Chapter 2

Review of Literature

Access to sufficient amount of safe and nutritious food is essential for sustaining life and maintaining good health. FSSA, 2006 defines food safety as an assurance that food is acceptable for human consumption according to its use, and according to FAO (2003), food safety refers to all those hazards, whether chronic or acute, that may make food injurious to the health of the consumer. Unsafe food containing harmful bacteria, viruses, parasites or chemical substances, causes more than 200 diseases – ranging from diarrhoea to cancers. Foodborne diseases (FBD) impede socioeconomic development by straining healthcare systems and harming national economies, tourism, and trade (WHO, 2017).

Today food safety is not only a public health priority (WHO,2017) but food safety warranty is also a fundamental principle of international trade(Carneiro and Kaneene 2017) and to ensure that imported foods conform to national requirements (FAO & WHO,2003). The critical components of a Food Safety System (FSS) are: setting and maintaining science-based standards; robust enforcement and surveillance mechanisms; ensuring proper food safety management systems; and regularly transparently communicating to the stakeholders. All these components of FSS backed by legislation and regulations are also activities of food control, which is defined by FAO (2003) as:

….a mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling,

storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements, and are honestly and accurately labelled as prescribed by law.

The foremost responsibility of food control is to enforce the food law(s) protecting the consumer against unsafe, impure and fraudulently presented food by prohibiting the sale of food not of nature, substance or quality demanded by the purchaser. An efficient National Food Control System (NFCS) involves the integration of a mandatory regulatory approach with preventive and educational strategies that ensures food safety from farm to table (WHO & FAO, 2003). Effective national food control systems are not only necessary to maintain the safety of food to protect domestic consumers, but also to ensure the safety and quality of exported and imported food (FAO & WHO, 2006).

NFCS are vital tools in governing the safety and quality of food intended for human consumption(Al-Busaidi and Jukes 2015) and are a key element in the protection of consumers from unsafe foods and other fraudulent practices(Alomirah, Al-Zenki, et al. 2010). Thus, a food control system apart from having the essential elements of food law; national food control strategy; food control functions; inspection services, analytical services; compliance functions; a mechanism for consumer education, information and access should also have a public service orientation. This means there should be a level of sensitivity to the importance of protecting consumer health and safety from foodborne sources of risk. It also implies there should be a degree of dedication to carrying out the mission with fairness and balance, considering the sometimes competing interests of food industry development and

consumer protection. It further means that food control functions are performed with integrity and at a level of excellence which instills consumer and industry confidence ((Whitehead 1995).

Today, many governments have chosen to centralize their food control systems as a means to improve effectiveness and efficiency. There has been a growing tendency to enhance the national administrative framework for food control by establishing a primary authority to oversee the whole food chain from farm to fork. International Organizations have worked to assist food control authorities in reviewing and adjusting their national regulatory frameworks for food, supporting at many times, the centralization of food-related activities and suggesting that a self-contained structure would best serve the goals of integration and a food chain approach to food safety while eliminating inconsistencies and gaps(Al-Kandari and Jukes 2012).

Classical hazard-based criteria to food safety relying heavily on regulatory inspection and sampling regimes cannot sufficiently ensure consumer protection. In hazard-based approaches, merely the presence of a potentially harmful agent at a detectable level in food is used as a basis for legislation and/or risk management action. On the other hand, risk-based approaches allow consideration of exposure in assessing whether there may be unacceptable risks to health(Barlow, Boobis, et al. 2015). In the last decade, food safety management at international level has been moving towards a more risk-based approach to food safety control with regulators around the world adopting the risk analysis framework as the basis for their decision-making (Koutsoumanis and Aspridou 2016). This is also in sync with the risk analysis framework laid down by CAC, mandated with laying down

international standards for food (Kotwal 2016). The scientific rationale for food safety regulation is incorporated into the framework of risk analysis, a structured approach whereby risks to human health are assessed, and the best means for their control identified. Best practice dictates that this consists of a three-stage process as follows (FAO/WHO, 1995, 1997) (1) *risk assessment*: an assessment is made of the risk to human health associated with a particular food-borne hazard; (2) *risk management*: decisions are made regarding the acceptable level of risk and measures implemented for the control of this risk; and (3) *risk communication*: information about the risk and chosen methods of control are communicated amongst interested parties.

A generic framework for a risk-based food safety management system consists of 4 steps (FAO, 2006). The process starts with the first step that includes a number of preliminary risk management activities including: (a) identification of a food safety issue, (b) development of a risk profile(c) establishment of risk management goals, (d) decision about the need for the risk assessment, (e) establishment of the risk assessment policy, (f) commission of the risk assessment and/or risk ranking and (g) analysis of the risk assessment results.

In the second step, the different risk management options are identified and, after evaluation, the preferred option(s) is selected. The third step includes the implementation of the risk management measures. Measures can be implemented in the food sector using mandatory (legislation) or voluntary (codes of practice and guidelines) means. In the former case, competent authorities verify that the control

measures have been effectively implemented by the industry operators. Communication tools can also be used to implement consumers-related risk management decisions (e.g., encouragement of vulnerable persons to avoid the consumption of certain foods with high risk). During step four, monitoring activities are undertaken at appropriate points in the food chain and used to review the effectiveness of the implemented risk management measures. This step usually includes surveillance of public health to collect data on the changes in food-borne illness rates that may follow the implementation of risk management measures. When these data show that the goals are not being achieved, the redesign of food safety controls is needed, and the cyclical process can be repeated as many times as necessary(Koutsoumanis and Aspridou 2016).

How do we best protect our citizens to allow the highest quality of life? Where do we put our food safety resources so that we gain the most significant positive impact? RA provides the critical scientific basis for these types of critical risk management decisions. Increasingly, risk assessment is used to guide legislated and voluntary changes intended to improve safety, yet its formal application for enhanced food safety is in its infancy (Foegeding 1997). RA is a process that provides an estimate of the probability and impact of adverse health effects attributable to potentially contaminated foods. The objective is to characterize the nature and likelihood of harm resulting from human exposure to hazards present in foods. It is a science-based investigation consisting of four steps: hazard identification, exposure assessment, hazard characterization and risk characterization. This is the framework adopted by the CAC. There are two general

approaches to risk assessment, described as qualitative and quantitative (FAO/WHO, 1995; CAC, 1999). Qualitative risk assessments are descriptive or categorical treatments of information, whereas quantitative assessments are mathematical analyses of numerical data. A quantitative risk assessment is a preferred choice if the necessary quantitative information and resources are available. However, the risk assessment must involve high-quality data (Lozowicka, Jankowska, & Kaczynski, 2012). When data, time and/or other resources are limited, the only option available may be to conduct a qualitative risk assessment(Lammerding and Fazil 2000).

Following RA, risk management (RM) aspects of public regulation of food safety can take place in some ways that differ in the degree to which they impede freedom of activity. At one extreme, information measures require suppliers to disclose specific facts about their products but do not otherwise restrict behaviour. At the other, suppliers may need prior approval of a product from an official agency before being permitted to release it onto the market; such approval will be based on pre-specified safety criteria. Food safety standards allow suppliers to release products onto the market without any prior control, but suppliers that fail to meet certain minimum safety standards commit an offense (Henson and Caswell 1999). Sustaining food safety standards will depend on constant vigilance maintained by monitoring and surveillance but, with the rising importance of other food-related issues, such as food security, obesity, and climate change, competition for resources in the future to enable this may be fierce. Also, the pathogen populations relevant to food safety are not static(Newell, Koopmans, et al. 2010)

Increasingly, risk assessment is used to guide legislated, and voluntary changes intended to improve safety, yet its formal application for enhanced food safety is in its infancy. Risk assessment includes disease characterization, dose-response assessment, exposure assessment, and risk characterization. Quantitative data is critical for risk assessment to realize its full value, yet much of our knowledge about the incidence of pathogens or toxins in foods, dose-response knowledge, the incidence of acute food-borne illness, incidence of chronic sequelae, and cost of food-borne illness is qualitative, or estimates are controversial. Predictive modeling should help to improve estimates and thereby allow quantitation of food safety risks. Predictive modeling will also find application for assessing prevention strategies in risk management(Foegeding 1997).

Different countries are setting up agencies to perform science-based risk assessment so that data on risks associated with food are collected and analyzed on a continuous basis for RM and RC. In China, the National Food Safety Assessment Centre (NFSAC) was established in October 2011 as an independent agency to perform the science-based risk assessment. NFSAC is going to support food safety risk assessment committee as professional technical authority. It goes to assess and monitor food safety risk, collect and analyze related data, submit risk assessment results to food safety risk assessment committee, provide pre-alert, communicate with media and public, and develop scientific research(Jia and Jukes 2013). In 2013, the Omani government approved the setting up of national Centre for Food Safety and Quality(CFSQ) to raise the country's food safety monitoring and auditing capabilities. CFSQ will be equipped with laboratories to carry out all the various

analyses for protection of public health, licensing of food handlers, national capacity building, as well as the implementation of scientific studies and research in all fields related to safety and quality of food (Al-Busaidi and Jukes 2015). The Centre for Food Safety (CFS) was established by the Food and Environmental Hygiene Department (FEHD) of the Government of Hong Kong Special Administration Region (HKSAR) in 2006 as a specialized government agency mainly responsible for food safety supervision from "farm to table," except for local farm products. The CFS consists of the Food Surveillance and Control Division (FSCD), the Risk Assessment and Communication Division (RACD) and the Centre Administration Division (CAD) (Wu, Ye et al. 2014).

Similarly, regulatory and institutional food safety governance systems have been developed in the European Union (EU), Canada, France, and USA (Ghaida, Spinnler, et al. 2014). The European Food Safety Authority (EFSA), founded by Regulation EC 178/2002 provides scientific advice and scientific and technical support in all fields which have a direct or indirect impact on food and feed safety; assessment of emerging and other risks; collection and evaluation of data for characterizing and monitoring risks in food and feed sectors; risk communication in food and feed sectors; and networking and collaboration with institutions and organizations in Member States(Silano and Silano 2008). Beyond having formally established meetings with restricted access for participants – like the Stakeholders' Consultative Platform and the Annual Colloquium, – EFSA engages through its "Public Consultation" web-based Window (PCW). It allows listening to anybody who wishes to submit comments on technical issues(Finardi, Pellegrini, et al. 2012). A Rapid

Alert System for Food and Feed (RASFF) was also established to rapidly disseminate information on food safety to all countries in the EU and to ensure timely recall of all potentially dangerous products.

On the other hand, food safety programs in some countries may also be underfunded. Developing countries, in particular, may not have the expertise, laboratory resources for testing, and established inspection programs to adequately promote the safety of foods (Jiang, 2009).

The analysis and prevention of food safety issues require a large amount of information about regulation, supervision, detection methods and previous cases. Increasingly, Information Technology is being used to collect and analyze data from various sources including that is available in the public domain. Database-website systems aimed at improving the efficiency of searching and analysis are being developed. A comprehensive food glossary and a keyword-frequency counting technique are adopted to make intelligent content analyses. This database-website system is useful in reviewing previous food safety issues, understanding the current conditions and developing tools for prevention. Development of open systems for users allow them to not only just explore the food safety information within one group, but also to compare the ones from different stakeholders(Chen, Huang, et al. 2016).

Also, a constant dialogue between public health, veterinary and food safety experts, with multidisciplinary skills, and multi-pathogen expertise is essential to monitor changing trends in the well-recognized diseases and detect emerging pathogens. It

will also be necessary to understand the multiple interactions these pathogens have with their environments during transmission along the food chain to develop effective prevention and control strategies (Newell, Koopmans, et al. 2010).

To enhance public trust in the food safety regulatory system, public health agencies must communicate easily understood transparent, scientific information to the public. This information must be delivered by a trusted source. Inspection disclosure systems have been useful in increasing transparency, thereby improving public trust. The society expects public health agencies to take action to protect the food supply. Public health agencies must have a strong presence in a coordinated food safety regulatory framework(Papadopoulos, Sargeant, et al. 2012).

It is also crucial for food regulatory bodies to recognize that risk communication (RC) is also a key component of the quality risk assessment process for which problems of subjectivity and uncertainty may arise. Risk communication strategies should be such that will minimize the effects of food safety risks by influencing stakeholder behaviour, improve overall interactions between the food regulatory agency and relevant stakeholders, and strengthen food safety risk prevention and mitigation systems (Charlebois and Summan 2015). RC should be governed by knowledge of consumer risk perceptions and information needs, including individual differences in consumer preferences and requirements, and differences in these relating to the socio-historical context associated with regulation. Also, information about what is being done to identify, prevent and manage food risks need to be communicated to consumers, together with consistent messages regarding preventative programs, enforcement systems, and scientific uncertainty

and variability associated with risk assessments (Cope, Frewer, et al. 2010). From 2009, the CFS of the government of HKSAR has released the "Food Safety Report" every month to allow the public to obtain the latest food safety information(Wu, Ye et al. 2014).

In India, the Prevention of Food Adulteration (PFA) Act, 1954 was the key legislation so far as the safety of food was concerned. It was administered by Ministry of Health & Family Welfare (MH&FW), and the focus was on prevention of adulteration. The regulation of specific other food products was subject to other different legislations by other Ministries/Departments such as the Fruit Products Order, 1955, Meat Food Products Order, 1973, Vegetable Oil Products (Control) order, 1947, Milk and Milk Products Order, 1992, etc. In India, nine different Ministries/Departments were involved in controlling various aspects of food. The changing food safety standards, stricter sanitary and phytosanitary requirements and improved global product norms triggered the necessity to enhance food safety legislative framework of the country.The Food Safety and Standards Act, 2006 (the FSSA,2006) was passed to integrate the food safety laws in India, in-order-to systematically and scientifically re-orient food processing and manufacturing industry from regulation to self-compliance. All previous food laws that existed before 2006 like the Prevention of Food Adulteration Act were repealed once the FSSA was implemented. Today FSSA, 2006, rules and regulations made thereunder are the only point of reference for all matters concerning food safety in India. The enactment of the FSSA led to the formation of the Food Safety and Standards

Authority of India (FSSAI). It is the FSSAI that formulates standards and regulations about food and enforces the FSSA(Vats and Arora 2016).

A more holistic approach is seen in new scientific standard development, and FSSA covers a broader variety of products including functional food, novel food, and beverages. The requirements of food hygiene and Good Manufacturing Practice (GMP) practices as described by CAC are important for any national food safety control. However, there exists a gap in infrastructure and risk-based approach to both implementation and enforcement (Shukla et al. 2014).

In the last ten years or so since the implementation of the FSSA in 2006 and setting up of FSSAI in 2008, there has been an increased focus on food safety in the country. However, not too many academic articles have been written on the Indian Food Regulatory system when compared with the available literature on Chinese, EU or USA food regulatory systems. The implementation of the Act has primarily focussed on risk management through harmonisation of food standards with Codex Alimentarius. Not too much focus has been given to set up systems for monitoring, surveillance, the collection of data from various sources and its analysis for decision making. There is no single centralised body where data from multiple sources as part of RA is being analyzed for decision making. There is also no evidence to indicate whether Regulatory Impact Assessment (RIA) is being undertaken before undertaking regulation making.

Based on the literature survey, gaps have been found in the implementation of a multi-disciplinary and integrated perspective to achieve public health outcomes by

ensuring safe food. Noncommunicable diseases (NCDs)[13] tend to be of long duration and are the result of a combination of genetic, physiological, environmental and behavioural factors. World-wide there is an increase in Non-Communicable Diseases (NCDs), and NCDs are top killers in the South-East Asia Region[14], claiming an estimated 8.5 million lives each year. The main types of NCDs are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructive pulmonary disease and asthma) and diabetes. Tobacco use, physical inactivity, the harmful use of alcohol and unhealthy diets all increase the risk of dying from an NCD. However, more focus is required on the linkage between an increase in the NCDs and overall food safety not limited to unhealthy diets. As per the literature survey, it is also observed that even the epidemiological/food-borne disease (communicable disease) data analysis is not being done by a nodal authority to arrive at a holistic picture.

With the proliferation of IT, there is a need to exploit its full potential by integrating various systems, collating information from multiple sources and then undertaking data analytics. There is also the need for examining the feasibility of implementing an e-based intelligent food control systems.

Review of data about individual countries and EU reveals different strategies that have been adopted to implement food regulatory systems. Also, the procedure to react in case of food-related emergency is different and it needs to be documented and managed for effective implementation. EU RASFF ensures quick action and

[13] http://www.who.int/mediacentre/factsheets/fs355/en/ accessed on 29th May 2017
[14] http://www.searo.who.int/entity/noncommunicable_diseases/en/ accessed on 29th May 2017

rapid alert while dealing with food emergencies(Djekic, Jankovic, et al. 2017). Keeping all these aspects in mind, Indian food regulatory system will be examined along with the current status of laboratory and analytical capabilities. It would also be useful to explore the steps that are required to implement an integrated RA system.