework regulation 315/93; Regulation 1881/2006 on mycotoxins and chemicals; Regulation 2073/2005 on microbiological criteria; Regulation 396/2005 on pesticide residues; Regulation 2377/90 on veterinary drugs and Directive 96/22 on hormones.

[87] *See* Regulation 852/2004.

[88] OJ 6.5.2000 L 109/29. A proposal for a modernization of this legislation is currently in procedure.

foodstuffs, the net quantity; the date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the 'use by' date; the name or business name and address of the manufacturer or packager, or of a seller established within the Community.

Specific labeling requirements demand that the presence of additives, novel ingredients and GMOs be mentioned on the label.

In 2006 a new Regulation on nutrition and health claims was published.[89] Nutrition claims must conform to the annex to this regulation. The annex states among other things that the expression 'light' may be only used in case of a reduction of at least 30% of certain nutrients or energy. Health claims e.g. claims about the effects of a certain food on health must be approved and science based. Foods bearing health claims are sometimes called 'functional foods'.

At present nutrition labeling, e.g. mentioning the nutrients and energy present in the food product, is voluntary except when a claim is made.[90] Legislation is in preparation to make it mandatory.

2.9.8 Science in EU Food Law

The general principle that food law in the EU is science based mainly means that authorities need scientific advice—for which the European Food Safety Authority is responsible at the community level—when they take decisions on requests for approval of certain foods or health claims and when they set maximum levels for contaminants.

2.10 NEAR EAST

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2.10.1 Geography

When dealing with food safety issues in this part of the world care must be taken to use the correct geo-political terminology. "Near East" is the term used by *Codex Alimentarius*. The Near East countries listed by Codex are the ones discussed in this section. They are: Algeria, Bahrain, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Oman, Qatar, Saudi Arabia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates and Yemen. It is important to draw a distinction between this list and the equivalent regional grouping of countries used by the World Health Organization and by various national governments. In a food safety context the countries in the "Near East" listed above do not always equate with the countries in the various geo-political definitions of the term "Middle East."

2.10.2 History

The history of food safety in the Near East is short. One reason is some of the countries became independent in recent times. So, it has taken time to develop a national food safety system. A second reason is countries in the Near East are net importers of food. There was a tendency until recently to sometimes rely on the safety measures taken by the authorities in the food exporting country to ensure that the food entering the region was safe. This is no longer the situation. National emphasis is now placed on the safety of both imported *and* exported food, resulting in a streamlining of food safety programs. Furthermore, food safety was assessed by multiple agencies in most countries. This resulted frequently in unnecessary duplication and breakdowns in communication between agencies. Adding to the problem was the application of different safety criteria to a food depending on whether it was produced locally or was

[89]Regulation 1924/2006.
[90]Directive 90/496.

imported; higher food safety requirements usually applied to the imported food. A significant impetus to food safety in the region is the rapid growth of tourism. This has produced increased efforts to ensure a safe food supply nationally and regionally.

Countries in the Near East who have made significant progress recently in modernizing and streamlining their food safety programs include Jordan, Saudi Arabia, United Arab Emirates, Egypt and Lebanon.

2.10.3 Jordan

Jordan established the Jordan Food and Drug Administration (JFDA) on 16 April 2003. It was established under the JFDA Act, 2003. The basic legislation regulating food control in Jordan is Food Law no. 79/2001. This law makes JFDA the responsible official agency entrusted to regulate and supervise food control activities in Jordan. Considerable resources were committed recently to ensuring that food laws were consistent with WTO rules and international standards. Laboratory facilities were improved significantly.

2.10.4 Saudi Arabia

Saudi Arabia established the Saudi Food and Drug Authority (SFDA) on 10 March 2003. This consolidated into one government authority all agencies previously involved with food and drug safety. The Saudi FDA was given a 5-year period to develop its structure, hire staff and establish laboratories. It was then required to submit a food safety law to ensure that all imported and indigenous food conforms to national and to internationally recognized standards.

2.10.5 United Arab Emirates

United Arab Emirates (UAE) has the Emirates Authority for Standardization and Metrology to regulate standards. Municipalities have the responsibility for ensuring food safety within each of the seven emirates in the UAE. The largest of these are in Dubai (Food Control Department under Public Health Services) and Abu Dhabi (Abu Dhabi Food Control Authority, ADFCA). Each emirate has its own food inspection system and food safety laboratories. Dubai has an annual food safety conference which is a forum for regional and international issues in food safety.

2.10.6 Egypt

Egypt has food laws dating back to the 1940s. The laws, inspection service and food safety laboratories have now been considered as inadequate by both the public and private sectors.

Much activity is taking place to improve the entire system by creating a single, unified food safety authority in Egypt. At the time of writing, a draft food safety law is being prepared for presentation to the Egyptian parliament.

2.10.7 Lebanon

Lebanon has made access to safe and healthy food a priority. It is modernizing its food safety legislation and strengthening public administration concerned with quality control and safety along the entire food chain. The Minister of Economy and Trade mandated the Lebanese Food Safety Panel to draft the new Lebanese Food Law by May 2003 to comply with international requirements. This is a work in progress still.

2.10.8 Other Countries

Algeria, Bahrain, Iran (Islamic Republic of), Iraq, Kuwait, Libyan Arab Jamahiriya, Oman, Qatar, Sudan, Syrian Arab Republic, Tunisia and Yemen are engaged also, to varying degrees, in modernization and streamlining their national food safety programs. In this group the Islamic Republic of Iran has the longest history in food

safety. Its Ministries of Agriculture, Health, Hygiene and Medical Education and the Iran Veterinary Organization (IVO) are engaged in food safety work. The Institute of Standards and Industrial Research of Iran was established in 1960.

2.10.9 Harmonization

There are encouraging signs of increased harmonization of food safety regulations between countries in the Near East. There is also a growing awareness of the importance of harmonization with internationally accepted food safety regulations. Examples of harmonization at the national level include the 2005 Memorandum of Understanding (MOU) signed between Dubai and Abu Dhabi on food control and veterinary services. This was done to better coordinate food safety and public health issues between the two authorities within the UAE.

The countries of the Gulf Cooperation Council (GCC) have a coordinated system of food control which they are improving further. The GCC countries are: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates.

An example of interest in harmonization at the regional level was the discussion paper on mutual recognition agreements between Near East countries on import/export accreditation. This was presented in 2005 by Jordan at the 3rd Session, Joint FAO/WHO Food Standards Program, FAO/WHO Coordinating Committee for the Near East. It describes a conceptual framework of a harmonized and cooperative regional approach towards the application of mutual recognition agreement(s) on a bilateral and/or multilateral basis between countries in the region. The paper highlighted the importance of accreditation of imports/exports and for the need to establish mechanisms for food import and export control based on equivalency systems.

Some recent examples of regional harmonization efforts are the drafting of a Code of Practice for Street Vended Foods, a regional Code of Practice for the Packaging and Transport of Fresh Fish, nutritional labeling in the region, and regional standards for harissa, doogh, pomegranate and for halawa with tehena. All of these were to be discussed at the January 2009 meeting of the FAO/WHO Coordinating Committee for the Near East.

In summary, there are efforts by all countries in the Near East region to improve and streamline their food safety systems. This is being done with attention to coordination with international standards and procedures.

2.11 NORTHEAST ASIA

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2.11.1 Introduction

Public concern regarding the safety of food is increasing due to the frequent food safety incidents such as BSE, dioxin, and melamine contamination of food that occurred over the past few years. In order to protect the health of the public, significant advances in food regulations and regulatory systems have been made to modify and upgrade the existing regulations and control systems in the Northeast Asia.

The food regulations in the region used to focus on the traditional food safety control measures such as necessary legal powers, relevant government bodies, regulatory enforcement actions, criminal investigations, import controls, business licenses, inspection and certification systems, quality and safety standards of foods, prohibition of unapproved/illegal uses of drugs and chemicals, and penalties/punishments for adulterated/misbranded foods or fraudulent health claims.

In recent years, however, more emphasis has been made on harmonized approaches with the international standards, science-based risk analysis, enhanced risk communication, better coordination among different authorities, and emergency response systems. The recently adopted "Food Safety Basic Law" in Japan and Korea provides a legal basis for consolidated efforts for coordinated regulatory framework and policy implementation among different agencies involved.

2.11.2 Development

The food regulations in most countries used to focus mainly on the traditional food safety control measures such as the designation of authorities with necessary legal powers for regulatory actions and criminal investigations, enforcement schemes, import controls, inspection and certification systems, business licenses, quality and safety standards of foods, prohibition of unapproved/illegal uses of drugs and chemicals, penalties and punishments for adulterated/misbranded foods or fraudulent health claims. Due to the diversity and complex nature of numerous food products ranging from agricultural, fisheries, meat and poultry products to processed foods, various ministries and local authorities were involved in the food control schemes by sharing the responsibilities of the safety and quality of the foods at different stages of the food supply chain; production, manufacturing, distribution, and sales of foods.

For the past few decades, China, Japan, and Korea had a Food Hygiene Law that played an important role in their national food safety control systems in covering the basic rules of hygienic practices and requirements for safe food to protect the public health. Each country has its own texts of the Food Hygiene Law, which was first enacted in Japan in 1947, followed by the Republic of Korea (South Korea) in 1962, and by the People's Republic of China in 1965.

Since the establishment of the World Trade Organization (WTO) in 1995, increasing volumes of international food trade have emerged. Because of growing concerns over food safety due to continuous occurrences of food safety incidents such as BSE, dioxin, and melamine contamination, there is an urgent need for significant changes in updating and upgrading food regulations and food safety control systems.

In an attempt to restore public confidence and consumer assurance, new legislation by the name of Food Safety Basic Law was introduced covering new control measures for prompt responses in emergency situations, securing science based risk analysis approach, better coordination and cooperation among different ministries to minimize any loopholes in the control system by establishing the Food Safety Commission or Food Safety Council.

Japan enacted the Food Safety Basic Law in 2003, and South Korea enacted its Food Safety Basic Law in 2008. China enacted its Food Safety Law on 28 February 2009 with the concept of organizing the Food Safety Council under the State Council to control and coordinate the works done by different ministries/authorities more efficiently. The Food Safety Council in Korea oversees the overall activities of the relevant authorities for policy directions and coordination, while the Food Safety Commission in Japan performs the risk assessment activities independently from other government agencies responsible for risk management decisions. At the time of writing, it has not yet been determined what role the Food Safety Council to be established in China will play; however, the Food Safety Law of China came into effect on 1 June 2009 and it replaces the Food Hygiene Law entirely.

The Food Safety Basic Law generally reflects the current interests and demands of the consumers in each country for better public assurance and emphasizes the importance of transparency, public information, traceability, nationwide food safety education, prompt response and preparedness for emergency situations. In addition,

harmonization with the international standards based on sound scientific evidence, responsibilities of governments and business operators, and role of consumers are emphasized to ensure the safety of foods.

2.11.3 Food Regulations in Japan

Japanese food regulations and administration are currently based on the Food Safety Basic Law enacted in May 2003, the Food Sanitation Law, the Abattoir Law, the Poultry Slaughtering Business Control and Poultry Inspection Law, and other related laws.[91] The Food Safety Basic Law was introduced to solve the various challenges faced by the relevant authorities, triggered by the occurrence of BSE (Bovine Spongiform Encephalopathy, so called Mad Cow's Disease) in 2001. An internationally harmonized risk analysis approach was broadly applied to the food safety policy of Japan by establishing the Food Safety Commission under the Cabinet Office mainly responsible for science based risk assessment, independent from the risk management roles carried out by the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Agriculture (MOA).

The Food Safety Commission is composed of seven Members, 16 Expert Committees, and the Secretariat. The Committees such as 'Planning Expert Committee', 'Risk Communication Committee', and the 'Emergency Response Committee' with 11 other Expert Committees review technical information for the risk assessment of potential hazards in foods.

The Food Sanitation Law (11 Chapters, 79 Articles) enacted in 1947, has been revised more than 30 times. It covers various responsibilities of the hygiene requirements of the manufacture and sale of food, business licenses, and standards/specifications for food, food additives, and food packages. The Abattoir Law and the Poultry Slaughtering Business Control and Poultry Inspection Law cover the hygiene requirements for livestock meat products for processing and sales. The Ministry of Health, Labor and Welfare is mainly responsible for the safe processing and sales of the food, while the Ministry of Agriculture is responsible for the safe production of agriculture, fisheries, and meat and poultry products under the Agricultural Products Quality Control Law and other related regulations such as the Plant Protection Law and the Quarantine Law.

2.11.4 Food Regulations in Korea

Food regulations and administration in Korea are currently based on the Food Safety Basic Law enacted in June 2008, the Food Sanitation Law, the Meat and Poultry Products Processing Law, the Health Functional Food Law, the Agricultural Products Quality Control Law, along with other related quarantine regulations.

The 2008 Food Safety Basic Law emphasized enhanced coordination and cooperation of different authorities dealing with various food safety issues more efficiently and effectively. The Food Safety Council was established under the Prime Minister's Office to oversee and coordinate the overall aspects of food safety activities and issues with an emphasis on risk management, risk assessment, and risk communication approaches for enhanced cooperation activities among relevant authorities. The emergency response system, promotion of public information, traceability, expert committees, and harmonization efforts with the international standards and norms are also emphasized.

The Food Sanitation Law (13 Chapters, 102 Articles) revised in full in 2009 covers the basic responsibilities and the hygiene requirements of the manufacture, process, distribution and sale of food, standards/specifications for food,

[91]Japanese Laws and Regulations, Cabinet Secretariat, Japan

food additives, and food packaging materials, The Ministry of Health, Welfare and Family Affairs (MOHWF) and Korea Food and Drug Administration (KFDA) are responsible for policy directions and enforcement of the overall food safety control systems.

The most recent revision of the Food Sanitation Law reinforced government's responsibility for emergency preparedness and prompt response, foodborne disease surveillance, inspection, certification of official laboratories, immediate recalls and prohibition of sale of contaminated food, extensive monitoring for risk assessment, establishment of the food safety information center, enhanced consumer participation to promote consumer assurance on various food safety issues.

The Meat and Poultry Product Processing and Handling Law enacted in 1962 highlighted the hygiene requirements and conditions for the processing and handling of meat and poultry products for distribution and sale and currently managed by the Ministry of Agriculture.

2.11.5 Food Regulations in China

The People's Republic of China Food Safety Law[92] was recently enacted on 28 February 2009, fully revising and replacing the existing Food Hygiene Act of 1995, and came into effect on 1 June 2009. Food hygiene regulations implemented and authorized by the State Council in 1965 have been revised and updated in various forms of regulations such as the Food Hygiene Act, the Product Quality Act, Animal Quarantine Act, and other related regulations.

The Food Safety Law enacted in 2009 (10 Chapters, 104 Articles) includes the fundamental hygiene requirements for the manufacture, processing, distribution and sale of food, mandatory safety assessment requirements for food additives and novel foods, legal requirements for standards, specifications for food, food additives, reporting of foodborne disease incidents, record keeping, risk assessment, and import and export inspection and certification systems, and the role and responsibilities of relevant authorities.

The Food Safety Law also authorizes the State Council to establish a Food Safety Council in order to enhance efficient coordination and cooperation among relevant authorities. The Ministry of Health is responsible for overall coordination and comprehensive management[93], investigation of major food related incidents, while the Ministry of Agriculture focuses on the production sector along with other relevant authorities. The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is responsible for import, export and quarantine of the products and inspection of the food manufactures. The State Food and Drug Administration (SFDA) supervises hygiene requirements of restaurants, and drugs. State Administration for Industry and Commerce (SAIC) regulates market activities and trade for consumer products including food products on sale.

The next section of this chapter discusses the situation in China more in detail.

2.11.6 Conclusion

The food regulations and food control systems in China, Japan, and Korea share some similarities and differences based on their social, political, and cultural backgrounds. In order to promote public confidence and consumer assurances for food safety, Japan and Korea have adopted new legislation, the Food Safety Basic Law, for complementary cooperation and better coordination among competent authorities. They have also reinforced the provisions of Food Hygiene Laws for prompt responses and

[92]China Food Safety Web, the People's Republic of China.
[93]Food Laws and Regulations, China Light Industry Press 2006.

management of the increasing number of food safety incidents.

China recently enacted the Food Safety Law complementing and replacing existing Food Hygiene Law to minimize the occurrence of food safety incidents and strengthen the coordination of multiple authorities involved in the food safety control system. The Food Safety Commission of Japan carries out the role for science based risk assessment activities, while the Food Safety Council of Korea mainly carries out the consultative role for decision making by coordinating all aspects of food safety activities of the ministries involved. China's Food Safety Council will be expected to carry out a similar role as the Food Safety Council of Korea to strengthen and streamline inter-agency coordination of food safety management system.

Due to recent advances in telecommunications including internet and cellular phones and increased international food trade, food safety in one country is no longer just a national issue. More transparent efforts should be made to enhance the food safety control systems and their capabilities to protect the health of consumers and to ensure fair practices in the international food trade.

2.12 CHINA

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2.12.1 Introduction

Having the largest population in the world, China always had a tough mission to ensure food security for its people. Meanwhile, with economic and social developments, especially the improvement of people's living standards, people have increasingly higher requirements and expectations on food safety, health and nutrition. However, the repeatedly emerging food safety issues within and outside China have triggered the public's great concerns and injured their confidence in food safety. The melamine incident in 2008 was a case in point. Given the importance of food safety regulation both for consumer protection and for food trade, the current food safety regulation in China is submitted to a reform for which the implementation of the Chinese Food Safety Law will be a catalyst. In this context several special issues on Chinese food safety regulation are worth mentioning to better understand the necessity of its reform. These can be analyzed as follows.

2.12.1.1 Gaps in the Current Food Legal Framework

The overall legal framework of China has changed significantly after implementation of the policy of reform and opening up in the late 1970s. Though China is a unified country, its legislative structure is multi-level, including the state laws (Constitution and basic laws) made by the National People's Congress and its Standing Committee, administrative laws and regulations by the State Council and its relevant departments respectively, and local regulations formulated by the relevant administrative organs of ordinary localities and governments etc.[94] With regard to food regulation, the total number of the food related laws, regulations and regulatory documents drafted by government departments at the ministerial level or above amounted to 832, but more than 40 have been invalidated since December 1978 (Zhang, 2008). Among the existing laws regarding food, the Food Hygiene Act and Product Quality Act are relatively important. The purpose of the Food Hygiene Act is to regulate the food activities such as the food

[94]For more information about the legislative structure in China, see <http://www.china.org.cn/english/kuaixun/76212.htm>.

production, processing, distribution, storage, purchasing, marketing and displaying, etc. The Product Quality Act is aimed at regulating the production and marketing of processed food. Although several stages of the food chains have been covered by these two acts, and the regulatory tasks based on sectors have been assigned to different competent authorities, not every stage of the food chain from farm to fork was being regulated in accordance with these laws. For example, the coverage of the Food Hygiene Act did not include plant agriculture and animal husbandry, and one contributing factor to the contaminated milk powder incident of 2008 was a lack of regulation on milk collection from individual farmers. Thus, a systematic and complete legal framework in the field of food safety regulation did not exist yet. This was partly because law making was done on an ad hoc basis and legislative power had been delegated to various agencies with different functions and at different levels. As a result, duplications and gaps, as well as regulatory conflicts between the different specialized laws made law enforcement difficult. Besides, the existing Food Hygiene Act was not sufficient to provide a legal basis for the whole food safety regulatory activities in the mainland. In this situation, the eagerly awaited first Chinese Food Safety Law has been promulgated and came into force on 1 June 2009.

2.12.1.2 Outdated Food Technological Standards

With the development of science and technology, technological standards concerning food safety have become obsolete, and to make matters worse, most of China's food technological standards were established back in the 1960s when the issue of food safety had not yet been well recognized. Generally speaking, the issues with the current food technological standards can be grouped into six key points. First of all, the high number of standard setting bodies has given rise to conflicting standards, for example between hygiene standards and quality standards. Secondly, some standards are inconsistent with the associated laws. Thirdly, the standards set by food companies are conflicting with government standards. Fourthly, there are no hygiene standards for certain foods which are already in production and being marketed on a large scale. Fifthly, the threshold for the same food products can differ from standard to standard. Sixthly, a large number of the food standards are out of date (Du Gangjian, 2008).

2.12.1.3 The Complicated Food Regulatory System

A typical issue in the multi-agency food regulatory system, is the ambiguity of the functions and responsibilities of the various competent authorities. These involve the Ministry of Health, the Ministry of Agriculture, the State Administration for Industry and Commerce, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), etc. Previously, great efforts have been made to try to solve this issue. Pursuant to article 3 of the Food Hygiene Law of 1995, the Ministry of Health, which is the administrative department of public health under the State Council, is in charge of supervision and control of food hygiene throughout the country while other relevant departments under the State Council shall, within the scope of their respective functions and duties, be responsible for control of food hygiene. However, lack of clarity in the delineation of the functions and responsibilities in this area has led to the system being dubbed as 'over eight departments that cannot figure out how to regulate one pig coordinately'. In this context, there have been administrative rules set up for clarifying the functions and responsibilities of the concerned departments like the Decision of the State Council on Further Strengthening Food Safety issued in 2004. Up until 2007, the attribution of the functions and responsibilities was sector based: the production of primary agricultural

products is supervised by the agriculture department; the quality and daily hygiene supervision of food processing is overseen by the quality supervision and inspection department; supervision of food circulation and distribution is done by the department of industry and commerce; and that of the catering industry and canteens is taken care of by the health department. The integrated foodsafety supervision and coordination as well as investigation of and penalties imposed for major incidents in this regard are the responsibility of the department of Food and Drug Administration, while imported and exported agricultural products and other foodstuffs are supervised by the quality supervision and inspection department.[95] Unfortunately, during the new round of administrative reform early in 2008 the Ministry of Health was reorganized; the State Food and Drug Administration (SFDA) was incorporated in that ministry. Several functions and responsibilities have been redistributed. The previous functions of the SFDA to supervise and coordinate activities with regard to food safety as well as to investigate major food safety incidents have been transferred to the newly established "Super Ministry of Health" while the SFDA is only responsible for the new tasks such as the supervision of food circulation and distribution. So far, the newly established 'Super Ministry of Health' did not succeed in preventing criminal acts such as the melamine incident.

2.12.2 The Chinese Food Safety Law

2.12.2.1 Introduction

The Chinese Food Safety Law was passed during its fourth review at the seventh session of the Eleventh National People's Congress Standing Committee in early 2009 and will come into force quickly. After several revisions, this law puts greater emphasis on the accountability of both the central government (relevant competent authorities) and local governments and the responsibility of food operators. The significance of the Chinese Food Safety Law, is analyzed here below.

2.12.2.2 The Authority of the Food Safety Law

Although food safety regulation is only one kind of administrative activity undertaken by the government to ensure food safety and to promote the food economy, the enactment of the Food Safety Law should still be in the form of basic law, given its important role serving as the legal basis in the food safety regulatory framework. As a basic law, it should be enacted and amended by the National People's Congress in China and all of the administrative regulations issued by the departments of government should be subjected to it. In other words, both law enforcement activities and law-making activities of the relevant competent authorities responsible for food safety regulation should conform to the Food Safety Law once it is in force.

2.12.2.3 The Main Elements of the Food Safety Law

As mentioned above, the Food Safety Law is a basic law. Its main concerns are the general principles and requirements. The Chinese legislators have taken inspiration from the principles and requirements as enacted elsewhere even though they may differ from country to country. Generally speaking, the following points have been embodied in the existing basic food laws in some countries/regions or recommended by international organizations such as FAO and WHO.

[95]State Council Information Office. 2007. White Paper on Food Quality and Safety. For more detailed information, see: The State Council, The Decision of the State Council on Further Strengthening Food Safety in 2004.

2.12.2.4 The Role of Science in Terms of Risk Analysis

It is universally recognized that food safety regulation should be based on scientific grounds as there are a growing number of risks that are becoming threats to human health. Against this background, a risk based measure, risk analysis, has been widely applied by developed countries. Risk analysis is composed of risk assessment, risk management and risk communication. However, the application of risk analysis in reality still varies from country to country and in China, only risk assessment has been put into place up till now. In this regard, the Chinese Food Safety Law has set up the provisions on risk assessment in order to base the whole food safety regulation on science. Several issues have been emphasized, including the monitoring system on risk, the circulation of the information about risks, the organization of risk assessment and its application, etc.[96]

2.12.2.5 The Food Standards

Chinese food standards consist of state standards, local standards, industry standards and enterprise standards. The multi level standards sometimes conflict with each other, and most of those standards are outdated or lower than the international ones. To systematize those food standards, China has committed to unify national food safety standards by conferring standard making powers on the Ministry of Health.[97] Furthermore, given situations such as the production and marketing of substandard food and food products, the conflicting standards set by different bodies, the regulation based on outdated standards or without established standards, it is also necessary to set up the general principles and requirements with regard to the standard setting procedures in order to ensure uniformity and consistence. To this end, Article 23 has provided that the national food safety standards should be approved by the national committee on standard review which consists of experts with food related background and government officials. In addition to this, before decisions are taken, the committee should consider the comments of different stakeholders and the results of risk assessment as a basis for setting standards.[98]

2.12.2.6 The Regulatory System

As mentioned above, after the latest round of administrative reform in early 2008, the food regulatory system still failed to realize its commitment to ensure the food safety. In light of the seriousness of this issue, this has been readdressed in the Chinese Food Safety Law which clarifies the functions and responsibilities of the different competent authorities with the Ministry of Health taking the leading role. Also, a new national food safety committee will be established to take charge of the cooperative and coordinated work in the field of food safety. Given the unknown structure of the newly created national food safety committee and the potential conflicts between the functions and responsibilities of the committee and the Ministry of Health (since both have been mentioned to have the function to coordinate work in regulation), it is still too early to conclude if the Food Safety Law will play out its role as designed.

2.12.3 Conclusion

Admittedly, there are high expectations for the Chinese Food Safety Law since it intends to introduce a new paradigm in the field of food safety regulation with its role serving as the sound legal foundation. Nonetheless, the formulation of a new food safety law is not a panacea

[96]Articles 11-17, Chinese Food Safety Law, 2009
[97]Articles 21 and 22, Chinese Food Safety Law, 2009.
[98]Article 23, Chinese Food Safety Law, 2009.

to solve existing food safety issues, as this also depends on law enforcement and compliance, let alone that there is still much room for improvement of the new food safety law in its current state. But it goes without saying that the enactment and implementation of the food safety law is still an essential step to improve food safety regulation in China, since as a 'constitution' in this field, the Food Safety Law will provide a legal basis for people to ensure their right to adequate food and for the regulators and regulatees to fulfill their obligation respectively.

2.13 THE RUSSIAN FEDERATION

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2.13.1 Introduction

Food law is not officially considered to be a separate branch of law in the Russian Federation. Politicians and scientists identify food quality and safety as a separate area of a more complicated sphere of social relations which is defined as food security. In its turn, food security is a part of an even more complex system determining the degree of social stability, and is included into the general notion of national security (Figure 2.1).

Food Law proper includes rules of constitutional, civil, administrative, criminal, customs law and some other items out of different spheres of Federal legislation as well as numerous by-laws (governmental decrees, departmental instructions, regulations, orders, etc.).

Food Law is considered an important element of consumer safety and even national security. The most important factors determining this attitude are the following:

1. Numerous counterfeit food items produced both domestically and abroad increasingly threaten consumers' lives and health. According to the National Fund of Protection of Consumers' Rights 50–85% (Chernova, 2008) of food items and 95% (Khurshudyan, 2008) of bioactive supplements at wholesale markets in the Russian Federation are forged in toto or partially, alcoholic beverages topping the list.
2. Poor quality food items both home made and imported do not meet normative requirements. 10-13% of the tested food items are reported as not corresponding to standards (Platishkin, 2007). Sanitary control authorities check more than 3,000,000 food items annually. In 2007 alone, 20% of imported fish and seafood, 14% of canned food, 66% of cereals and 60% of margarine were rejected as defective (APK, 2008). Every year around 1,000,000 people in Russia die prematurely of unnatural causes, one of the main reasons being diseases of the digestive system.
3. Increased use of genetically modified organisms in food items, among them such popular products as sausage, sweets, yogurts, chocolates, pastry and bread, corn, potatoes, tobacco and so on. Although the consequences of consuming genetically modified products are not yet sufficiently studied, scientists are extremely alerted as according to some oncological research, liver, blood, kidney diseases, alongside obesity

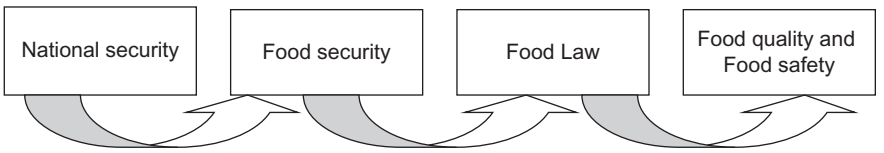

FIGURE 2.1 The hierarchy of food security in the general notion of national security in Russia.

and allergies, may be caused by such kinds of food. Sanitary authorities annually report around 2,000 non-registered transgenic food items (Platishkin, 2007). Unfortunately, consumers are not always necessarily informed about food composition, thus their subjective right of choice is violated.

4. Other Factors. Poor quality of food can be responsible as an indirect cause of a large number of demographic, medical, social and other federal problems.

It is a common truth that 17–20% of imported foods in the domestic market are considered crucial, and it is well-known that the developed countries are planning to decrease the share of imported food items down to zero. On the other hand, over 40% of food items in Russia are imported, the quantity increasing up to 70% in bigger cities. These and some other factors become a serious threat to lives and health of practically all the citizens of the Russian Federation. This is the reason why establishing a national food security system has become a matter of vital importance for the government and for the nation. In terms of its formation and efficient functioning the role of normative and legal regulations in the sphere of Food Law cannot be overestimated. It can significantly diminish the risks and improve the current situation.

2.13.2 The Current Condition of Legislation

It might seem while analyzing the Russian Federation Food Law that Russia is the most advanced country in terms of the quantity of current laws and by-laws defining the quality of food and its safety. But the truth is that Russia suffers more from the abundance of laws and their low quality rather than from their insufficiency. The multitude of by-laws hinders their implementation, as departments and controlling authorities (numbering more than ten at present) result in overlapping functions and activities. Therefore, the whole food chain has become inefficient. This directly causes the growth of the bureaucratic apparatus, thus encouraging corruption and massive violations of the law.

Apart from this the definitive part of the Russian legislation is of the reference nature and has some declarative elements. To implement the law, many ministries and departments have to elaborate regulations and instructions of their own, besides the above mentioned regulations. These are not necessarily well coordinated with each other. This factor also facilitates corruption and hinders the establishment of efficient control and supervision system.

One can see quite a clear-cut formally established legislation vertical in the sphere of food safety and subjective rights of the Russian Federation citizens who are the rightful participants of food legal relationship. In the number of its articles (Article 7, 17, 41, etc.), the Russian Federation Constitution of 1993 corroborates that the state assumes the functions of social protection and health care of its citizens, and that the appropriate provision of food supplies is considered to be one of the conditions for adequate life and free development of a person.

The main normative basis for providing the home market of the Russian Federation with food items all the way through the food chain are the following main Federal laws:

- No. 52-ФЗ 'On sanitary and epidemiologic well-being of population,' dated 30 March 1999, edited in 2007;
- No. 29-ФЗ 'On quality and safety of food items,' dated 2 January 2000, edited in 2008;
- No. 86-ФЗ 'On the state regulation of genetic engineering,' dated 5 July 1996, edited in 2000;
- No. 184-ФЗ 'On technical regulation,' dated 12 December 2002;
- No. 2300-1 'On protection of consumers' rights,' dated 1 February 1992, edited in 2008.

Alongside the above-mentioned, there are several fundamental normative legal acts being elaborated on in the Parliament (Duma) and in the government of the Russian Federation. They are as follows:

- Doctrine of food safety of the Russian Federation;
- Federal law 'On food security of the Russian Federation';
- A number of standards, technical regulations and Federal programs of the food market.

Presently there exist over 7,000 specifying hygienic regulations of food safety, among them 1,024 on sanitary chemical indicators; 1,432 on sanitary microbiological indicators; 2,890 on pesticides; 917 on substances and materials contacting food items, and 797 on biologically active supplements (Tutelyan, 2008). Basic notions of '*counterfeit food items*' and '*identification of food items*' are defined in the above mentioned Federal law 'On quality and safety of food items'. The term '*counterfeit product*' is defined in the Civil Code, although the Criminal Code of the Russian Federation and the Administrative Violations Code lack quite a number of principal notions from the sphere of substantive and procedural law which prevents the efficient and successful counteraction to the corresponding violations of law.

Current realities are such that the existing system of federal control and supervision over the quality and safety of food items cannot adequately cope with the recent changes in agricultural production and turnover. No proper attention is paid to control of the raw agricultural product.

Contemporary systems of quality management are based on thorough studies of the whole technological production process. Control and supervision over the manufactured items cannot be efficient at all. Another significant shortcoming is that legislators are especially interested only in a couple of parameters of control and supervision, for example, in obligatory testing of standard safety criteria evaluation. Other quality indicators are thus ignored by producers and this cannot be considered a positive tendency of the food law development.

2.13.3 Nearest Prospects

The forthcoming membership of the Russian Federation to the WTO involves multiple legal and organizational issues. Actual markets convergence requires coordination of national legal and technical normatives with international ones. Special committees are working on including provisions of *Codex Alimentarius* into many national standards and regulations.

A major joint project of the European Union and the RF Ministry of Agriculture was launched in Russia in February 2007. The Federal Service of Veterinarian and Herbal Supervision participates in the Project with the purpose of coordinating normative regulations in the sphere of sanitation and herbal sanitation in Russia. The Project was timed to function for 30 month with a budget of € 4,000,000.

Summing it all up, one can say that the Russian Federation is fully aware of the positive reaction on global integration and is working hard in that direction even though reckless convergence into the world market is fraught with economic dependence and loss of national identity.

2.14 CONCLUDING OBSERVATIONS

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2.14.1 Introduction

This chapter may well be unique in the development of food law as an international academic discipline. It may be the first time that such a wide variety of jurisdictions has been addressed in a single publication.

The materials on the worldwide development of food legislation that have been brought together in this chapter are of an explorative nature. They do not allow to draw hard conclusions, nevertheless some interesting observations can be made.

2.14.2 Current Situation

2.14.2.1 Rights Based?

In all the countries and regions presented in this chapter, the subject matter of food law clearly overlaps with the scope of the human right to food as recognized in the International Covenant on Economic, Social and Cultural Rights and similar international documents. Ensuring people access to safe and wholesome food and protection against risks to their life and health are key issues. Nevertheless, only in a few sections specific reference is made to this human right (e.g. Eastern Africa, Latin America, China and Russia). Probably food law is not usually perceived as human rights based.

2.14.2.2 Incident Driven

The sections in this chapter show that food legislation has developed worldwide since the dawn of time, but most rapidly during the last century. In most of the examples presented (with the exception of East Africa and the Near East), we see that legislation on food has a long history (current forms are often based on Nineteenth Century legislation in the UK as is the case with India, South Africa, Australia, New Zealand, USA and Canada). Food law's development over a longer period of time has given rise to a complicated structure (India, South Africa, Australia, New Zealand). Development has been prompted by incidents that occurred more or less spontaneously (animal health incidents, BSE in particular, EU, Japan) and by fraudulent adulteration (South Africa, Australia, New Zealand, USA, China, Russia). The latter was dealt with under criminal law (India, USA).

We have seen similar occurrences taking place in times and places far apart. An observation in the section on the Russian Federation for example ('50–85% of food items and 95% of bioactive supplements at wholesale markets in the Russian Federation are in toto or partially forged') sounds like an almost word perfect repetition of information given in the section on the USA ('Frederick Accum documented adulteration so widespread that he found it difficult to find a single type of food that was not adulterated; and some foods he scarcely ever found genuine') and Canada ('50% of all foods sold in Canada at the time were adulterated. Similar to the United States, nearly all coffee and pepper were adulterated, milk was diluted with water, and other high value items, such as tea and chocolate were often adulterated'). The Russian section refers to the situation as it stands today. The section on the USA and Canada on the other hand, is about a distant past (almost two over one century ago, respectively). Apparently, the battle against adulteration is a timeless feature of food law. In the Russian Federation, food safety is even considered a matter of national security.

Some authors observe a relationship between the occurrence of incidents and technological development. New ways of processing food bring new opportunities for fraud and new risks (USA, Canada). Genetic modification in particular is mentioned as a concern (in the contributions on Eastern Africa, EU and Russia). On the other hand, new technologies increase the possibilities to identify problems (USA, Canada).

A factor partly related to the protection against risks and incidents and partly a value in itself that stimulated development of food law, is the desire to facilitate interstate trade in federal societies (India, Australia, USA), international trade (WTO, Codex, Eastern Africa, Latin America, EU, Russia) and globalization more in general (Eastern Africa) sometimes expressed in terms of telecommunications (Northeast Asia). Even tourism is mentioned as a factor stimulating the development of food law (Near East).

2.14.3 The Way Forward

2.14.3.1 Quality of Food Law

Problems encountered within food legislation are expressed in terms of complexity, fragmentation, lack of cooperation, coordination (Latin America), coherence and consistency (India, Russia, China), conflicting provisions (China), scattered responsibility (South Africa, Near East, Northeast Asia), overlapping competences (India, Russia, China), bureaucracy and corruption (Russia). Implementation, supervision and enforcement are problematic issues as well (Australia, New Zealand, Eastern Africa, Latin America, China, Russia).

Developments like increase in national and international trade, globalisation more in general, increased processing of food accompanied by increased adulteration (USA, Canada, Russia), have contributed to a sense of urgency to take measures to reduce barriers (Australia, New Zealand, EU) to trade but also to protect public health and food safety (Australia, New Zealand). This issue is at the forefront in all countries discussed, but in particular in those that have been struck by food safety crises resulting in public outrage (sulphanilamide-USA, BSE-EU, melamine-China).

2.14.3.2 General Legislation

Recognition of food law as a branch of law in its own right seems to be a relatively new development in most countries and is only about to start in some other countries (Russian Federation). This development is expressed in attempts at chain integration (from farm to fork and from paddock to plate) (Australia, New Zealand, Latin America, EU, China) and the enactment of basic or general laws holding principles (EU: General Food Law, 2002, Japan: Food Safety Basic Law, 2003; India: Food Safety and Standards Act, 2006; Korea: Food Safety Basic Law, 2008; China: Food Safety Law, 2009). Maybe also the African Model Law on Safety in Biotechnology (AU) can be mentioned in this context.

Recurring expressions are harmonization (Latin America, EU, Near East, Russia) (or even uniformity—Australia) and mutual recognition (Australia, New Zealand, Latin America, EU, Near East).

2.14.3.3 Food Safety Authorities

Many countries have instituted a specialized body or central authority to consolidate food safety issues under 'one umbrella'. The roles of these authorities greatly vary from advice (FLAG-South Africa), coordination (Food Safety Council-Korea; Food Safety Council-China), risk assessment (EFSA-EU; Food Safety Commission-Japan), to regulation/legislation (Food and Drug Administration-USA; FSANZ-Australia and New Zealand; Tanzania Food, Drug Authority), and enforcement (Food and Drug Administration-Korea; State Food and Drug Administration-China), or combinations (Food Safety and Standards Authority of India; Jordan Food and Drug Administration). In some situations importance of independence is underscored (Eastern Africa, EU, Japan).

2.14.4 Outlook

Generally the contributions in this chapter are optimistic in tone. Food legislation is seen as progressing and improving. There are some concerns regarding its capability to ensure food safety (China, Russia). Hardly any side effects are mentioned except for the risk that too tight legislation may inhibit innovation (Australia). Deregulation is not mentioned as a way to go, but was once a part of the cause of problems (USA).

2.14.5 Features of Future Food Law

2.14.5.1 Common Aspects Worldwide

In twenty-first century food law, we seem to encounter similar features worldwide like the premarket approval of food additives (South Africa,

USA, EU, China) and sometimes other foods like food supplements and GMOs (South Africa, EU, China), an emphasis on health protection through food hygiene (including HACCP) (Codex, India, South Africa, Australia, New Zealand, Latin America, EU) and powers of incident management, sometimes on traceability (EU, Japan, Korea) and on labeling requirements (Codex, India, South Africa, Australia, New Zealand, EU) including protection of consumers from misleading practices (South Africa, EU) and empowering them to make informed choices (Australia, New Zealand, Eastern Africa, EU, Russia). Stakeholder involvement seems to be a feature increasing in relevance in the creation of food legislation (India, South Africa, Eastern Africa, Australia, New Zealand, Latin America, Japan, Korea, China). Still the aim of reducing barriers to trade is present in virtually all systems.

2.14.5.2 Science Based

More markedly we see a worldwide influence of the WTO and increasing reliance on international standards—the *Codex Alimentarius* in particular—(India, South Africa, Eastern Africa, Australia, Russia, Northeast Asia) and on natural science through the risk analysis methodology for the protection of public health (Codex, SPS Agreement, India, Eastern Africa, Australia, New Zealand, Latin America, EU, Near East, Northeast Asia, China). By consequence science holds an increasing responsibility. It is precisely this responsibility that is at the heart of the Global Harmonization Initiative.

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