

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.

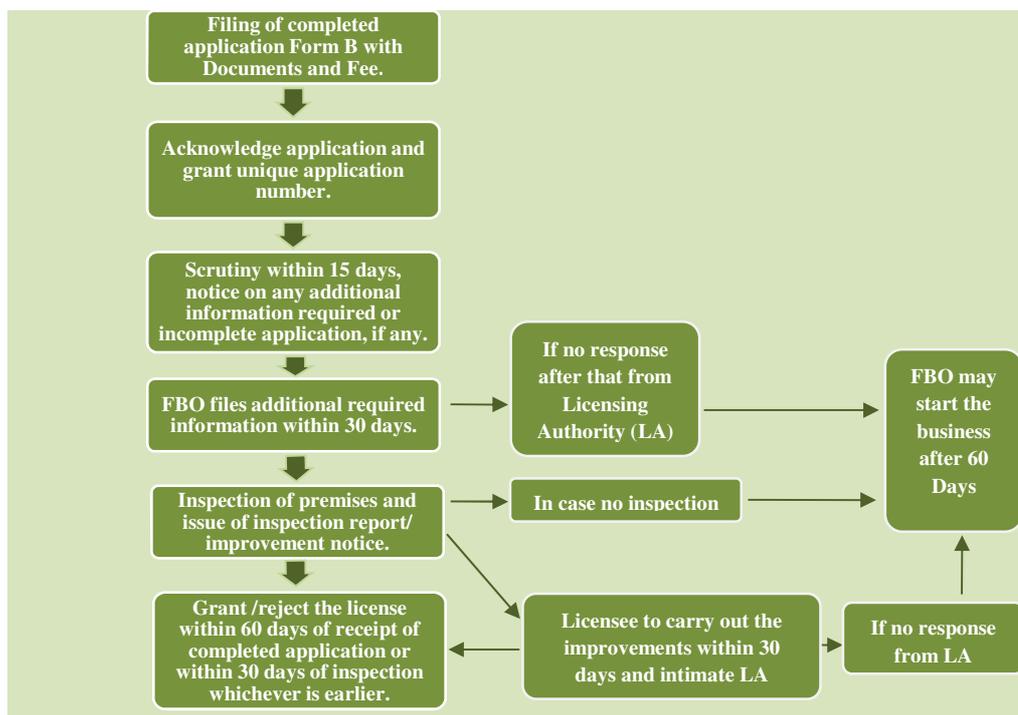


Figure 3.1: Flow chart explaining licensing procedure

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). The 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, the 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.*