



**Report of the
Comptroller and Auditor General of India
on
Performance Audit of
Implementation of
Food Safety and Standards Act, 2006**



**Union Government (Civil)
Ministry of Health and Family Welfare
Report No. 37 of 2017
(Performance Audit)**

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Preface

The Food Safety and Standards Act, 2006 was enacted to consolidate multiple laws in the country relating to food safety, to establish a single point reference system, and to establish the Food Safety and Standards Authority of India (FSSAI) for formulating science based standards for food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption.

The performance audit attempts to examine the efficacy of the regulatory and administrative mechanisms for implementation of the Act, the food testing laboratory infrastructure and human resources framework, adherence to Licensing and Registration procedures in terms of the Act, systems for inspection, sampling and prosecution procedures, regulation of import of food articles, mechanisms for grievance redressal, and IEC (information, education and communication) activities of FSSAI.

The audit revealed systemic inefficiencies, including delays and deficiencies in the framing of various regulations and standards. Audit also observed amendments to regulations in violation of the Act and specific directions of the Supreme Court. Most of the state foods laboratories entrusted with food testing and certification functions, were not only ill equipped but also did not possess accreditation of the National Accreditation Board for Testing and Calibration Laboratories (NABL). Further, enforcement activities relating to licensing, registration, inspection, sampling and prosecution were inadequate. FSSAI has failed to finalise the recruitment regulations. Irregularities were also observed in the appointment of contractual employees.

While the performance audit primarily covers the period from 2011-2012 to 2015-2016, matters relating to subsequent periods have also been included, wherever necessary.

The report of the Comptroller and Auditor General of India containing the results of audit of Implementation of Food Safety and Standards Act, 2006 has been prepared for submission to the President under Article 151 of the Constitution of India. The audit has been conducted in conformity with the Auditing Standards issued by the Comptroller and Auditor General of India.

Executive Summary

Food safety covers the entire food chain, and includes the stages of manufacturing/preparation, handling, transportation and storage of food in ways that prevent contamination and food borne diseases. Any relaxation of food safety standards and their enforcement may lead to proliferation of illegal, dishonest manufacturers and suppliers, which is detrimental to public health. Good understanding among governments, producers and consumers may contribute towards ensuring food safety along with efficient and effective enforcement.

After Independence, the Prevention of Food Adulteration Act (PFA), 1954 was the primary law governing foods safety, along with other laws/orders specifically targeting the food sector. Proliferating laws over the years with varying standards and enforcement agencies spread across various Ministries and departments in the Central and state governments led to confusion among consumers, traders, investors and manufacturers. Inadequate manpower, food laboratories and other resources under various authorities administering these laws, affected the effective fixing of science based food standards and their enforcement. Parliament enacted the Food Safety and Standards Act, 2006 to overcome the difficulties and to consolidate and subsume the existing Acts and Orders and establish a single point reference system in the country and to establish the Food Safety and Standards Authority (Food Authority) for laying down science based standards and regulating the manufacture, storage, distribution, sale and import of food products to ensure availability of safe and wholesome food for human consumption. The Act does not apply to any farmer or fisherman or farming operations or crops or livestock or aquaculture or supplies used or produced in farming or products of crops produced by a farmer/fisherman at initial production level.

This performance audit on food safety was taken up with a view to assess the performance of the Ministry of Health and Family Welfare (the Ministry), Food Authority, and the food authorities in ten selected states.

The important findings of the performance audit are given below:

Regulatory and Administrative Framework

- Even after more than a decade of the enactment of the Act, the Ministry and Food Authority are yet to frame regulations governing various procedures, guidelines and mechanisms enunciated in different sections of the Act.

(Para 2.2)

- Food Authority failed to devise action plans to identify areas on which standards are to be formulated/revised within specified time frames and the manner of selection of food products for formulation of standards. FSSAI has, for some food categories, entrusted the task of suggesting revision of standards to representatives of the food business operators (FBO), whose opinions cannot be considered unbiased. FSSAI notified regulations and standards without considering the comments of stakeholders. Primarily because of the absence of policy guidelines and standard operating procedures (SOP), Food Authority took between one year and three years to notify amendments.

(Para 2.5, 2.6 & 2.7)

- Possibility that unsafe/declared unsafe food articles continued to be manufactured and sold is not ruled out due to failure of the Authority to monitor and cancel licenses issued under the product approval system declared unlawful by the Supreme Court.

(Para 2.8)

- FSSAI continues to issue directions without following the procedure of previous approval of the Central Government, previous publication and notification (as contained in section 92 of the Act), the placing of such regulations and rules before Parliament (as contained in section 93 of the Act), despite the Supreme Court declaring such procedure as mandatory. Audit noticed many instances where FSSAI issued directions and notified regulations without the requisite approval of Food Authority and the Ministry.

(Para 2.9, 2.10 & 2.11)

- Despite recommendation of the Central Advisory Committee (CAC) that at least *75 per cent* of the food license fee collections should be used for Information, Education and Communication (IEC) activities, most states had not allocated any budgets for these activities.

(Para 2.16)

Licensing, Registration, Inspection and Sampling

- FSSAI and state food safety authorities did not conduct survey for enforcement and administration of the Act and of the FBOs under their jurisdiction, though required to do so under the Act.

(Para 3.1.1)

- Licenses were issued on the basis of incomplete documents in more than *50 per cent* of cases test checked in Audit.

(Para 3.1.5)

- Neither FSSAI nor the state food authorities have documented policies and procedures on risk based inspections, and the FSSAI does not have any database on food business.

(Para 3.2)

- FSSAI has failed to ensure that the Customs authorities follow up the Non-Conformance Reports issued by the FSSAI, and take appropriate action to ensure that unsafe foods do not enter the country.

(Para 3.6.3)

Analysis of Food and Prosecution

- 65 out of the 72 State food laboratories to which FSSAI and state food safety authorities sent food samples for testing do not possess National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation. Consequently, the quality of testing by these laboratories cannot be assured.

(Para 4.3)

- Though the Act stipulates gazette notification of empanelled food laboratories, FSSAI empanelled, between September 2011 and March 2014, 67 food laboratories through office orders.

(Para 4.4.1)

- FSSAI has no data on public analysts declared eligible under the erstwhile Prevention of Food Adulteration Act who continue to function under the FSS Act. FSSAI also has no data on whether all the notified empanelled food laboratories have qualified food analysts. Audit test check found that 15 out of the 16 test checked food laboratories did not have qualified food analysts.

(Para 4.6.1)

- Shortage of qualified manpower and functional food testing equipment in state food laboratories and referral laboratories resulted in deficient testing of food samples.

(Para 4.7.1 & 4.7.2)

- There were significant delays in finalization of cases by Adjudicating Officers. Further, a significant portion of the penalty imposed remained uncollected.

(Para 4.9.1)

Human Resources

- Failure of the Ministry and the FSSAI to frame the recruitment regulations even after a decade of the enactment of the Act, resulted in acute shortages of regular staff at various levels.

(Para 5.2 & 5.3)

- Acute shortage of licensing and enforcement officers (Designated Officers and Food Safety Officers) in the states severely affected food safety measures in the states.

(Para 5.9)

Recommendations:

Based on the audit findings, some of the recommendations are provided below:

- *Ministry/FSSAI may expedite the notification of regulations on areas that have been specified in the Act, but are yet uncovered.*
- *FSSAI may frame standard operating procedures on the formulation and review of standards, and ensure that these are adhered to.*
- *FSSAI may ensure that all licenses issued under the erstwhile system of product approvals are reviewed, and licenses cancelled and reissued as warranted under the present procedure.*
- *FSSAI may review all directions issued under section 16(5) of the Act in the light of directions of the Hon'ble Bombay High Court and Hon'ble Supreme Court.*
- *FSSAI and state food authorities may conduct surveys of food business activity under their jurisdiction to ensure a comprehensive and reliable database of FBOs and to ensure better enforcement and administration of the FSS Act.*
- *FSSAI may frame and notify policy guidelines and procedures on risk based inspections, including the periodicity of inspections. All states may be persuaded to specify the periodicity of inspections and ensure that the periodicity is adhered to.*
- *Ministry is required to ensure accreditation of all state food laboratories, and ensure that state food laboratories and referral laboratories are fully equipped and functional.*
- *The Ministry/FSSAI may take steps to expeditiously notify the recruitment regulations and fill up vacancies.*

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.

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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.

Chapter-II : Regulatory and Administrative Framework

2.1 Introduction

The Food Safety and Standards Authority of India (FSSAI), under the Ministry of Health and Family Welfare in the Government of India, is responsible for regulating and monitoring food safety in the country, in terms of the Food Safety and Standards Act, 2006, the Food Safety and Standards Rules, 2011 and various regulations on food notified (and amended) since 2011.

2.2 Regulations yet to be framed

Till March 2017, i.e., more than a decade after the enactment of the FSS Act, FSSAI was yet to frame regulations governing various procedures, guidelines and mechanisms on areas covered in different sections of the Act, as below:

- Accreditation of food testing laboratories (Section 16(2)(e)).
- Conducting surveys for enforcement and administration of the Act (Section 16(2)(g)).
- Risk analysis/assessment/communication and management (Section 16(2)(i)).
- Accreditation of food certification bodies engaged in certification of food safety management systems for food businesses (Section 16(2)(c)).
- Organic foods (Section 22)
- Restriction of advertisement and prohibition of unfair trade practices (Section 24).
- Financial Regulations (Section 92(2)(t)).

The Ministry stated (June 2017) that it was not obligatory for FSSAI to make regulations in all cases and it had framed regulations where these were needed the most. The fact remains that FSSAI failed to examine the requirement to frame regulations in respect of aforesaid areas even after a decade of enactment of the Act. This has been discussed in detail in the relevant chapters of this report.

2.3 Failure of FSSAI to regulate Organic Foods

In 2015-16 alone, India produced around 1.35 million metric tonnes (MT) of certified organic products which includes all varieties of food products, and exported organic foods valued at around USD 298 million¹. Testing centres accredited by the Agricultural and Processed Food Products Export Development Authority (APEDA) certify organic foods manufactured in India. Audit observed that though section 22 of FSS Act stipulates that manufacture, distribution, sale, or import of organic foods is covered under the Act, FSSAI has not framed any regulations regarding organic foods.

The FSSAI and the Ministry accepted the facts (May and June 2017 respectively), but informed that it has now been decided to incorporate the existing National Programme for Organic Production of the Ministry of Commerce and Industry, and the Participatory Guarantee System (PGS) adopted by the Ministry of Agriculture and Farmers' Welfare, and accordingly draft regulations have been framed. The fact, however, remains that no regulations have been notified in respect of organic foods even a decade after the enactment of the Act.

2.4 Deficiencies in the adoption of BIS/AGMARK certifications for specified food products

The Directorate of Marketing and Inspection (DMI) under the Department of Agriculture and Co-operation, Government of India and the Bureau of Indian Standards (BIS) under the Ministry of Consumer Affairs, Food and Public Distribution, Government of India certify agriculture and non-agriculture products respectively². AGMARK and BIS certifications are optional. In terms of FSS regulations³, AGMARK and BIS certifications are mandatory for 8 and 14 food products respectively.

Audit noted that the FSS regulations have imported all the 22 mandatory certification categories from the erstwhile Prevention of Food Adulteration (PFA) Act, 1954, and the last category under PFA Act was included in June 2009. Audit observed that though perceptions, ingredients, products and processes relating to food safety are continually evolving, and this would necessitate modifications/

¹ Source: Website of Agricultural and Processed Food Products Export Development Authority (APEDA)

² In terms of the Agricultural Produce Grading and Marking (AGMARK) Act, 1937, and the Bureau of Indian Standards (BIS) Act, 1986 respectively.

³ FSS (Prohibition and Restriction on Sales) Regulations, 2011 and FSS (Packaging and Labelling) Regulations, 2011.

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deletions/additions to the certification standards identified under the erstwhile PFA Act, FSSAI has made no efforts to review, for the purpose of possible addition/deletion, the list of mandatory AGMARK and BIS certifications under PFA Act at the time of framing FSS regulations in 2011, or thereafter. Such exercise would also cover areas where the existing BIS/AGMARK certifications are deficient or insufficient.

FSSAI in its reply (May 2017) stated that the industry or consumers have not requested for discontinuation of mandatory certification provisions except the category of blended edible vegetable oils which is mandatorily required to be certified under AGMARK. The Ministry in its reply (June 2017) endorsed the views of FSSAI.

The stand of the Ministry and FSSAI is unacceptable, since the FSSAI is required to independently review mandatory certifications for the purpose of addition/deletion.

2.5 Deficiencies in the formulation of standards

FSSAI formulates standards for various food articles (including their constituents and additives) and processes of manufacture, storage, transportation, sale etc., to ensure availability of safe and wholesome food for human consumption. Audit noticed that though FSSAI has framed standards through regulations, such standards were framed at different periods of time from 2011 onwards, and there is no clarity on the reasons underlying the identification of food products that were standardised, identified ahead of others, and some food products like organic foods (discussed in paragraph 2.3 above) remain to be standardised. Though FSSAI has framed regulations on the working of Scientific Panels and Scientific Committee⁴, the areas on which the Panels/Committee deliberate and offer opinion are determined by the executive of FSSAI, and are not based on any defined operating procedure (SOP). There is no clarity on why such areas (and not others) are selected by FSSAI. Further, in some areas, like the framing of regulations on proprietary foods (mentioned in paragraph 2.10(2) below), FSSAI did not involve the Scientific Panels/Committee and the rationale for such exclusions is not clear. FSSAI has also not formulated internal time frames for the processing of standards (apart from the time frames relating to the issue of draft notification and final notification etc.), as a result of which, there were inordinate delays (for instance, the final notification regarding potassium bromate as food

⁴ FSSAI (Transaction of Business and Procedure of Scientific Committee and Scientific Panels) Regulations, 2010 (amended in 2016).

additive referred to in the case study below paragraph 2.7.2 was issued five years after identification of risks, mainly because of absence of internal time lines). Ultimately, FSSAI failed to devise action plans to identify areas on which standards are to be formulated/ revisited for revision, if necessary, within specified time frames⁵.

The Ministry informed (March 2017) that the identification of areas for examination by the Scientific Panels/Committee and for framing standards is based on scientific evidence. Further, in response to the audit observation, while Ministry had forwarded a statement delineating the process/steps involved in framing regulations, Audit observed that there is no clarity on the first step itself (involving identification of food products on which standards are to be developed/ reviewed), since there is no information on the process through which such identification takes place.

Following the initial audit observation, FSSAI set up eight standards review groups (SRG) in December 2016 to review existing standards applicable to different food categories, and to propose broad new standards; the report of the SRGs would be placed before the concerned Scientific Panels for review and necessary action. However, there is no such provision in the Act to entrust this work to other groups comprised of representatives of FBOs only. This also gives additional credence to the audit observation that identification of areas of examination was not based on scientific process, since there is no evidence on why only eight areas were chosen in the first instance for review of standards. It is also observed that no time frame has been given to the groups for this exercise. Therefore, their opinions/recommendations cannot be considered to be unbiased and beneficial to the interest of food safety affecting the common man.

FSSAI in its reply (May 2017) stated that in the context of revision of standards/formulation of new standards, the Food Authority generally followed a prioritisation approach to address the issues of food safety first. FSSAI further stated that the SRGs are tasked to only suggest areas of new work. Ministry in its reply (June 2017) endorsed the views of FSSAI and stated that this is an internal arrangement for facilitating work and setting up such groups is perfectly in order and desirable in many cases.

The replies are not tenable. There is no evidence to support the FSSAI's contention that it followed a prioritisation approach. The orders on formation of

⁵ For instance, the Bureau of Indian Standards has a protocol for revision of standards every five years.

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SRGs clearly stated that they were formed for review of existing standards and to propose new standards. Therefore, the concerns of audit on the risks of primarily relying on industry representatives for review of standards, which is the mandate of FSSAI, remain unaddressed.

2.6 Notification without awaiting recommendation of the Scientific Panel/Committee and without considering stakeholders' comments

Sections 13 and 14 of the Act state that the Scientific Committee assisted by the Scientific Panels provide scientific opinion to the Food Authority. As per section 18(2)(d) of the Act, the FSSAI is required to ensure open and transparent public consultation during the preparation and revision of regulations/standards. Therefore, involvement of the Scientific Panels/Committee and transparent public consultation is inherent to the process of notification of regulations on standards. However, during test check, Audit found a case (discussed below) pertaining to amendment to regulations⁶, where the FSSAI bypassed the Scientific Panel/Committee and did not consider the comments of stakeholders before final notification.

Case Study

Stakeholders' comments on the draft notification (February 2015) to include Steviol Glycoside⁷ in various food products were placed before the Scientific Panel in its 23rd meeting on 15 October 2015, which directed one of its members to review them for further discussion by the Panel. Without considering the stakeholders' comments or awaiting the review thereon and recommendations of the Scientific Panel, FSSAI notified the final regulation (13 November 2015), without the previous approval of the Ministry as required under section 92 of the Act⁸. Audit further observed that the detailed stakeholders' comments pointed out, *inter-alia*, an error in the draft notification, which did not specify ash content. However, this remained uncorrected in the final notification.

FSSAI/ Ministry in reply (May/June 2017), stated that most of the comments related to inclusion of more food categories in the regulation for use of steviol glycoside. Hence, it was decided to notify the said standards as such without any further delay and that the stakeholders' proposals in respect of addition of more food categories would be covered in the subsequent harmonisation process in

⁶ FSS (Food Product Standards and Food Additives) Regulations, 2011.

⁷ Chemical compounds responsible for the sweet taste of the leaves of the South American plant *Stevia Rebaudiana* (Asteraceae), and the main ingredients (or precursors) of many sweeteners marketed under the generic name 'Stevia' and several trade names.

⁸ Ministry accorded ex-post facto approval on 25 November 2015.

respect of food additives provisions, which has also been completed since then. Further, the omission of changes in the draft standards was not deliberate but an editorial error.

The replies are not acceptable as there was no record to substantiate that the FSSAI had decided to include more food categories separately. In any event, the notification of regulations without awaiting the opinion of scientific panel was incorrect.

2.7 Delays in notifying amendments to Regulations

Between February 2013 and December 2016, FSSAI notified 43 amendments to three regulations on food standards⁹. During test check of eleven amendments notified up to June 2016 (out of 25 amendment notifications), Audit observed delays in notifying these amendments, which are primarily attributable to lack of policy guidelines and standard operating procedures (SOP). It was noticed that after approval by the Scientific Panels, FSSAI took between 14 to 24 months to notify six amendments, and between 28 to 39 months to notify five amendments. Details are given below:

2.7.1 Delays and deficiencies in referring draft notification to Ministry

Audit observed delays in the following six cases involving amendment to the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, as recounted below:

Case Study 1

After the approval of Food Authority (September 2012) to include ‘pullulan’¹⁰ as food additive, the Regulation Division of FSSAI retained the file for 19 months without action, and thereafter referred the file to the Scientific Panel and Scientific Committee for clarifications. The action of the Division to seek clarification on the matter after approval by the Food Authority was inappropriate and inordinately delayed the notification process which was concluded in October 2014.

⁹ FSS (Food Product Standards and Food Additives) Regulations, 2011; FSS (Contaminants, Toxins and Residues) Regulations, 2011; and FSS (Packaging and Labelling) Regulations, 2011.

¹⁰ An edible, mostly tasteless polymer, mainly used in various breath freshener or oral hygiene products and as food additive.

Case Study 2

The Scientific Panel recommended (January 2014) five issues to be included in the amendment to the FSS (FPS and FA) Regulation, 2011 for 'salted fish/ dried salted fish'. The Food Authority, however, decided to include only four issues in the amendment, leaving the fifth issue to be covered in a future amendment. At the time of sending the draft notification (August 2014) to Ministry for approval, FSSAI failed to intimate the reason for exclusion of the fifth issue, leading the Ministry to seek clarification (September 2014). Though the decision to exclude the fifth issue had been taken by the Food Authority and not the Scientific Panel (SP) or Scientific Committee (SC), the Regulation Division needlessly referred the matter to the SP and SC (though the decision of the Food Authority was available on the file with the Regulation Division), resulting in five months delay in sending clarification to the Ministry. The draft regulations were notified (June 2015), 17 months after the recommendation of the Scientific Panel.

Case Study 3

FSSAI took more than 19 months, after the recommendations of the Panel (July 2012), to send the file to the Ministry (March 2014) for approval of the draft notification to change the standards for use of different enzymes in bread.

Case Study 4

For amendment to the regulation on revision of standards for blended edible vegetable oil regarding unsaponifiable matter¹¹ and relaxation or harmonisation of iodine value in imported cotton seed oil with Codex Standards¹², FSSAI took 24 months, after the recommendations (May 2013) of the Expert Group¹³, and 19 months after the approval of the Food Authority (January 2014), to send the file to the Ministry for approval of the draft notification. Detailed Audit scrutiny revealed that after approval by the Food Authority (January 2014) certain queries were raised by CEO, FSSAI (May 2014) and it was proposed to discuss these in the Expert Group. However, the matter was not discussed either in the Expert Group or the Scientific Panel which replaced it. It was only after a reminder was received from an FBO (August 2015), did FSSAI realise that the file was unnecessarily pending with them, and sent it to the Ministry (November 2015), without addressing the queries raised by CEO.

¹¹ Components of an oily (oil, fat, wax) mixture that fail to form soaps when blended with sodium hydroxide (lye) or potassium hydroxide.

¹² A collection of internationally recognised standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety.

¹³ Expert Groups on specific matters were replaced by the creation of appropriate Scientific Panels.

Case Study 5

FSSAI took more than 17 months after the recommendations of the Scientific Panel (July 2012), to send the file to the Ministry for approval of the draft notification (January 2014) for amendment to the regulation relating to 'edible common salt'.

Case Study 6

After the Ministry had approved the final regulation (July 2013) on Maximum Residual Limits (MRLs) of antibiotics in honey, FSSAI belatedly realised that prior reference to the World Trade Organisation (WTO) was required, which had not been done. The regulation was finally notified in December 2014, one and a half years after the Ministry's approval.

Though the FSSAI accepted the facts in respect of case studies 1, 3, 5 and 6, it did not respond to the audit observations contained in case studies 2 and 4.

2.7.2 Undue delays in notification of final regulations

The Lok Sabha Committee on Subordinate Legislations had, *inter-alia*, stipulated (December 2011) that the final notification be issued within three months of the last date of receipt of comments/suggestions from stakeholders on the draft notification, if no/less number of comments were received from stakeholders¹⁴. Audit observed that though only one to two comments of minor nature were received on the draft notifications in four cases, FSSAI took five to ten months for final notification.

The Ministry in their reply (June 2017) endorsed the FSSAI's response (May 2017) that framing regulations is a time consuming process which requires careful assessment of the aspects by different bodies. The replies are not tenable as the committee had limited the period to six months only where many comments were received, which was not the case here. Also, the replies did not address the specific cases pointed out by Audit, where the delays were avoidable.

In the exit conference (June 2017), FSSAI accepted the delays and attributed the delays to the scientific, technical and administrative aspects involved in the process. FSSAI further added that efforts will be made to meet the recommendations of the Lok Sabha Committee on Subordinate Legislation and extensions will be sought wherever required.

¹⁴ Details on the stipulations by the Committee are given in paragraph 2.9 below.

Case Study

Delay in banning Potassium Bromate as Food Additive

FSSAI took nearly five years to ban (June 2016) the use of Potassium Bromate in bread and bakery products after the Scientific Panel recommended (July 2011) its ban on the ground that it was carcinogenic. Audit scrutiny revealed that, for reasons not on record, FSSAI first delayed issuing the draft notification (April 2013) after the belated approval (June 2012) of the Food Authority. Thereafter, for reasons not on record, FSSAI, without informing the Ministry, failed to act on the stakeholders' comments on the draft notification, violating the limit of six months stipulated by the Lok Sabha Committee. However, Potassium Bromate was removed from the list of permitted additives in the regulations¹⁵ notified in September 2016.

Accepting the facts, the Ministry replied (March 2017) that the issue of Potassium Bromate was linked to the work on harmonisation of all the additive provisions with Codex General Standard for Food Additives¹⁶. The reply is not tenable. There was no evidence on record to support the Ministry's contention that the ban on Potassium Bromate was linked to the harmonisation of the codex (incidentally, the codex had declared Potassium Bromate as a banned item in 2012). It was also observed, that even while the harmonisation exercise was in progress, FSSAI notified other amendments (e.g., the inclusion of pullulan as a food additive). Therefore the notification of standards (including the banning of certain items) is an exercise independent of harmonisation. Finally, and in any case, regulations on the banning of a carcinogenic substance as additive in daily foods should not have been kept pending for five years.

2.8 Product Approval

Between January 2012 and May 2013, the FSSAI issued, without the approval of the Ministry, a series of advisories covering the category of proprietary foods, which have been defined in section 22 of the Act as articles of food for which standards have not been specified but are not unsafe, provided that such food does not contain any of the foods and ingredients prohibited under the Act and regulations made thereunder. These advisories permitted the FSSAI to issue

¹⁵ FSS (Food Products Standards and Food Additives) Amendment Regulations, 2015.

¹⁶ Part of the "Codex Alimentarius" (Food Code), a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission, which is central part of the Joint Food and Agriculture Organisation (FAO) /World Health Organisation (WHO) Food Standards Programme and was established to protect consumer health and promote fair practices in food.

product approvals to individual FBOs for products which were not covered under existing standards.

Audit observed, however, that though the initial advisories required the issue of product approvals to be based on the recommendations of the Scientific Panels, the FSSAI, through subsequent advisories, adopted the issuance of No Objection Certificates (NOC) by the Product Approval division of the FSSAI, for a period of one year, pending recommendation of the Scientific Panels. Such issuance of provisional approvals is not contemplated in the Act, and further, the decision on whether a food product is safe or unsafe (as stipulated in section 22 of the Act) can only be determined by way of scientific opinion, which, only Scientific Panels/ Committee can provide under sections 13 and 14 of the Act.

The last advisory of May 2013 was struck down by the Hon'ble Bombay High Court¹⁷ on 01 August 2014 (and the Hon'ble Supreme Court dismissed the appeal on 19 August 2015) on the ground that the advisories issued by FSSAI without following the procedure laid down under sections 92 (requiring prior approval of the Ministry and previous publication by notification) and 93 of the Act (requiring placing the notified regulations before Parliament) have no force of law. Audit observed, however, that though the FSSAI discontinued the product approval system, it did not take steps to withdraw the licenses issued under the now invalid system, and ensure product recalls. Some of these licenses merited cancellation even under the redundant system, after the FSSAI itself withdrew the NOCs but failed to ensure the cancellation of licenses at that time. Consequently, the possibility that unsafe foods continued to be imported/ produced/ distributed/ sold based on the now invalid licenses cannot be ruled out. Details are given below.

2.8.1 Continuation of licenses issued in terms of flawed NOC procedure

As given in the case studies in the succeeding sub-paragraphs, Audit observed occasions where the NOC issued earlier by the Product Approval division had to be withdrawn because the application for product approval for a similar or identical product was denied by the Scientific Committee/Scientific Panels. It is therefore evident that FSSAI permitted possibly unsafe foods (and foods subsequently determined by the Scientific Panels to be not safe) to be manufactured, distributed, sold or imported in the country. Audit further observed that though the NOCs were valid only for a maximum period of one year, FSSAI did not ensure that the licenses issued on the basis of these NOCs were

¹⁷ Writ Petition No. 2746 of 2013 dated 1 August 2013

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accordingly valid for the period of the NOC. Further, after withdrawing the NOCs, FSSAI did not ensure that the Central Licensing Authorities (CLA) also cancelled the licenses that had been issued on the basis of the now withdrawn NOCs and also that the FBOs had stopped the manufacture, distribution and sale of such products.

2.8.2 Continuance/renewal of licenses in violation of Supreme Court orders

In terms of the advisory, the NOCs were valid for a maximum period of one year, Audit, however, observed that after the judgement of the Bombay High Court (01 August 2014) declaring the process of advisories as invalid, FSSAI issued blanket instructions (29 September 2014) to the Central Licensing Authorities (CLA) and directed them to renew/ continue, as required, all existing licenses issued on the basis of NOCs. Consequently, FSSAI permitted the indefinite manufacture, distribution, sale or import of possibly unsafe foods. FSSAI did not take any action after the final orders of the Supreme Court (19 August 2015) to withdraw these blanket instructions. Further, FSSAI failed to withdraw the blanket instructions even after the notification of the amended regulations in respect of proprietary foods (October 2016).

2.8.3 Unauthorised issue of product approvals for proprietary foods by state food authorities

Under the advisory system, only FSSAI had the authority to issue product approvals for proprietary foods on the recommendation of the Scientific Panels. Audit, however, observed that FSSAI did not have any mechanism to ensure that state food authorities did not issue licenses/product approvals on proprietary foods. Test check in Audit revealed that the designated officers in Solan and Sirmaur districts in Himachal Pradesh granted product approvals for a total of 20 proprietary food products during 2014-15, without authority.

2.8.4 Withdrawal of wrongly issued NOCs

2.8.4.1 Issue of NOCs based on recommendations of PA&SC

Under sections 13 and 14 of the Act, only the Scientific Committee/Scientific Panels have been entrusted with the responsibility of providing scientific advice to the Food Authority. Under the product approval system, proposals for product approvals required examination by the Scientific Committee/Scientific Panels. FSSAI constituted a Product Approval and Screening Committee (PA&SC) headed by the Director, Product Approval division to screen the proposals based

on preliminary risk assessment. Audit observed however, that bypassing the requirement for examination by the Scientific Committee/Scientific Panels, the Product Approval division acted on the recommendation of PA&SC and issued NOCs. Moreover, FSSAI had neither framed any Standard Operating Procedures (SOP) to determine the authority competent to approve food products, nor did it delegate such powers to the Product Approval division.

Moreover, the NOCs should have been issued only on the receipt of complete information required for product approval. Audit observed, however, instances where FSSAI issued NOCs even when the product information received was incomplete. In 20 cases (9 *per cent* of the 212 NOCs issued), FSSAI had withdrawn the NOCs issued earlier for reasons including non-furnishing of the complete information by the FBOs. Audit also observed that FSSAI had no mechanism to call for the missing information promptly, and to ensure prompt receipt of wanting information. Illustrative cases are given below:

Case Study 1

FSSAI issued NOC (October 2012) to M/s Art Life Wellness Products for fortified candies (sweets), based on PA&SC recommendation. Thereafter, FSSAI withdrew the NOC (February 2015), due to failure of FBO to furnish the complete details required for submission to the Scientific Panel. Thus, failure of FSSAI to ensure complete documentation before issue of NOC resulted in manufacture and sale of possibly unsafe foods for 28 months between October 2012 and February 2015.

Case Study 2

FSSAI issued NOC (August 2013) to M/s Pushpam Foods and Beverages for four types of energy drinks based on recommendation of PA&SC. However, NOC was withdrawn (November 2014) on the ground that the Scientific Panel had observed (March 2014) in another similar case that the product had an irrational combination of caffeine and ginseng¹⁸, which have opposing effect on the human body. Audit further observed that FSSAI delayed issuing the letter for product recall till May 2015, thereby allowing the FBO a further six months' time to manufacture and sell a product for which NOC had been withdrawn. Overall, the Product Approval division delayed the product recall by 15 months from the date of observation of the Scientific Panel. This resulted in manufacture and sale of

¹⁸ Import of Monster Energy Drink by M/s Narang Danone Access Pvt. Ltd., referred to in paragraph 2.8.4.2 below.

unsafe food products (energy drinks) for 21 months between August 2013 and May 2015.

Case Study 3

Similar to the above case, on recommendation of PA&SC, FSSAI issued NOC (December 2013) to the above FBO (M/s Pushpam Foods and Beverages) for another energy drink, which was withdrawn (June 2015), on the same ground as in the earlier case. Thus, issue of NOC by FSSAI without risk assessment by the Scientific Panel resulted in manufacture and sale of an unsafe food product (energy drink) between December 2013 and June 2015. Audit scrutiny of the website of FBO revealed (April 2017) that the product (Restless caffeinated beverage containing ginseng) continued to be marketed despite the withdrawal of NOC by FSSAI in June 2015.

Case Study 4

FSSAI issued four NOCs (May 2012) to M/s Jagdale Industries for four products (drops, powder, syrup and capsules) sold under the trade name 'Mulmin'. However, the four NOCs were withdrawn (June 2015) after the Scientific Panel did not recommend approval of the products (April 2015). Audit further observed that though the Product Approval division had received all wanting information from the FBO in January 2014, it took 15 months to place the matter before the Scientific Panel, for reasons not on record. Thus, issue of NOC by FSSAI without risk assessment by the Scientific Panel resulted in manufacture and sale of unsafe food products between May 2012 and June 2015. Audit scrutiny of the website of FBO revealed (April 2017) that the unsafe products (drops, powder, syrup and capsules) sold under the trade name 'Mulmin' continued to be marketed despite the withdrawal of NOC by FSSAI in June 2015.

2.8.4.2 Unauthorised and wrong issue of NOC for energy drinks

The FBO, M/s Narang Danone Access Private Limited, applied (December 2012) for product approval for two variations of an energy drink marketed under the trade name "Monster Energy" and intimated that the application for the license would be submitted soon. However, without waiting for FSSAI's product approval, the FBO imported the consignment and intimated (March 2013) FSSAI that 50,632 cases¹⁹ of the product (475 ml. cans) were held up at Nhava Sheva Port, and requested a one-time clearance. The can size exceeded FSSAI's draft

¹⁹ Number of cans per case in this consignment is not known. However canned beverages are normally sold in cases of 24 cans (though, it can range between 12 to 36 cans per case).

standards for caffeinated beverages (250 ml.)²⁰, which were in the notice of the FBO and were at the final stages of notification (Draft regulations notified on 18 April 2013), and the product (by its nature) could not be repacked in smaller cans even after import. However, for reasons not on record, FSSAI issued permission (April 2013) to transport the product from the wharf area to the FBO's godown. Thereafter, the matter was referred to three different Scientific Panels²¹ for examination of various aspects relating to the concerned energy drink. Even while the matter remained under examination with these Scientific Panels, FSSAI issued NOC (October 2013) on the recommendation of the PA&SC. Such issue of NOC on the basis of PA&SC recommendation violated even the FSSAI advisories that did not provide for the PA&SC to review any application that was under examination by the Scientific Panels. Further, FSSAI had no authority to issue NOC on a product that did not meet packaging standards (475 ml. can instead of 250 ml. can). Ultimately, the Scientific Panel on Functional Foods etc., rejected (March 2014) the product, on the ground that it contained irrational combination of caffeine and ginseng, which have opposing effect on the human body. FSSAI withdrew the NOC (September 2014), but the Bombay High Court stayed the matter till May 2015, after which FSSAI once again withdrew the NOC and issued product recall. Audit observed, however, that FSSAI took no steps to ensure that follow up action had been taken on product recall.

2.8.4.3 Non cancellation of licenses of foods declared not safe by Scientific Panel

Audit observed that even after the withdrawal of NOCs, there was no mechanism to ensure that the licenses issued on the basis of the withdrawn NOCs were cancelled. The four cases recounted below relate to withdrawal of NOCs after the Scientific Panels refused product approval. Consequently, unsafe foods continued to be manufactured, distributed, sold and imported despite their rejection by the Scientific Panel, as detailed below:

Case Study 1

FSSAI issued NOC (August 2013) to M/s Surya Herbal Ltd. for Sunova Spirulina Tablets. However, the FBO failed to submit application as required for examination by the Scientific Panel, and NOC was withdrawn (August 2014).

²⁰ The final notification of 2 December 2016 deleted the reference to per can size limit and only specified that the daily consumption should not exceed 500 ml. per day. Reasons for the deletion by FSSAI are not known.

²¹ The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials; the Scientific Panel on Labelling and Claims/ Advertisements; and the Scientific Panel on Functional Foods, Nutraceuticals, Dietetic Products and Other Similar Products.

Audit observed however, that the license of the FBO was not modified/ cancelled accordingly. The Central Licensing Authority (Delhi) informed (August 2016) that they had not received any notice of rejection of the product and the licence issued on the basis of NOC (which has been cancelled) is valid up to December 2017.

Case Study 2

FSSAI issued NOC (July 2012) to M/s. S.K. Industries for two products, based on recommendation of PA&SC. Subsequently, PA&SC reviewed its earlier decision, and FSSAI withdrew the NOC (September 2014). Though the Central Licensing Authority (Delhi) informed that the license of the product had been cancelled, the website of FSSAI continued to show that the license was valid till 01.07.2019. Consequent to the Audit observation in August 2016, FSSAI removed this depiction from its website. Thus, FSSAI took almost two years to remove the food article from the FBO's license after withdrawal of NOC.

Case Study 3

FSSAI issued product approval (January 2013) to M/s. BioCon Ltd. for S-Adenosyl Methionine Tablets. However, in August 2013, product approval was denied to M/s Sun Pharmaceutical Industries Ltd. for the same product. FSSAI failed to resolve this contradiction for more than a year, till it withdrew product approval in the case of BioCon in October 2014. Further, despite withdrawing the product approval to BioCon, FSSAI failed to cancel the corresponding license to BioCon, which continues to be valid upto May 2020.

Case Study 4

FSSAI issued a composite NOC in September 2012 to M/s Hector Beverages for three types of energy drinks. Though FSSAI withdrew the NOC (April 2015) and issued directions for product recall for all three categories (May 2015), the license has not been cancelled till December 2016. The Central Licensing Authority (Delhi) stated (August 2016) that the license was for caffeinated beverages and not for the proprietary products for which NOC had been withdrawn. The reply is not relevant. One specific ground for withdrawal of NOC was the finding of the Scientific Panel that products containing combinations of caffeine and ginseng (as was the case in the three energy drinks under consideration) should not be allowed. Consequently, inaction of FSSAI to cancel the product license resulted in continued sale of an unsafe product more than a year after cancellation of NOC.

2.8.5 Non withdrawal of NOCs

2.8.5.1 Non withdrawal of NOCs despite rejection by Scientific Panel

Test check in Audit of 50 cases (24 per cent of the 212 cases where NOCs had been granted by FSSAI) revealed that in four cases, though the Scientific Panel had rejected the food articles, NOCs had not been withdrawn even 31 to 47 months after rejection by the Scientific Panel, resulting in continued manufacture/import and sale of possibly harmful food products. These have been described below.

Case Study 1

FSSAI issued NOC (December 2013) to M/s Pushpam Foods and Beverages for an energy drink which contained caffeine-ginseng combination. Following the vacation of stay by the Bombay High Court (01 May 2015) in the case of another FBO whose product had similar combination of caffeine-ginseng which had been rejected by FSSAI²², the Chairperson ordered (July 2015) issue of show cause notice to M/s Pushpam also. However, FSSAI failed to issue the show cause notice to the FBO, as a result of which NOC was not withdrawn. (Incidentally, it is observed that FSSAI withdrew NOCs in six other cases based on the same recommendation of the Scientific Panel, without issue of show-cause notice).

Case Study 2

FSSAI issued NOC (August 2012) to M/s Chemical International for a mushroom based nutraceutical. Though the Scientific Panel thereafter rejected (September 2012) the application on the ground of absence of clinical data on immunity benefit claimed by FBO, FSSAI failed to cancel the NOC.

Case Study 3

FSSAI issued NOC (July 2012) to M/s Apex Laboratories for three products (syrup and tablets) with the brand name “Zincovit”. Audit observed that though the technical officer in the Product Approval division informed (April 2012) that the syrup contained various ingredients that are not permitted in nutraceuticals, the PA&SC recommended issue of NOC without addressing the concerns on safety and ineligibility of the ingredients used in the syrup. Thereafter, even the Scientific Panel recommended (December 2013) rejection of the products. FSSAI has, however, not cancelled the NOC.

²² Import of Monster Energy Drink by M/s Narang Danone Access, referred to in paragraph 2.8.4.2 above.

Case Study 4

FSSAI issued NOC (July 2012) to M/s Alkem Laboratories for multivitamin tablets with the brand name “A to Z NS tablets”. Though thereafter, the Scientific Panel recommended rejection (December 2013) of the products, FSSAI did not cancel the NOC.

2.8.5.2 No action taken despite failures of FBOs

Audit observed that in the following seven cases (14 *per cent* of the 50 cases referred to above), FSSAI issued NOCs despite failure of FBOs to furnish complete information at the application stage; thereafter, FSSAI delayed in calling the required information; and finally, though the FBOs failed to furnish the information, FSSAI did not take any action against them. Consequently, possibly harmful food products continued to be manufactured/ imported and sold from as early as June 2012. The following case studies illustrate this.

Case Study 1

FSSAI issued seven NOC (April 2013) to M/s Jeevanseva Enterprises for products containing liquid chlorophyll, guarana (a plant containing caffeine), ganoderma (a genus of mushroom), goat's milk candy and ginseng. FSSAI however, wrote to the FBO (September 2014) seventeen months after the issue of NOC, seeking further information from the FBO for submission to the Scientific Panel. Immediately thereafter, the FBO informed (October 2014) FSSAI about the change of its name, but did not furnish any other information. Though the change in name itself warranted immediate change in the status and validity of the NOCs, FSSAI failed to take any action, and there was no change in the status of the seven NOCs.

Case Study 2

FSSAI issued NOC (June 2012) to M/s Sonerge Pharma for New Zealand Royal Jelly (chewable tablets). FSSAI however, took 26 months to process the case for submission to the Scientific Panel, and wrote to the FBO (August 2014) seeking additional information, which has not been provided. FSSAI, however, has failed to take any action against the FBO.

Case Study 3

FSSAI issued NOC (January 2013) to M/s Genext Labs for an energy drink. FSSAI however, took eighteen months to process the case for submission to the Scientific Panel, and wrote to the FBO (July 2015) seeking additional

information. However, despite failure of the FBO to furnish information, FSSAI has failed to take any action against the FBO.

Case Study 4

FSSAI issued NOC (September 2014) to M/s ABN Enterprises for a caffeinated energy drink. Though the FBO failed to furnish information sought by FSSAI in September 2014 and July 2015, FSSAI has failed to take any action against the FBO.

Case Study 5

FSSAI issued NOC (January 2013) to M/s Sundyota Numandis Probioceticals, but took twenty months to process the case for submission to the Scientific Panel, for which purpose, FSSAI wrote to the FBO (September 2014), seeking certain information. However, despite failure of the FBO to furnish information, no action was taken against the FBO.

Case Study 6

FSSAI issued NOC (February 2013) to M/s Red Bull India for the “Red Bull” brand energy drink, but took twenty nine months to process the case for submission to the Scientific Panel, for which purpose FSSAI wrote to the FBO (July 2015) seeking clarifications on certain defects in the application. However, despite failure of the FBO to furnish information, FSSAI failed to take any action against the FBO.

Case Study 7

FSSAI issued NOC (June 2013) to M/s Power Horse India for an energy drink, but failed to submit the case to the concerned Scientific Panel at any time. In the meantime, FSSAI itself found certain deficiencies in the application and sought clarifications from the FBO (July 2015). However, despite failure of the FBO to furnish information, no action was taken against the FBO.

The Ministry replied (March 2017) that FSSAI had decided not to issue product approvals and NOCs in 2,094 cases where information/documents were not furnished by FBOs. The reply is not relevant, since it does not address the issue of delay by FSSAI (for more than one year and for almost three years) to process the applications for examination by the Scientific Panel, and FSSAI’s further failure to take action against the FBOs who had failed to furnish information.

2.8.6 NOC cases not submitted to Scientific Panels despite specific PA&SC recommendation

Though the PA&SC issued 212 NOCs, FSSAI failed to confirm to Audit on the number of cases out of these 212 cases which were referred to Scientific Panel. Audit observed, however, that though, in 27 out of 50 cases test checked (54 *per cent*), the PA&SC had recommended referring the cases to the Scientific Panels for examination and appropriate decision, FSSAI failed to do so, and without recording any reasons, issued NOCs (October 2012 to January 2015) in all these cases.

In response to the Audit observations contained in paragraph 2.8 (and subparagraphs thereunder), the Ministry reiterated (June 2017) the reply of the FSSAI (May 2017) that the issue pertaining to the erstwhile product approval system appeared to be redundant in view of its withdrawal upon the directions of the Hon'ble Bombay High Court and Supreme Court. The Ministry/ FSSAI further stated that the Food Authority has approved new regulations concerning approval of non-specified foods and ingredients in May 2017 and all old cases could be resolved once these are notified.

The replies are not acceptable, since they have not addressed the primary audit concern that the FSSAI had failed to ensure the cancellation of the licenses issued under the product approval system declared unlawful by the Supreme Court, and order product recalls, resulting in possibly unsafe food continuing to be imported/manufactured/distributed/sold in the country. The response that the issue was now redundant cannot be used to brush away the serious defects in the functioning of the product approval system, which reflects poorly on the systemic functioning of the FSSAI itself.

2.9 Wrongful operationalisation of Regulations under Section 16(5)

In terms of the judgements of the Bombay High Court and the Supreme Court (referred to in paragraph 2.8 above), the powers exercised by Food Authority under sections 16(1) and 16(5)²³, the general principles of food safety enshrined in section 18, and the specific provisions relating to proprietary foods etc., in section 22, shall be subject to the overarching provisions of sections 92 and 93 of

²³ Section 16(1) states the duties of the Food Authority. Section 16(5) empowers the Food Authority to give binding directions to the Commissioners of Food Safety (*viz.*, the CEO, FSSAI in respect of the Centre, and the Commissioner nominated by the concerned State government).

the Act. Section 92 stipulates, *inter-alia*, that the Food Authority may (a) with the previous approval of the Central Government and (b) after previous publication, (c) by notification, make regulations under the Act. Section 93 requires all rules and regulations to be laid, after they are made, before each house of Parliament. The report of the Committee on Subordinate Legislation²⁴ has stipulated that, before complying with the requirement of 'previous publication' under an Act, the following procedure was to be followed, *viz.*, the framing of draft rules in consultation with Ministry of Law and Justice, their publication in the official gazette inviting objections and suggestions within thirty days, obtaining suggestions from interested groups, considering the objections/views, finally notifying the rules (in consultation with Ministry of Law and Justice) within six months of last date of receipt of comments (if number of responses are large) and within three months (if number of responses are small or nil).

Audit noticed many instances where, contrary to the above requirements, FSSAI issued directions under section 16(5) without adhering to the requirements of sections 92 and 93 of the Act. FSSAI, by these directions, wrongly operationalised the codex standards for various commodities, prescribed the permissible limits of iron filings in tea, removed zinc from the list of contaminants, and introduced a new category for unprocessed whole raw pulses with reduced standards. Details are given below.

2.9.1 Directions issued by-passing open and transparent public consultation

Case Study

FSSAI operationalised (April 2016) Codex Standards for various commodities by exercising its powers under section 16(5), by-passing the process of open and transparent public consultation (mandated under section 18(2)(d) of the Act), without the prior approval of the Central Government and previous publication by notification (mandated under section 92 of the Act) or the Food Authority.

2.9.2 Directions issued without progressing beyond stage of issue of draft notification

Case Study 1

FSSAI had issued three advisories (May 2014, November 2014, and May 2015) prescribing the permissible limit of iron filings in tea. Though these advisories became invalid from 19 August 2015 (the date of the Supreme Court judgement),

²⁴ 15th Lok Sabha (2011-12) dated 16 December 2011.

FSSAI, contrary to the judgement, allowed the third advisory to continue till 21 November 2015, its normal expiry date. Thereafter, FSSAI issued a draft notification on 04 December 2015, followed by a revised draft notification of 17 May 2016. On 22 April 2016 (i.e., prior to the issue of the second draft notification), FSSAI, without the approval of the Food Authority or the Ministry, issued directions under section 16(5) of the Act implementing the draft standard that prescribed the limit of not more than 150 mg/ kg of iron filings in tea. The regulation was finally notified on 29 December 2016, eight months after the unauthorised operationalisation. The operationalisation of standards under section 16(5) without completing the procedure delineated under section 92 and 93 amounted to violation of the Act.

Case Study 2

FSSAI issued the draft notification for 11,000 food additives on 04 August 2015. On 20 June 2016, without issuing the final notification, and without the approval of the Food Authority or the Ministry, and violating the Supreme Court judgement, FSSAI issued directions under section 16(5), and operationalised the standards. The regulations were finally notified on 05 September 2016.

Case Study 3

FSSAI issued the draft notification (April 2016) for removal of zinc from the list of contaminants. However, FSSAI issued directions under section 16(5) of the Act, and implemented the regulation with effect from 02 May 2016 before notifying the final regulations. Such use of section 16(5) without following the provisions of section 92 violated the Act. The regulations were finally notified on 10 October 2016.

Case Study 4

FSSAI issued draft notification (28 April 2016) to create a new category: “unprocessed whole raw pulses (not for direct human consumption)” containing reduced standards on permissible limit of foreign (extraneous) matter otherwise applicable to the general raw pulses category. The final regulation was notified on 14 September 2016. Audit observed that, even prior to the issue of the draft notification, FSSAI issued directions (13 April 2016) under section 16(5) implementing the proposed regulation with immediate effect in violation of the Act.

2.9.3 Extension of date of implementation of regulations without amendment notification

In the following two cases, without following the process mandated under section 92 of the Act, and in violation of the Supreme Court judgement, FSSAI wrongly exercised section 16(5) to extend the date of implementation specified in the gazette notification.

Case Study 1

The gazette notification (May 2016) amending the regulations on labelling of pre-packaged foods in the category of edible vegetable oil/ fat, stipulated that the amendment came into effect on 25 May 2016. FSSAI, however, on 30 July 2016, invoked section 16(5) and extended the date of effect to 02 December 2016, bypassing the requirement of amendment to the earlier regulation through gazette notification.

Case Study 2

The gazette notification dated 04 August 2016 amending the regulations on margarine and fat spreads was to become effective from 27 August 2016. On 10 August 2016, FSSAI wrongly exercised section 16(5) of the Act, and extended the date of effect to 27 February 2017, bypassing the requirement of amendment through gazette notification.

The Ministry accepted (June 2017) the Audit contention that the date of implementation of a regulation notified in the official gazette with the approval of the Central Government should not be modified except by way of amendment in the said regulation through a gazette notification with the approval of the Central Government.

As recounted in the seven case studies above, FSSAI violated the Act and also Supreme Court judgement by taking recourse to section 16(5) of the Act to operationalise regulations without completing the procedure stipulated in section 92 of the Act.

Replying to the Audit observations, the Ministry stated (January 2017 and March 2017) that the judicial pronouncement was only with reference to a particular case relating to nutraceuticals and had no bearing on the powers conferred on FSSAI under section 16(5) of the Act to issue binding directions to the Commissioners. The Ministry also stated that these directions were issued to operationalise the standards on interim basis so that FBOs can use the standards, and based on their feedback, the standards can be revised at the time of final notification. The

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Ministry further stated that the exercise of section 16(5) was legitimate and became inevitable after the product approval system was discontinued and earlier approved products could not be regulated and new proposals could not be entertained.

The replies of the Ministry are not acceptable. Though the writ petition in the case was initially heard by a two member Bench of the Bombay High Court on a limited issue, due to a difference of opinion between the two learned judges, they referred the matter to the Chief Justice of the High Court to frame the matter on the fundamental issue of whether FSSAI is empowered to apply other provisions of the Act, including section 16(5), without following the procedures contained in sections 92 and 93 of the Act. In these circumstances, once the three member bench of the High Court constituted by the Chief Justice decided (on which the Supreme Court also refused to intervene) that all the other sections are subordinate to sections 92 and 93 of the Act, the contentions of the Ministry regarding the interim instructions issued under section 16(5) are also untenable. The Ministry should have sought the opinion of the Ministry of Law, rather than attempting an interpretation of the scope of the orders of the Bombay High Court and the Supreme Court judgement.

FSSAI in its further reply (May 2017), stated that if the Ministry agrees, opinion of the Law Ministry will be sought.

2.10 Deficiencies in the amendment to regulations relating to proprietary foods

In the aftermath of Hon'ble Bombay High Court and Hon'ble Supreme Court judgements in August 2014 and August 2015 respectively, FSSAI discontinued the product approval system in August 2015. Thereafter FSSAI initiated the process for notifying regulations to regulate proprietary foods. The process began with notification of interim regulations on proprietary foods on 12 January 2016 and culminated on 10 October 2016 with notification of Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016 for proprietary foods.

Audit noted the following deficiencies in the process underlying the final notification for proprietary foods:

- (1) To ensure open and transparent public consultation in terms of the procedure delineated under section 92 of the Act and by the Lok Sabha

Committee on Subordinate Legislations, all regulations are required to follow a detailed consultative process with stakeholders. However, section 18(2)(d) of the Act contains an exception, permitting the Food Authority to dispense with such consultation in the making or amendment of regulations, where it is of the opinion that there is an urgency concerning food safety or public health. Such exception is, however, subject to the condition that such regulations shall remain in force for not more than six months. Audit noted that on 11 December 2015, the Ministry issued directions under section 85 of the Act (empowering the Ministry to, *inter-alia*, issue directions to FSSAI) stating that to cover the time required to frame regulations in place of the existing advisories, FSSAI may operate the urgency clause, i.e. section 18(2)(d), and issue regulations without public consultation, for a period not exceeding three months. Though the interim regulations on proprietary foods were accordingly notified on 12 January 2016, FSSAI failed to notify the final regulations within the time stipulated by the Ministry, and therefore, the interim regulations ceased to be in force after 11 April 2016. To overcome this failure to notify the final regulations in time, FSSAI wrongly exercised (22 August 2016) the provisions of section 16(5) to operationalise draft regulations issued on 19 April 2016. In the absence of underlying regulations under section 92, operationalisation of the regulations under section 16(5) was a violation of the Act, which gets further substantiated in the light of the orders of the Bombay High Court and the Supreme Court. Audit observed that between 11 April 2016 (date of cessation of interim regulations) and 21 August 2016 (date of invoking of section 16(5)), FSSAI had issued 118 licenses and between 22 August 2016 and 10 October 2016 (date of notification of final regulations), FSSAI had issued 20 licenses.

The Ministry replied (March 2017) that consequent to the orders of the Supreme Court it was no longer possible to continue the process of product approvals and issuing of advisories. Hence, several food products, both domestic and imported, for which product approval was sought from FSSAI before the Supreme Court's orders were left in limbo. Further, no new proposals from the industry could be entertained any more. Therefore, it was necessary to implement these standards with immediate effect to address the issues of food safety and to regulate the non-standardised food products, which constitute a major portion of product approvals.

The reply is unacceptable as FSSAI and Ministry invoked the urgency provisions of 18(2)(d) on 12 January 2016, i.e., more than four months after the Supreme Court orders. Further FSSAI/ Ministry took nine months after the invoking of

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section 18(2)(d) and more than thirteen months after the Supreme Court orders to notify the final regulations on 10 October 2016. The reasons for FSSAI's inability to adhere to these time lines have also not been explained by the Ministry.

(2) In terms of the framework (stated by FSSAI to be followed by them), all matters regarding standards are required to be first referred to the Scientific Panels and the Scientific Committee. Audit observed, however, that the regulations on proprietary foods notified on 10 October 2016 were not referred to the Scientific Panels and Scientific Committee at any stage.

The Ministry replied (March 2017) that the original regulations of 2011 had defined proprietary foods. In view of the generality of this definition, which provides an explanation about the ingredients including food additives that can be used in proprietary foods and various other requirements pertaining to microbiological quality, labelling, etc., no technical inputs from the Scientific Panels and Scientific Committee were required.

The reply is not acceptable as the Ministry's reply does not include any evidence that a conscious decision was taken by the competent authority to dispense with referral to Scientific Panel and Scientific Committee in this case. Further, as explained in the sub-paragraph below, the final regulation of 2016 has deviated from the definition of propriety foods and novel foods as defined in the Act and contained in the original regulations of 2011. For this reason at least, the regulations should have been referred to the Scientific Panels and Scientific Committee.

(3) Section 22 of the Act defines proprietary foods and novel foods similarly (treating them same), as articles of food for which standards have not been specified but are not unsafe or contain any of the foods and ingredients prohibited under the Act and regulations made thereunder. This definition was followed in the original (amendment) regulations of 2011. Audit observed, however, that the amended regulation of 2016 defined proprietary foods as excluding novel foods.

Admitting the difference in the definition between the Act and the regulations of 2016, Ministry replied (March 2017) that this was mainly done for facilitating innovations by the industry and for protection of consumer's interest. Though the Act provides for the same definition for the proprietary food and novel food, technically, novel foods are those foods which contain ingredients and additives which do not have any history of use in the particular region/country; or the foods

which are manufactured using a new technology other than conventional technology.

The reply of the Ministry is not acceptable. No regulation can contain a definition different from the underlying Act. The Ministry was therefore required to either amend the definition in the regulations so that it was in consonance with the Act or take measures to amend the Act itself.

(4) Audit also observed that the amended regulations merely state that individual ingredients should conform to the standards prescribed by FSSAI (or in the case of micronutrients, i.e., vitamins and minerals, the limits of recommended daily average)²⁵, without mentioning which combinations of ingredients (though individually meeting the standards), would violate the overall stipulation of food safety. For instance, the Scientific Panel had rejected (in January 2014 and March 2014) caffeine-ginseng combinations in energy drinks on the ground that it may have opposing effect on the human body (discussed in case studies 2 and 3 below paragraph 2.8.4.1, paragraph 2.8.4.2, case study 4 below paragraph 2.8.4.3 and case study 1 below paragraph 2.8.5.1).

FSSAI stated (May 2017) that it would holistically look into the issue of combinatorial effect of ingredients including that of caffeine and ginseng in the near future based on the international best practices.

The Ministry (June 2017) agreed with Audit that the Ministry's approval should be taken before operationalising/notifying any regulations.

2.11 Deficiencies in operationalisation of Import Regulations

FSSAI notified the draft Food Safety and Standards (Food Import) Regulation on 17 May 2013, but failed to finalise it. In the interim, FSSAI issued various advisories on imports, which became invalid in light of the Supreme Court decision of 19 August 2015. Despite this, decisions continued to be taken on the basis of the invalid advisories.

On 14 January 2016, citing the urgency clause contained in section 18(2)(d) of the Act, FSSAI operationalised a revised draft regulation and placed it on its website. This action of FSSAI violated the Act as Section 92(2)(g) of the Act stipulates that the exercise of section 18(2)(d) requires the previous approval of the Central

²⁵ Though the Scientific Committee/Scientific Panels of FSSAI cite the RDA limits for micronutrients prescribed by the Indian Council of Medical Research (ICMR), this authority has not been mentioned by FSSAI in the regulations.

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Government. In this case, since the earlier draft notification was superseded by the revised draft notification which was approved by the Ministry only on 15 July 2016²⁶, the condition of previous approval of the Central Government were not met. Despite this, the Ministry accorded *ex-post facto* approval (15 July 2016) for invoking section 18(2)(d).

In keeping with the time limit of six months stipulated in section 18(2)(d) of the Act relating to the urgency clause, the Ministry exercised its powers under section 85 of the Act, and limited the period to three months²⁷. Therefore, even had the regulations of 14 January 2016 been valid, they remained in force only till 13 April 2016. Since FSSAI did not notify the final regulations before this date, the invalid regulations also lapsed within three months of issue. FSSAI finally issued fresh directions on 02 September 2016 and operationalised the draft revised regulations invoking section 18(2)(d) read with section 16(5) of the Act. Since FSSAI was under the mistaken impression that the earlier operationalisation remained in force for six months, it retrospectively operationalised the regulations from 15 July 2016. The second operationalisation suffered from the same defects as the first operationalisation, in that, it was issued without previous approval of the Central Government. In addition, the simultaneous exercise of sections 16(5) and 18(2)(d) is contradictory, since the former section relates to the exclusive powers of FSSAI to ensure furtherance of the Act, Regulations and Rules, and the latter section relates to the exclusive power of the Ministry to give previous approval. In any case, FSSAI had no authority to invoke section 16(5) in this case, since the situation of FSSAI necessitating the issue of regulations to replace the earlier advisories arose only after the Bombay High Court and Supreme Court had decided that the powers of FSSAI under section 16(5) could not override the provisions of sections 92 and 93 of the Act. Further, neither FSSAI nor the Ministry have the power to extend the maximum period of six months provided under the exception clause in section 18(2)(d) of the Act. In any case, FSSAI did not refer the second operationalisation to the Ministry for approval at any stage. And finally, the Act does not provide for any retrospective effect to regulations.

As in the case of the first operationalisation, FSSAI was under the mistaken impression that the second operationalisation remained in force till 14 January 2017. Accordingly, and since the revised draft notification (issued on 25 October 2016) was still under process for being notified as regulations, FSSAI, in

²⁶ The revised draft regulation was notified on 25 October 2016.

²⁷ Ministry of Health and Family Welfare Directions No. P15025/250/2015 (1)-DFQC dated 11 December 2015.

continuance of its earlier unauthorised and incorrect actions, operationalised the regulation for the third time, with effect from 14 January 2017. The final regulations were notified on 09 March 2017.

In their reply (March 2017), the Ministry has tried to justify the use of section 18(2)(d) by stating that this was inevitable once the existing advisories on imports became redundant following the Supreme Court decision. The reply is not acceptable, since, the Ministry was not even aware of the fact that FSSAI had exercised the exception clause under section 18(2)(d) on the second and third occasion. Further, the exercise of the exception clause under section 18(2)(d) without the previous approval of the Ministry on all three occasions cannot be justified, as also, the extensions beyond 14 July 2016 (the maximum period of six months) contrary to the Act.

FSSAI stated (May 2017) that it was not under a mistaken impression that the operationalisation remained in force for six months, since this is specifically mentioned in the Act. FSSAI has also contended that section 18(2)(d) does not mention that the urgency clause should be invoked only once for a regulation. The Ministry, however, stated (June 2017) that the approval of the Ministry should be taken before operationalising any regulations. The Ministry's views conform to the Audit contention.

2.12 Food borne diseases

Section 35 of the Act states that the Food Authority may, by notification, require registered medical practitioners carrying on their profession in any local area specified in the notification, to report all occurrences of food poisoning coming to their notice to such officer as may be specified. Audit, however, noted that no such notification was ever issued/ published by the Food Authority.

The Ministry, while accepting the Audit observation, replied (March 2017) that the Food Authority was in the process of issuing the notification.

2.13 Non-preparation of General Plan for Crisis Management

Sub-section (3)(d) of Section 16 of the Act states that the Food Authority shall provide scientific and technical advice and assistance to the Central Government and the State Governments in implementation of crisis management procedures with regard to food safety and to draw up a general plan for crisis management and work in close co-operation with the crisis unit set up by the Central

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Government in this regard. Audit noted that FSSAI has initiated no mechanism to provide technical advice to the Central and State Governments.

The Ministry in its reply (June 2017) accepted the facts.

2.14 State/District Advisory Committees

As per Section 2.1.15 of Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2011 and directives (July 2012) of the Central Advisory Committee of FSSAI, a State Level Steering Committee (SLSC) or State Advisory committee (SAC), with Chief Secretary as its Chairperson, and District Level Steering Committee (DLSC) or District Advisory Committee (DAC) with District Collector as its Chairperson be constituted to assist, aid or advise on any matter concerning food safety in the State. Decisions taken at the monthly meetings of these committees are to be forwarded to appropriate authority for action.

Audit test check in ten States revealed that SACs had not been constituted in Odisha and West Bengal. In Delhi, Haryana, Himachal Pradesh and Tamil Nadu, the SACs did not hold any meetings. In Assam, Gujarat, Uttar Pradesh, the SACs met only once during the entire audit period and in Maharashtra it met twice.

No DACs had been constituted in the test checked districts in Odisha, Delhi and Haryana. Only one of the six districts test checked in Maharashtra, three of the five districts test checked in Tamil Nadu, seven of the ten districts test checked in Uttar Pradesh, and one of five districts test checked in West Bengal had DACs. Even after the Central Advisory Committee issued directives (July 2012) to hold regular meetings, till date (March 2016), in the five test checked districts of Assam, no meetings were held in four districts and only two meetings were held in one district; in Maharashtra, out of six test checked districts, five districts did not have committees and in the sixth district, five meetings were held; in Tamil Nadu, out of six test checked districts, the committees did not hold any meeting in two districts, two meetings were held in one district and one meeting each in the remaining three districts; in Uttar Pradesh, out of ten test checked districts, no committees have been constituted in three districts; out of the remaining seven districts, the committees did not hold any meeting in five districts, ten meetings were held in one district and only one meeting in the last district; in West Bengal, out of five test checked districts, no committees have been formed in four district and in one district, three meetings have been held; in Gujarat and Himachal

Pradesh, no meetings were held during the entire audit period by any of the test checked DACs.

While accepting the Audit observation, the Ministry replied (January and March 2017) that the issue of holding regular meetings of SAC and DAC had been the point of discussion in various meetings of the CAC and instructions had been reiterated to Food Safety Commissioners to ensure this. The fact, however, remains that the requirements regarding the constitution/regular meetings of SAC and DAC are yet to be fully complied with.

2.15 Management of internally generated funds

2.15.1 Funds lying unutilized

As per rule 209(6)(xiv) of the GFR, 2005, the grant sanctioning authorities should take into account the internally generated resources while regulating award of grants.

Audit observed that FSSAI had collected ₹ 100.73 crore by way of license fee, testing and laboratory fee etc., since 2008 onwards, which remained unutilised. FSSAI did not frame regulations for utilisation of these funds.

FSSAI in its reply (March 2017) stated that financial regulations/ guidelines in this regard are being formulated.

2.15.2 Non refund of product approval fee

Audit observed that though 1,876 applications for product approval were pending with FSSAI after the Supreme Court judgement (19 August 2015), FSSAI has not refunded ₹ 4.69 crore (at ₹ 25,000 per application) to the applicants. In their reply (January, March and May 2017), FSSAI/Ministry stated that FSSAI had decided that where tangible action had been taken on applications, fees need not be refunded and all pending applications would be processed based on existing regulations and new regulations as and when notified. Ministry has defined “tangible action” as the process of screening, examining, processing, segregation and recommending for issue of license in accordance with new regulations. It contended that the application fee may not be considered for the purpose of issuing NOC/product approval alone but also for taking action on the application. The reply is not tenable. In the aftermath of the Supreme Court decision, FSSAI has no authority to issue any more NOC/product approvals and therefore has no

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reason for considering such applications. Ministry may consider approaching Ministry of Finance for clarity on the issue.

In the exit conference (June 2017), FSSAI/Ministry stated that the fee cannot be refunded, however, under the new regulations being framed in-lieu-of product approval system, no fees will be charged from such applicants.

2.16 Insufficient Information, Education and Communication (IEC) activities by States

The Central Advisory Committee (CAC) in its 8th meeting (July 2012) advised that at least 75 *per cent* of the food license fee collections (₹ 302.85 crore during the audit period) be used for IEC activities. Test check in the ten selected states revealed that this was not done. Further, none of the state governments had framed any policy for IEC activities. Only two states (Assam and Tamil Nadu) had allocated budget for IEC activities, while the other states (Odisha, Himachal Pradesh, Gujarat, West Bengal, Uttar Pradesh, Haryana and Delhi²⁸) did not allocate any budget for IEC activities.

The Ministry (March and June 2017) stated that it had been repeatedly reminding the State Governments to take necessary measures for implementation of the above cited advisory of CAC. The fact remains that the advisory of the CAC is yet to be complied with.

2.17 Use of advertising by FBO on FSSAI publications

FSSAI published two booklets²⁹ for the elucidation of safe food practices to the general public. Audit, however, observed that two leading FBOs advertised on the back page of the publications. Such practices would lead the public to believe that the FBOs had the official sanction of the FSSAI in its capacity of food regulator, which is not desirable, and adversely impacts the FSSAI's role as an independent regulator.

FSSAI in its reply (May 2017) stated that, these activities were carried out by FBOs under CSR (Corporate Social Responsibility) in public interest as these documents have been made available as open source inputs in the public domain through the FSSAI website and other portals. For greater clarity, a policy on use of CSR and other voluntary initiatives to be taken up in public interest has now

²⁸ Information regarding Maharashtra is not available.

²⁹ (i) DART- Detect adulteration with Rapid Test and (ii) The Pink Book- Your guide for safe and nutritious food at home.

been approved by the Food Authority in its meeting held on 25 May 2017. The Ministry (June 2017) reiterated the stance of FSSAI. The reply, however, does not address the specific concerns of Audit. The Ministry is required to frame guidelines to ensure that the role of FSSAI as an independent regulator is not compromised.

2.18 Defects and deficiencies in grievance redressal

FSSAI primarily handles complaints received through the Centralised Public Grievance Redress and Monitoring System (CPGRAMS) of Department of Administrative Reforms and Public Grievances (DARPG), letters from complainants, various Ministries, faxes and its own web portal. FSSAI, however, has not framed any standard operating procedure (SOP) on handling, redressal, and disposal of complaints. Audit scrutiny also revealed that there was no mechanism to redress the grievance and respond to the complainant.

Audit further observed that out of the 163 complaint cases received at the FSSAI during August 2011 to March 2016 pertaining to eight states (Delhi, Gujarat, Haryana, Himachal Pradesh, Maharashtra, Odisha, Tamil Nadu and Uttar Pradesh), 11 cases were not forwarded to the respective State Food Commissioners, while in the remaining cases the State Food Safety Commissioners had not responded. The state food authority, Delhi could furnish Audit with documentary proof of redressal only in respect of ten out of the 58 cases referred to it by the FSSAI. Three states (Odisha, Himachal Pradesh, and Tamil Nadu) did not have a Grievance Redressal Mechanism. In five States (Assam, Delhi, Haryana, Gujarat and Uttar Pradesh), the system was not effective.

The FSSAI/Ministry (May/June 2017) accepted the audit observation.

Conclusion:

Even after more than a decade of the enactment of the Act, FSSAI is yet to frame regulations governing various procedures, guidelines and mechanisms enunciated in different sections of the Act. FSSAI failed to devise action plans to identify areas on which standards are to be formulated/revisited for revision within specified time frames, and the manner of selection of food products for formulation of standards. FSSAI did not involve the Scientific Panels/Scientific Committee in the formulation of standards of certain foods. FSSAI notified regulations and standards without considering the comments of stakeholders. In absence of standard operating procedures (SOP), FSSAI took between one year

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and three years to notify amendments. Possibility of unsafe/declared unsafe foods continued to be manufactured and sold could not be ruled out due to failure of FSSAI to monitor and cancel licenses issued under flawed procedure for NOC, even subsequent to the Supreme Court declaring the entire procedure of issuing advisories on NOC and product approvals as unlawful. FSSAI continues to issue directions under section 16(5) of the Act without following the procedure underlying sections 92 and 93 of the Act, despite the orders of the Supreme Court that such orders do not have the force of law. FSSAI has not yet issued notifications requiring registered medical practitioners to report all occurrences of food poisoning in their jurisdiction. FSSAI has not drawn up a general plan for food crisis management and introduced a mechanism to ensure its implementation. FSSAI has not ensured that all states have constituted State and District Advisory Committees, and that these are functioning effectively. FSSAI did not frame regulations for utilisation of funds of ₹ 100.73 crore it had collected since 2008 by way of license fee, testing and laboratory fee etc., which remained unutilised. Despite recommendation of the Central Advisory Committee (CAC) that at least 75 per cent of the food license fee collections are used for Information, Education and Communication (IEC) activities, most states had not allocated any budgets for these activities.

Recommendations:

- *Ministry/FSSAI may expedite the notification of regulations on areas that have been specified in the Act, but are yet uncovered.*
- *FSSAI may frame standard operating procedures on the formulation and review of standards and ensure that these are adhered to.*
- *FSSAI may ensure that all licenses issued under the erstwhile system of product approvals are reviewed, and licenses cancelled and reissued as warranted under the present procedure.*
- *FSSAI may review all directions issued under section 16(5) of the Act in the light of directions of the Hon'ble Bombay High Court and Hon'ble Supreme Court.*
- *FSSAI may expedite the notification of financial regulations for utilisation of funds collected by way of license fee, testing and laboratory fee etc., collected since 2008 onwards.*

Chapter III : Licensing, Registration, Inspection and Sampling

3.1 Licensing and Registration¹

Section 31 of the Act stipulates that, other than petty manufacturers or petty retailers who shall register themselves with the food authority, no person shall commence or carry on any food business except under a license. Separate licenses shall be issued for one or more articles of food manufactured/sold in the same or different establishments/premises in the same area. Registering Authority means Designated Officers (DO) appointed by State Food Safety Commissioners (SFSC), Food Safety Officers (FSO) or any officer of the Panchayat, Municipal Corporation or any other local body of the area, notified as such by the Food Safety Commissioners². Licensing Authority means either the Central Licensing Authority (CLA) i.e., DO appointed by CEO of FSSAI in his capacity of Food Safety Commissioner; or the State Licensing Authority (SLA) i.e., DO appointed by the SFSC³. Section 63 of the Act contains punitive provisions relating to the carrying out of food business without license.

As on 31 March 2016, FSSAI and the state governments had issued 27.65 lakh registrations and 7.09 lakh licenses.⁴

Procedure for obtaining licenses

Central licenses are issued by FSSAI through its regional offices (CLA), whereas state licenses are issued by the state offices (SLA). The procedure for obtaining license is depicted below:

¹ Covered under the Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2011.

² In terms of paragraph 1.2.1 (5) of the Regulations of 2011.

³ As defined in paragraphs 1.2.1 (1) and (6) respectively of the Regulations of 2011.

⁴ As per information furnished to Audit by FSSAI.

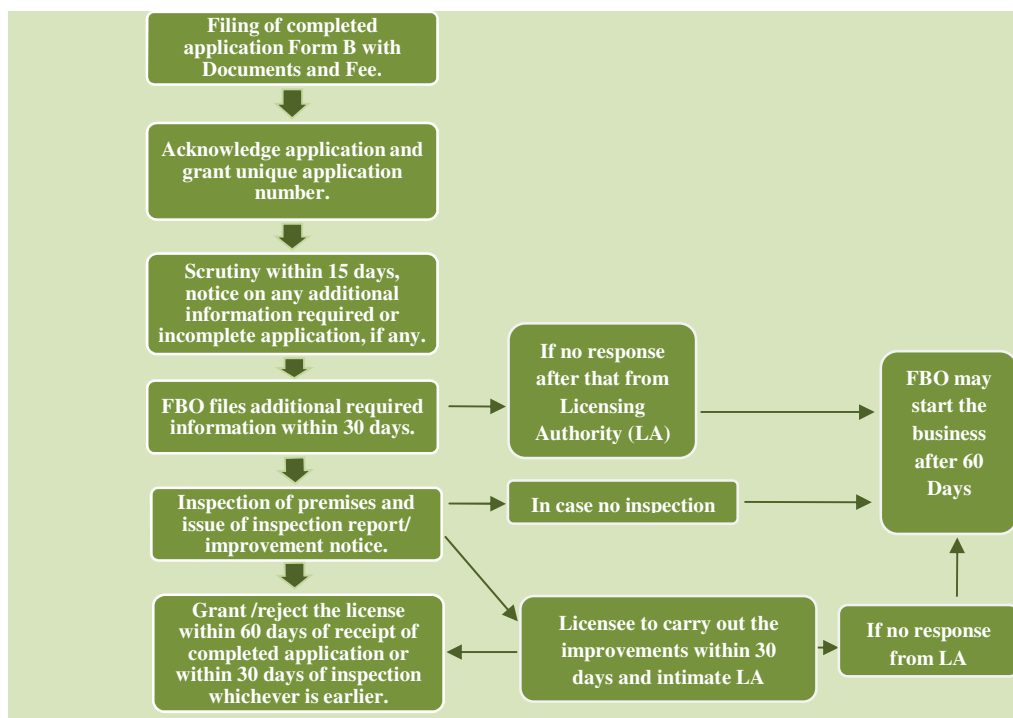


Figure 3.1: Flow chart explaining licensing procedure

3.1.1 No survey for identification of FBOs

Sub-section 16(2)(g) of the Act stipulates that it shall be the duty of FSSAI to conduct survey for enforcement and administration of the Act. Similarly, sub-section 30(2)(b) stipulates that the SFSC shall carry out survey of industrial units engaged in the manufacture or processing of food in the state. Further, sub-clause 2.1.3(4)(iii)(f) of FSS Rules, 2011 states that it is the duty of FSO to maintain a database of all the food business within the area assigned to him. Audit found however, that neither FSSAI nor the Food Safety Commissioners of the 10 states selected for audit had conducted or got conducted any such survey. In the absence of such data, Audit noticed that FSSAI gave different figures⁵ on different occasions, based on which important decisions were taken by the Government and the Food Authority.

The Ministry replied (January 2017) that the process of licensing and registration is an ongoing activity. The figures referred to in the audit report for total number of FBOs was a guess-estimate at that time. Commissioners of food safety of states/UTs have been requested to conduct an intensive survey for coverage of

⁵ Figure of 550 lakh FBOs as on 05 June 2013 to Expenditure Finance Committee (EFC) on 03 January 2014 and of 103.11 lakh FBOs in October 2016 in reply to an Audit query.

FBOs in Food Licensing and Registration System (FLRS). FSSAI further stated (May 2017) that the variance in the data shared by FSSAI on different occasions was not deliberate.

The reply is not acceptable, since it does not answer why no steps were taken to carry out survey as stipulated in the Act and Regulations. Also, neither the central and state governments nor FSSAI had reliable data to help decision making. Further, neither the Ministry nor the Food Authority was informed at the time of decision making that the figures supplied to them were inaccurate.

3.1.2 Unnecessary extensions of time for conversion of licenses

Sub-section 97(3) of the Act stipulates that, licenses issued under the erstwhile Acts/Orders would continue to be in force till the date of their expiry. Clause 2.1.2 (1) of the Regulations⁶ permitted such FBOs having licenses issued under the erstwhile Acts/Orders to convert their licenses to licenses/registrations under the Act within a period of one year.

On request of various stakeholders, including state governments, Members of Parliament and trade bodies, Ministry invoking section 85 of the Act, issued directions to FSSAI to extend the period of conversion of existing licenses from time to time (up to 4 August 2016).

Audit examination revealed that neither the Ministry nor FSSAI had any information regarding the number of FBOs whose licenses issued under the erstwhile Acts/Orders continued to be valid even after the enactment of the Act. The directions of Ministry to frequently extend the date of conversion of licenses resulted in a situation where even FBOs whose licenses had expired, continued with the food business. The same was pointed out from time to time by FSSAI and various SFSCs who complained that FBOs were not willing to renew their registrations and licenses due to such continued extensions. Thus the repetitive extensions of time for conversion till 04 August 2016 on the directions of the Ministry were not only contrary to the Act, they were also unnecessary, and resulted in FBOs whose licenses had expired, to continue food business without licenses (as discussed in paragraph 3.1.4(i) & (ii)), adversely affecting food safety measures, and thus endangering public health in the country.

⁶ FSS (Licensing and Registration of Food Business) Regulations, 2011 effective from 05 August 2011. Unless specified otherwise, Regulations would refer to these regulations only in this chapter.

Ministry in its reply (June 2017) stated that, operational matters are dealt with by FSSAI at its own level and Ministry was not required to maintain such details. Further, the extensions were considered necessary for ensuring smooth transition and the decision was accordingly taken.

The reply is not acceptable as FSSAI and the state authorities accepted on record that there was confusion among FBOs on obtaining license from FSSAI due to the repeated extensions. Further, the Ministry cannot absolve itself of the responsibility as it had exercised its power under section 85 of the Act and directed FSSAI to issue necessary orders for extensions.

3.1.3 Dilution of standards for exporting FBOs

Sub-section 3(1)(n) of the Act defines food business as including, *inter-alia*, manufacture, processing, packaging, storage and transportation of food. Sub-section 16(1) stipulates that it shall be the duty of the Food Authority to regulate and monitor the manufacture, processing, distribution, sale and import of food. Further, item VI of schedule 1 of the Regulations specifies ‘100 *per cent* Export Oriented Units’ (EOU)⁷ in the list of food businesses falling under the purview of CLA.

Scrutiny of the records revealed that earlier, licenses were issued under the erstwhile Prevention of Food Adulteration Act to all FBOs engaged in food business, including FBOs who did not opt for the 100 *per cent* EOU scheme, but who exported their production entirely outside the scheme (designated as ‘only export FBOs’). FSSAI, to facilitate trade, issued an order dated 21 January 2015, permitting the issue of licenses to such ‘only exporting FBOs’ by creating a distinct category of “Exporting FBOs”. As on 30 September 2016, 731 licenses were issued under this category.

In this connection, Audit observed as follows:

- i) The orders of 21 January 2015 were issued by invoking section 16(5) of the Act, which require that any directions thereunder are to be issued by the Food Authority. However, FSSAI issued the orders with the approval of the Chairperson, and not with the approval of the Food Authority.

⁷ Subject to certain requirements and restrictions, ‘100 *per cent* EOUs’ receive central excise duty, customs duty and central sales tax relief among other benefits and can also access domestic market up to specific limits.

- ii) The orders stipulate grant of license for “only exporting FBOs” subject to their products meeting the standards and specifications applicable to the importing country without there being any mechanism to verify the same.
- iii) The orders also permitted such FBOs to sell the products within the country subject to the condition of their submitting a certificate that the food products conform to the Indian standards. Such permission to these FBOs to sell their products domestically adversely discriminates against other FBOs who are required to adhere to more rigorous standards and checks at the time of securing licenses.

The Ministry (June 2017) stated that, there was no violation of the Act since FSSAI was empowered to issue licenses through an advisory in respect of ‘only export’ FBOs also, and this has been agreed to by the Food Authority in its meeting of 25 May 2017. The reply cannot be accepted as there is no mandate under the Act for the Food Authority to regulate food business except through Regulations specifying the standards. In the exit conference (June 2017), FSSAI agreed to review this issue.

3.1.4 Deficiencies in process of issue of licenses

Clauses 2.1.7(1) to (5) of the Regulations stipulate that a registration or license shall be valid for a period of 1 to 5 years as chosen by FBO, from the date of issue of registration or license. Further, any application for the renewal of such registration or license shall be filed not later than 30 days prior to the expiry date indicated in the registration/license; or if filed later, but before the expiry of the license, on payment of late fee for each day of delay. Registration or license for which renewal has not been applied for within the above period shall expire and FBO shall stop all business activities at the premises, and apply for fresh registration or license if it wants to restart the business. Sub-clause 2.1.3(4)(iii)(f) of FSS Rules states that it shall be the duty of FSO to maintain a database of all food business within the area assigned to him.

Audit test check revealed the following:

- i) In 49 cases pertaining to CLA, Kolkata and Guwahati, FBOs applied for renewal of licenses (2011-14) issued under the erstwhile Acts/Orders after their expiry. Despite the fact that the licenses had already expired at the time of application, and instead of issuing fresh licenses as stipulated in clause

2.1.7 of the Regulations, CLAs renewed the licenses. In further violation of the Regulations, CLAs renewed the licenses retrospectively even for the period when the erstwhile Acts/Orders were in operation (the gap between the expiry of the licenses and their irregular renewal ranged from one year to five and a half years in eight cases). CLAs thus, irregularly legitimised the gap period of food business during which FBOs, operated without valid licenses in violation of section 31 of the Act. Also, CLAs did not maintain a database of all food businesses within their area as required under FSS Rules.

- ii) In nine states⁸ and six central⁹ offices of FSSAI, Audit observed instances where licenses/registrations issued under the Act had expired. Out of 7,056 licenses test checked in SLAs, 2,616 (37.07 *per cent*), and out of 2,863 licenses test checked in CLAs, 626 (21.87 *per cent*) licenses were found to have expired. Out of 2,299 registrations test checked in states, 698 (30.36 *per cent*) registrations were found to have expired. The SLAs confirmed that they could not ensure whether such FBOs had stopped all food business activity after expiry of their licenses/registrations. Further, during joint physical inspection by a team comprising officials of Audit and FSOs in Odisha, 15 out of 40 test checked FBOs were found operational despite expiry of their licenses. Another test check at FSSAI RO, Mumbai revealed that six FBOs continued with their business even though they had not even applied for the renewal of their earlier licenses, and conducted food business valued at ₹ 252.64 crore during the period without license.

In the exit conference (June 2017) FSSAI/Ministry accepted the audit observation and CEO, FSSAI informed that the matter will be taken up with state food authorities.

3.1.5 Licenses issued on the basis of incomplete documents

Regulation 2.1.3 stipulates that the application for grant of license shall be accompanied by a self-attested declaration in the prescribed format along with copies of documents, *viz.*, layout plan, list of directors with full address and contact details, name and list of equipment and machinery, identity and address proof of FBO etc. Test check by Audit of five SLAs and three CLAs, revealed that in 3,119 (52.73 *per cent*) out of the 5,915 test checked cases licenses had been issued to FBOs on the basis of incomplete documents.

⁸ Assam, Delhi, Gujarat, Haryana, Himachal Pradesh, Maharashtra, Odisha, Tamil Nadu, and West Bengal.

⁹ Chandigarh, Chennai, Delhi, Kolkata, Lucknow, and Mumbai.

FSSAI during the exit conference (June 2017) stated that necessary actions will be taken by way of systemic improvements in the online FLRS (Food Licensing and Registration System).

Case Study

License renewed without verification of documentary evidence

When applying for new license (9 May 2014), M/s Om Sai Ram Industries, Odisha, a manufacturer of packaged drinking water, carbonated water etc., stated the qualification of the technical in-charge of operations as '10th pass'. Since Annexure-3 of Schedule 2 of the FSS (Licensing & Registration of Food Business) Regulations, relating to 'Conditions of License' stipulates that FBO should employ at least one technical person to supervise the production process who shall possess at least a degree in science, CLA, Kolkata returned the application to FBO who then furnished a revised application (29 May 2014) after changing the qualification of the same person to 'B.Sc. Chemistry (Hons.)' without providing any proof of educational qualification. Without further verification, CLA, Kolkata issued (November 2014) the license and later renewed it (October 2015) in violation of the stipulation mentioned in Annexure-2 of Schedule 2 of the Regulations that the document of qualification needs to be verified during renewal of license.

Thus, CLA, Kolkata failed to verify the supporting document at the stage of renewal of license.

3.2 Food Inspections

The procedures for collection, analysis and reporting have been defined and prescribed in Rules, Regulations¹⁰, and sub-section 16(2)(i) of the Act stipulating that it shall be the duty of FSSAI to specify through Regulations the manner and the procedure subject to which risk assessment, risk analysis, risk communication and risk management shall be undertaken. Audit however, observed that FSSAI has not notified any Regulations in this regard.

¹⁰ Sections 46 (2) and 47 of the Act, paragraph 2.1.3.4 of FSS Rules, 2011, Chapter 2 of FSS (Licensing and Registration) Regulations, 2011 and FSS (Laboratory and Sample Analysis) Regulations, 2011.

Neither FSSAI nor states had any documented policy or procedures for risk-based inspection (including sampling) of domestically-produced food. In August 2016, risk based sampling for only imported food was operationalised. Also, FSSAI does not have any database on records of food premises and food inspections.

Audit noted that though the Regulations provide for inspection of registered FBOs at least once in a year, no such periodicity is prescribed in respect of licensed FBOs¹¹. Instead, the Regulations leave it to the discretion of DO to decide the periodicity of inspections. The reasons for such discrimination are not clear. Audit noted that out of the ten selected states, only Himachal Pradesh had prescribed the periodicity, but even these instructions were not followed and periodicity of inspections was low or even zero. Scrutiny of records relating to 6,02,677 FBOs in 52 districts in the 10 selected states revealed that in 15 districts¹² having 1,02,595 FBOs (17 *per cent*), no inspection was conducted at all during 2011-16. In Tamil Nadu and Uttar Pradesh, DOs of the test checked districts did not have any records to substantiate their claims of high number of inspections conducted¹³, and therefore the claims made by these two states cannot be accepted. Audit observed that the deployment of FSOs was extremely low in comparison to the sanctioned strength or strength recommended by the Central Advisory Committee of FSSAI (for details refer para 5.9 of chapter 5 in this report).

FSSAI (May 2017) stated that necessary amendments will be proposed.

3.3 Lifting of Samples

As per Section 38(1) of the Act, FSO may take a sample of any food, or any substance, which appears to him to be intended for sale, or to have been sold for human consumption, or of any article of food or substance which is found by him on or in any such premises, which he has reason to believe may be required as evidence in proceedings under any of the provisions of the Act or of the Regulations or Orders made thereunder.

¹¹ In terms of section 31 of the Act, registration procedure is applicable to petty manufacturers.

¹² Delhi (South Delhi); Gujarat (Junagarh, Rajkot municipal corporation and Surat municipal corporation); Haryana (Ambala, Faridabad, Gurgaon and Sonapat); Himachal Pradesh (Kangra); Odisha (Balasore, Deogarh, Kendrapada and Mayurbhanj); Uttar Pradesh (Kanpur Nagar); and West Bengal (Paschim Medinipur).

¹³ For example, the Designated Officers in three of the six selected districts claimed 100 *per cent* inspections.

3.3.1 Samples lifted not commensurate with number of licenses and registrations issued

In 53 selected districts of ten selected states for the period 2011-2016, Audit noticed that food authorities lifted 51,972 samples of food articles for analysis out of 7,17,628 FBOs. Audit noted that, the lifting of samples was less than 10 per cent of total licensed and registered FBO in 29 (55 per cent) of the 53 selected districts; out of which, in seven districts¹⁴ the lifting of samples was below one per cent. Audit further noted that, five¹⁵ of the 10 selected states did not fix any targets for lifting of samples. In the remaining five¹⁶ states the targets were fixed without risk assessment for different categories of FBOs but were not achieved by most of the FSOs. The state Authorities attributed the non-achievement of targets to shortage of staff and paucity of funds.

FSSAI (May 2017) and Ministry (June 2017) accepted the facts and stated that necessary steps are being taken.

3.3.2 Violations of procedure for lifting of food samples

Rule 2.4.1 of FSS Rules prescribes the procedure for lifting of samples. Audit observed deficiencies in the procedure by food safety authorities as provided in the following case studies:

Case Study 1

Sample handling procedure

In fifteen samples pertaining to seven districts in Orissa, FSOs had added formalin to the milk samples sent for testing, without declaring it as a preservative, as required under the procedure. Consequently, the test was declared defective. The FSOs informed that they were not trained on the procedure of lifting, keeping and sending samples to the laboratory.

¹⁴ Deogarh and Jharsuguda (Odisha) Theni, Tirunelveli and Trichy (Tamil Nadu); Paschim Medinipur and Purulia (West Bengal).

¹⁵ Assam, Delhi, Maharashtra, Uttar Pradesh and West Bengal.

¹⁶ Gujarat, Haryana, Himachal Pradesh, Odisha, Tamil Nadu.

Case Study 2

Failure of DOs to monitor status of receipt of samples sent for analysis.

- (a) Food Analyst of CTL, Kandaghat received (June-July 2013) two food samples from FSO, Kullu, Himachal Pradesh, which were found unfit for analysis. Though the laboratory requisitioned the second part of the sample as stipulated in sub-section 47(1)(c) of the Act, the concerned DO failed to send the sample. The DO informed Audit that the letters requisitioning the second part of the food samples were not received.
- (b) Following differences in the test findings on the first and second parts of the sample of a product (flavoured water), the third sample was sent (January 2014) to the referral laboratory in Kolkata. DO, Theni, Tamil Nadu sent an email reminder to the laboratory only in February 2015, after the shelf life of the product had expired (June 2014). The laboratory informed that records did not show that the sample had been received by them. DO attributed failure to issue reminder to heavy workload and shortage of manpower. The reply is not acceptable. Among all the states test checked in Audit, Tamil Nadu is in the best position in respect of manpower, with vacancies ranging only from 14 to 17 *per cent* in all the years. In 2014 and 2015, against sanctioned strength of 14 FSOs, DO Theni had 10 to 11 FSOs.

The Ministry accepted (June 2017) the facts.

3.3.3 Non-availability of adequate infrastructure for sampling

Sub-section 47(1)(c) of the Act provides that when the FSO takes a sample of food for analysis, he shall send one of the parts for analysis to the Food Analyst and two parts to DO for keeping in safe custody. Audit observed deficiencies in the required infrastructure for safe custody of samples such as lockable/secure fridge/ freezer, cold chain boxes, insulated boxes, etc. In absence of the requisite infrastructure, the samples were stored in almirahs and cupboards. Consequently, the samples were deteriorating/getting spoiled/damaged and were not fit for analysis. In Kamrup district of Assam, for instance, two samples of milk products were rejected by the referral laboratory as the sample retained by the DO in steel almirahs got spoiled. Due to absence of proper storage facilities, test checked districts in Assam, Himachal Pradesh did not lift samples of perishable items such

as fruits and vegetables. In Tamil Nadu, samples of tea seized from an FBO were sent for testing for adulteration. After sending the first part for testing, the remaining three parts were retained by the DO, Theni. When the lab report confirmed adulteration, the DO Theni discovered that the remaining three parts of the sample (which, because of inadequate storage space, was kept in the open), had been tampered with/damaged. Consequently, no legal action could be taken against the FBO.

The Ministry accepted (June 2017) the facts.



Photograph-3.1 Food samples stored in an almirah in Kangra district



Photograph-3.2 & 3.3 Food samples stored in steel almirah in Kamrup (Metro) district

3.4 Food Safety Audit: Violation of regulations

As per Section 44 of the Act, the Food Authority may recognise any organisation or agency for the purposes of food safety audit and checking compliance with the Food Safety Management System (FSMS) required under the Act and Rules or Regulations made thereunder. In terms of clause 2.1.3 of Regulation, FBOs were required to furnish FSMS plan or certificate¹⁷, if any, along with their application for new licenses or renewal thereof. However, citing difficulties faced by FBOs during the transition period, FSSAI issued an advisory (April 2012), making it optional for FBOs to furnish FSMS plan or certificate and allowed them to furnish an affidavit regarding compliance on a non-judicial stamp paper (later replaced by FSSAI in March 2015 with self-declaration by FBO).

Audit observed that FSSAI had no authority to issue such advisory relaxing provisions of the Regulation. Further, the interim measure, intended for the transition period of one year was made permanent. In the meantime, FSSAI empaneled eight food safety audit agencies in January 2012 and further four agencies in October 2012. Such empanelment was irregular, since, in terms of sub-section 16(2)(c) of the Act, FSSAI is required to frame Regulations underlying the mechanisms and guidelines for accreditation of such certification bodies, which had not been done. Ultimately, the eight irregularly empaneled accreditation bodies were not assigned any work, and FSSAI also decided not to extend their initial term of one year. Consequently, the entire food safety audit system stipulated in the Act and Regulations failed to take off.

The Ministry accepted (June 2017) the facts.

3.5 Enforcement of Centrally Licensed FBOs

As per sub-section 29(1) of the Act, the Food Authority and state food safety authorities are responsible for the enforcement of the Act. Audit observed that based on the recommendation of the Central Advisory Committee, FSSAI, without the approval of the Food Authority or the Ministry, issued an advisory (June 2013) transferring the enforcement activities relating to FBOs having central licenses, from FSSAI to state food safety commissioners. Such delegation of powers to the state food authorities violated section 10(5) of the Act (which entrusted the CEO, FSSAI with the powers of the Commissioner of Food Safety)

¹⁷ Certification is the procedure by which official certification bodies and such officially recognised bodies provide written or equivalent assurance that food or food control systems conform to requirements.

read with sub-section 30(2) covering the duties of the Commissioners of Food Safety, sub-section 30(3) of the Act permitting delegation of the powers of the Commissioners of Food Safety only to their subordinate officers (state food authorities are not subordinate to the CEO, FSSAI), and sub-section 29(1) of the Act (which, *inter-alia*, entrusts the Food Authority with the responsibility for enforcement of the Act, in respect of food businesses falling under the purview of the central licensing authority).

FSSAI replied (March 2017) that it was a conscious decision to delegate the work of enforcement even for the centrally licensed units to the offices of state governments since they have the requisite manpower as well as easy access to FBOs as they have FSOs/DOs at district levels. The reply is not acceptable since such delegation was done without the approval of the Ministry at that time. Further, even the state licensing authorities do not have sufficient staff to effectively fulfill their own enforcement activities. Audit had also observed that state food authorities do not maintain or monitor the information on the central licenses issued, and therefore, they are in no position to enforce compliance. Consequently, the FSSAI was unable to ensure that centrally licensed units fulfill their licensing requirements.

The Ministry in its reply (June 2017) stated that, there was no provision for central or state license as per the Act, 2006 and this bifurcation has been done later on, as per administrative convenience and to give separate responsibilities to the FSSAI and state food safety authorities based upon certain volume/turnover etc., of FBOs. The reply is not acceptable as the provisions for central and state licenses were incorporated in the FSS (Licensing and Registration of Food Businesses) Regulations, 2011 and this was not merely an administrative bifurcation. Moreover, the state food authorities are only responsible for the enforcement of state licenses, and the decision to delegate them the powers of enforcement of central licenses violated the Regulations.

3.6 Lack of coordination between FSSAI and Customs Authorities

3.6.1 Non-presence of FSSAI in ports

The import of food products into India is controlled by FSSAI by Section 25 of the Act, which stipulates that no unsafe misbranded or substandard product is to be imported into India.

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Audit noted that out of the total 635 entry points in India, FSSAI had its presence at only 21 points in six¹⁸ ports, and for 135 points, FSSAI had appointed Customs officials by designation as Authorised Officers¹⁹ (AO) under Section 47(5) of the Act. The appointment by designation is not in compliance with the regulations, which required AOs/FSOs to have a degree in any of the prescribed disciplines²⁰ from a recognised university. Further, the appointment was belated and inadequate, since it was done for the first time in March 2016, a decade after the Act was enacted; also, there is no FSSAI presence either directly, or through its authorised representatives at the remaining point of entries, leaving the food products entering through these entry points unregulated under the Act. Further, FSSAI had no mechanism to monitor the functioning of the Customs officials appointed as AOs.

The Ministry accepted (June 2017) the facts.

Good Practice

The Customs Department, in consultation with other participating Government agencies including FSSAI, has now introduced a Single Window interface for Facilitating Trade (SWIFT). The integrated application is filed on SWIFT which performs a risk assessment for selection of samples for testing. If sampling and testing is required, the application is referred to FSSAI's Food Import Clearance System (FICS).

3.6.2 No final action taken on samples

Clause 14²¹ of the Import Regulations directs the AO to issue a No Objection Certificate (NOC) or Non-Conformance Report (NCR) after assessing the safety of food being imported under these regulations under his seal and signature for allowing/disallowing the import of food, and shall communicate such order in a specified manner to the customs and the Food Importer. Further, sub-clause 13(2)(s)²² of the Regulations empowers the AO to seek data or information on imported articles of food consignment from the customs authority.

¹⁸ Chennai, Cochin, Delhi, Kolkata, Mumbai, Tuticorin.

¹⁹ Term by which FSOs are addressed in respect of imports.

²⁰ Food Technology, Dairy Technology, Biotechnology, Oil Technology, Agricultural Science, Veterinary Sciences, Bio-Chemistry, Microbiology, Chemistry and Medicine.

²¹ Clause 11 of the erstwhile draft Import Regulations

²² Sub-clause 10(2)(s) of the erstwhile draft Import Regulations

Audit scrutiny of records pertaining to regional offices Mumbai and Delhi during the period 2011-2016 revealed 9,264 cases of imports²³ where, AOs who lifted samples for analysis, thereafter failed to issue either NOC or NCR, rendering the fate of those consignments unknown.

Ministry in its reply (June 2017) stated that, though the sample id is generated as and when the payment was made, in some cases however, importer do not turn up for subsequent follow-up/procedure i.e. for visual inspection, hence, no NOC/NCR was issued for such cases. Further, Customs department does not share the details with FSSAI about the end result of these applications.

The reply is not tenable as it was the duty of AOs to assess the safety of food being imported and issue NOC or NCR accordingly. Moreover, FSSAI being the primary food import regulator should make sure that no food product enters the country without NOC. Audit found nothing on record to indicate that FSSAI had ever requested the Customs department to share details in this regard.

3.6.3 Failure to follow-up on NCR of imported food products

Clause 14(7)²⁴ of the Import regulations directs the AO, with prior approval of the Food Authority, to pass necessary orders for mandatory destruction of articles of food against which NCR had been issued. Clause 14(8) states that the Customs shall provide a report to the AO informing all the pertinent details of the destruction.

Test check of records in regional offices of FSSAI in Chennai and Kochi and cross-verification with the Indian Customs Electronic Data Interchange (EDI) System revealed that the Customs authorities had released 24 food consignments (06 in Chennai and 18 in Kochi) despite the issue of NCR against them. Thus the provisions of Regulations were not enforced.

The Ministry in its reply (June 2017) stated that it is for the Customs department to take a final decision on the imported consignment. The reply is not acceptable as it is the mandate of FSSAI to regulate the import of food under the Act, which it failed to comply within these cases while attempting to transfer its responsibilities to the Customs department.

²³ 9,203 cases in Mumbai and 61 cases in Delhi

²⁴ Clause 11.3 of the erstwhile draft Import Regulations

Conclusions

FSSAI and the state food safety authorities did not conduct required surveys for enforcement and administration of the Act. Periodic extensions of the time period were provided to FBOs under the erstwhile Acts and Orders to get their licenses converted under the Act. FSSAI's decision to issue licenses to 'only exporting FBOs' without insisting that they follow set Standards, Rules and Regulations, violated the provisions of the Act. Instances were noticed where expired licenses were renewed retrospectively. Neither FSSAI nor SLAs could confirm that FBOs whose licenses/registrations had expired, stopped all food business activities. Licenses were issued on the basis of incomplete documentation. Neither FSSAI nor the state food authorities have a documented policy and procedures on risk based inspections. While the Act prescribes the periodicity for inspection of registered FBOs, no such periodicity is prescribed in the case of licensed FBOs. FSSAI by-passed the provisions in the Act and Regulations requiring certification of food business in accordance with the Food Safety Management System (FSMS) and permitted FBOs to instead furnish self-certification. Ultimately, the entire food safety audit system stipulated in the Act and Regulations failed. In violation of the Act, FSSAI delegated its responsibility on enforcement of central licensing units to state food authorities. FSSAI had limited presence at import food entry points thereby leaving the food articles entering into the country through unattended entry points as unregulated. FSSAI failed to ensure that after their issue of NCC/NCR, the Customs authorities take appropriate action to ensure that unsafe foods do not enter the country.

Recommendations:

- *FSSAI and state food authorities may conduct surveys of food business activity under their jurisdiction to ensure a comprehensive and reliable database of FBOs and to ensure better enforcement and administration of the Act.*
- *FSSAI and state food authorities may introduce mechanisms to ensure that FBOs whose licenses and registrations expire submit closure reports in terms of the Regulations and do not conduct food business without valid licenses/registration.*

- *FSSAI may frame and notify policy guidelines and procedures on risk based inspections, including the periodicity of inspections. All states may be persuaded to specify the periodicity of inspections and ensure that the periodicity is adhered to.*
- *The Ministry/FSSAI is required to devise a mechanism to effectively monitor the entry of food articles in all the entry points into the country.*
- *The Ministry/FSSAI is required to introduce measures to ensure that FSSAI's directives on NCR are fully complied with by the Customs authorities.*

Chapter-IV: Analysis of Food and Prosecution

4.1 Introduction

Analysis of food samples for physical, chemical and microbiological contamination is important to ensure the safety and quality of food that is produced domestically or imported, and to enable appropriate action, whenever necessary, to be taken to protect consumers. In terms of section 38 of the Act, the Food Safety Officer is empowered (except in respect of imported food, where the FSSAI will authorise an officer) to take samples and send them to the food analyst of the local area within which such samples have been taken. In terms of sub-section 46(2) read with sub-section 43(1) of the Act, the food analyst shall cause such samples to be analysed by food laboratories and research institutions accredited¹ by National Accreditation Board for Testing and Calibration Laboratories (NABL)² or any other accreditation agency. Sub-sections 43(2) and (3) of the Act stipulate the notification of referral food laboratories and the framing of regulations for this purpose. Paragraph 2.2.1 of the Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011 delineates the functions of referral laboratories. Section 47(1)(c) of the Act stipulates that the food safety officer shall send one part of the sample to the food analyst, two parts to the designated officer and one part to the accredited laboratory at the request of the FBO. In case of an appeal against the report of the food analyst, or if there is a difference in the test reports of the laboratory to which the food analyst has sent the sample and the laboratory to which the sample has been sent at the request of the FBO, sub-section 46(4) and proviso below section 47(c)(iii) respectively provide for referral by the designated officer to a referral food laboratory.

4.2 Laboratories under FSS Act

There are 209 laboratories recognised by FSSAI for testing of food samples as of December 2016. These include:

¹ Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence for specific tests/measurements, based on international standard.

² NABL is an autonomous body under the Department of Science and Technology, Ministry of Science and Technology, Government of India.

- i) 72 laboratories³ functioning under the state/Union Territory governments (for primary analysis of samples by food analysts). Of these, only 62 are functioning⁴.
- ii) 121 NABL accredited laboratories⁵ notified by FSSAI.
- iii) 16 Referral Laboratories⁶ under various Central Government Ministries and Departments⁷.

4.3 Non-accreditation of state food laboratories and referral laboratories

Only seven⁸ out of 72⁹ state food laboratories and only eight¹⁰ out of 16¹¹ referral laboratories were NABL accredited as of September 2016. The Ministry of Health and Family Welfare informed (March 2017) that under the new scheme announced in October 2016, all state laboratories would be required to acquire NABL accreditation within two years. It was further stated by the Ministry that NABL accreditation is not a pre-condition for notification of referral laboratories under the Act. It is observed that FSSAI/Ministry had similarly informed the Rajya Sabha in July 2015, that, referral laboratories are not mandated to be accredited by the NABL, and are only to be notified by the Food Authority. However, para 2.2.1(5) of the FSS (laboratory and sample analysis) Regulations, 2011 state that referral laboratory shall maintain high standards of accuracy, reliability, credibility in the operations of laboratory and achieving and maintaining required level of accreditation and reliability. In view of such regulations, it became desirable that they are accredited by NABL to establish and prove their accuracy, reliability and credibility.

³ 72 state food testing laboratories functioning under the erstwhile Prevention of Food Adulteration Act (section 98 of the FSS Act permits such transition from earlier Acts).

⁴ Non-functional laboratories: Karnataka (1 out of 4 labs), Punjab (2 out of 3 labs), Rajasthan (3 out of 8 labs), Tamil Nadu (1 out of 7 labs), and West Bengal (3 out of 5 labs).

⁵ 109 notified laboratories are private laboratories and 12 are under Central/State Governments

⁶ Four referral laboratories were notified through the Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011. Thereafter, 12 more referral laboratories were notified through gazette (as of December 2016).

⁷ Of these, the Central Food Laboratories at Kolkata and Ghaziabad function under FSSAI.

⁸ Four in Gujarat, one each in Maharashtra, Telangana and Uttar Pradesh

⁹ Daman & Diu and Uttarakhand have no state food laboratory; 15 states have one state food laboratory each; Maharashtra has the maximum number of state food laboratories (11).

¹⁰ Andhra Pradesh (1), Karnataka (2), Kerala (1), Maharashtra (1), Tamil Nadu (2), West Bengal (1)

¹¹ Andhra Pradesh (1), Gujarat (1), J&K (1), Karnataka (2), Kerala (2), Maharashtra (2), Tamil Nadu (2), Telangana (2), Uttar Pradesh (2), and West Bengal (1). Of these, one referral lab each in J&K, Kerala, Tamil Nadu and Telangana were set up in 2015-16.

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The fact of non-accreditation of laboratories and testing by accredited laboratories for non-accredited parameters had been criticised by the Hon'ble Bombay High Court¹². Audit check of 183 and 374 tests performed between 2011-2016 in two accredited state laboratories (Ahmedabad and Vadodara) in Gujarat revealed that, on average, 68 per cent of the tests by the state laboratory in Ahmadabad, and 77 per cent of the tests performed by the state laboratory in Vadodara were for parameters where the state labs did not have NABL accreditation.

In view of the above, the quality of testing by 65 out of the 72 state food laboratories and 8 of the 16 referral laboratories cannot be assured.

Regarding the referral laboratories, the FSSAI stated (May 2017) that 14 are NABL accredited, and hence the quality and legality of food testing is being maintained. The replies cannot be accepted in view of the fact that the state food testing laboratories and referral laboratories necessarily have to maintain high standards of accuracy, reliability and creditability.

4.4 Notification of food testing laboratories

Sub-section 43(1) of the Act provides for the notification of food laboratories to carry out analysis of samples by food analysts, and notification of referral food laboratories. Sections 43(2) and 43(3) of the Act stipulate that the Food Authority shall notify referral laboratories, and frame Regulations specifying the functions of such laboratories and the local areas of their functioning.

4.4.1 Irregular recognition/notification of food testing laboratories

From September 2011 till March 2014, FSSAI empanelled 67 laboratories through office orders (without notification), in violation of Section 43(1) of the Act. The empanelment was also without the required approval of the Food Authority and the Ministry. To this audit observation, Ministry replied (March 2017) that FSSAI had notified 64 food laboratories till December, 2014. The reply is incorrect as FSSAI had recognised 67 laboratories between September 2011 and March 2014, by way of office orders and not notification. On 02 December 2014, FSSAI had, with the approval of the Ministry, notified, for the first time, 64 accredited laboratories, which included 56 laboratories empanelled earlier. Thus, the process for recognition through notification as stipulated in the Act was not followed by FSSAI.

¹² FSSAI vs Nestle India and Others Writ Petition 1688/2015.

4.4.2 Irregular notification of referral laboratories

Clause 2.2.2 of the Regulations¹³ identifies four referral laboratories, in Kolkata, Mysore, Pune and Ghaziabad and the distinct local areas of their functioning. In light of these provisions, any change in the number, scope and area of functioning of referral food laboratories can only be by way of amendment to the regulations by the Food Authority, through gazette notification.

Audit observed during May 2013 to March 2016, FSSAI had 14 referral laboratories notified without the approval of Food Authority. Further, the functional areas of laboratories were changed through office orders and notifications. Hence the process of amendment through office orders or simple notifications and not through amendment in regulation has resulted in violation of the Act.

The Ministry endorsed (June 2017) the view of the FSSAI (May 2017) that the Food Authority had full powers to notify referral food laboratories and the Chairperson approved such notification in advance subject to ratification by the Food Authority at its subsequent meeting. The replies cannot be accepted. The Ministry and the FSSAI have not covered the aspect that the Act stipulates notification of referral laboratories and the framing of Regulations specifying the functions of such laboratories and the local areas of their functioning. Any change in jurisdiction can only be done through amendment in the regulation and not through mere office orders or notification. Further, though the FSSAI issued administrative orders/ notifications relating to referral food laboratories, the same were ratified by the Food Authority only on 25 May 2017 (and not in December 2016 as wrongly stated by the FSSAI).

4.5 Food testing at NABL accredited laboratories

4.5.1 Failure of FSSAI to ensure sending of samples to appropriate laboratories

Audit observed that, while FSSAI has framed Regulations¹⁴ containing vertical

¹³ Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011 notified on 01 August 2011.

¹⁴ FSS (Food Products Standards and Food Additives) Regulations, FSS (Prohibition and Restrictions on Sales) regulations, and FSS (Contaminants, Toxins and Residues) Regulations.

and horizontal product standards¹⁵, these standards have not been integrated, to permit users and stakeholders to straightaway identify the contaminant, toxin and residue standards that are applicable to specific food categories. FSSAI also does not have any mechanism to link its individual standards with the specific type of accreditation of the NABL laboratories applying for empanelment. Such juxtaposition is important because, NABL accredits laboratories for specific disciplines (e.g., chemical testing, biological testing etc.), with further levels below them¹⁶. There are multiple specific tests within the testing parameters (for instance, the parameter for metal residue has many specific tests, e.g. cadmium, mercury, arsenic, lead, methyl mercury etc.) and NABL accredited laboratories may have accreditation for only some of the specific tests. Such juxtaposition would provide a transparent linking of standards to the specific tests for which the empanelled laboratories have accreditation, enabling FSSAI to better evaluate the eligibility of laboratories for empanelment, and making the selection of relevant laboratories to which the enforcement arms (designated officers of FSSAI and states, and authorised officers¹⁷ in respect of imports) send samples for testing, more effective.

FSSAI had not framed any Standard Operating Procedures (SOP) for examination and approval of applications for empanelment. FSSAI also does not have any mechanism to promptly update the status of NABL accreditation (such updated status may include withdrawal of NABL accreditation or addition/deletion of specific tests for which accreditation is given) of the empanelled laboratories.

Though NABL accreditation is accorded not only for the specific discipline but also for the multiple tiers or levels below (as explained in footnote 16), FSSAI notifies empanelled laboratories only for two of the broad disciplines (chemical and biological) without providing tier/level details to the enforcement arms of the FSSAI and the states.

¹⁵ Vertical standards apply to a particular food product, whereas horizontal standards apply across the board for the entire food sector or categories thereof. For instance, the FSS (Food Products Standards and Food Additives) Regulations contain vertical standards covering nature, composition and properties of specific categories of food products; and also contain horizontal standards covering limits of permitted additives/ contaminants etc., which may be different for different food categories (for instance, the permissible limits for lead are 0.5 ppm parts per million- for edible oils, 10 ppm for baking powder etc.).

¹⁶ For instance, the first level, say, Level I is the product category (e.g., Food and Agricultural Products); Level II is the sub-product category (e.g., Fish and Fishery Products); Level III is the test parameter in respect of Level II (e.g., Metal Residue in Fish and Fishery Products); and Level IV is the specific test in respect of Level III (e.g., tests for mercury in fish).

¹⁷ Appointed by CEO, FSSAI, in terms of section 47 (5) of the Act read with section 25 of the Act dealing with imports.

Hence, the enforcement arms sent samples to the empanelled laboratories, without knowing the current status of NABL accreditation of the laboratory, or the specific tests that are required to be conducted on the food product that is proposed to be sampled and analysed, or whether the concerned laboratory has NABL accreditation for the specific food category, parameter or tests that are required to be conducted.

In their replies (May 2017 and June 2017 respectively), the FSSAI and the Ministry stated that they are putting a system in place to address the issue.

4.5.2 Testing of samples by laboratories with no accreditation or empanelment

Audit noted that NABL accreditation of four notified laboratories had expired/ were not in the notified list of laboratories for varying periods between January 2014 and March 2016. Despite this, FSSAI regional offices in Chennai, Delhi and Mumbai had sent 6,845 import samples to these laboratories for testing during these periods when they were not accredited/notified.

In their replies (May 2017 and June 2017 respectively), FSSAI and the Ministry accepted the Audit observations.

4.5.3 Testing of samples by laboratories without accreditation for specific parameters

Audit test check of 1,803 import samples sent to empanelled food laboratories by the four regional offices (Chennai, Delhi, Kolkata and Mumbai) between August 2011 and March 2016 revealed that in 264 cases (14.64 *per cent*), the private laboratories did not have accreditation for the parameters (e.g. ethyl alcohol, reducing sugar, esters as ethyl acetate, higher alcohol as amyl alcohol, aldehyde, sulphur dioxide etc.) on which it conducted tests.

In reply, the Ministry stated (March 2017) that it may not be practically feasible for a laboratory to have accreditation for all the test parameters across all food products and that all the notified laboratories have been advised to upgrade their facilities for complete testing and NABL accreditation as per the requirement of FSS Regulations. The reply is not acceptable, since, under section 43(1) of the Act, the Food Authority is mandated to ensure that private laboratories test and report on only such parameters for which they have accreditation, so that, criticisms of the type contained in the Bombay High Court judgement referred to in paragraph 4.3 above are avoided.

In their replies (May 2017 and June 2017 respectively), the FSSAI and the Ministry stated that they are putting a system in place to address the issue.

4.5.4 Non-testing of samples on all prescribed parameters

The Regulations¹⁸ specify the standards (in terms of constituents, nutrients, properties etc.) and permissible limits of contaminants, toxins, additives and residues. Laboratories are required to test on such parameters as applicable to specific foods. Audit test check of 1,309 import cases, however, revealed that in 303 cases (23.15 per cent) the laboratories to whom the regional offices of FSSAI in Chennai, Kolkata and Mumbai had sent samples did not perform the checks on all the prescribed parameters applicable to the specified food item, despite which the concerned regional offices issued No Objection Certificates (NOC) for the import of these items.

In reply, Ministry stated (March 2017) that for the purpose of quick clearance of imported food items, tests are conducted on most common and essential safety parameters without compromising with the risk factors. The reply is not acceptable. FSSAI has not defined which of its parameters are essential and which are non-essential.

4.5.5 Ineffective monitoring of functioning of empanelled laboratories

Apart from NABL accreditation, FSSAI is required to ensure that the performance of empanelled laboratories is satisfactory. FSSAI, however, did not enter into any agreement with the empanelled laboratories prior to December 2014. Resultantly, FSSAI had no mechanism to ensure that the empanelled laboratories adhered to the conditions of empanelment. Though, clause 2.3 of the now extant agreement with the laboratories requires FSSAI to monitor the continuing conformity with the requirements prescribed at the time of recognition, and gives FSSAI the right to carry out additional or unscheduled assessments or investigation over and above the NABL assessment, FSSAI is yet to formulate any procedure¹⁹ till date for surveillance audits, periodicity of special/supervisory visits and suspension/revocation of suspension, renewal, de-recognition, etc., of the laboratories. Consequently, there is no effective monitoring of the empanelled laboratories by FSSAI.

¹⁸ Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

¹⁹ Unlike the Bureau of Indian Standards (BIS), for instance, who have framed detailed guidelines in this regard.

The FSSAI and Ministry accepted (May 2017 and June 2017 respectively), the Audit observations.

4.6 Food Analysts

Food analysts are required, in terms of section 46 of the Act to, *inter-alia*, undertake analysis of food samples sent by the authorised officer (in respect of imports) or the food safety officer (in all other cases). Section 45 of the Act prescribes the appointment of food analysts through notification, and further stipulates that such persons should have the qualifications prescribed by the Central Government. Such qualifications have been prescribed in paragraphs 2.1.4(1)(i) and (ii) of FSS Rules, and are mandatory for food analysts functioning under the Act (except for those persons declared qualified for appointment as public analysts under the erstwhile Prevention of Food Adulteration Act and who had been functioning as public analysts on the date of commencement of FSS Rules). Paragraph 2.1.4(1)(ii) of the Rules stipulates that food analysts should have been declared qualified for appointment by a board appointed and notified by FSSAI. After the framing of FSS Rules, FSSAI has conducted, commencing from February 2012, examinations for the purpose of qualifying food analysts under the Act²⁰. Consequently, 57 candidates were declared by a board constituted by the FSSAI to be eligible²¹. Further, the agreements entered into by FSSAI when empanelling laboratories from December 2014²², stipulated that the food laboratory should have a qualified food analyst for testing food samples under the Act.

4.6.1 Food analysts functioning in notified food laboratories without qualification by board

Audit noted that FSSAI has no data on eligible persons who were functioning as public analysts under the erstwhile Prevention of Food Adulteration Act, and who continued to function in the posts of public analysts/food analysts after the framing of FSS Rules. Further, in response to an audit query on the availability of qualified analysts in the empanelled notified food laboratories, FSSAI admitted (December 2016) that no such record was available. Test check in Audit, however, revealed that out of the 16 notified food laboratories to which the

²⁰ In February 2012, January and July 2014 (covered in the present report), and February 2017.

²¹ For the period covered in audit. A further 127 candidates were declared qualified by the board based on the examination conducted in February 2017.

²² As mentioned in paragraph 4.5.5 of this report, there was no formal agreement between FSSAI and the empanelled private laboratories prior to December 2014.

authorised officers in Delhi and Mumbai sent 49193 cases of imported food samples for testing during 2015-16, 15 food laboratories did not have a food analyst qualified by FSSAI board. It is not clear how many of these samples had been sent for testing by food analysts who are qualified either in terms of the Prevention of Food Adulteration Act or by orders of FSSAI board. Hence tests conducted by state food laboratories and empanelled private laboratories that do not have food analysts with the stipulated qualification were in violation of the Rules.

In their replies (May 2017 and June 2017 respectively), FSSAI and the Ministry accepted the Audit observation and stated that now it will insist on the notified laboratories to appoint Food Analyst as per the Act.

4.6.2 Non-notification of FSSAI board for qualifying food analysts

Audit observed that, contrary to the stipulation in paragraph 2.1.4(1)(ii) of FSS Rules, FSSAI had not notified the board for qualifying food analysts for the period covered in audit²³. Hence, during the period checked by audit, tests on food were performed in laboratories by food analysts approved by a board which had not been notified in accordance with the Rules.

In their replies (May 2017 and June 2017 respectively), FSSAI and the Ministry stated that the board has since been notified and is in place now. The reply however, does not address the issue of Food Analysts already declared qualified by the board which had not been notified.

4.7 State Food and Referral Laboratories

A baseline survey conducted (between September 2013 and January 2014) by FSSAI found that of 72 state food laboratories, only 62 laboratories were functional, with most of the functioning laboratories not having testing facilities for pesticide residues, heavy metals, naturally occurring toxic substances and microbiological parameters.

Audit test check of 20 state food laboratories and one referral laboratory, Central Food Laboratory, Kolkata (CFLK), revealed that they were lacking in technical manpower and important food testing equipment were either not available or were non-functional. This resulted in failure to fully/partially analyse food samples received in these laboratories during 2011-16 with regard to metal contaminants,

²³ The board that conducted the February 2017 examinations was, however, notified.

crop contaminants, insecticides/pesticides, microbiological, as stipulated in the regulations²⁴. Details are discussed in the following paragraphs:

4.7.1 Shortage of technical staff

In test checked laboratories, shortfall of technical staff ranged from 18 to 30 *per cent* in 5 laboratories, 30 to 40 *per cent* in 3 laboratories and more than 40 *per cent* in 10 laboratories. In CFLK there were only 29 technical staff against the sanctioned strength of 53. This affected the performance of the laboratories as illustrated in the case study below:

Case Study

Public Health Laboratory, Surat Municipal Corporation (SMC)

The laboratory was non-functional since August 2014 due to vacant post of Food Analyst though all other facilities like equipment and staff were available. Consequently, the Food Safety Officers (FSO) in the municipality did not lift any food samples between August 2014 and March 2015. Lifting of food samples commenced after April 2015, but were sent for analysis to food laboratories at Rajkot and Bhuj.

4.7.2 Absence of functional food testing equipment

In five state laboratories and Central Food Laboratory Kolkata (CFLK), 18 vital food testing equipment valued at ₹ 8.83 crore²⁵ purchased between February 2003 and July 2015 were non-functional due to repairs or non-installation of equipment. Audit test check of the state laboratories in the selected states²⁶ revealed that they lacked facilities to test many essential parameters like microbiological, pesticide and heavy metal contamination.

Audit verification of 4,895²⁷ food analysis reports of state food laboratories revealed that these laboratories had not tested for mandatory pesticides and microbiology tests in 4,866 cases (99 *per cent*) and 4,698 cases (96 *per cent*) respectively. Some interesting findings are discussed below:

²⁴ FSS (Contaminants, Toxins and Residues) Regulations, 2011 and FSS (Food Product Standards and Food Additives) Regulations, 2011.

²⁵ Three equipment valued at ₹1.26 crore were procured by CFLK between 2005 and 2007.

²⁶ Assam (1), Delhi (1), Gujarat (3 out of 6 state laboratories were checked), Haryana (2), Himachal Pradesh (1), Maharashtra (4 out of 11), Orissa (1), Tamil Nadu (2 out of 7), Uttar Pradesh (3) and West Bengal (2 out of 5).

²⁷ Milk and milk products (1,190 cases), edible oils (641 cases), packaged drinking water (114 cases), sweets and confectionery (686 cases), spices (274 cases) and other foods (1,990 cases).

Case study 1

Testing of vegetables and fruits for pesticides residue in Delhi by non-accredited and ill-equipped laboratory

The State Grading Laboratory of the state Directorate of Agricultural Marketing to whom the food safety department, Delhi had sent food samples for analysis during 2014-15, had declared 2,676 samples as conforming to standards. Audit observed, however, that the laboratory was neither accredited by NABL nor notified by FSSAI. Further, against 113 types of pesticides for fruits and vegetables (including 53 banned pesticides), which are required to be tested in terms of the FSS Regulations, the laboratory was equipped to test only 28 type of pesticides (including 18 banned pesticides). Consequently, food products with possibly harmful pesticide presence (including banned pesticides) impacting food safety were declared safe for human consumption.

Case Study 2

Inadequate testing of milk by ill equipped state laboratory

Out of 324 samples of milk analysed in Delhi from 5 August 2011 to 31 March 2016, 274 samples were found 'genuine' by the Delhi State Laboratory though the laboratory did not have required equipment and manpower to test for microbiological safety, metal contaminants, pesticides. Further, the laboratory did not test for the presence of caustic soda, refined white paint, refined oil, and nitrate arising from addition of pond water to milk. Consequently, food products with possibly harmful contaminants impacting food safety were declared safe for human consumption. The Department admitted (September 2016) the facts.

Case Study 3

Inadequate testing of food samples by ill equipped referral laboratory

Audit test check of 293 food samples of various products analysed by CFLK during the audit period revealed the following:

- (i) CFLK declared 178 samples (60.75 *per cent*) of the above food samples to be conforming to standards, even though these were not analysed for various parameters like pesticides, heavy metal, metal contamination, microbiology etc.
- (ii) Against 149 types of pesticide residues required to be tested in these food products, CFLK was equipped to analyse only 12 types of pesticide residues.
- (iii) No 'Pesticides/Insecticides' residue analysis could be carried out after February 2015 due to breakdown and obsolete conditions of equipment.

Consequently, food products with possibly harmful pesticide presence impacting food safety were declared safe for human consumption. CFLK admitted the facts (June 2016).

In their replies (May 2017 and June 2017 respectively), FSSAI and the Ministry accepted the Audit observation and stated that necessary steps are being taken.

4.7.3 Delays in sending reports by food analysts

Rule 2.4.2 of FSS Rules, 2011 provides that the report of the food analyst shall be sent within 14 days of the receipt of the article of food for analysis. However, no such time limit has been prescribed in respect of referral laboratories. Audit noted that there were considerable delays in sending the analysis report by the food analysts, as discussed below:

- In four states²⁸, out of test checked 2,637 cases, delays²⁹ were noticed in 1,638 cases (62 per cent). The worst delays (in 95 per cent of the cases), were observed in Uttar Pradesh, with 558 cases (47 per cent) not reported even after two months; of these, in 42 cases, the reports had not been received even after nine months (September 2016).
- In 124 randomly selected referral sample cases (out of 3,217 cases tested by CFLK during the audit period), in 100 cases (81 per cent), CFLK had taken between 14 to 210 days in sending reports. CFLK admitted the facts (August 2016), attributing the delays to shortage of infrastructure and manpower.

In their replies (May 2017 and June 2017 respectively), FSSAI and the Ministry accepted the Audit observation and stated that this bottleneck would be suitably addressed.

4.8 Prosecution

Section 42 of the Act stipulates that the Designated Officer (DO), shall, after scrutiny of the report of Food Analyst, decide whether the contravention is punishable with imprisonment or fine only, and in case of the former, send his recommendations within fourteen days to the Commissioner of Food Safety for sanctioning prosecution. In terms of FSS Rules, DOs authorise the FSOs to file an application with the Adjudicating Officer(s) (AOs), who, in terms of section 68 of the Act, is empowered to impose penalty on the FBO(s). Section 96 of the Act

²⁸ Gujarat, Himachal Pradesh, Uttar Pradesh and West Bengal.

²⁹ Delay of 1 to 10 days in 337 cases, 11 to 30 days in 407 cases, 31 to 60 days in 301 cases and above 60 days in 593 cases.

further provides that if penalty imposed is not paid, it shall be recovered as an arrear of land revenue and the defaulter's license shall be suspended till the penalty is paid.

As mentioned in paragraph 3.5, the enforcement of central licensing cases has been delegated to the state food safety authorities, who do not have any mechanism to monitor these cases separately. Therefore, audit has not segregated central licensing and state licensing prosecution cases. Nevertheless, the findings relating to prosecution by state food safety authorities are given below.

Section 42(4) of the Act permits the Commissioner of Food Safety to decide whether, depending on the gravity of the offense, the matter is to be referred to a Special Court (for offenses punishable with imprisonment for more than three years) or to a court of ordinary jurisdiction (for offenses punishable with imprisonment for lesser terms). Audit noted that Special Courts have been set up in only three States (Assam, Delhi and Uttar Pradesh) out of ten test checked states. Audit further observed that though section 42(4)(b) of the Act permits trial by courts of ordinary jurisdiction where no Special Courts exist, the state food safety authorities in Tamil Nadu have failed to launch prosecution on offenses punishable with imprisonment of more than three years on the ground that the state government is yet to create the Special Court. This has given rise to an anomalous situation, where, FBOs charged with less grave offenses are fined/prosecuted, while those accused of far more serious offenses escape unpunished.

In their replies (May 2017 and June 2017 respectively), FSSAI and the Ministry stated that these observations would be shared with the state and UT governments for corrective action.

4.9 Adjudication

4.9.1 Delays in adjudication

Rule 3.1.1(4) and (9) of FSS Rules state that the Adjudicating Officer (AO) shall pass the final order within 90 days from the date of first hearing. In test checked districts of the ten selected states, Audit observed that out of 8,294 cases registered during the audit period (2011-16) 2,126 (26 *per cent*) cases were pending (March 2016) with the AOs for more than 90 days from the date of first hearing. Maximum pendency was in Maharashtra (694 cases or 20 *per cent*) and Uttar Pradesh (1,107 cases or 44 *per cent*), as on March 2016.

In their replies (May 2017 and June 2017 respectively), FSSAI and the Ministry accepted the Audit observations, and stated that these observations would be shared with the state and UT governments for corrective action.

4.9.2 Non-recovery of penalty from Food Business Operators

Audit noted that a penalty of ₹ 12.92 crore was imposed on FBOs by concerned Adjudicating Officers in 10 test checked States/UTs during 2011-2016, whereas penalty amounting to ₹ 6.83 crore was deposited by the FBOs and balance amount of ₹ 6.09 crore (47 per cent) was yet to be recovered from FBOs. No further action was taken by the Department to recover the penalty or to suspend the license as per provisions of the Act.

In their replies (May 2017 and June 2017 respectively), FSSAI and the Ministry stated that necessary corrective actions would be introduced in the licensing system.

4.10 Appellate Tribunal

Under Section 70 of the Act, the Central/State Governments, as the case may be, may, by notification, establish one or more tribunals to be known as the Food Safety Appellate Tribunal to hear appeals on the decisions of the Adjudicating Officer. Audit observed that Food Safety Appellate Tribunals have not been established in two of the ten test checked states (Odisha and Tamil Nadu), leading to appeal cases lying unattended in these states. In Maharashtra, Presidents of District Consumer Forums have been declared as Presiding Officers of Food Safety Appellate Tribunals as an interim measure in April 2013.

FSSAI and the Ministry accepted (May 2017 and June 2017 respectively) the Audit observation.

Conclusions:

Many state food laboratories and referral laboratories to which FSSAI and state food safety authorities sent food samples for testing do not possess NABL accreditation. Though the Act stipulated gazette notification of empanelled food laboratories, FSSAI empanelled food laboratories through office orders. Contrary to the provisions of the FSS Act, FSSAI (and not the Food Authority), either through office orders or notification (and not through regulation), amended the number, scope and local areas of functioning of referral laboratories. FSSAI has not integrated its vertical and horizontal food product standards and linked them to the specific tests contained in the NABL accreditation. FSSAI failed to monitor

the current status of NABL accreditation of empanelled laboratories. FSSAI has no data on public analysts declared eligible under the erstwhile Prevention of Food Adulteration Act who continue to function under the FSS Act. FSSAI also has no data on whether all the notified empanelled food laboratories have qualified food analysts. Contrary to FSS Rules, FSSAI did not notify, till June 2016, the board for qualifying food analysts. Shortage of qualified manpower and functional food testing equipment in state food laboratories and referral laboratories resulted in deficient testing of food samples. Special Courts for offenses punishable with imprisonment for more than three years have not been set up in seven States. There were significant delays in finalisation of cases by Adjudicating Officers and a significant portion of penalties imposed remained uncollected.

Recommendations:

- *Ministry is required to ensure accreditation of all state food laboratories, and ensure that state food laboratories and referral laboratories are fully equipped and functional.*
- *Ministry should ensure that the due process delineated in the Act stipulating empanelment of food laboratories through notification, and amendments relating to referral laboratories through regulations are followed, and the process of securing the Food Authority prior approval is not bypassed.*
- *FSSAI should (i) frame transparent standard operating procedures (SOP) for the empanelment of laboratories; (ii) integrate the vertical and horizontal food product standards with the specific tests contained in NABL accreditation; (iii) ensure prompt communication on change in accreditation status of empanelled laboratories, to its enforcement arms; (iv) more effectively monitor the performance of empanelled laboratories; (v) maintain database of public analysts declared eligible under the erstwhile Prevention of Food Adulteration Act who continue to function under the FSS Act; (vi) ensure that all empanelled laboratories have qualified food analysts; and (vii) ensure that the board that qualifies food analysts is invariably notified.*
- *FSSAI may ensure that all states establish Special Courts and Food Safety Appellate Tribunals and persuade the states to effectively monitor the functioning of Adjudicating Officers, food safety courts and appellate tribunals.*

Chapter-V : Human Resources

5.1 Introduction

The mandate of FSSAI, which includes framing of regulations in respect of food standards, upgrading the existing public food laboratories and creating new ones, ensuring effective enforcement of the food safety and standards and training of all the stakeholders, requires diverse skill sets and knowledge to discharge its functions. The Act extends to the whole of India, requiring co-ordination with the state authorities for enforcement of the Act. This can only be achieved through optimal human resource management, which, *inter-alia*, requires judicious deployment of human resources possessing requisite technical, scientific and administrative skills.

Section 9(2) of the Act stipulates that the Food Authority may, with the approval of the Central Government, determine the number, nature and categories of officers and employees required for its functioning. As per section 9(3) of the Act the salaries, allowances and other conditions of service of CEO, officers and employees of FSSAI shall be such as may be specified by Regulations by the Food Authority with the approval of the Central Government.

5.2 Chronic shortage of regular manpower leading to excessive reliance on contractual employees

The Ministry had sanctioned 356 posts for FSSAI at various levels. However, since FSSAI failed to finalise its recruitment regulations (RPs), most of these posts remained unfilled in all categories¹ by regular employees. The number of regular staff in FSSAI was 115 while it had appointed 261 contractual staff as of December 2016. These contractual employees manned nine *per cent* of Group A posts, 88 *per cent* of Group B posts, and 89 *per cent* of Group C sanctioned posts of the FSSAI. Overall, 73 *per cent* of the personnel employed in FSSAI were on contract (*Annexure-5.1*).

In their reply (May 2017), FSSAI stated that against 356 sanctioned posts, 327 persons were in position, and as such there was no shortage of staff in FSSAI.

¹ For instance, as of December 2016, out of 12 sanctioned senior level posts, only eight (including CEO) were filled (33 *per cent* vacancy); out of 30 posts in the scientific services category only three were filled (90 *per cent* vacancy); out of 74 posts in the technical services, only 24 were filled (68 *per cent* vacancy); and out of 87 posts in laboratories, only 24 were filled (72 *per cent* vacancy).

The reply is not acceptable since most of the regular posts remained unfilled. In the Group A cadre alone, 72 posts (52 per cent) remained vacant.

5.3 Failure to notify recruitment regulations even after a decade

The FSSAI (Salary, allowances and other conditions of service of Officers and Employees) Regulations, 2013 and Draft FSSAI (Recruitment and Appointment) Regulations were sent by FSSAI to the Ministry in 2012. The FSSAI (Salary, allowances and other conditions of service of Officers and Employees) Regulations, 2013 got notified on 24 July 2013. However, the FSSAI (Recruitment and Appointment) Regulations are still under finalisation and the draft FSSAI (Recruitment and Appointment) Regulations were circulated for public comments on March 2016 and were yet to be finalised as of May 2017.

Accepting the facts, the Ministry stated (June 2017) that the finalisation of RRs has been unduly delayed. It further intimated that the draft recruitment regulations have been recast and new recruitment regulations have now been approved by the Food Authority.

The fact remains that even after a decade of enactment of the Act the Food Authority has not notified its recruitment regulations.

5.4 Unauthorised appointments on contractual basis

FSSAI had on its rolls (as of December 2016), 261 contractual employees in the technical, scientific, administrative and general categories. Audit observed that these contractual employees were performing routine functions, defeating the intention of appointing contractual employees only for specific tasks of defined duration. Of these, 51 contractual employees were appointed in 2016 alone. Further, 61 contractual employees have been working in FSSAI for more than five years (as of December 2016)². Audit also observed that the FSSAI had not, prior to their engagement, identified the specific work, expected output and timeframe for completion of the work. The deficiencies noticed during audit scrutiny are discussed in the succeeding paragraphs.

FSSAI admitted (May 2017) that the contractual staff had been engaged for even more than five years and they (other than experts on part-time basis) have been working like regular staff and not in any time-bound specific activity. This supports the Audit observation.

² Contrary to clause 17 of the draft recruitment regulations which stipulates that contractual appointments are to be limited to a maximum period of three years.

The Ministry (June 2017) stated that considering that FSSAI is not a typical government department, but is a professional body with specialised nature of work, some recruitments have been made on contractual basis which are provided for in the Regulations. However, the fact remains that majority of staff was on contractual basis.

In the exit conference (June 2017), FSSAI stated that an internal committee had been set up to review all contractual appointments including their remuneration, increments and tenure.

5.4.1 Deficiencies in appointment of technical officers

Against 17 vacancies in the cadre of technical officers (TOs), 93 appointed on contractual basis were on roll as of December 2016. Such appointments were in excess of sanctioned strength of TO cadre approved by the Ministry.

FSSAI (May 2017) stated that TOs fall in the Group B cadre, and against 111 sanctioned post in Group B, there are 115 persons, while there is a shortage of 64 persons in Group A. Since FSSAI could not attract people in senior and middle levels, many posts are being operated at lower levels. This has resulted in significant savings for the Food Authority without compromising on the work. The Ministry, in its reply (June 2017) endorsed the FSSAI's reply.

The reply is not tenable since categories of posts under each Group are specifically sanctioned by the Ministry and cannot be used inter-changeably.

5.5 Scheme for engagement of consultants (other than IT professionals)

5.5.1 Deficiencies in the scheme

The Scheme for engagement of consultants (other than IT professionals), formulated in December 2014, suffered from various defects as follows: (a) the regulations of the FSSAI do not include the category of consultants and hence creation of this category by the FSSAI was unauthorised; (b) the scheme was approved at the level of the Chairperson FSSAI and was not referred to Food Authority/Ministry, as was done subsequently in the case of scheme for engagement of IT professionals; (c) while the general conditions for engaging consultants (contained in clause 1 of the scheme) specifically state that the consultants would invariably be appointed on full-time basis, clause 5.2 of the scheme provides for remuneration for part-time engagement also; these clauses therefore appear to be contradictory; (d) under the scheme, part-time consultants who were required to work for only two weeks in a month were paid two-thirds to three-fourths the remuneration received by full-time consultants who were

required to work all four weeks in a month; further, while the full-time consultants received no transport facility, part-time consultants were entitled to return airfare. The justification for this is not on record. Audit also observed that the FSSAI did not advertise the scheme, and appointments were made from the applications received from retired government servants and others. The scheme therefore violated the principles of equity, competition and transparency.

Ministry endorsed (June 2017) the reply of FSSAI (May 2017) that, in view of deficiencies, the scheme was not in operation now. Seven retired persons were engaged on full-time basis and one on part-time basis under that scheme, while it was in operation. The reply is not acceptable as there is no evidence on the winding-up of the scheme, and some of the retired persons engaged under this scheme are continuing in FSSAI under the same conditions of the scheme. The part-time employee appointed under the scheme has now been transferred to a new scheme³ created by FSSAI in 2016.

5.5.2 Deficiencies in the appointment of full-time contractual staff

Under the above scheme, FSSAI engaged three full-time consultants in March 2015. Audit observed that though, in terms of the scheme, such engagements are temporary, to be extended on case to case basis depending on the specific job and the time frame for their completion, these consultants were engaged on routine or general tasks without specific time frames for completion, and their tenure was periodically renewed. For instance, two of the consultants were engaged in March 2015 for the specific purpose of development of standards and to be members of the Product Approval and Screening Committee (PA&SC). The two consultants were not engaged in the task of the PA&SC, and in any case, the mechanism of product approval was wound up in August 2015 after the Supreme Court orders. The only record of the work performed by these consultants is with reference to the co-ordination of scientific panels, but this work is general and routine in nature and cannot be classified as a specific task in terms of the scheme for appointment of consultants. Despite this, the tenures of these consultants have been periodically extended and they continue to be engaged by the FSSAI. Similarly, another consultant who was engaged in March 2015 has been assigned the routine tasks of establishment and vigilance, which is contrary to the scheme guidelines, and he continues in that position with periodic extensions.

³ Scheme for empanelment of expert resources, professionals and individual consultants (short term).

The Ministry endorsed (June 2017) the reply of FSSAI (May 2017) that the consultants were discharging specialised tasks and not those of general and routine nature. The replies cannot be accepted. The task of coordinating with Scientific Panel and task of establishment and vigilance cannot be called a specialised task.

5.6 Deficiencies in appointment of full time consultant outside the scheme

A retired Joint Secretary to the Government of India was appointed by FSSAI on single source basis, on the grounds of urgency and temporary arrangement in January 2016. FSSAI invoked GFR 176 for the appointment, which permits single-source selection for which full justification should be recorded on file and approved by the competent authority. The person was appointed against the vacant post of Chief Management Services Officer (CMSO). When a regular officer joined the post of CMSO in April 2016, the services of the consultant were not terminated even though the original condition of urgency necessitating temporary filling up of the post no longer existed. Instead, he was appointed as Head of the General Administration Division, a post which was carved out of the existing post of CMSO, for which, no sanction of the Ministry was available.

The replies of the Ministry/FSSAI were not specific to the audit observations.

5.7 Irregular grant of higher grade to a category of contractual employees

In terms of sanction orders (September 2010) of the Ministry, Assistants and Accounts Assistants/Administration cum Accounts Assistants in the FSSAI are only entitled to grade pay of ₹ 4,200. However, without the approval of the Food Authority/Ministry, the CEO, FSSAI approved (March 2015) fixation of remuneration payable to contractual employees based on the grade pay of ₹ 4,600 against the post of Assistants and Accounts Assistants/Administration cum Accounts Assistants.

FSSAI (May 2017) accepted the facts and stated that the rationale for this has not been found on records so far. In case, there is no good reason, this would be reverted to ₹ 4,200.

5.8 Irregular payment to specific consultants at rates higher than those prescribed by FSSAI

Between April and June 2016, the FSSAI appointed nine contractual employees (whom they designated as consultants) in three disciplines, viz., (i) skill training and capacity building (three consultants); (ii) legislative drafting, legal and

regulatory affairs (four consultants); and (iii) IT and data analytics (two consultants). The appointments were made by adopting NITI Aayog's scheme (July 2015) under the young professional programme. Audit noticed the following deficiencies:

(a) The NITI Aayog's scheme was not a general scheme and had no provision for adoption by any other government body.

(b) Though NITI Aayog guidelines specified remuneration in the range of ₹ 40,000 to ₹ 70,000, FSSAI's notice inviting applications (February 2016) stated that the upper limit for remuneration would be suitably revised depending on years of relevant experience. Reasons for deviation were not found available on records.

(c) The job description specified that the requirement was to identify gaps in skill and capacity of available manpower oriented to the requirements of FSSAI, and to develop training and capacity building modules. Therefore, an essential pre-requisite for eligibility for skill and capacity building in FSSAI is experience in the food business. However, FSSAI specified the qualifications of Master's degree in any discipline, preferably English, and relevant experience in schools/skill development with no preference being given to experience in food business.

(d) There is no record of the manner in which the selection committee based its ranking of candidates and assignment of different remuneration packages. To elaborate, while the selection committee recommended five candidates for appointment and ranked them in the order of merit, the committee recommended remuneration of ₹ 70,000, ₹ 50,000, ₹ 75,000, ₹ 90,000, and ₹ 50,000 in the same order. Thus, the candidates ranked lower in merit were considered for higher remuneration than higher ranked candidates.

(e) Further, the candidate ranked fourth in the order of merit was not only recommended more remuneration than all the higher ranked candidates without any justification, the candidate was eventually paid a higher monthly remuneration of ₹ 1.10 lakh on the ground that she had 20 years of experience. Audit noted however, that the candidate had teaching and training experience (required for the job) of less than six years.

The Ministry endorsed (May 2017) the reply of FSSAI (June 2017) that this category of consultants should be equated to Information Technology (IT)

consultants who receive consolidated remuneration based on market rates and in each case, the amount was based on salary in previous employment plus 15 *per cent* increase. The replies cannot be accepted, since they do not address the issue of how candidates ranked lower in the order of merit can be recommended and paid remuneration higher than higher ranked candidates. Further, the professional requirements of the IT field cannot be equated to the skills related to tasks like skill training and capacity building, and legislative drafting, legal and regulatory affairs.

5.9 Shortfall of Designated Officers (DOs) and Food Safety Officers (FSOs) in States

In terms of section 36 of the Act, Designated Officers (DOs) under FSSAI and State food authorities are, *inter-alia*, empowered to issue or cancel licenses of Food Business Operators (FBOs), to prohibit sale of food, to get analysed the food samples received from Food Safety Officers (FSOs), and to recommend sanction of prosecution under the Act. In terms of section 38 of the Act, FSOs are, *inter-alia*, empowered to lift food samples and have them inspected, to investigate complaints, and to maintain data bases of all FBOs within their areas.

Following the recommendation (August 2014) of the Central Advisory Committee requiring one DO for every district and one FSO for each block in rural areas and for every thousand FBOs in urban areas, FSSAI conducted a gap analysis (September 2016), and found shortfalls of DOs ranging from 5 to 80 *per cent* in 12 States; against requirement of 17,003 only 2,952 FSOs were available in all the states, with shortfalls ranging from 33 to 99 *per cent* in all the States, and with shortfall of more than 90 *per cent* in 12 States. Audit observed shortfalls of DOs ranging from 7 to 81 *per cent* in six states (Assam, Delhi, Haryana, Himachal Pradesh, Odisha and Uttar Pradesh), and shortfalls of FSOs ranging from 34 to 98 *per cent* in the test checked States. Such shortages severely affected the functioning of the State food safety authorities as discussed in paragraphs 3.2 and 3.3.1 of this report.

FSSAI/Ministry in its reply (May/June 2017) accepted the audit observations and stated that corrective measures are being taken.


Conclusion:

Failure of the Ministry/FSSAI to notify the recruitment regulations, even after more than a decade, resulted in acute shortages of regular staff at various levels (by as much as 33 *per cent* to 90 *per cent* in critical posts). There were irregularities in appointment of contractual staff and acute shortage of Designated Officers and Food Safety Officers in state food safety authorities.

Recommendation:

- *The Ministry/FSSAI may take steps to expeditiously notify the recruitment regulations and fill up vacancies.*
- *The Ministry may also comprehensively review the engagement of all the contractual employees appointed by FSSAI.*
- *The Ministry and FSSAI may frame more effective measures to persuade the State food safety authorities to fill up the large number of vacancies in the cadres of Designated Officers and Food Safety Officers.*

New Delhi
Dated: 04 August 2017


(MUKESH PRASAD SINGH)
Director General of Audit
Central Expenditure

Countersigned

New Delhi
Dated: 08 August 2017


(SHASHI KANT SHARMA)
Comptroller and Auditor General of India

ANNEXURES

Annexure-1.1
(Refer para 1.2)

Composition of Food Authority

The Food Authority consists of a Chairperson and the following twenty-two members out of whom one-third shall be women:

- a. Seven Members, not below the rank of Joint Secretary to the Government of India, to be appointed by the Central Government, to respectively represent the Ministries or Departments of the Central Government dealing with:
 - i. Agriculture,
 - ii. Commerce,
 - iii. Consumer Affairs,
 - iv. Food Processing,
 - v. Health,
 - vi. Legislative Affairs and
 - vii. Small Scale Industries,who shall be Members ex officio;
- b. two representatives from food industry of which one shall be from small scale industries;
- c. two representatives from consumer organisations;
- d. three eminent food technologists or scientists;
- e. five members to be appointed by rotation every three years, one each in seriatim from the Zones as specified in the First Schedule to represent the States and the Union territories;
- f. two persons to represent farmers' organisations;
- g. one person to represent retailers' organisations.

Annexure-1.2
(Refer para 1.3)

Rules and Regulations notified by FSSAI (as of December 2016)

- Food Safety and Standards Rules, 2011,
- Food Safety and Standards (Licensing and Registration of Food Business) Regulation, 2011 amended in 2013 and 2016,
- Food Safety and Standards (Packaging and Labelling) Regulation, 2011 amended in 2016,
- Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 amended from time to time,
- Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011 amended from time to time,
- Food Safety and Standards (Prohibitions and Restrictions on sales) Regulation, 2011 amended from time to time,
- Food Safety and Standards (Laboratory and Sample Analysis) Regulation, 2011,
- Food Safety and Standards (Transaction of Business at its Meetings) Regulation, 2010 amended in 2016,
- Food Safety and Standards (Procedure for Transaction of Business of Central Advisory Committee) Regulations, 2010 amended in 2015 and 2016,
- Food Safety and Standards (Procedure of Scientific Committee and Scientific Panels) Regulations, 2010 amended in 2016,
- Food Safety and Standards Authority of India (Salary, Allowances and other Conditions of Service of Officers and Employees) Regulations, 2013, and
- Food Safety and Standards (Food for Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical purpose, Functional Foods, and Novel Food) regulations, 2015.

Annexure-1.3
(Refer para 1.4.2 & 1.4.3)

Sample Selection¹

(a) **Details of States, UT, regional and sub regional offices of FSSAI selected for audit scrutiny**

States and Union Territory selected		Regional/Sub-Regional (RO/SRO) offices of the Food Authority	
		Regional offices (RO)	Sub-Regional offices (SRO) ²
Assam	Delhi (UT)	RO Mumbai	SRO Chandigarh
West Bengal	Haryana	RO Chennai	SRO Lucknow
Odisha	Himachal Pradesh	RO Delhi	
Maharashtra	Uttar Pradesh	RO Kolkata	
Gujarat	Tamil Nadu	RO Guwahati	

(b) **Details of Districts selected in Audit**

State	District	No of test checked Licenses	No. of test checked Registrations	No. of test checked Food Samples
Assam	Dibrugarh	145	18	117
	Golaghat	148	36	87
	Jorhat	165	35	121
	Kamrup	162	42	125
	Nagaon	160	55	119
Total		780	186	569
Delhi	East	120	30	125
	West	120	30	125
	South	120	30	125
Total		360	90	375
Gujarat	Ahmedabad Municipal Corporation	200	50	125
	Anand	200	50	125
	Banaskantha	160	50	125
	Dahod	191	50	125
	Junagadh	196	50	125
	Rajkot Municipal Corporation	160	40	125

¹ Districts where the number of cases available for licenses, registrations, food samples and import were less than the prescribed sample sizes, the actual number of cases available were selected for the same.

² Status as of 31 March 2016. In April 2016, FSSAI closed the Sub-Regional Offices at Chandigarh and Lucknow, transferring their work to Regional Office Delhi.

	Surat Municipal Corporation	160	40	125
Total		1267	330	875
Haryana	Ambala	164	50	122
	Faridabad	160	50	125
	Gurgaon	167	40	106
	Sonepat	160	45	125
Total		651	185	478
Himachal Pradesh	Kangra	162	50	95
	Solan	169	40	125
Total		331	90	220
Maharashtra	Nagpur	200	49	95
	Bhandara	200	50	77
	Aurangabad	200	50	27
	Nashik	200	50	41
	Mumbai	200	45	53
	Pune	200	50	30
Total		1200	294	323
Odisha	Balasore	162	101	19
	Deogarh	33	5	0
	Kandhamal	106	102	15
	Kendrapara	152	103	15
	Jharsuguda	161	43	5
	Mayurbhanj	160	100	23
Total		774	454	77
Tamil Nadu	Chennai	200	40	100
	Coimbatore	178	40	108
	Salem	160	40	113
	Theni	160	50	71
	Tirunelveli	160	50	70
	Trichy	160	50	60
Total		1018	270	522
Uttar Pradesh	Varanasi	167	40	125
	Agra	160	40	125
	Chandauli	181	40	125
	Budaun	160	40	125
	GautamBudh Nagar	172	40	125
	Hathras	160	40	125
	Kanpur Nagar	120	30	125
	LakhimpurKheri	160	40	125
	Sitapur	160	40	125
	Rae Bareli	200	40	125
Total		1640	390	1250
West Bengal	Darjeeling	160	100	91
	Kolkata	161	100	91
	PashimMedinipur	163	111	1
	Purulia	196	125	13
Total		680	436	196

(c) Details of State/Public Laboratories test checked in Audit

Sl. No.	Name of State	Number of Lab examined	Name of Labs
1.	Assam	1	State Public Health Laboratory, Guwahati
2.	Delhi	1	Combined Food & Drugs Laboratory, Delhi
3.	Gujarat	3	Food and Drugs Laboratory, Vadodara, Public Health Laboratory, Ahmadabad Public Health Laboratory, Surat
4.	Haryana	2	(i) District Food Laboratory, Civil Hospital, Karnal (ii) State Food, Water and Excise Laboratory, Govt of Haryana, Chandigarh
5.	Himachal Pradesh	1	Composite Testing Laboratory, Kandaghat, Solan ,
6.	Maharashtra	4	Mumbai, Nasik, Aurgangabad, Nagpur
7.	Odisha	1	State Public Health Laboratory, Bhubaneswar
8.	Tamil Nadu	2	Madurai and Salem
9.	Uttar Pradesh	3	Regional Public Analyst Laboratory, Agra & Varanasi and State Laboratory, Lucknow
10	West Bengal	2	Public Health Laboratory, Kolkata, Central Food Laboratory, Kolkata
Total		20	

(d) Details of Ports selected for Audit

Name of Region	Name of Selected Port	No. of Samples selected
Kolkata	Kolkata Sea Port, Haldia Sea Port	500
Mumbai	JNPT, Mumbai Air Cargo	409
Delhi	IGI Airport, ICD Tuglakabad	496
Chennai	Customs House Chennai, Customs House Cochin	400

Annexure-5.1

(Refer para-5.2)

Deployment of staff in FSSAI as on December 2016 is given below:

Category	Sanctioned Posts	Absorbed*/Direct recruitment	Deemed Deputation*	Deputation	Contractual employees [#]
Group A	139	20	1	36	13
Group B	125	04	10	01	110
Group C	92	01	42	0	82
Total	356	25	53[@]	37	205

* These two categories joined FSSAI from other Ministries in terms of section 90 of the Act. The difference is that the latter category comprises employees who have not exercised their option to be absorbed in FSSAI

[#]Applies only to contractual employees whose consolidated salaries have been aligned to sanctioned posts. Does not include 18 retired government officers/ staff and 38 IT personnel/ 'specialised functional domains' also engaged at different emoluments. Consequently, FSSAI has on its rolls, 261 non-regular employees.

[@] Does not include two persons appointed against temporary posts.

LIST OF ABBREVIATIONS

List of Abbreviations

Term	Details
AGMARK	Agricultural Produce Grading and Marking
AO	Authorised Officer
APEDA	Agricultural and Processed Food Products Export Development Authority
BIS	Bureau of Indian Standards
CAC	Central Advisory Committee
CAG	Comptroller and Auditor General of India
CEO	Chief Executive Officer
CFL	Central Food Laboratory
CFLK	Central Food Laboratory Kolkata
CLA	Central Licensing Authority
CMSO	Chief Management Services Officer
CPGRAMS	Centralized Public Grievance Redress and Monitoring System
CSR	Corporate Social Responsibility
CTL	Composite Testing laboratory
DAC	District Advisory Committee
DARPG	Department of Administrative Reforms and Public Grievances
DART	Detect Adulteration with Rapid Test
DLSC	District Level Steering Committee
DO	Designated officer
EDI	Electronic Data Input System
EFC	Expenditure Finance Committee
EOU	Export Oriented Unit
FA	Food Analyst
FAO	Food & Agriculture Organisation of the United Nations
FBO	Food Business Operator
FICS	Food Import and Clearance System
FLRS	Food Licensing and Registration System
FPS & FA	Food Product Standards & Food Additives
FSMS	Food Safety Management System
FSO	Food Safety Officer
FSS	Food Safety and Standards
FSSAI	Food Safety and Standards Authority of India
FSSR	Food Safety and Standards Rules/Regulations
GFR	General Financial Rules
HQ	Headquarters
ICMR	Indian Council of Medical Research

IDEA	Idea Data Analysis Software
IE Code	Import Export Code
IEC	Information, Education and Communication
IT	Information Technology
JNPT	Jawaharlal Nehru Port Trust
MRL	Maximum Residual Limit
MT	Metric Tonnes
NABL	National Accreditation Board for Testing and Calibration Laboratories
NCC	Non-Conforming Certificate
NCR	Non-Confirmatory Report
NITI	National Institute for Transforming India
NOC	No Objection Certificate
PA	Product Approval
PA & SC	Product Approval and Screening Committee
PFA	Prevention of Food Adulteration Act
PPSWOR	Probability Proportional to Size Without Replacement Method
RDA	Recommended Dietary Allowances
RO	Regional Office
RR	Recruitment Regulations
SAC	State Advisory committee
SC	Scientific Committee
SFSC	State Food Safety Commissioner
SLA	State Licensing Authority
SLSC	State Level Steering Committee
SMC	Surat Municipal Corporation
SOP	Standard Operating Procedures
SP	Scientific Panel
SPHL	State Public Health Laboratory
SRO	Sub Regional Office
SRG	Standards Review Groups
SWIFT	Single Window Interface for Facilitating Trade
TO	Technical Officers
USD	United States Dollar
UT	Union Territory
WHO	World Health Organisation
WTO	World Trade Organisation

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