

Chapter 1

Introduction

1. Introduction

1.1 India was a food deficit country till the advent of green revolution in the late 1960's/the early 1970s. In this age of scarcity, the focus of food regulation in the supply chain was on availability rather than strict quality and safety standards. The key problem during this phase was intentional contamination of food articles with its lower grade look-alike substances going into the supply chain for meeting the growing demand. Thus, the focus of Prevention of Food Adulteration (PFA) Act, 1954, the legislation in vogue was on prevention of adulteration. Also, there were multiple Ministries/Departments regulating various aspects of food.

1.2 The enactment of Food Safety & Standards Act (FSSA), 2006 (hereinafter referred to as FSSA, 2006) replacing PFA, 1954 marked a paradigm shift from 'adulteration' to 'food safety' and its basis on the scientific principles of risk analysis. The mandate of Food Safety and Standards Authority of India (FSSAI) established under FSSA, 2006 is to lay down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale, and import, to ensure availability of *safe and wholesome food* for human consumption. Though *safe and wholesome food* has not been defined in the FSSA, 2006 food safety is defined as "assurance that food is acceptable for human consumption according to its intended use."

1.3 Access to sufficient amounts of safe and nutritious food is a key to sustaining life and promoting good health. Unsafe food containing harmful bacteria, viruses,

parasites or chemical substances, causes more than 200 diseases – ranging from diarrhoea to cancers. An estimated 600 million – almost 1 in 10 people in the world – fall ill after eating contaminated food and 420 000 die every year, resulting in the loss of 33 million healthy life years (DALYs). Food safety, nutrition, and food security are inextricably linked. Unsafe food creates a vicious cycle of disease and malnutrition, particularly affecting infants, young children, elderly and the sick. Foodborne diseases (FBD) impede socioeconomic development by straining health care systems and harming national economies, tourism and trade¹. The World Health Organisation (WHO) South East Asia Region of which India is also a part has the highest burden of FBD per population. It is second only to African region, but in absolute numbers, annually more people living in WHO South East Asia Region fall ill & die from FBD than in any other WHO region². Hence, food safety and health the twin objectives should be there in every country's public health goals.

1.4 Food safety and health are measurable indices of the incidence of food borne illnesses and quality of life or the alleviation from communicable (food poisoning, acute diarrhea, etc.) & non-communicable (obesity, diabetes, hypertension, etc.) diseases. Together they provide the health status of its population. The Integrated Disease Surveillance Programme (IDSP) launched in 2004 by the National Centre for Disease Control (NCDC), India collects data on diseases outbreaks for the country as a whole excluding the non-communicable diseases. Aggregate analysis of data from

¹ <http://www.who.int/mediacentre/factsheets/fs399/en/>

² http://www.searo.who.int/about/administration_structure/cds/burden-of-foodborne-sear.pdf

2011-2016 shows foodborne diseases together with acute diarrheal diseases constitute nearly half of outbreaks reported under IDSP from 2011-2016³.

1.5 There are also cases of food poisoning reported in the media on a regular basis. In recent times, worst such case happened on 16th July 2013 when the children in Gandaman village in Bihar fell violently sick after eating a school lunch. Twenty-three died, many within a few hours of eating⁴. The poisoning occurred from the consumption of a free lunch of rice, soybeans, and lentils cooked with oil contaminated with monocrotophos, an organophosphate pesticide. The oil had been stored in a pesticide container and sold to the school⁵. Cases of food-poisoning⁶ and other FBDs⁷ are also regularly reported from various parts of the country.

1.6 The Second International Conference on Nutrition (ICN2), held in Rome in November 2014, reiterated the importance of food safety in achieving better human nutrition through healthy nutritious diets⁸. It also reiterated the need to develop, establish, enforce and strengthen, as appropriate, food control systems, including reviewing and modernizing national food safety legislation and regulations to ensure that food producers and suppliers throughout the food chain operate responsibly⁹. Improving food safety is also a key to achieving Sustainable Development Goals (SDGs). The SDGs, otherwise known as the Global goals, are a universal call to action

³ CD Alert (March.2017), DGHS, GOI. Food-borne diseases in India and Food safety. Available on: <http://www.ncdc.gov.in/writereaddata/linkimages/cdalert03175347761127.pdf>

⁴ <https://link.springer.com/article/10.1007/s00204-013-1113-6>

⁵ <http://oem.bmj.com/content/71/3/228.2.short>

⁶ <https://pdfs.semanticscholar.org/0c4c/c51a44946fbd2cda57dc7c94895d345d6384.pdf>

⁷ <http://indianexpress.com/article/india/eighty-students-fall-ill-after-taking-mid-day-meal-in-odisha-4844906/>

⁸ <http://www.fao.org/3/a-ml542e.pdf>

⁹ <http://www.fao.org/3/a-mm215e.pdf>

to end poverty, protect the planet and ensure that all people enjoy peace and prosperity¹⁰. Out of the 17 SDGs, SDG 1 (No poverty), SDG 2 (Zero hunger), SDG 3 (Good health & well-being), SDG 6 (Clean water & sanitation) and SDG 10 (Reduced inequalities) are closely linked to food safety. However, of particular relevance is SDG3 that aims to ensure healthy lives and promote well-being for all at all ages. Eradicating wide range of diseases and addressing many persistent and emerging health issues is a priority. Looking at the impact of FBDs on the overall human health, food safety should be made a public health priority. Governments play a pivotal role in developing policies and regulatory frameworks, establishing and implementing effective food safety systems that ensure that food producers and suppliers along the whole food chain operate responsibly and supply safe food to consumers.

1.7 In this context, it would be relevant to examine the food safety regulatory system envisaged under the FSSA, 2006 to achieve the objective of *safe and wholesome food* for human consumption. To maintain a food regulatory system that delivers the public health goals for the population, by enabling consumer choice, maintaining public confidence in the food regulator, requires a robust construct of a scientific and technical centralized pool or hub of data collected from various sources (food testing, epidemiological, food surveys, outbreaks, food recall, import data etc) for risk assessment. Thereafter, based on risk assessment the most effective risk management option and risk communication strategy can be determined. Given these factors, the risk-based framework of FSSA 2006, needs to be critically

¹⁰ <http://www.undp.org/content/undp/en/home/sustainable-development-goals.html>

evaluated for its ability in achieving these objectives with particular focus on risk assessment.

2. Risk Analysis Framework under FSSA, 2006

1.8 Sections 16 & 18 of the FSSA mandate several procedures, processes, functions, duties and general principles including the establishment of the Risk Analysis framework consisting of Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC). It is to be followed in achieving the objective of safe and wholesome food for human consumption. “Risk” has been defined under the FSSA *in relation to any article of food, means the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard.* “Hazard” has been defined as *a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.*

1.9 “Working Principles for Risk Analysis for Application in the Framework of the Alimentarius” were adopted by Codex Alimentarius Commission (CAC), joint FAO-WHO Food Standards programme in 2003(**Figure 1**). The same risk analysis framework has been defined in FSSA and follows a structured approach comprising of the three distinct but closely linked components of risk analysis (RA, RM, and RC). There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an

iterative process, and interaction between risk managers and risk assessors is essential for practical application.

Figure 1: Process of Risk Analysis



1.10 Therefore, the essential characteristics of the Risk Analysis process as given in the CAC Guidelines (CAC/GL 62-2007) are described in Box 1¹¹ below:

Box 1: Essential characteristics of Risk Analysis (CAC/GL 62-2007)

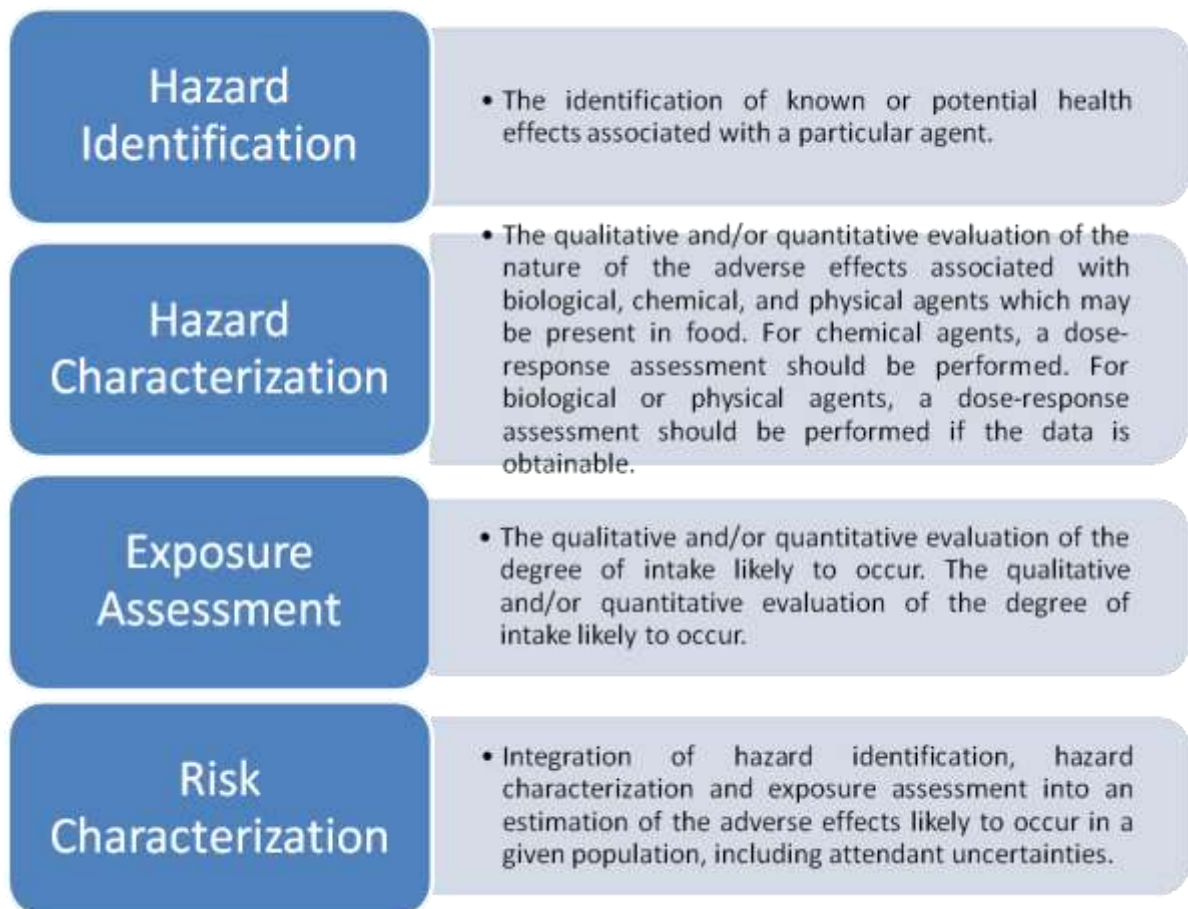
- a. A Repeated interaction between and among risk managers, risk assessors and other participants
- b. Regular monitoring of the success and impact of the decision
- c. Follows a structured approach comprised of the three distinct components: risk management, assessment, and communication
- d. Based on the best available scientific evidence
- e. Applied consistently, for instance, to hazards of different types and from country to country
- f. Carried out in an open, transparent and well-documented process
- g. Clear in its treatment of uncertainty and variability

¹¹ http://www.fao.org/input/download/standards/10751/CXG_062e.pdf (Working principles for food safety for application by Governments)

(a) Risk Assessment

1.11 Risk assessment (RA) means a scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization. The steps involved in risk assessment are as follows (**Figure 2**):

Figure 2: Steps involved in risk assessment



1.12 Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse

health effects. It should seek and incorporate relevant data from different parts of the country. These data should notably include epidemiological surveillance data, analytical and exposure data. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out the risk assessment, where relevant. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

(b) Risk Management

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

(c) Risk Communication

1.14 The process of risk communication (RC) is defined as the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties,

including the explanation of risk assessment findings and the basis of risk management decisions.

3. Food Safety Regulatory System in India and implementation of Risk Analysis

Framework: A critical study

1.15 The challenge for food regulators is to maintain a food regulatory/control system that delivers safe food for the population, enables consumers to make informed choices and also supports public confidence in the food regulations. Public confidence in the food regulations will depend, firstly, on evidence that there is a low level of risk and, secondly, on assurance that adequate systems are in place to monitor and analyse food, and to respond when situations of potential harm occur.

1.16 The Oxfam “Good Enough to Eat Index” released in January 2014¹² asks four questions related to food: accessibility to food, affordability of food, quality of food (diversification of diet and access to clean and safe water) and the unhealthy outcomes of people’s diet (measured by diabetes and obesity). Out of the 125 countries that were ranked on the combined index, Netherlands is at number one position whereas India is at 96th place. The report also highlighted unhealthy eating as a growing problem on account of rise in obesity and diabetes across the world. Therefore, not only food safety but the quality of food too is a critical component in ensuring safe food.

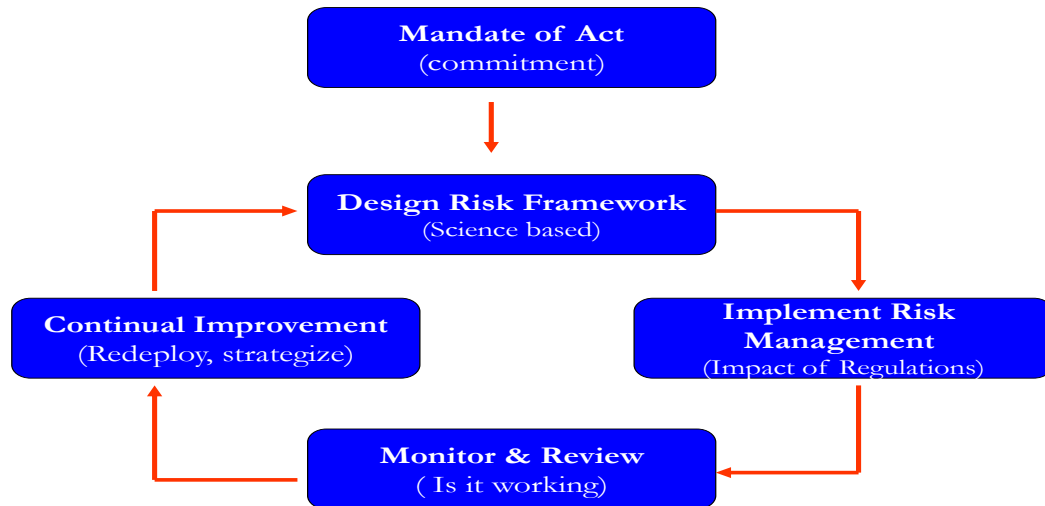
¹²<https://www.oxfam.org/sites/www.oxfam.org/files/good-enough-to-eat-oxfam-media-brief-012014.pdf>

1.17 To attain the same and respond to, reduce and finally eliminate the cyclic effects of adulterated harmful food, the functions of the Indian food safety regulator can be highlighted as:

- i. The setting of limits for food additives, contaminants, residues, processing aids, etc. based on risk assessment. Risk assessment process requires information and data. The data should include the database on hazards in food, data generated from testing of chemical and biological agents, dietary intake surveys, epidemiological surveys of consumer populations, and investigation of the outbreak of foodborne diseases. Food testing laboratory infrastructure, as well as the laboratories in the public health domain, will play an essential role in generation of the data.
- ii. Monitoring, inspection and surveillance activities of domestic as well as imported foods allow focusing on potential areas requiring attention.
- iii. Prepare the standards and guidelines to regulate the safety of food; accreditation of laboratories and certification bodies engaged in certification of Food Safety and Management Systems (FSMS); Methods of sampling, analysis, and exchange of information among enforcement authorities for risk management.
- iv. Procedure and the enforcement of quality control and their notification to stakeholders and laying down food labelling standards including claims on health, nutrition, special dietary uses and food category systems for foods as part of risk communication.

1.18 For implementing the mandate of the FSSA, 2006 it is, therefore, important to base decisions on scientific information, evidence/and or risk analysis principles. Continuous improvement, monitoring, and review form an integral part of the national food safety regulatory/control systems (**Figure 3**).

Figure 3: Framework for the National Food Regulatory System



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4. Research Outline and Methodology

1.19 Based on the brief outline above, the study aims to research to evaluate the implementation of the risk analysis framework, which is the building block of FSSAI's regulatory work. It is an appropriate time to carry out this evaluation ten years after FSSAI's operationalization in 2008. It is hoped that the findings and

recommendations of the study would be beneficial to the Government particularly, FSSAI to undertake any mid-course correction, if required.

1.20 With this background, the current study attempts to fulfil following objectives:

(a) Objectives

- i. To examine the food safety regulatory mechanism in the country and its effectiveness
- ii. To critically assess the various parameters that determine the components of the risk analysis framework for the food safety regulatory system
- iii. To examine, in particular, the implementation of risk assessment strategies with a focus on structural capacities and capabilities
- iv. To suggest an integrated risk assessment strategy for ensuring food safety based on the outcome of the research and compare with few other country models

(b) Research Questions

- i. What is the current status of the Laboratory & Analytical capabilities for food testing in the country?
- ii. Whether food monitoring, surveillance and epidemiological data {Integrated Disease Surveillance Programme (IDSP) as well Health Management Information System (HMIS)} has been integrated?
- iii. Is the existing food risk assessment mechanism adequate to ensure safe food?

- iv. What steps are required to integrate the various stand-alone elements to develop & implement an integrated risk assessment system that leads to a strong risk analysis framework?

(c)Methodology

Study based on both Primary and Secondary sources

The study will gather data about: Laboratory & Analytical Systems; Food Monitoring & Surveillance; Food consumption and exposure assessments, epidemiological data; and research being conducted in the area of food safety.

Primary Research will be based on:

- **Survey:** Questionnaire is to be administered on the various stakeholders of the food regulatory system in the country viz., Central Regulator (1); State Regulators; National Centre for Disease Control (1); Research Institutes' (National Institute of Nutrition (NIN), Indian Toxicological Research Centre (ITRC) , Central Food Technology Research Institute (CFTRI), All India Network Project on Pesticide Residues (AINPPR); Industry (food processing industries & also private FSSAI accredited laboratories); Food Scientists and researchers; and few Consumers.

Secondary Research based on:

- Case Studies of international organisations and certain countries
- Books; academic papers; reports; newspaper and magazine articles

(d) Chapterisation

- Chapter 1 Introduction. The chapter focuses on:
- i. Food Regulatory System and the risk analysis framework
 - ii. Contextualisation of the problem and the research gaps proposed to be addressed
 - iii. Research Methodology
- Chapter 2: The Chapter on Review of literature carries out comprehensive review of the available literature on the subject with a focus on:
- i. The theoretical framework for food safety regulatory/control systems
 - ii. International and country-specific studies
 - iii. Linking with the research gaps
- Chapter 3: The chapter elaborates on the various stakeholders in the Food Safety Regulatory System in India and their roles.
- i. Analysis of stakeholders in the food safety regulatory/control system
 - ii. Their roles and functions
- Chapter 4: The chapter focuses on the risk analysis framework for food safety in India.
- i. Explaining the three components of risk analysis in the context of FSSA, 2006
 - ii. Role of various entities in RA, RM & RC
- Chapter 5: This chapter highlights the implementation of the risk analysis in food regulatory systems in some International organisations & countries with particular emphasis on risk assessment functions.
- i. International Institutions-CAC and EFSA
 - ii. National Examples of Canada, France & USA

- Chapter 6: This chapter discusses in detail the responses to the questionnaires of the survey designed as a part of the study covering the stakeholders in the food safety regulatory/control system in the country.
- i. Analysis of the responses received from various stakeholders
- Chapter 7: Based on the survey findings and desk-based research, this chapter analyses the objectives of the study and the answers to the questions that were raised as part of the study. The focus is on discussion and the conclusions that can be drawn.
- Chapter 8: The chapter titled “Recommendations” will present a framework for strengthening the risk assessment mechanism in the country.