

Chapter-I : Introduction

1.1 Overview

Access to sufficient amounts of safe and nutritious food is 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 60 crore – almost 1 in 10 people globally– fall ill after eating contaminated food and 4.20 lakh die every year. Children under five years of age carry 40 *per cent* of the food borne disease burden, with 1.25 lakh deaths every year. 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.¹

Due to its geographic, economic and demographic diversity, the challenges to ensure safety of food in India are immense. The Prevention of Food Adulteration Act (PFA), 1954 marked the initial step in this direction, followed by other Acts/Orders specifically governing the food sector, such as the Fruit Products Order, 1955; the Meat Food Products Order, 1973; the Vegetable Oil Products (Control) Order, 1947; the Edible Oils Packaging (Regulation) Order, 1998; the Solvent Extracted Oil, De-oiled Meal, and Edible Flour (Control) Order, 1967; the Milk and Milk Products Order, 1992; and other Orders issued under the Essential Commodities Act, 1955 (10 of 1955). Proliferating laws over the years with varying standards and different enforcement agencies spread across various Ministries/Departments led to confusion among consumers, investors, manufacturers and traders. Inadequate manpower, food laboratories and other resources of various authorities administering these laws, contributed to ineffective formulation of science based food standards and their enforcement.

The Food Safety and Standards Act, 2006 (the Act) was enacted to address these issues, subsuming all the earlier Acts and Orders. The said Act was to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India (FSSAI) for formulating 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 and for matters connected therewith or incidental thereto. The Act, however, does not apply to any farmer or fisherman or farming operations or crops or livestock or

¹ World Health Organisation's Fact Sheet on Food Safety (December 2015).

aquaculture or supplies used or produced in farming or products of crops produced by a farmer/fisherman at initial production level.

1.2 Duties and responsibilities of the Food Authority

The Government of India notified (September 2008) the Food Authority, a body corporate comprising Chairperson and 22 Members (*Annexure-1.1*), which, under the Central Government (i.e., the Ministry of Health and Family Welfare), was empowered to determine and issue directions on technical and administrative matters relating to food safety and standards in the country. These directions were to be implemented by FSSAI², headed by the Chairperson and Chief Executive Officer (CEO)³ FSSAI. FSSAI has five regional offices (Chennai, Delhi, Kolkata, Guwahati and Mumbai) and two sub-regional offices (Chandigarh and Lucknow)⁴.

Under the Act, the Food Authority is mandated to regulate and monitor the manufacture, processing, distribution, sale and import of food and by regulations specify the standards, guidelines etc. in relation to articles of food.

1.3 Enforcement Structure

The Food Authority and the state⁵ food safety authorities are responsible for enforcement of the Act and Rules and Regulations notified by FSSAI (details of various Rules and Regulations notified by FSSAI as of December 2016 are provided in *Annexure-1.2*). These authorities are empowered to monitor and verify the relevant requirements to be fulfilled by FBOs (food business operators), maintain a system of control, public communication on food safety and risk, food safety surveillance and other monitoring activities covering all stages of food business. CEO, FSSAI acts as the Central Food Safety Commissioner and appoints a Designated Officer (DO) as the Central Licensing Authority (CLA) for enforcement of the Act. Similarly, the respective State Food Commissioner

² Throughout the report, the term 'Food Authority' refers to the body corporate comprising the Chairperson and Members created under the Act; the term 'FSSAI' refers to the executive wing of the Food Authority, comprising the Chairperson, CEO and Divisions thereunder.

³ Like the Chairperson and Members, CEO, FSSAI is appointed by the Central Government. CEO is Member-Secretary of the FSSAI but without power to vote.

⁴ In April 2016, FSSAI closed the sub-regional offices at Chandigarh and Lucknow, transferring their work to Regional Office Delhi.

⁵ Throughout this report, the term 'states' includes Union Territories.

appoints a DO as the State Licensing Authority (SLA). DOs are assisted by Food Safety Officers (FSO).

1.4 Audit Approach

1.4.1 Audit Objectives

The objectives of the performance audit were to ascertain whether:

- i) regulatory and administrative mechanisms for implementation of the Act exist;
- ii) licensing registration, inspections, and sampling were conducted as envisaged in the Act;
- iii) food testing laboratory infrastructure and prosecution procedures exist; and
- iv) appointment and deployment of human resources were as per the extant instructions/rules.

1.4.2 Scope of Audit

The audit covered the period from August 2011 to March 2016. Records in the Ministry of Health and Family Welfare, FSSAI along with its regional and sub-regional offices and the corresponding department/offices in the nine selected states and one union territory (UT) (*Annexure-1.3*) were examined.

1.4.3 Sampling Methodology

In the selected states, 20 *per cent* of districts, subject to a minimum of two and maximum of ten, were selected by using PPSWOR⁶ with size measure as the total number of licenses/registrations certificates issued. In each sampled district, 40 licenses and 10 registration certificates per year were selected based on usage of food articles by general populace, economically weaker sections and children/infants. Using the same criteria, 25 licenses per year were selected in each Central Licensing Authority (CLA), regional office and sub-regional office. In each sampled district, 25 food samples per year were selected, being a mix of samples which were found to be conforming and non-conforming.

⁶ Probability Proportional to Size Without Replacement.

Further, in each selected state, 30 *per cent* of the state laboratories were selected subject to a minimum of one. Two ports under the respective jurisdiction of each Regional office of Food Authority at Delhi, Mumbai, Kolkata and Chennai, where the number of cases of imports/samples was highest were selected. Thereafter, 50 cases per year per port were selected through random selection.

Thus, 53 districts and 20 state laboratories in nine states and one Union Territory and eight ports were selected. Details of sample selected states/UT and selection are provided in *Annexure-1.3*.

1.5 Audit Methodology and Response of the Ministry and Food Authority

The performance audit commenced with an Entry Conference with the Ministry of Health and Family Welfare and FSSAI officials on 03 May 2016 where the audit objectives, scope and methodology were explained. Entry conferences were also held at the state level.

The audit teams scrutinised the records relating to implementation of the Food Safety and Standards Act, 2006 at the Ministry of Health and Family Welfare; FSSAI HQ; regional offices/sub-regional offices of FSSAI; Commissioners of Food Safety; and districts and laboratories in the selected states and UT.

The draft audit report was first issued to the Ministry on 3 November 2016. Based on replies received and further examination of documents, the draft audit report was revised, and re-issued on 16 May 2017. Exit Conference with the Ministry was held on 29 June 2017 wherein major audit findings and other issues were discussed. Replies received from the Ministry (January 2017, March 2017 and June 2017) and state food authorities and deliberations during the exit conference have been considered and suitably incorporated.

1.6 Audit Criteria

The criteria for this performance audit were derived from the following sources:

- i) Cabinet Notes.
- ii) Food Safety and Standards Act, 2006.
- iii) Food Safety and Standards Rules and Food Safety and Standards Regulations, 2011.

- iv) Guidelines and Manuals notified/issued by the Ministry and FSSAI from time to time.
- v) Food and Agriculture Organisation of the United Nations (FAO) document: 'Strengthening national food control systems - Guidelines to assess capacity building needs' of 2006.
- vi) General Financial Rules, 2005 and other Government of India instructions issued from time to time.

1.7 Acknowledgement

Audit acknowledges the co-operation extended by the Ministry of Health and Family Welfare, FSSAI, and food authorities of the state governments for the conduct of this audit.