

*Facilitating Ease of Doing Business in India's Food Sector*

# Streamlining Food Safety Compliance Ecosystem in India

ICRIER

INDIAN COUNCIL FOR RESEARCH ON  
INTERNATIONAL ECONOMIC RELATIONS

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*Streamlining Food Safety Compliance Ecosystem in India: Facilitating Ease of  
Doing Business in India's Food Sector*

Ali Mehdi, Priyanka Tomar, Divya Chaudhry and Pallavi Joshi

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**Pawan Agarwal, IAS**  
Secretary to Government of India & Chief Executive Officer



## FOREWORD

Food is one of the few things that is so intimately associated with our culture, society, environment and the economy, all at once – and unsurprisingly, therefore, with our sense of self, happiness and, not least, health. One indicator of the centrality of food to our lives is the revenue in the food and beverage sector worldwide – USD 108 billion in 2019, poised to rise to USD 159 billion by 2023.<sup>i</sup> On the other hand, the centrality of food makes food safety and the role of the food safety regulator equally central too. Foodborne illnesses were estimated to have led to 420,000 deaths in 2010<sup>ii</sup> and productivity losses worth USD 95 billion in low- and middle-income countries alone in 2016.<sup>iii</sup>

The Food Safety and Standards Authority of India (FSSAI) was created as per the Food Safety and Standards Act, 2006 and operationalised with the notification of Food Safety and Standards Rules, 2011 and six regulations with effect from August 2011. Its objective is to lay down science-based standards for food articles, regulate their manufacture, storage, distribution, sale and import as well as 'to ensure availability of safe and wholesome food for human consumption' and related matters. FSSAI has learnt from the international food regulatory landscape, yet is unique in more ways than one – for e.g., it has brought food safety and nutrition together, focuses on consumer empowerment and works through partnerships and convergence. Within a decade, FSSAI has undertaken a series of reforms to enhance food safety in the country and is committed to many more in the years ahead.

With the desire to pursue food safety regulation in a balanced and integrated manner – in the spirit of the 2030 Agenda – we invited ICRIER to conduct an independent review of compliance burden of our food safety regulatory ecosystem and share recommendations for streamlining it on the basis of desk research and stakeholder interactions in India and the UK. Our counterpart in the UK – the Food Standards Agency (FSA) – as well as the UK's Department for Environment, Food and Rural Affairs (DEFRA) and the Department for Business, Energy and Industrial Strategy (BEIS) have initiated several measures to modernize the way food businesses are regulated in the UK, in a 'risk-based, proportionate, robust and resilient' manner. We are interested in understanding what lessons can be drawn and what partnerships forged from the perspective of our own specific Indian context.

I am delighted that, within a short span of 3 months, ICRIER's team has produced this insightful, and one of its kind, report based on extensive desk and field research in India and the UK. Although FSSAI may not be on the same page with the report vis-à-vis certain findings or recommendations, it will be enormously helpful not only for us as we move ahead with our reforms, but also for other present and prospective stakeholders of India's food safety ecosystem.

I wish to thank all stakeholders in India and the UK who shared their insights with the authors and contributed to making this report successful in various ways. I also thank and congratulate ICRIER and look forward to our continued engagement in the future.

  
(Pawan Kumar Agarwal)

New Delhi, 18<sup>th</sup> June 2019



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# About the Report

This is one of the two reports requested by the Food Safety and Standards Authority of India (FSSAI), Ministry of Health & Family Welfare, Government of India to streamline the process of food imports and reduce the compliance burden on the food industry based on learning from best practices in the United Kingdom (UK). This report has been supported by the Government of United Kingdom's Prosperity Fund India Programme. Research for these reports was conducted by the Indian Council for Research on International Economic Relations (ICRIER), an autonomous policy research institute ranked by University of Pennsylvania for the third year running as India's foremost in 'International Economics' as well as 'International Development Policy'.

Given the significant contribution of the food industry to economic growth and employment generation in both India and the UK, this report, the first of its kind, undertakes a comparative assessment of the food safety regulatory compliance ecosystems in the two countries, surveys and analyses the compliance burden faced by the food industry in India and suggests steps that FSSAI and related government agencies could consider in order to make food safety compliance rational and proportionate vis-à-vis its stated objectives and to reduce the compliance burden on the food industry in India. A coordinated approach to public policy and regulation is needed in the era of Sustainable Development Goals (SDGs) – an 'integrated', 'indivisible' and 'balanced' approach to 'the three dimensions of sustainable development: the economic, social and environment' has been

advocated in the 2030 Agenda and endorsed by world leaders at the United Nations General Assembly on September 25, 2015.

This report is based on –

- Situation and problem analysis based on desk research as well as field interactions with FSSAI representatives at their New Delhi headquarters (regulatory compliance and IT teams) and Chennai zonal office as well as 21 domestic/multinational food companies across different firm sizes and food industry segments in Delhi, Gurgaon, Mumbai and Chennai;
- Interactions with the UK's food regulator, the Food Standards Agency (FSA), the Department for Environment, Food & Rural Affairs (DEFRA) and the Department for Business, Energy & Industrial Strategy (BEIS) as well as a few major food companies, the British Retail Consortium (BRC) and a food safety consultancy in London.

Desk research involved an extensive review of official documents available on the websites of FSSAI, FSA and GOV.UK, journal articles, reports of industry associations, consultancies, autonomous government bodies and relevant ministries. Reports and documents shared by regulatory authorities in India and the UK were also reviewed to supplement the analysis. Field research involved semi-structured interviews with the stakeholders mentioned above.

# Summary of Challenges Faced by Food Business Operators (FBOs) in India

1. Almost all FBOs who participated in our survey (n=21) felt that FSSAI has dramatically strengthened the food regulatory system in the country over the past four years.
2. Although they do not view its food safety compliance requirements as 'burdensome', there are challenges, which they have highlighted.
3. Impediments to transparency
  - a. *Awareness*: Most FBOs felt that small- and medium enterprises (SMEs) in particular are not adequately aware of FSSAI's rules and regulations. There is a disproportionately large unorganised sector, which often does not have access to the internet or media messages. Even those who do have to keep visiting FSSAI's website to keep abreast of new regulations or changes to existing ones. Relevant information is not easily accessible and exhaustive exploration of the FSSAI website is needed. With the exception of Food Licensing and Registration System (FLRS), FBOs are unaware of FSSAI's initiatives to streamline compliance procedures.
  - b. *Interpretation*: Most FBOs, including multinational companies, felt it is difficult to accurately interpret FSSAI's guidelines. Language is a barrier (not available in regional languages). They are 'too technical'. Some FBOs felt that there are contradictory statements even in a single document. There are also no guidelines for certain food products and provider categories.
  - c. *Inspections*: Our survey confirms that the risk-based approach to inspections is currently not followed in India. All food service providers who we met during our survey were quite satisfied with the current inspection process. They said that inspections take around 30-45 minutes and in addition to examining the hygiene of their kitchens, Food Safety Officers (FSOs) also ensure whether the FBOs are procuring ingredients from only FSSAI certified suppliers. On the other hand, owners of food processing businesses in Mumbai and Chennai complained about the 'bribe-seeking behaviour of FSOs' at the time of inspections.
  - d. *Sampling*: Delays/misinformation in sending samples to laboratories, especially perishable products, is the most worrying aspect for FBOs vis-à-vis sampling. There is dearth of infrastructure (e.g. refrigerators and insulated containers) for safe storage of samples. Some operators are reimbursed for the samples taken, others are not.
  - e. *Consultations*: While FBOs get an opportunity to share comments on draft versions of new/revised regulations, many believed there is lack of transparency in the way they are finalised and want to be involved in consultations from the early stages.

4. Impediments to predictability

- a. *Changes*: Frequent/abrupt changes in regulations (especially labelling), which lead to huge losses and general uncertainty is a major concern.
- b. *Alcohol*: Alcohol labelling requirements have traditionally been governed by state/UT excise departments and differ across states/UTs. FSSAI has issued its own directive and FBOs find it challenging to comply with dual labelling directives, especially those who also package liquor in small bottles. FBOs are required to register their labels with state/UT excise departments before the beginning of every financial year and this process is both costly and time-consuming. If there is any change in labelling requirements, they have to discard existing labels and seek re-registration of new labels.

5. Impediments to consistency

- a. *Documentation*: License renewal and product approval are cumbersome – they involve submission of all documents already submitted. A modified license is needed every time an FBO has to diversify operations, even if that diversification is only marginal. The FSSAI has not specified any timeline for the approval of non-specified foods.
- b. *Enforcement*: Inconsistency in enforcement is a massive issue, acknowledged by the

FSSAI itself. Interpretation of food safety laws by FSOs starkly varies from that of FSSAI's regional offices and headquarters. There is lack of coordination between FSSAI's regional and state/UT food safety authorities – even when the license has been issued by the FSSAI, state/UT authorities conduct inspections and at times do not even inform the FSSAI before, or after inspections; the FSSAI may go ahead with renewing licenses without being aware of inspection results.

6. Other impediments

- a. *Compliance costs*: All respondents emphatically stated that compliance costs have increased in the last four to five years. Many complained of the exorbitant laboratory testing costs that they have to incur annually or half-yearly. These are particularly substantial for SMEs as they constitute a relatively sizable proportion of their revenues. Sometimes, there is no scientific basis for tests that certain categories of FBOs have to get done. According to one of our respondents, they have to test for heavy metals and antimicrobial residues despite it not being required in their business of manufacturing perishable products.
- b. *Training*: Several FBOs feel that Food Safety Training and Certification (FOSTAC) training is not very beneficial to them. Some doubt the training quality.



# Summary of Our Recommendations

1. FSSAI should develop a formal and clear statement of Regulatory Philosophy/ Principles/Approach, as in the US and the UK, for instance.
2. The Government of India should have a government-/country-wide regulatory statement to ensure regulatory consistency within and across sectors and states. It should have an agency that monitors the measurement of regulatory burden, and co-ordinates its reduction and ensures that the regulation that remains is smarter, better targeted and less costly to businesses. The Ministry of Commerce and Industry is already collaborating with Regulatory Delivery International in the Department for Business, Energy and Industrial Strategy (BEIS), UK, and such a statement could be a part of such collaboration.
3. Regulations should impose the least possible burden and should be predictable enough to ensure certainty.
4. FSSAI should have a nuanced approach to compliance vis-à-vis segment and size as well as the evolving nature of the food industry. That is possible with a robust surveillance system in place. Such a surveillance system will not only help in more systematic risk-based inspections, but also help identify FBOs that need support in terms of compliance. In India, with limited awareness and resources among SMEs, a proactive and promotive approach to compliance by the regulator is essential.
5. FSSAI should view FBOs as partners and develop a collaborative approach to compliance. It could also work with international standards agencies active in India to rationalise its own limited resources in terms of inspections, etc.
6. FSSAI can collaborate with FSA (UK) to develop a strategic food surveillance system which could be used to develop a prevention-oriented, resource-optimising risk-based inspection/intervention system. These systems should be developed to ensure interoperability with other surveillance/data systems in the spirit of the 2030 Agenda so that cross-sectoral and cross-country action could also be taken to ensure the primary mandate of food safety. This can also help in inter-agency regulatory collaboration within and outside the country.
7. FSSAI should regularly conduct or commission independent potential impact assessments (PIAs) to assess the impact of policy options being considered. Regulatory impact assessments (RIAs) should also be conducted to assess the actual impact of the regulatory food safety ecosystem on FBOs – especially SMEs – and other stakeholders as well as how other spheres affect and are affected by food safety in general and regulatory ecosystem in particular.
8. FSSAI should strengthen a rational, proportionate and smart approach vis-à-vis food safety to compliance and consider alternative non-regulatory options to achieve its mandate.



9. FSSAI's mandate should be clearly focused and outcome-oriented – food safety. It should not focus on nutrition or health promotion. Other agencies should deal with these issues. A rational and focused mandate is the first step towards a rational and focused compliance ecosystem.
10. In line with international regulatory agencies like FSA (UK), FSSAI could consider a non-ministerial government department model and work with state/UT food safety authorities to develop a Local Authority and Primary Authority based system in the country. The contours of such a system for the Indian context require thorough and careful consideration. FSSAI should consider this and try to build consensus on it at the level of the central and state/UT governments.
11. Our interactions with FBOs revealed that FSSAI's regulations excessively focus on achieving specific regulatory objectives that are often formulated without any systematic consultation with FBOs. A dynamic consultative rule-making process is needed to ensure that regulations move in tandem with evolving industry and there are no abrupt changes without due consultation with FBOs.
12. In order to improve awareness and understanding of compliance requirements among FBOs, particularly SMEs, as well as cognizance and redressal of grievances in a structured manner, industry associations could be involved to play a more prominent role.
13. FSSAI should redesign its website and provide information in a clear and structured manner.
14. FSSAI should develop quick interactive mechanisms such as – social media, chatbot, etc. – to proactively help address the grievances of FBOs on a real-time basis.
15. To update FBOs about new or revised regulations, FSSAI can introduce a system of issuing mass alerts or RSS feeds in the website through which content could be distributed in real-time, reflecting the latest published content on the website.
16. Enhanced co-ordination between FSSAI's zonal and state/UT food authorities is required to update FSOs of its latest compliance requirements and to ensure a co-ordinated approach to surveillance, inspections and other activities.
17. In addition to a shared manual for inspections, regular workshops should be conducted to enhance uniformity in inspection protocols.





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This report is primarily based on stakeholder interactions – as such, we are thankful to all those who agreed to take time out from their busy schedules and share their insights with us. I hope we have done justice in representing their viewpoints and challenges as well as in developing our recommendations for reform.

Last, but not the least, we would like to thank Dr Rajat Kathuria, Director and Chief Executive, ICRIER, for his moral support throughout the course of research.

# 1

## Introduction

Public sector regulation in a free market economy is critical from the perspective of citizens as well as the economy. In the area of food safety, for instance, the regulator has to ensure that the food available in the market is safe and is actually what it says it is – most citizens lack the expertise to decide this on their own. Food-borne illnesses led to 420,000 deaths in 2010, according to the WHO *Estimates of the Global Burden of Foodborne Diseases* (2015) report, and productivity losses close to USD 95 billion in low- and middle-income countries alone in 2016, according to the World Bank's *The Safe Food Imperative* (2019) report. From this perspective, food safety regulators act as keepers of consumer trust, which is their primary mandate. The manner in which they seek to realise this mandate has implications for the regulated – i.e. the industry – in a direct sense, as well as for other stakeholders and spheres indirectly. It would, therefore, be pertinent to ask if:

- i) the measures adopted by the regulator to ensure food safety are rational, proportionate and efficient in the first place,
- ii) if the measures could be designed and pursued to minimise any negative impact on the regulated without compromising their primary mandate.

World leaders adopted the 2030 Agenda for Sustainable Development/SDGs at the United Nations General Assembly on September 25, 2015, the essence of which is the 'integrated', 'indivisible' and 'balanced' pursuit of 'the three dimensions of sustainable development: the economic, social and

environmental' as their strategy 'to free the human race from the tyranny of poverty and want and to heal and secure our planet'. In the spirit of this Agenda, food safety regulators need to ensure food safety while also considering the social, economic and environmental implications. Measures therefore, need to be rational, proportionate and efficient while maintaining their primary mandate. However, this is often not the case, particularly in countries with weak regulatory capacities. Regulators need to adopt whole-of-society and whole-of-government approaches and work collaboratively with relevant stakeholders and agencies to understand and address cross-sectoral implications 'for' as well as 'of' food safety for other sectors. Needless to say, food safety is not the only public concern, although it is the primary one for the food safety regulator. But food safety cannot be ensured in isolation from other concerns, and its regulator cannot work in a silo.<sup>1</sup>

- Recommendation 1 – FSSAI should conduct or commission independent regulatory impact assessments (RIAs) on a regular basis that assess food safety for consumers, the effect of the food safety regulatory ecosystem on the regulated and other stakeholders as well as how other spheres affect – and are affected

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1. According to the World Bank, 'today's food system is the main driver of deforestation and biodiversity loss and generates a quarter of the world's greenhouse gas pollution' (<https://bit.ly/2urxBII>, 10/4/2018, 12:37 hours). While the food safety regulator may argue that this is strictly outside the scope of its mandate, there are steps it could take to contribute to the redressal of this larger challenge.

by – food safety<sup>2</sup> in general and the food safety regulatory ecosystem in particular. RIAs have become common in most OECD countries, especially from the perspective of SMEs (OECD 2018).

- Recommendation 2 – While RIAs could be conducted based on focused stakeholder surveys; the FSSAI should strengthen its food safety surveillance system considering the experience of the UK (see footnote 2 below) so that there is a regular availability of data on a broader range of indicators which will help conduct more detailed RIAs.
- Recommendation 3 – FSSAI should have a clear statement of its Regulatory Philosophy/ Principles/Approach. In fact, the Government of India should have such a government- and country-wide statement to ensure regulatory consistency within and across sectors and states. Besides, there should be a nodal agency to monitor its operationalisation and compliance – a sort of regulator of regulators.<sup>3</sup>

For instance, the US Presidential Executive Order 13563 of January 18, 2011 ('Improving Regulation and Regulatory Review') outlines the following general principles of regulation:

- **Goals:** Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.
- **Characteristics:** It must –
  - a. be based on the best available science;
  - b. allow for public participation and an open exchange of ideas;
  - c. promote predictability;
  - d. reduce uncertainty;
  - e. use the best, most innovative, and least burdensome tools for achieving regulatory ends;

2. The FSA (UK) has a strong international surveillance system in place, which looks at diverse determinants of food safety in the UK and proactively undertakes preventive measures through various channels to ensure, for instance, that the food that arrives at its ports is safe.
3. A consultation paper of the erstwhile Planning Commission recommended "an Act of Parliament laying down the overarching principles of regulation cutting across different sectors. The proposed statute would be supplemented by the existing sector specific legislations that set out specific objectives to be achieved" (Planning Commission 2006: 30).

- f. take into account benefits and costs, both quantitative and qualitative;
- g. ensure that regulations are accessible, consistent, written in plain language, and easy to understand;
- h. measure and seek to improve, the actual results of regulatory requirements.<sup>4</sup>

The regulator also needs to decide whether its approach to compliance should be control-based, collaboration-based, rule based or goal-oriented. Within a control approach, compliance rules are given primacy and the regulatory focus is on ensuring through inspections that the regulated entity complies with the rules. Within a collaborative approach, there are rules – as well as other potentially feasible alternative policy instruments (regulatory and non-regulatory). The primary focus is goals (food safety and ensuring that the food is what it says it is) and how these can be achieved using a collaborative approach with the regulated entities and other stakeholders. There is support for this sort of approach in compliance literature as well. For instance, Clifford Shearing quotes a joint work by Ian Ayres and John Braithwaite (1992), arguing that 'policy makers should be very wary indeed of an approach that regards compliance with rules, whether achieved through co-operation or coercion, as hallmarks of sound regulatory practices. Regulatory policy should be goal rather than rule-oriented' (Shearing 1993: 75). Thus, FSSAI should develop a collaborative and goal-oriented approach to compliance.

Both the food regulator and the industry in India show an inclination towards a collaborative model, although the operational approach may not be such at the moment. Both recognise that regulation/ compliance enhances the credibility of the industry. For instance, consider the following quote from a news item –

*FSSAI chief executive Pawan Agarwal reportedly said, "With increasing use of ecommerce platforms by consumers, the guidelines are aimed at stepping up vigilance on the safety of food provided to consumers. These guidelines will help in building confidence in the ecommerce food business sector and increase its credibility.... Zomato spokesperson told Inc42, "We welcome any move by FSSAI which will help us make the restaurant industry safer for consumers. We provide last mile delivery to our users and are taking stringent steps to*

4. Federal Register, Vol. 76, No. 14, 21 January 2011. Presidential Documents. <https://bit.ly/2KeFM2g> (19/12/2018, 13:50 hours).

*ensure the safety of food. While we are already compliant with the mandatory directives in the FSS act, we will work with FSSAI on any measures required to drive the development in the ecosystem.”<sup>5</sup>*

- Recommendation 4 – FSSAI should develop a collaborative approach to compliance. As part of this approach, it can work with the international standards agencies active in India (for instance, the International Organization for Standardization or ISO, Global Food Safety Initiative or GFSI and the British Retail Consortium Global Standards BRCS) and rationalise its own limited resources in terms of inspections.

Before we go on to discuss the food safety compliance ecosystems in India and the UK, let us quickly offer a snapshot of the food industry in the two countries and why it is important to take the economic dimension into consideration while primarily focusing on food safety.

### 1.1 The Food Industry in India and the UK

While there exists no formal definition of the ‘food industry’, it is perceived as a broad term that encompasses diverse aspects associated with production and supply of food. It comprises of a range of activities that include the raising of crops and livestock, manufacture of farm equipment, agrochemicals, food processing, packaging and labelling, storage, distribution, marketing, retailing, food service, catering, research and scientific trials on food safety and technology, etc. Given the broad ambit of the term, it is difficult to provide an exact valuation of the food industry domestically or internationally. Nevertheless, certain components of the food industry, such as food processing and food services merit attention, in particular in the context of India and the UK, since they are major drivers of growth.

The food processing industry was valued at roughly USD 194 billion and recorded a growth rate of 20 percent per annum in 2015 (Grant Thornton and

Assocham India 2017). In 2015-16, the food processing sector in India contributed 8.71 per cent and 10.04 per cent to gross value added (GVA) through agriculture and manufacturing sector respectively at 2011-12 prices. Further, since food processing is a labour intensive industry, it accounted for 12.77 per cent of employment generated in factories registered under the Factories Act 1948, which was roughly equivalent to 1.77 million workers in 2014-15. The unregistered food processing sector accounted for 13.72 per cent of employment in the unregistered manufacturing sector in India and supported nearly 4.79 million workers, according to estimates provided by NSSO 67th round for 2010-11 (Ministry of Food Processing Industries 2017-18). With respect to its food services sector, India has shown remarkable gains in recent years – the sector was estimated at INR 3,375 billion in 2017 and was projected to grow at a compound annual growth rate (CAGR) of 10 percent over the next 5 years to reach INR 5,520 billion by 2022. In 2016, it was estimated that the food services sector in India provided direct employment to 5.5-6 million people, which was projected to increase up to 8.5-9 million by 2021 (FICCI 2017). It is also crucial to mention here that, while the food processing sector in India is largely dominated by micro, small and medium enterprises (MSMEs),<sup>6</sup> the food services sector consists of a myriad of unorganised players, many of whom appear to be outside the food safety regulatory ambit.

The food processing industry in the UK, widely known as the ‘food and drink’ industry, is the largest manufacturing industry in the UK, accounting for 17 per cent all manufacturing GVA, and contributes nearly £28.2 billion (USD 36.85 billion)<sup>7</sup> to the economy per annum. It covers close to 6,800 businesses and provides direct employment to 400,000 people (FDF 2017). UK’s food service market is the fourth largest consumer market in the UK, following food retail, motoring, clothing and footwear. It was valued at USD 66 billion in 2017 and is growing rapidly at a CAGR of 2.91 per cent for the forecast period 2018-2023.<sup>8</sup>

5. Bhumika Khatri. 28 December 2018. ‘Food regulator FSSAI steps up scrutiny for ecommerce food companies’. <https://bit.ly/2GLH5ro> (28/12/2018, 15:52 hours).

6. The Government of India enacted the Micro, Small and Medium Enterprises Development (MSMED) Act 2006, according to which a micro enterprise is one where investment in plant and machinery is less than INR 25 lakh; a small enterprise is one where it is more than INR 25 lakh, but less than INR 5 crore; a medium enterprise is an enterprise where it is more than INR 5 crore, but less than INR 10 crore.

7. Conversion rate used: £1 = USD 1.31.

8. <https://www.mordorintelligence.com/industry-reports/united-kingdom-foodservice-market> (7/3/2019, 17:00 hours).

# 2

## Food Safety Regulatory Ecosystem in India

FSSAI is the main authority ensuring food regulatory compliance in India that has been established for laying down science based standards<sup>9</sup> 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. The Food Safety and Standards Act, 2006 (FSS Act), and the rules and regulations under the act form the legal bases for food safety in India and elaborate food safety compliance requirements of FSSAI (Table 1). As such, there are no overarching regulatory philosophy and principles; in essence, the overall regulatory approach of FSSAI is a combination of preventive command and control approach and self compliance. FSSAI lays down food safety standards in the country with periodic checks in the form of audits, testing and inspections; more recently, it has empaneled third party auditors for food businesses and training of food handlers, which indicates a push for self-compliance as a salient feature of food safety regulations.

**Table 1**  
**Food Safety Legislation in India**

Act	Food Safety and Standards Act, 2006 (FSS Act)
Rules	The Food Safety and Standards Rules, 2011
Regulations	
Food Safety and Standards Regulations	Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011
	Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011
	Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011
	Food Safety and Standards (Packaging and Labelling) Regulation, 2011
	Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011
	Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011
	Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016
	Food Safety and Standards (Food Recall Procedure) Regulation, 2017
	Food Safety and Standards (Import) Regulation, 2017
	Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017
	Food Safety and Standards (Organic Food) Regulation, 2017

9. FSSAI is responsible for framing both horizontal and vertical product standards. Horizontal ones cut across categories of foods including standards on contaminants, toxins, residues, packaging, labelling, etc. And vertical standards include identity and compositional standards of specific food products which cover additives, microbiological requirements etc.



	Food Safety and Standards (Alcoholic Beverages) Regulations, 2018
	Food Safety and Standards (Fortification of Foods) Regulations, 2018
	Food Safety and Standards (Food Safety Auditing) Regulations, 2018
	Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2018
	Food Safety and Standards (Advertising and Claims) Regulations, 2018
Enforcement agencies	FSS Act, rules and regulations are applicable on FSSAI and its zonal offices as well as state/UT food authorities

Source: Authors' compilation from FSSAI website (<https://archive.fssai.gov.in/home/fss-legislation/fss-regulations.html>, 26/06/2019, 11:57 hours).

## 2.1 Enforcement of Food Safety Act, Rules and Regulations Thereof

The FSSAI (through the regional offices) and State Food Safety Authorities are responsible for the enforcement of the FSS Act, and monitor and verify that the relevant requirements of law are fulfilled by food business operators (FBOs)<sup>10</sup> at all stages of the food business. The FSSAI includes a Chairperson and CEO appointed by the central government and 22 members representing ministries and departments including agriculture, commerce, consumer affairs, food processing, health, legislative affairs, and stakeholders representing farmers, scientists and technologists, and retail organisations. To fulfil its mandate, the FSSAI is also assisted by scientific panels and scientific committees to set standards and a Central Advisory Committee to strengthen efforts to streamline enforcement of FSS Act across states.<sup>11</sup> There are five FSSAI regional/zonal offices – Chennai, Delhi, Guwahati, Kolkata, Mumbai – in the

country, which cover designated states/UTs<sup>12</sup> within their respective region. These regional offices grant central licenses and are responsible for monitoring and conducting inspections of central license holders. At the state level, there are Commissioners of Food Safety appointed by state governments, who are responsible for efficient implementation of food safety and standards and other requirements laid down under the FSS Act, Rules and Regulations. Further, the Commissioner of Food Safety appoints the Designated Officer (DO), Food Safety Officers (FSOs), and Food Analysts (FAs). DOs are in-charge of the food safety administration of the area and the grant of license to start a food business. As per the FSS Act, there should be one DO for each district. FSOs are *inter-alia* responsible for inspection of food businesses and drawing samples of food for analysis. FAs analyse samples received from an FSO or any other person. In case of contravention of the FSS Act, Rules and Regulations, Adjudicating Officers have the powers to impose penalties in accordance with the provisions, relating to that offence, in the legislation.

Several challenges in the enforcement of food safety legislations were highlighted during our interactions with various stakeholders, the foremost being, differences in interpretation of law by enforcement officers (FSOs) and weak administrative capacity. In general, there is inadequate wherewithal (lack of adequate technical capacity, human resources and finances, and corruption etc., at various levels) to carry out focused regulatory procedures, particularly as only a few states have fully dedicated food safety authorities<sup>13</sup> and most state food safety departments are under government departments (for instance under health/agriculture department). Nevertheless, FSSAI has taken various measures to enhance uniformity of enforcement across states, including regular meeting of health ministers, videoconferencing of FSSAI officials with state/UT food safety agencies, quarterly meetings of the Central Advisory Committee, mandatory induction

10. As per the FSS Act, "Food business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution of food, import and includes food services, catering services, sale of food or food ingredients. And "Food business operator" in relation to food business means a person by whom the business is carried on or owned and is responsible for ensuring the compliance of this Act, rules and regulations made thereunder.

11. The Central Advisory Committee – which comprises CEO FSSAI, states'/UTs' Commissioners of Food Safety, representatives from agriculture/food industry/consumers, relevant research bodies and food laboratories – has quarterly meetings *inter alia* to deliberate on strengthening efforts to streamline enforcement of FSS Act across states.

12. Delhi - Delhi, Haryana, Uttarakhand, Rajasthan, Himachal Pradesh, Punjab, Jammu and Kashmir, Chandigarh, Uttar Pradesh  
Chennai - Kerala, Tamil Nadu, Karnataka, Andhra Pradesh, Telangana, Puducherry, Lakshadweep  
Guwahati - Assam, Arunachal Pradesh, Tripura, Manipur, Mizoram, Meghalaya, Nagaland  
Kolkata - West Bengal, Odisha, Bihar, Jharkhand, Chhattisgarh, Sikkim, A & N Islands  
Mumbai - Maharashtra, Gujarat and Madhya Pradesh, Dadra & Nagar Haveli, Daman & Diu, Goa

13. States like Maharashtra, Madhya Pradesh, and Gujarat are better placed in terms of infrastructure and have separate Food and Drug Administration offices.

and training of enforcement officials to ensure laws are applied uniformly. Additionally, some IT initiatives of FSSAI are also aimed at reducing enforcement challenges – for example, food safety compliance through regular inspection and sampling system (FoSCoRIS) is a web-based real time platform for streamlining inspections. The challenges faced by FBOs in the context of the present legislative framework are discussed in a later section of the report.

## 2.2 Licensing and Registration

Based on the turnover, size and nature of the business (Table 2), FBOs have to register/obtain a license for all their premises before starting their businesses. FSSAI's regional offices are responsible for issuing central licenses in their region and conduct inspections and monitoring of premises licensed by them. On the other hand, state/UT Food Safety Authorities are responsible for granting the state license and registration, and monitoring, and inspections of premises licensed by/registered with them.

Taking prior approval of non-specified food and food ingredients is a necessary precursor to licensing/registration. FBOs have to declare the top three ingredients that constitute 51 percent of the total product composition. For standardised products, i.e., food products/ingredients for which standards are prescribed in the FSS Act, Rules and Regulations, which FBOs conform to, they do not require an approval. In order to cover the other products/ingredients (proprietary and novel) FSSAI has notified the following regulations:

- Food Safety and Standards (Food Product Standards and Food Additives) Ninth Amendment Regulations, 2016,
- Food Safety and Standards (Food or health supplements, nutraceuticals, foods for special dietary uses, foods for medical purposes, functional foods, and novel foods) Regulations, 2016,
- Food Safety and Standards (Food Product Standards and Food Additives) Seventh Amendment Regulations, 2016, and
- Food Safety and Standards (Approval of non-specified food and food ingredients) Regulations, 2017.<sup>14</sup>

14. Press Note, Food Safety and Standards (Approval of non-specified food and food ingredients) Regulations,

In order to clarify regulatory requirements, FBOs may access Indian Food Standards 'Quick Access' which provides standards including general standards and specific standards relating to limits of antibiotic and other pharmacological active substances, food additives, and contaminants<sup>15</sup> for all products. As per our interactions with FSSAI officials, FSSAI has also developed an online system called Indian Food Verification System (IFVS) to help FBOs identify products that require an 'approval' from FSSAI as per Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017. While for the standardised products FBOs get instant approval, approval for proprietary products takes a minimum of 7-10 days for a decision<sup>16</sup> and a fee of INR 50,000. After the approvals, FBOs get a PIN (Product Identity Number) which can be used to apply for a license through the Food Licensing and Registration System (FLRS). FSSAI has facilitated online submission of all documents for licensing/registration through FLRS, which is now operational in all States and Union Territories except Nagaland, and is the most successful IT tool of FSSAI. In future, FSSAI plans to make the FLRS platform more comprehensive by integrating filing of annual returns, inspection details, the generation and tracking of improvement notices, etc.

The legal basis for licensing and registration of food businesses is laid down under Section 31 of FSS Act and Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011. These provide details on procedural requirements and timelines.

Once an FBO has submitted its application, the concerned licensing authority (central/state) may ask FBOs to furnish additional information within 15 days. Subsequently, the applicant has to furnish the required additional information within a period

2017, ([https://fssai.gov.in/dam/jcr:57425cac-1486-4518-add4-6e11f99673bf/Press\\_Note\\_Non\\_Specified\\_Food\\_09\\_02\\_2017.pdf](https://fssai.gov.in/dam/jcr:57425cac-1486-4518-add4-6e11f99673bf/Press_Note_Non_Specified_Food_09_02_2017.pdf), 9/1/2019; 12:15 hours).

15. Also see: Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

16. In some cases, particularly for Novel products, there are high safety concerns. The FBOs are required to submit dossiers containing scientific studies viz. toxicology studies, clinical studies, etc. for the ingredients and additives in use to demonstrate safety of the product composition and health benefits (if any). The dossier is then examined by scientific panel of FSSAI. There is no defined timeline to approve such products; the approval is contingent upon whether the FBO has submitted enough evidence to establish that the novel food is safe for human consumption.

Table 2

**Eligibility Criterion on the Basis of Turnover and Nature of Business to Obtain Licenses or Registration and Timeline for Approval**

	Registration	State Licensing	Central Licensing
Turnover	Less than INR 12 lakhs	Between INR 12 lakh to 20 crore	More than INR 20 crore
Nature of business	<ul style="list-style-type: none"> <li>A petty food manufacturer, i.e., someone who manufactures or sells any article of food himself or a petty retailer, hawker, itinerant vendor or temporary stall holder; or distributes foods including in any religious or social gathering except a caterer</li> <li>Such other food businesses including small scale or cottage or such other industries relating to food business or tiny food businesses with an annual turnover not exceeding INR 12 lakhs and/or whose,</li> <li>Production capacity of food (other than milk and milk products and meat and meat products) does not exceed 100 kg/litres per day or</li> <li>Procurement or handling and collection of milk is up to 500 litres of milk per day or</li> <li>Slaughtering capacity is 2 large animals or 10 small animals or 50 poultry birds per day or less.</li> </ul>	<ul style="list-style-type: none"> <li>All FBOs except mentioned in Column 1 and 3</li> <li>All grains, cereals and pulses milling units.</li> </ul>	<ul style="list-style-type: none"> <li>Manufacturing</li> <li>Dairy units including milk chilling units equipped to handle or process more than 50,000 litres of liquid milk/day or 2500 MT of milk solid per annum.</li> <li>Vegetable oil processing units and units producing vegetable oil by the process of solvent extraction and refineries including oil expeller unit having installed capacity more than 2 MT per day.</li> <li>Slaughter houses equipped to slaughter more than 50 large animals or 150 or more small animals including sheep and goats or 1000 or more poultry birds per day.</li> <li>Meat processing units equipped to handle or process more than 500 kg of meat per day or 150 MT per annum.</li> <li>All food processing units including re-packers and re-labellers having installed capacity more than 2 MT/day except grains, cereals and pulses milling units.</li> <li>FBOs manufacturing/processing/importing any proprietary food for which NOC has been given by FSSAI.</li> <li>100 per cent export-oriented units.</li> <li>Importers</li> <li>All importers importing food items including food ingredients and additives for commercial use.</li> <li>Other businesses</li> <li>Storage (except cold and controlled) with capacity more than 50,000 MT</li> <li>Storage (cold/refrigerated) with capacity of more than 10,000 MT</li> <li>Storage (controlled atmosphere + cold) with capacity more than 1,000 MT</li> <li>Wholesaler/Distributor/Supplier/Caterer/Restaurant/Marketer with turnover greater than INR 20 crores</li> <li>Hotels with 5 star and above accreditation</li> <li>Premises in central government offices</li> <li>Food catering services in establishments and units under Central government Agencies like Railways, Air and airport, Seaport, Defence etc.</li> <li>Storage/Wholesaler/Retailer/Distributor premises in central government agencies</li> <li>Premises in Air/Seaport</li> <li>Registered/Head office of FBOs operating in two or more states.</li> <li>All e-commerce food businesses</li> </ul>



Timeline for approval	<ul style="list-style-type: none"> <li>If registration is not granted, or denied, or inspection is not ordered within 7 days or no decision is communicated within 30 days – the petty food manufacturer may start the business</li> </ul>	<ul style="list-style-type: none"> <li>In case additional information is sought the applicant is required to submit the information within 30 days from such a notice, failing which the application may be rejected.</li> <li>Once the application is completed, the licensing authority may direct an FSO to conduct an inspection, and within a period of 30 days from the receipt of the inspection report (excluding the time taken by the applicant to comply with any remedial advice), the licensing authority may grant license/reject the application.</li> <li>In case no additional information/no remedial actions are indicated in the inspection report within 60 days, the approval is deemed to have been granted, and the FBO may commence business.</li> </ul>
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Source: Food Safety and Standards (Licensing and Registration of Food Businesses), FSSAI Regulations, 2011.

of 30 days from such a notice. In case an applicant fails to submit the information within the stipulated timeframe, the application for license is rejected. Upon receipt of a complete application, the applicant is issued an 'application ID' and the concerned licensing authority may instruct an FSO to inspect the premise.<sup>17</sup> The licensing authority may either grant license or reject the application for license within a period of 30 days from the receipt of inspection report (excluding the time taken by the applicant to comply with advice, if any, as stated in the inspection report). In case, the applicant has not received an intimation of inadequacy or an inspection reports indicating defects within 60 days of making an application, the applicant may start the business. On the other hand, in case of registration, if it is not granted, or denied, or inspection is not ordered within 7 days or no decision is communicated within 30 days, the petty food manufacturer may start the business. FBOs get a unique license number (in Form 'C') to conduct the food business at the particular premise for which license is granted. The FBOs are required to buy and sell food products only from, or to, licensed/registered vendors and maintain its record. All FBOs are required to ensure that the conditions<sup>18</sup> of the license are met at all times during the course of their business. One such condition is furnishing periodic annual returns (Form D-1), in case of milk and milk products (Form D-2) half yearly returns are to be furnished.<sup>19</sup> A registration/license is valid for a period of 1 to 5 years from the date of issue of

registration/license (as chosen by FBOs at the time of making application) from the date of issue of registration/license. As per our discussion with FSSAI office, FLRS notifies the registered user to renew the license within stipulated time of expiry. However, at times, the FBOs do not get SMS alerts because they get licenses through consultants, in which case the consultant gets the alert and not the FBO. If an FBO applies for renewal after the expiry of stipulated time, then the renewal application is considered as a fresh application and a new license number is given. However, as per FSSAI HQ, even in such cases FBOs are given a period of 1.5 years to sell inventory with the old license number.

To regulate online marketing companies involved in the selling of food items, FSSAI has also operationalized, the Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulations, 2018. In this regard, the category 'e-commerce' has been included under food business and procedures for licensing and registration of e-commerce business operators along with their responsibilities have also been prescribed. Whether or not an online food aggregator/e-commerce business requires a license depends on the nature of the business it is involved in. For instance, if the aggregator is only offering an online platform, then it has to have an e-commerce license along with ensuring that their vendors have FSSAI license/registration. In case, it is a multi-brand store, which is not only providing a platform, but is also involved in storage and retailing, they have to obtain separate licenses. Therefore, the liability of businesses depends upon the nature and spread of their operations.

## 2.3 Packaging and Labelling

To raise the food safety bar by emphasizing the role of packaging and labelling, FSSAI, in December

17. As per our discussions with FSSAI's officials, premise inspection before granting license is not mandatory and is dependent upon the nature of the business. Usually, inspection is done for high risk businesses, including meat, poultry, and all animal origin products.

18. 'Conditions of license' (<https://foodlicensing.fssai.gov.in/PDF/LicenseCondition.pdf> (2/1/2019, 10:00 hours).

19. As per our interactions with FSSAI regional office in Chennai, Form D, adjudication and penalty imposed are still manual and have not been made online.

2018, decided to divide the packaging and labelling requirements of FSSAI (as under Food Safety and Standards (Packaging and Labelling) Regulations, 2011) into two separate regulations - (i) the Food Safety and Standards (Packaging) Regulations, 2018; and (ii) the Food Safety and Standards (Labelling and Display) Regulations, 2018.

Food Safety and Standards (Packaging) Regulations, 2018<sup>20</sup> lays down general requirements for the packaging material or any material that comes in direct contact with food or is likely to come in contact with the food. The regulations also lay down specific requirements for primary food packaging including paper and board materials, glass containers, metal and metal alloys, and plastic materials intended to come in contact with food products, and provide a list of suggestive packaging materials for different food categories. These regulations are also aimed at addressing concerns emerged from studies conducted by the FSSAI through the Indian Institute of Packaging, Mumbai and the National Test House, Kolkata on migration of chemical contamination and heavy metals from packaging materials, and chemical contamination from loose packaging material, respectively. These studies reveal that while packaging materials used by the organised sector are largely safe, there are concerns about the use of packaging material by the unorganised/informal sector. Further, the study also highlighted serious concerns about the safety of loose packaging material. In this regard, these regulations prohibit the use of packaging material made of recycled plastics including carry bags for packaging, storing, carrying, or dispensing articles of food. These regulations also prohibit the use of newspaper and such other materials for packing or wrapping of food articles and lays down Indian standards for printing inks for use on food packages taking the carcinogenic effect of inks and dyes into consideration.<sup>21</sup>

The draft Food Safety and Standards (Labelling and Display) Regulations, 2018 specifies general and labelling requirements of pre-packaged foods and display of essential information on premises where food is manufactured, processed, served and stored. The following are some requirements that every package shall carry on its label:

- name of food
- list of ingredients
- nutritional information
- vegetarian/non-vegetarian logo
- declaration regarding food additives
- name and complete address of brand owner
- FSSAI logo and license number
- net quantity, retail sale price and consumer care details
- lot/code/batch identification
- date marking
- country of origin for imported food
- instructions for use

The regulations on packaging and labelling have been a major bone of contention for the FBOs, mainly because of the frequent changes introduced by FSSAI Legal Metrology (Ministry of Consumer Affairs, Food & Public Distribution).<sup>22</sup> Hence, FSSAI has made efforts to reconcile these and new and improved regulations have been brought out after constant revisions.

FSSAI has also finalised Food Safety and Standards (Advertising<sup>23</sup> and Claims) Regulations, 2018<sup>24</sup> which keeps a check on claims and advertisements by FBOs in respect of their food products. As per these regulations, except under specific conditions, FBOs

20. [https://www.fssai.gov.in/dam/jcr:0c1302a2-0a5c-4e40-a124-f91ab3a45b19/Gazette\\_Notification\\_Packaging\\_03\\_01\\_2019.pdf](https://www.fssai.gov.in/dam/jcr:0c1302a2-0a5c-4e40-a124-f91ab3a45b19/Gazette_Notification_Packaging_03_01_2019.pdf) (10/3/2019, 12:00 hours).

21. [https://fssai.gov.in/dam/jcr:d2ed6e25-2cb9-4925-b094-749f9c0e710/Press\\_Release\\_Packaging\\_03\\_01\\_2019.pdf](https://fssai.gov.in/dam/jcr:d2ed6e25-2cb9-4925-b094-749f9c0e710/Press_Release_Packaging_03_01_2019.pdf) (10/3/2019, 12:10 hours).

22. The Legal Metrology (Packaged Commodities) Rules, 2011 were prescribed in order to regulate pre-packaged commodities. Under the said rules, pre-packaged commodities are required to comply with certain mandatory labelling requirements with respect to net quantity, MRP and customer care information. To encourage ease of business operations, amendments to the packaged commodity rules have been notified by harmonising labelling provisions with respect to food products, as laid down under the Food Safety & Standard Regulations, 2017.

23. As per FSSAI Annual Report (2016-17), FSSAI has signed a Memorandum of Understanding (MOU) with the Advertising Standards Council of India (ASCI), to effectively monitor cases of misleading advertisements in the food and beverage (F & B) sector across various media channels.

24. These regulations provide definitions; general principles for claims and advertisements; criteria for nutrition claims (including nutrient content or nutrient comparative claims), non-addition claims (including non-addition of sugars and sodium salts), health claims (reduction of disease risk), claims related to dietary guidelines or healthy diets, and conditional claims; claims that are specifically prohibited; and procedures for approval of claims and redressal of non-compliances under these regulations. See [https://www.fssai.gov.in/dam/jcr:09bc698a-fa5e-45f6-a244-2699092c11ff/Gazette\\_Notification\\_Advertising\\_Claims\\_27\\_11\\_2018.pdf](https://www.fssai.gov.in/dam/jcr:09bc698a-fa5e-45f6-a244-2699092c11ff/Gazette_Notification_Advertising_Claims_27_11_2018.pdf) (10/3/2019, 12:15 hours).

are prohibited open-ended use of words/phrases including 'natural', 'fresh', 'original', 'traditional', 'authentic', 'genuine', 'real' etc. on the food labels.<sup>25</sup> FBOs are directed to comply with all the provisions of these regulations by July 1, 2019.

## 2.4 Ensuring Food Safety by Training and Inspections

While FSSAI regional offices grant central licenses and conduct inspections on such premises, the state/UT food safety agencies grant licenses and conduct inspections for state licenses/registration. Due to the shortage of manpower at the regional offices of the FSSAI, the states bear the larger responsibility to conduct inspections. Additionally, inspectors from the Bureau of Indian Standards (Ministry of Consumer Affairs, Food & Public Distribution) and AGMARK (Ministry of Agriculture & Farmers Welfare) also inspect premises that deal in products under their respective purview.<sup>26</sup> For central licenses, the focus is mainly on inspecting 'high risk' premises viz. meat and poultry (and products of animal origin). It may be noted that all the inspections are premise-based and not company-based because premises of the same company may have different compliance levels due to various reasons (type of license, quality of premise, inputs, etc.). For this reason, even if one premise of a company is compliant, the other premises may still be subjected to inspection. On an average, a standard inspection is reported to last for 20-25 minutes.

Chapter VIII of FSS Act mandates food safety authorities to test food at labs to ensure compliance with food safety standards. It also lays out procedural clarity on sampling and analysis. FSOs take samples of food for analysis and are required to divide the

samples into four parts; one is sent to FAs to analyse samples, two are kept with DO, and one is sent to an accredited laboratory on request of an FBO. In case the report of the FA and accredited laboratory are found to be at variance, the DO sends one of the samples in his custody to the referral laboratory. The cost of samples collected by these regulatory officers is reimbursed to FBOs.

Ensuring food safety is a function of adoption of requisite safety measures in the end-to-end process. Hence merely relying on testing of the finished product may not satisfy the ultimate objective of the regulators. In this regard, as per conditions of license under Food Safety and Standards (Licensing & Registration of Food Businesses) Regulations, 2011, FSSAI requires FBOs to implement an efficient Food Safety Management System (FSMS) based on Hazard Analysis and Critical Control Point (HACCP) and suitable pre-requisites to ensure adequate food safety procedures and practices are followed by FBOs to actively control hazards throughout the food chain. Further, Section 3(1)(s) of FSS Act specifies the adoption of Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP), HACCP, etc. for FBOs. However, FSSAI noted that FSMS requirements are not being completely implemented by some FBOs due to various factors including complexity of regulatory requirements, lack of understanding and awareness about the importance of food safety by food handlers, and the inadequate emphasis paid on the implementation and usefulness of the FSMS plan by the food inspectors in general (FSSAI 2017: 41). To facilitate compliance, FSSAI has developed certain sector-specific FSMS Guidance Documents<sup>27</sup> that lay down general requirements on good hygienic practices to be followed by FBOs and indicate practical approaches, which a business should adopt to ensure food safety. The main aim of these documents is to provide implementation guidance to FBOs (especially the SMEs) involved in manufacturing, packing, storage and transportation to ensure that critical food safety related aspects are addressed throughout the supply chain. The documents are recommendatory in nature and provide the basic knowledge and criteria for implementation of HACCP system by FBOs. In order to introduce fact and data-based technical briefs, the FSMS guidance documents and on-line training programs, FSSAI has also signed a MoU with CHIFSS (CII-HUL Initiative on

25. In case, such names appear on trade mark/brand name of a product, FBOs are required to put a disclaimer on the label (in not less than 3mm size) stating that – "This is only a brand name or trade mark and does not represent its true nature".

26. Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011 has prescribed mandatory certification under the bis act for the following products: Infant formula (IS14433), milk cereal based weaning food (IS1656), processed cereal based weaning food (IS11536), follow up formula (IS15757), packaged drinking water (IS14543), packaged mineral water (IS13428), milk powder (IS1165), skimmed milk powder (IS13334), partly skimmed milk powder (IS14542), condensed milk, partly skimmed and skimmed condensed milk (IS1166). While the AGMARK certification scheme is essentially voluntary, the Food Safety and Standards (Prohibition and Restriction on Sale) Regulations, 2011 have prescribed mandatory certification under AGMARK for certain products including blended edible vegetable oil, fat spread. The FSSAI has prescribed few conditional restrictions in case of til oil, carbia callosa, honey dew, tea and ghee.

27. <https://www.fssai.gov.in/home/safe-food-practices/FSMS-GUIDANCE-DOCUMENTS-FOR-THE-FOOD-BUSINESSES.html> (20/2/2019, 10:00 hours).

Food Safety Sciences)<sup>28</sup> in 2016. Under this initiative, several technical workshops have been organised and guidance documents for bakery items, edible oils, ice-cream, ghee, jams, jelly and marmalade, meat and meat products (poultry), fish and fish products have been published.<sup>29</sup>

Further, with the prime moto of 'educate first and then examine', FSSAI has also initiated Food Safety Training and Certification (FoSTaC) for capacity building of FBOs across the food value chain. In this regard, FSSAI has developed 16 short duration courses (4 to 12 hours) focusing on FSMS practices, GHP and GMP at 3 levels – basic, advanced and special – for training of Food Safety Supervisors covering various sectors of the food business, viz., catering, manufacturing, storage, retail and transport, and even for product-specific areas including milk, meat and poultry, oil etc. FSSAI recommends that under FoSTaC all licensed FBOs must have at least one trained and certified Food Safety Supervisor for every 25 food handlers in each premise. Under FoSTaC, around 4000 training programmes have already been conducted.<sup>30</sup>

Further, FSSAI has developed inspection checklists based on Schedule 4 of the Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011, for general manufacturing, milk processing, meat processing, slaughtering, catering, retailing, transporting, storing and warehousing. These checklists cover five major sections including design and facilities, control of operation, maintenance and sanitation, personal hygiene, and training and complaint handling. FSOs inspect the premises of FBOs according to the requirements laid down in these inspection checklists and mark the level of compliance by FBOs (table 3). The final grading of premises is done at 4 levels, which is shared with the FBOs for corrective action. Hence, the final inspection reports are also shared with the FBOs, and in case their performance is not up to the mark, they are given improvement notices. In case the defaults are significant from the perspective of food safety, licenses can be cancelled, however, such an event has been quite rare. In this regard, FSSAI also affirms that while its central focus is on food safety, it also constantly work towards streamlining compliance requirements for FBOs without jeopardising its main objectives.

At present, the data generated through manual inspections is not centralised and state-wise information is not aggregated and shared across the states. In order to increase transparency and conduct inspections objectively, FSSAI has developed FoSCoRIS (Food Safety Compliance through Regular Inspections and Sampling), a system to verify compliance with food safety and hygiene standards by FBOs as per regulatory requirements through inspections and sampling. As per our discussions with FSSAI, FoSCoRIS has only been introduced in 3 states - Tamil Nadu, Madhya Pradesh, and Punjab. Since it is the prerogative of the states to introduce it, FSSAI is in the process of building consensus with more states. In the case of states that lack adequate wherewithal, FSSAI is also taking steps to facilitate the development of required infrastructure and is planning to develop offline modules of FoSCoRIS.

## 2.5 Towards Risk-based Inspections

To develop an overall approach to compliance on part with the global standards, FSSAI is in the process of adopting a risk-based approach for inspections and surveillance. The major objectives of risk-based inspection system (RBIS) are (i) to prevent unsafe food being placed on the domestic market (ii) to transform the food inspection system from a product-based process to a risk-based process that can be used by food inspectors across the entire food sector, regardless of the specific product(s) handled or manufactured and (iii) linking 'risk grade' with licensing and registration system (FSSAI 2017). FSSAI had also framed some guidelines for 'risk-based' inspections in 2017. 'Risk' is defined on the basis of 'premise' and 'nature and kind of business'. For instance, milk and meat establishments are frequently inspected due to high risk of contamination. In this regard, FSSAI has developed the following rule for risk-based inspections by defining grade rules for classification of FBOs to determine risk categories and inspection frequencies:

$$N = R_i \times Pr_i \times V_x$$

wherein N is the risk grade and,  $R_i$  is the theoretical risk of the establishment based on kind of business (milk, meat, etc.) and type of food handled in the premise (manufacturing, slaughter, processing, catering, storage, etc.). Two values for  $R_i$  have been suggested – '1' for establishments handling only food of plant origin/retail, and '4' for all establishments handling food of animal origin and catering services,  $Pr_i$  is the proposed product risk ranking for low-risk category (0.1), medium-risk category (.25), and high-

28. [https://fssai.gov.in/home/partnerships/FSSAI\\_MOUs.html](https://fssai.gov.in/home/partnerships/FSSAI_MOUs.html) (25/2/2019, 13:00 hours).

29. <http://www.chifss.in/fsm.html> (26/2/2019, 11:00 hours).

30. <https://fostac.fssai.gov.in/fostac/index> (12/2/2019, 12:00 hours).



Table 3

## Compliance Scores Given by FSOs Post Inspections

S. No.	Finding	Marks to be awarded	Marks to be awarded in Asterisk Mark (*) question
1	Compliance (C)	2	4
2	Non-compliance (NC)	0	0
3	Partial compliance (PC)	1	0
4	Not applicable/Not observed (NA)	2	4

Note: \* mark questions are critical to food safety.

C – Yes, the requirement is fully documented and implemented.

NC- No, the requirement is not documented and implemented. Non adherence with the requirement with major non - conformance is observed.

PC – Requirement is partially implemented but not documented or partially documented but not implemented. A non-conformity that, based on the judgement and experience of the FSO, is not likely to result in the failure of the food safety management system or reduce its ability to assure controlled processes or products. It may be either a failure in some part to a specified requirement or a single observed lapse. The observation, 'PC' is not applicable to requirements that are critical to food safety (i.e. the asterisk mark questions).

NA – Requirements are not applicable to premise & hence cannot be observed.

Source: FSSAI website (<https://archive.fssai.gov.in/home/compliance/FOOD-SAFETY-INSPECTION-CHECKLISTS-.html>, 26/06/2019, 12:13 hours).

risk category (.75), and V is the production volume for registration (V=1), state license (V=2) and central license (V=3). The risk matrix, based on risk grade and compliance profile, is expected to suggest the periodicity of inspection, and help in rationalising resources of enforcement agencies.<sup>31</sup>

FoSCoRIS is expected to help with risk-based inspections by facilitating a risk-matrix across states, which can help streamline and prioritize inspections by aggregating company-wise information and highlighting high risk premises. FSSAI has also developed an IT solution for the Indian food laboratory network called InFoLNet, which is a national track and trace lab network that targets details of samples allocated to the labs and integrates the process of sample testing at different stages. This laboratory management system (LMS) is a one-stop portal that contains all the information regarding a laboratory, including ownership details, infrastructure availability, technical capacity, and the scope of testing through to test results of different samples. This centralised system aims to connect and collate the network of laboratories and help categorise laboratories on the basis of regulatory requirements, routine testing, appellate testing etc. As per FSSAI, this LMS will also be integrated to other FSSAI core IT systems, such as FLRS (Licensing and Registration), FICS (Import Clearance), Quick access, FoSTAC, etc. and contribute to defining risk analysis, enriching

standards, capacity building and training.<sup>32</sup> It may be noted that, in their present form, some of the IT tools have duplicate information for instance, 'Quick Access' and a tab under InFoLNet provide the same information on standards. Such duplication could create confusions among FBOs. Multiple IT tools are also cumbersome to operate, and as is elaborated in later sections, most FBOs are not even familiar with most of these other tools apart from FLRS and FICS.

In this regard, FSSAI envisages to integrate most of its IT tools in form of Food Safety and Compliance System (FoSCoS) with the aim of increasing transparency and facilitating ease of doing business.

## 2.6 Self-compliance

Further, to promote a culture of self-compliance, FSSAI has issued a list of empanelled third party auditors through which FBOs can get their premises inspected. As of now, this is not mandatory. However, it may become mandatory for high-risk products wherein the risk classification will take into account factors including food type and intended use for consumer, kind of business, method of processing, consumer base etc. FBOs with satisfactory audits may be subjected to less frequent audits by central or state licensing authorities. This is seen to be helpful even from a regulatory perspective, as there is a dearth of FSOs in the system, and empanelled third

31. Manual for Food Safety Officers, FSSAI

32. <https://foodregulatory.fssai.gov.in/food-testing> (12/2/2019, 15:00 hours).

party auditors can share the inspection and auditing burden of central and state licensing authorities. Additionally, in order to enhance their credibility and foster public trust, FBOs (mainly with global presence)

also get voluntary certification from bodies such as ISO 22000<sup>33</sup> and a range of certification programmes that are recognised by the Global Food Safety Initiative.

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33. ISO 22000 is the family of international standards that addresses food safety management. ISO 22000:2018 states FSMS requirements for any origination under food chain. (<https://www.iso.org/standard/65464.html> (12/2/2019, 15:15 hours)).

# 3

## Food Safety Regulatory Ecosystem in the UK

### 3.1 FSA and Food Legislations in the UK

The Food Safety Authority (FSA) – an independent non-ministerial government department of the UK, which operates across England, Wales and Northern Ireland – is responsible for protecting public health and consumers' wider interest in relation to food. In April 2015, FSA's national office in Scotland was replaced by Food Standards Scotland. Therefore, now FSA's purview is limited to England, Wales and Northern Ireland and it is the Central Competent Authority for the regulation of food businesses located in these regions. Instead of being directly governed by ministers, FSA is governed by a board comprising of 8-12 members. These board members are selected by the Secretary of State for Health and Social Care.<sup>34</sup>

The premises of major food legislations in the UK are derived from European Union food safety legislations including General Food Law Regulation (EC) 178/2002, Food Information to Consumers Regulations (FIC) 1169/2011, Official controls for Feed and Food Law 882/2004, etc. The responsibility for formulating food law in the UK is divided between FSA, Department for Environment, Food and Rural Affairs (DEFRA)<sup>35</sup> and Department of Health. In England, DEFRA is responsible for food labelling, except for matters of food safety such as 'use by' dates, allergens labelling, etc., which is handled by the FSA. The Department

of Health has the central responsibility for nutrition-related food legislation in England. In Wales, the FSA retains responsibility for general food labelling. The Welsh Government is responsible for nutrition related food legislation. In Northern Ireland, the FSA retains responsibility for both general food labelling and nutrition related food legislation.

The Food Safety Act 1990, is the prime legislation on food safety and consumer protection and covers all activities across the food value chain. The Act covers food operations including preparing, presentation and labelling, storing, transporting, selling and possessing with a view to sale and import and export of food.<sup>36</sup> FSA is the principal government department responsible for preparing specific regulations under the Act. Table 4 presents the key regulations that provide a framework for the legal basis to ensure food safety in the UK.

### 3.2 Registration Process

Registration of the premise is the first step for starting any food business in the UK. FBOs operating in the UK need to get their businesses registered with the local authority (LA). FBOs should contact LA at least 28 days before starting any food operations. All kinds of food businesses that directly sell to customers including restaurants, cafes and takeaways; catering businesses run from home, bed and breakfast hotels, mobile

34. One member is appointed by the Welsh Health Minister, and one by the Northern Ireland Health Minister.

35. DEFRA only works directly in England; it works closely with the devolved administrations in Wales, Scotland and Northern Ireland, and generally leads negotiations in the EU and internationally.

36. <https://www.food.gov.uk/sites/default/files/media/document/Food%20standards%20safety%20act%201990%20PDF.pdf> (5/3/2019, 15:20 hours).

Table 4

**Key Regulations – Legal Basis to Ensure Food Safety Requirements in the UK**

Key regulations	Explanations
Food Safety Act 1990 Parallel instrument in Ireland – Food Safety (Northern Ireland) Order 1991	Provides the framework for all domestic food legislation in England, Wales and Scotland and provides powers to make secondary legislation to implement EU food Laws.
Food Standards Act 1999	Established the FSA.
Novel Foods and Novel Food Ingredients Regulations 1997 Extends to the whole of UK.	Includes pre-market safety assessment and authorization.
Genetically Modified Food (England) Regulations 2004*	Formally designate the FSA as the national competent authority to receive applications for the authorisation of new genetically modified organisms for food use.
Materials and Articles in Contact with Food (England) Regulations 2012*	
Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013*	
Food Safety and Hygiene (England) Regulations 2013*  Amendments: The Food Safety and Hygiene (England) (Amendment) Regulations 2014, The Official Feed and Food Controls (England) and the Food Safety and Hygiene (England) (Amendment) Regulations 2014 and The Food Safety and Hygiene (England) (Amendment) Regulations 2016.	Apart from laying down the food hygiene rules for all food businesses, it also covers enforcement of certain provisions of Regulation (EC) 178/2002.
Food Information Regulation 2014	Instrument for enforcement of Regulation (EC) 1169/2011 on provision of food information to consumers. This regulation brings together general labelling, nutrition and allergen labelling into a single piece of legislation.
Food Hygiene Rating (Wales) Regulations 2016 Food Hygiene Rating Act (Northern Ireland) 2016	

Note: \* Parallel instruments for Wales and Northern Ireland exist.

Source: Authors' compilation from FSA (UK) website (<https://www.food.gov.uk/>, 26/06/2019, 12:17 hours).

catering and temporary businesses; marquees, food stalls, food pop-ups and food vans; nurseries, schools and care homes and distance selling, mail order and online food delivery need to get their businesses registered. In cases where an FBO operates in more than one premise, it needs to register separately with the LA of each of the premises. FBOs do not have to pay any registration fee for getting their food businesses registered.

In place of registration, wholesale businesses including establishments dealing with meat, fish, egg and dairy products need to apply for a 'food premise approval', which is given only after an inspection by the competent authority under Regulation (EC) No 853/2004.<sup>37</sup> As part of the approval process, the competent authority will inspect the equipment and structure of the establishment and assess whether

a food safety management system is in place. Once such a business gets approval, within three months veterinary officials come to assess production and compliance with the hygiene requirements of Regulation (EC) No 852/2004 and 853/2004. FBOs that are involved in direct supply of small quantities of primary products, food containing both products of plant origin and processed products of animal origin (composite products), collection centres and tanneries supplying raw material for the production of gelatine or collagen intended for human consumption are exempted from the process of getting approvals.

Apart from seeking a premise approval and applying for getting their businesses registered, FBOs need to inform local authorities if they want to make any changes to the premise where food operations are being handled. In case an FBO plans to construct something new or change the use of the building where food is being handled, a 'planning permission' will be required from the local planning authority.

37. List of approved food establishments has been uploaded on the FSA website and it is updated on a monthly basis.



### 3.3 Novel Foods Legislation

Novel foods<sup>38</sup> are required to have a pre-market safety assessment and authorisation, which is governed by the Novel Food Regulation (EC) No 2015/2283. The regulation is applicable on any food and food ingredient that have not been used significantly in the EU before May 1997. All novel foods already authorised by the EU are included in the union list (novel food catalogue). If an FBO intends to market a food that is not there in the union list then it needs to apply for authorisation under the Novel Food Regulation (EC) No 2015/2283. The European Food Safety Authority (EFSA) conducts safety evaluation and scientific risk assessment of these novel foods and provides their recommendations to the European Commission.

### 3.4 Labelling and Packaging Compliance Requirements

General food labelling and nutrition labelling legislations in the UK are based on the European Food Information to Consumers (FIC) Regulation 1169/2011. Northern Ireland, UK and Wales enforce this legislation through the Food Information Regulations 2014. It includes legislation on mandatory nutrition labelling on pre-packaged food, country of origin, date marking (including date of first freezing), clarity of food information, alcohol labelling, labelling of non-pre-packed foods and allergen labelling.

Mandatory food labelling requirements for all pre-packed food labels are the following:

- name of the food
- list of ingredients
- ingredients or processing aids causing allergies or intolerances
- quantity of certain ingredients or categories of ingredients
- net quantity of the food
- date of minimum durability or the 'use by' date
- special storage conditions and/or conditions of use
- name or business name and address of the food business operator
- country of origin or place of provenance
- instructions for use where it would be

difficult to make appropriate use of the food in the absence of such instructions

- alcohol strength by volume for beverages containing more than 1.2 % of alcohol
- nutritional declaration

Apart from these mandatory food labels, there are special labelling rules for certain products like bottled water, bread and flour, cocoa and chocolate products, fats and oils, fish, fruit juices and nectars, honey, jams and preserves, meat and meat products, milk and milk products, soluble coffee and sugar, etc. As a rule, food catering businesses also have to provide information about the use of allergenic ingredients to their customers.

### 3.5 Division of Responsibility

Apart from general labelling pertaining to safety (use by dates, allergen information, etc.) and nutrition, DEFRA is responsible for all food labelling and food compositional standards in the UK.

- Nutrition labelling: Food supplements, fortified foods and foods for specific nutritional uses must follow certain additional rules. The Department of Health has been given the responsibility for drafting legislations on food supplements in England. In Ireland, FSA is responsible for general food labelling including foods for nutritional uses. In Wales, the Welsh government is responsible for it.
- Organic food need to be certified from the UK approved organic control bodies. All those FBOs who are dealing with food sold as organic must be registered with an approved certification body; they are also subject to regular inspections.

### 3.6 Food Safety Inspections and Enforcement

Inspections are carried out by the LA to enforce food safety and hygiene laws in the UK. Authorised Officers (AOs) have to follow the Food Law Code of Practice (FLCP) while conducting these inspections. As per FLCP, AOs can inspect premises, food, records and procedures including identification of all food related activities undertaken by the business, areas of the establishment used for the preparation, production and storage of food items, all the processes used, the staff involved, etc. As part of inspections, AOs check compliance with product specific legislation, evaluate the efficacy of the controls in place for managing risk of cross contamination, ensure that FBOs have an

38. Newly developed, innovative food or food produced using new technologies and production processes, as well as food traditionally eaten outside of the EU.

active and HACCP plan for their premise and have a sound understanding of the hazards posed by food businesses activities. Apart from conducting hygiene and food standards inspections, AOs can also visit premises of FBOs for sampling, compliance follow-up and advisory visits. AOs can also take enforcement action against an FBO not complying with the food safety and hygiene compliance requirements of the FSA. FBOs can directly appeal against a decision made by the LA, if they disagree with the decision of the AOs.

FSA has also prepared a 'food safety checklist' for FBOs that covers the key aspects to be checked during an inspection.<sup>39</sup> FSA has created specific food safety guidelines for businesses in the food service sector i.e. restaurants, cafés, takeaways and other small catering businesses. These guidelines are called *Safer Food, Better Business (SFBB) packs* and it include information on cleaning, chilling, cooking and ways to avoid cross contamination. FBOs are required to maintain an SFBB diary either in electronic or printed forms. LA food safety officers inspect these diaries on a regular basis.

Enforcement of regulations on food standards, safety and hygiene is the responsibility of the local authorities<sup>40</sup> – Environmental Health Officers and Trading Standards Officers – under the oversight of the FSA. In particular, the Trading Standards Department of the LA ensures that food is correctly and accurately labelled, it contains legal ingredients and any claims made are truthful. They also act on national food safety alerts and issue press releases to inform local businesses and consumers about product recalls and food alerts. The Environmental Health Department of the LA deals with issues of hygiene, cases of microbiological contamination of foods, and with food that is unsafe (for any reason including chemical contamination) for consumption.

Businesses that present a higher risk to public health are more frequently inspected vis-à-vis businesses that do not pose such a risk. FSA is trying to implement a new 'risk management framework' that will determine the nature, frequency and intensity of the controls that a food business will be subject to in the future. Through this, FSA expects to identify those businesses that can demonstrate sustained compliance and intends to reduce their regulatory burden by ensuring that intervention is proportionate.

### 3.7 Coordination between the FSA and LAs

Through a 'framework agreement', the FSA oversees the work of LAs and provides them with guidance to ensure that LAs are consistent while enforcing the relevant laws for food and animal feed. In this manner, LAs are authorised to undertake a range of food related enforcement activities such as inspections of food businesses, auditing and sampling visits on behalf of FSA. Generally, FSA advises LAs on enforcement, particularly through the issuing of statutory Food Law Codes of Practice (FLCP).<sup>41</sup> To complement the FLCP, FSA has also issued separate 'practice guidance documents', which among other things, advises local authorities on the timing and frequency of inspections for food businesses. Local authorities are also audited as part of the 'Feed and Food Law Enforcement Standard in the Framework Agreement', which sets out the minimum standards of performance expected from LAs against their ambit of enforcement activities.

FSA also captures data on food law enforcement activity undertaken by LAs through a web-based system, 'Local Authority Enforcement Monitoring System (LAEMS)', which is published on an annual basis. It captures data on various aspects of food hygiene interventions including inspections and audits, verification and surveillance, sampling visits, etc., and food hygiene enforcement actions including the incidences of detention/seizing of food, suspension of license, hygiene improvement notices, simple cautions, written warnings, etc.

To ensure better coordination between the two agencies, FSA has developed a web-tool called FSA smarter communications,<sup>42</sup> which is the prime

39. <https://www.food.gov.uk/sites/default/files/media/document/food-safety-checklist.pdf> (13/3/2019, 14:30 hours).

40. Local government in England operates under either a one-tier system (unitary authorities) or a two-tier system (county or district councils). There are five types of local authorities in England: county councils, district councils, unitary authorities, metropolitan districts and London boroughs. There are 353 councils in England – Two-tier: 27 county councils (not including Isle of Wight unitary); 201 district councils and Single tier: 33 London boroughs (including the City of London); 36 metropolitan districts; 55 unitary authorities (including all county unitary authorities); and 1 Isles of Scilly. Scotland (32 councils), Wales (22 councils), North Ireland (11 councils) have unitary single-tier council structure.

41. Separate codes of practice are available for England, Scotland, Wales and Northern Ireland.

42. <https://fsa.riams.org/marketing> (13/3/2019, 14:30 hours).

portal to locate resources such as forms, templates, toolkits and guidance. Through this tool, LAs can also customise the type of communications they want to receive from FSA and the frequency of such communications. Within this web tool, there is a feature 'forum platform', where FSA, local authorities, councils and stakeholders can share documents and initiate discussions on relevant issues.

### 3.8 Primary Authority (PA)

Primary Authority (PA) is a statutory scheme established by the Regulatory Enforcement and Sanctions Act, 2008. The scheme was launched across England and Wales in 2009 by the Department for Business, Energy and Industrial Strategy (BEIS) to improve and streamline the enforcement of regulation by local authorities. Since April 2012, the PAs have been the responsibility of the Secretary of State and are administered by the Office for Product Safety and Standards (OPS&S) at the BEIS. The scheme allows an eligible business to form a legally recognised partnership with a single LA. PAs are critical from the perspective of shaping and improving the regulation practices of businesses that partner with them. Forming a legal partnership with the LA makes it easier for businesses to receive assured and consistent regulatory advice, which ensures that businesses are committed to comply with norms and regulations. A business can have two kinds of partnership with the PAs either - i) a direct partnership, or ii) a co-ordinated partnership which is co-ordinated by a third party such as a trade association. By sharing information and knowledge about the partner business, PAs could also help enforcing authorities to target their resources in a more efficient manner. After the feedback received from the enforcing authority, PAs are in a better situation to build a more comprehensive picture of compliance and provide assured regulatory advice that is more targeted to the needs and circumstances of individual business.

FSA is also trying to explore the role of PAs, especially in the context of regulation of multi-site food businesses or groups of food businesses, emphasising the need to put increased focus on controls that operate at the business level rather than at the level of each individual outlet. A PA partnership can cover the full range of regulatory services or some specific aspects of regulatory compliance such as product labelling, health and food safety, etc. PA also prepares an 'inspection plan', which serves as a practical guide and background information source and is quite useful for enforcing authorities while conducting

their checks on the business. An inspection plan assists the enforcing authority with reference to the risk assessment of a business premise. Based on this, the PA can also establish a 'national inspection strategy' (NIS) through which it takes on the responsibility for coordinating compliance checks on the business across all its premises, products or activities through a risk-based programme. If a food business is deemed to be well managed then the PA could reduce the frequency at which outlets are inspected by LAs. This allows LAs to use their scarce resources on establishments that pose a greater risk to public health.

To identify the feasibility and practicality of the concept of NIS, eight PA partnerships were brought together in 2017, which resulted in a feasibility study paving the way for the concept of NIS.<sup>43</sup> FSA has also developed three NIS draft standards that consist of a set of criteria that primary authorities should fulfil for operating an NIS for food hygiene and/or food standards.<sup>44</sup>

### 3.9 Food Hygiene Rating Scheme (FHRS)

FHRS aims to improve compliance through transparency and consumer choice with a greater objective of reducing food borne diseases. It provides consumers with better information to make decisions about where to eat. FHRS is applicable for businesses where food is directly sold or consumed — for instance, restaurants, canteens, hotels, supermarkets, food vans, etc. that directly supply to consumers. The premise of FHRS is the 'food hygiene intervention rating scheme' set out in the FLCP. Based on the findings of inspections conducted by AOs, food hygiene ratings are given to all food businesses. FHRS ratings are snapshot of the standards of food hygiene found at the time of inspection and are based on the performance of the businesses on the following parameters:<sup>45</sup>

- how hygienically the food is handled – how it is prepared, cooked, re-heated, cooled and stored

43. <https://www.food.gov.uk/about-us/sixth-edition-of-regulating-our-future-newsletter#primary-authority-national-inspection-strategy-feasibility-study> (11/3/2019, 11:50 hours).

44. Primary authorities seeking to develop a national inspection strategy for food must engage with the FSA at the earliest opportunity to discuss their proposal and how they intend to demonstrate meeting the relevant criteria.

45. <https://www.food.gov.uk/safety-hygiene/food-hygiene-rating-scheme> (13/3/2019, 14:30 hours).

- the physical condition of the business  
– including cleanliness, layout, lighting, ventilation, pest control and other facilities
- how the business manages ways of keeping food safe, looking at processes, training and systems to ensure good hygiene is maintained. Based on this, the officer can assess the level of confidence in standards that might be maintained in the future.

Ratings are given on a scale of zero to five<sup>46</sup> – a good rating represents that a particular food business premise is complying with requirements related to food hygiene. Currently, FHRS is voluntary in the UK while it is mandatory in Wales and Northern Ireland. These rating stickers are displayed at the premises and published online as well so that consumers can make informed choices. Through the mechanism of appeal procedures, FBOs can request LA for a re-inspection once they have made improvements based on the feedback given by AOs during their last inspection.

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46. Rating scale: 5 – hygiene standards are very good, 4 – hygiene standards are good, 3 – hygiene standards are generally satisfactory, 2 – some improvement is necessary, 1 – major improvement is necessary, 0 – urgent improvement is required.

# 4

## Challenges for Food Business Operators (FBOs) in India

Before proceeding with our discussion on challenges faced by FBOs in complying with FSSAI's food safety directives, it needs to be kept in mind that there are only a few studies/surveys vis-à-vis the food safety regulatory compliance burden in India based on industry interactions. We shall briefly discuss the scope of these studies here. First, the 'UKIBC's 4th annual doing business in India report: The UK perspective' (November 2018) presents survey responses from 89 UK companies, of which less than 6 percent were from the food and drinks sector. In terms of focus, it looks at broader barriers to doing business in India, not food safety regulatory compliance burden in the food and drinks sector. Second, the 'India food and beverage sector: The new wave' (2014) report of CII and Grant Thornton focused on selected sub-segments of the F&B sector and invited comments from some of the top players on opportunities and challenges. It occasionally refers to the food safety compliance burden without specifying the regulatory aspects leading to the burden or further analysis. Third, the CIFTI-FICCI survey on 'Industry challenges in food regulations' (May 2010) was about awareness, challenges and expectations vis-à-vis FSS Act of nearly 700 food processing domestic and multinational companies in India across sectors, states and size. Finally, the 'Food regulatory environment: Inspiring trust, assuring safe and nutritious food, creating an enabling business environment' (2017) report of MoFPI, FSSAI, CII and KPMG is purportedly a guide for both foreign and domestic food processing, food retail and related supply chain companies that are willing to invest or expand their operations in India.

As discussed before, since the enactment of the FSS Act in 2006 that consolidated all food safety legislations spanning across various ministries and departments, the realm of food safety has expanded beyond its primitive mandate of merely preventing food adulteration. However, it is often argued that the historic merger of erstwhile laws, rules and regulations for food safety should have been backed by reforms to alter existing institutional arrangements in order to deal with challenges emanating from financial constraints and human resource shortages. Despite the presence of such impediments, the FSSAI has taken significant measures to overhaul India's food safety ecosystem. At this juncture, it is worthwhile to point out that almost all our respondents were of the belief that the FSSAI has dramatically strengthened the food regulatory system in the country in the past four years. While our interactions revealed that the onus of understanding food regulations and changes made to these is entirely on FBOs, it would be unfair to term FSSAI's compliance requirements 'burdensome' from the perspective of FBOs. Nevertheless, it is imperative to discuss the challenges being faced by FBOs in complying with FSSAI's food safety regulations. We have segregated these challenges into broad themes and presented them below.

### 4.1 Impediments to Transparency

#### 4.1.1 Inadequate Awareness

All our respondents said that they regularly visit FSSAI's website to keep abreast of new regulations and changes made to existing regulations. This is often challenging for them because relevant information



is not easily accessible and exhaustive exploration of the website is often required to find up-to-date information. Further, prominent industry associations like the Federation of Indian Chambers of Commerce and Industry (FICCI) and the Confederation of Indian Industry (CII) share notifications about changes with member FBOs. However, most respondents believed Indian FBOs, particularly small and medium-sized enterprises (SMEs), are not adequately informed about FSSAI's regulations. The Parliamentary Committee Report (PCR) on the functioning of the FSSAI in August 2018 also pointed out that around one-third of FBOs in India are not aware about the FSS Act and its regulations. This is primarily because of a disproportionately large unorganised sector that often does not have access to the internet or digital media messages. While some FBOs felt that they sought clarification from FSSAI by calling on their helpline numbers, a few of them told us that they visited FSSAI's regional offices by taking prior appointments to seek clarity on regulations. It is also worthwhile to mention here that with the exception of FLRS, FBOs were not familiar with recently launched initiatives of the FSSAI for streamlining compliance procedures.

#### 4.1.2 Incorrect Interpretation

As noted by the Regulatory Reform Committee of the House of Commons in the UK Parliament (2008-09, Volume II: Ev 3), 'misunderstanding regulatory requirements can lead businesses to incur additional costs, through the use of external consultants or over-compliance with the rules. There is also the risk that a lack of clarity over regulatory responsibilities can lead some businesses to not comply fully or not adapt their business practices.' The report further points out that SMEs are particularly vulnerable on this issue. Most of our interviewees, including foreign multinational food companies, felt that it is difficult to accurately interpret FSSAI's food safety guidelines because they are 'too technical' to be understood and implemented by someone who does not have prior knowledge/background in food quality and safety. Moreover, language was cited as a major barrier to correctly understand food safety compliance requirements of FSSAI – the lack of an option to translate the documents into regional languages and the lack of proficiency in English/Hindi could be challenging for a vast majority of FBOs operating in the unorganised sector. We were also told that there are often ambiguities in the specified guidelines – FBOs felt that even within a single document, there are 'contradictory' statements.

According to several FBOs, unavailability of information on FSSAI's website in a structured way is the major reason why misunderstandings arise

with regard to implementing FSSAI's food safety directives. We were also informed that the absence of specific guidelines for certain food (like genetically modified) and provider (like cloud kitchens) categories is often an important cause of incomplete/incorrect understanding on the part of FBOs.

#### 4.1.3 Malpractices

While the food safety regime in India has undergone remarkable transformation over the last four years, the menace of corruption is still quite widespread in the food industry. As highlighted by the PCR, some FSOs engage in unscrupulous practices, blatantly violating the food safety norms specified in the FSS Act 2006 and jeopardizing the lives of millions of consumers.

- **Inspections:** Our survey confirms that the risk-based approach to inspections is currently not followed in India. However, all food service providers who we met during our survey were quite satisfied with the current inspection process. They said that inspections take around 30-45 minutes and in addition to examining the hygiene of their kitchens, FSOs also ensure whether the FBOs are procuring ingredients from only FSSAI certified suppliers. On the other hand, owners of food processing businesses in Mumbai and Chennai complained about the 'bribe-seeking behaviour of FSOs' at the time of inspections. According to one respondent:

'Inspections in my food processing unit have happened twice since 2011 and lasted for almost 13 hours each time. Both times, the FSOs entered my factory without signing the visitors' register. Despite knowing that all our transactions happen digitally and we use cash only for limited purposes, they compelled us to bribe them late at night. Our unit has an ISO 22000 certificate as well and we export our products to a number of countries. Unlike ISO officers who invariably act as guides, FSSAI's FSOs treat us as if we were culprits.'

In order to curb such unethical practices, the PCR recommended that all inspection reports should mandatorily be accompanied by photographs capturing different sections of a premise. FoSCoRIS, FSSAI's real-time web-based platform for increasing uniformity and transparency in inspections and sampling through special features like geo-tagging, time-stamping and real-time verifications, is expected to reduce the enormity of the problem.

- **Sampling and confiscation of food:** Although FSSAI has identified clear guidelines for procuring food samples from FBOs, our interactions revealed that problems related to lifting, storing and sending samples for analysis are quite common. Delays in sending food samples to laboratories, which can typically yield misleading results especially in the case of perishable products, is the most worrying aspect for FBOs. Further, as stated in the Comptroller and Auditor General report on the implementation of FSS Act (2017), dearth of required infrastructure such as refrigerators and insulated containers for safe storage of samples is another reason why samples deteriorate before they reach laboratories. In accordance with the recommendation of the PCR, the FBOs suggested that FSOs should submit samples to food analysts within a specified time limit that could vary by type of product. When asked whether or not they are reimbursed for food samples procured by FSOs, the responses we received from FBOs were mixed.

An additional aspect that merits attention in this context is related to the confiscation of food articles by FSOs. Misunderstandings with regard to seizure of food articles are likely to arise because the FSS Act does not have 'provisions fixing the responsibility for the custody of the seized article' (PCR 2018: 45). We would like to substantiate this point further by quoting one of our respondents:

'In our last inspection, the FSO took 3 samples for which we were not reimbursed. We did not even get the reports of our samples from the FSO. We had to pay INR 5,000 for getting the reports from the laboratory. The FSO also confiscated our *maida* on the pretext that it was bleached. We had procured the *maida* from an FSSAI certified vendor and the vendor had guaranteed us its authenticity. The FSO kept the *maida* separately and it is still there because we cannot legally discard confiscated products. The shelf life of *maida* is too short. We were told that we needed a certificate from the *Gram Panchayat* (the FBO operated within the jurisdiction of *Gram Panchayat*) to discard the *maida* but the *Gram Panchayat* told us that it could not give any such certificate to us.'

#### 4.1.4 Consultations

Even though all FBOs were of the view that they get an opportunity to share comments on draft versions of new/revised regulations with FSSAI,

many of them believed that there is lack of transparency in the way regulations are finalised. Unlike international regulators like FSA in the UK and Food and Drug Administration (FDA) in the US that seek comments from the industry, publish them and then give justifications for acceptance or rejection of comments, FBOs believed that the FSSAI does not provide a proper rationale before formulating regulations. Moreover, a number of FBOs recommended that they should be involved in consultations with FSSAI from the early stages of developing regulations.

## 4.2 Impediments to Predictability

### 4.2.1 Changes in Regulations

Frequent and sudden changes in regulations were reported as a major barrier to smooth functioning of FBOs. As one of our respondents puts it, 'uncertainty about changes does not let us do business with a free mind.' This is particularly true for food processing units that have to bear huge losses predominantly resulting from abrupt changes made to labelling regulations. For instance, one respondent whom we met in January 2019 had apparently come to know through 'insider' sources that FSSAI would issue a directive requiring all FBOs to relabel '*maida*' as '*refined wheat flour*' and '*atta*' as '*whole wheat flour*'. We were informed that this change is going to lead to enormous losses for the FBO as labels for inventory stored for upcoming months will have to be changed with immediate effect. Much to our surprise, this particular directive was actually issued by the FSSAI on February 4, 2019. It has been made mandatory for FBOs to comply with this order by April 30, 2019.

### 4.2.2 The Case of Alcohol

With effect from April 1, 2019, FSSAI has made it mandatory for alcoholic beverage companies to print a statutory warning on the label of all alcoholic beverages in the following manner:

'CONSUMPTION OF ALCOHOL IS INJURIOUS TO HEALTH.  
BE SAFE – DON'T DRINK AND DRIVE.'

Labelling requirements for alcohol have traditionally been governed by state excise departments, which are different for different states.<sup>46</sup> In Tamil Nadu, for

46. We were informed of a similar challenge that mega food suppliers in the UK face. Commenting on labelling requirements, these suppliers stated that they have to mandatorily follow 'specific formats' that vary across retailers.

instance, the state excise department commands all alcoholic beverage companies to print 'Alcohol Consumption is Injurious to Health' on bottle labels in Tamil. Now that the FSSAI has issued its own directive, alcoholic beverage companies are finding it challenging to comply with dual labelling directives. This is particularly difficult in the case of small alcohol bottles because:

- Printing warnings in different languages on labels can make the text illegible.
- Since FSSAI's warning alone cannot be printed on a label smaller than 3 mm, there is practically no space left to print any more text.

Although FSSAI has tried to negotiate this matter with state excise commissioners requesting them to adopt FSSAI's warnings with a provision to print the same labels in regional languages without repeating them in English, many states have asserted that they will still conform to their own requirements.<sup>47</sup> Liquor companies are required to register their labels with state excise departments before the beginning of every financial year and this process is both costly and time-consuming. If there is any change in labelling requirements, companies have to discard their existing labels and seek re-registration of new labels, which adversely affects their profitability and growth. FBOs strongly believed that they should be notified of such changes in advance.

#### 4.2.3 Menu Labelling

Certain food service providers expressed their apprehensions regarding FSSAI's menu labelling requirement, which is voluntary at present. In an attempt to nudge restaurants to promote safe and healthy eating practices and to enable consumers make informed food choices, FSSAI has asked them to voluntarily mention calorie counts of dishes on their menus. Even though the food regulator has acknowledged that this could be challenging in the Indian context because recipes are not standardised and the quantity of ingredients keeps changing, food service providers fear that this voluntary requirement may actually be a regulation in the offing.

47. Some FBOs reported a similar problem with respect to food safety compliance requirements in the UK. We were told that since 'each agency has its own specialised and focused mandate and is not concerned about anything else', compliance becomes inordinately troublesome for FBOs.

### 4.3 Impediments to Consistency

#### 4.3.1 Documentation

As reported by some FBOs, renewal of license and getting a product approved are cumbersome as these involve the submission of all documents that the FBOs might have already furnished before. In case of renewal or modification of license, all documents,<sup>48</sup> which are submitted by FBOs while applying for license for the first time, have to be uploaded again on the FLRS portal. Further, a modified license has to be procured every time an FBO has to diversify operations, even if that diversification is only marginal. For instance, FBOs, which manufacture products by combining additives, have to get a modified license for every combination of additives even if those additives have already been approved by FSSAI. Similarly, when an FBO is trying to expand its product portfolio by seeking approvals for non-specified food and food ingredients, they have to submit all documents that they would have submitted for acquiring approvals of such foods in the past. FBOs also conveyed that since the FSSAI has not specified any deadline for approval of non-specified foods, it is difficult for them to predict the maximum time that approval of their application may take.<sup>49</sup>

48. According to Annexure 2 of the *Food Safety and Standards (Licensing and Registration of Food Businesses), Regulations 2011*, 18 items are listed under 'Documents to be enclosed for new application for license to State/Central Licensing Authority', and 4 items are listed under 'Documents to be included for renewal or transfer of license given under other existing laws prior to these Regulations'. There is no separate section/list of documents required for registration – Form 'A' in Schedule 2 has to be submitted with documents mentioned in the Form itself (for e.g. 'proof of identity of applicant' (section c) and 'proof of income' (section g)). On the FSSAI website ([https://foodlicensing.fssai.gov.in/central\\_document\\_list.html#about-tab](https://foodlicensing.fssai.gov.in/central_document_list.html#about-tab)), 26, 4 and 20 items are listed as required documentation for new/renewal/modification of Central license respectively; the respective numbers for State license being 22, 4 and 20; and for registration, only 3 items are mentioned. Applications for registration (Schedule 2, Form A) as well as Central/State license (Schedule 2, Form B) and their renewal are the same. In ICRIER's stakeholder consultation on 29/5/2019, it was mentioned by the FSSAI representative from the Regulatory Compliance Division that as part of its planned reforms to promote ease of doing business, renewal will no longer be required.

49. Notes from an FBO interaction in Gurugram – "They have issues with licensing and renewal. When they have to go to the licensing authority for renewal or modification of license, they have to submit all the documents they had submitted earlier. So if there is any change in document it is okay to submit but submitting all the documents they had submitted before, is big hassle for companies. In addition, licenses have to be modified, in case any of the information submitted at the time of application changes. For instance, details of the officer applying for the license



### 4.3.2 Enforcement

One of the most pressing concerns reported extensively across FBOs was inconsistency in enforcement of FSSAI's compliance requirements. FBOs voiced their discontent with the interpretation of food safety laws by FSOs, which varies from the understanding of FSSAI's regional offices and headquarters. Lack of co-ordination between regional and state food safety authorities may have potentially hazardous implications for food safety. For instance, if an FSO cancels the license of a premise and does not report it to the regional office, the latter in all likelihood will renew the license of a non-conforming FBO. As recommended by the PCR, the FSSAI should

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have to be uploaded and in case that officer is replaced by another, the license has to be modified. The entire process of uploading all documents has to be repeated. Instead they should ideally refer to a digitally maintained document briefcase/locker for each FBO. Here all documents can be stored and in case of say a modification – only the modified piece of information and supporting documents should be uploaded/replaced and that will avoid uploading all other documents all over again. This does not exist in the FSSAI as of now but the FSSAI is thinking about it. In addition to this, they have additional requirements which ask FBOs to submit a CA certified turnover report. This should ideally be a self-certification requirement for an existing business. Now FSSAI has started asking for CGWA NOC for the manufacturing license but there is no place on the online system to upload this document. So now you have to apply for the modification/renewal, then FSSAI will send it back to you saying that documentation is incomplete and it is then up to the discretion of the licensing officer to say as to where the document has to be uploaded in the system, then you have to re-submit the application. Thus, it is a very time consuming process. As of date, this particular FBO has eight licenses which are not approved and they have applied for their renewal/modification around 7-8 months back. Modification here refers to the FBO changing their regional office (RO) address, so for that they applied for modification of the license and it has been a year and the online system still shows that the documents are under scrutiny. They are mostly facing these issues in Maharashtra, Haryana and Delhi. The FBO believes that FSSAI has to simplify this central licensing process further by – 1) Reducing the list of documents checklist: as of now they have to send a set of 30 documents to each of the 30 states in the country; 2) Creating a digital locker of documents; 3) Remove mandatory certification requirements. Such exhaustive list of documents and the complicated process of getting a license do not apply for obtaining a state license. In summary, getting, modifying and renewing a license are a very difficult and costly process. Also, irrespective of the nature of a modification, the entire exhaustive process of licensing and payment of fees applies to the FBO. Because licenses hinge on so many requirements, a change in any requirement/parameter leads to a modification. Therefore, the list of requirements for a license is too cumbersome, too lengthy and not required. It should be reduced, simplified and only relevant things should be asked for. The FBO believes that the processes are relatively less complex overseas because overseas each country promotes and in India there is a blockage everywhere.

consider establishing a central databank on FBOs to keep account of the number of licenses issued, re-issued, cancelled, expired, etc.

During our interactions, we also noted that inspections do not happen periodically and certain FBOs had not been inspected even once since they began operations. Our respondents were of the view that FSSAI should formulate policy guidelines on periodicity of inspections. Further, they suggested that similar to FOSTAC training, which is mandatory for FBOs, FSOs should also be imparted regular training for capacity building and updating them on the latest regulatory measures adopted by the FSSAI.

## 4.4 Other Impediments

### 4.4.1 Regulatory Costs

While all our respondents felt that regulatory costs have increased in the last four to five years, some of them highlighted that costs had increased primarily because non-compliance to food safety compliance requirements has declined considerably. Nevertheless, a significant proportion of FBOs complained about the exorbitant laboratory testing costs that they have to incur either annually or half yearly. These costs are particularly substantial for SMEs as they constitute a relatively sizable proportion of their revenues. We were also told that although it is compulsory for FBOs to perform these tests, these may not be relevant given the nature of business an FBO is undertaking. As reported by one of our respondents:

‘Testing for heavy metals and antimicrobial residues is not required in our business as we manufacture perishable products but we still have to.’

One respondent also asserted that sometimes, there is no scientific basis for conducting such tests. According to him:

‘Water and food microbial testing have to be done after every 6 months, which involve significant costs. When water content in food is less than 2 percent and there is no scope for microbial activity to occur scientifically, even then we have to test for microbial activity. Annual laboratory cost for these tests is roughly INR 800,000 for our business.’

### 4.4.2 Trainings

We received mixed reviews with respect to FSSAI's FOSTAC initiative that aims to train and certify food handlers in licensed premises. Many large FBOs

claimed that since their employees have to undergo compulsory training courses that are designed in accordance with international standards, the training provided under FOSTAC were not very beneficial to them. These FBOs also reflected willingness to

collaborate with FSSAI to provide training. Some FBOs expressed dissatisfaction with the quality of training provided under FOSTAC and were of the opinion that these are advantageous only for beginners.

# 5

## Learnings from the UK

Based on our case study of the UK's food safety framework, we would like to highlight the following best practices that can be considered by FSSAI and other related government agencies to rationalise food safety regulatory compliance in the Indian context.

### 5.1 Risk-based Food Surveillance System

FSA is in the process of developing a strategic food surveillance system – which will take into account the risks and vulnerabilities that food systems are exposed to – by using data science techniques and making better use of and strengthening open data sources. FSA is developing forecasting models based on historical climate and risk data – for instance, FSA has developed a predictive model using climate data for generating the Rapid Alert System for Food and Feed (RASFF)<sup>50</sup> alerts on time. Based on climatic condition data of the exporting country, FSA uses a technological solution to predict Aflatoxin<sup>51</sup> risk in all the food that is imported into the UK. Similarly, FSA is also monitoring allergenic risks within UK using

tools of social media analysis, which gives a count of allergens by type, source and local authorities.

- Recommendation 5 – FSSAI can collaborate with FSA (UK) to develop a strategic food surveillance system, which could be used to develop a prevention-oriented, resource-optimizing risk-based inspection/intervention system. These systems should be developed to ensure interoperability with other surveillance/data systems, in the spirit of the 2030 Agenda, so that cross-sectoral and cross-country action could also be taken to ensure the primary mandate of food safety. This can also help in inter-agency regulatory collaboration within and outside the country.

### 5.2 Impact Assessments (IAs)

IAs are regularly carried out by FSA to assess the impact of policy options being considered, including its expected costs and benefits. It also summarises the rationale for government intervention. Such IAs are based on stakeholder evidence and are published on FSA's website. In the past, FSA has carried out IAs on *Food Law Code of Practice Review 2015*, *Deletion of the requirement for a special health mark for emergency slaughtered carcasses and meat 2014*, *The Contaminants in Food (England) Regulations 2013*, etc.

- Recommendation 6 – FSSAI should regularly conduct or commission independent Potential Impact Assessments (PIAs) to assess the impact of policy options being considered as well as RIAs as suggested in the introduction.

50. Created in 1979, RASFF enables information to be shared efficiently between its members (EU Member State national food safety authorities, Commission, EFSA, ESA, Norway, Liechtenstein, Iceland and Switzerland) and provides round-the-clock service to ensure that urgent notifications are sent, received and responded to collectively and efficiently. Thanks to RASFF, many food safety risks had been averted (for more information, refer to [https://ec.europa.eu/food/safety/rasff\\_en](https://ec.europa.eu/food/safety/rasff_en)).

51. Aflatoxins are poisonous substances produced by certain kinds of fungi (moulds) that are found naturally all over the world; they can contaminate food crops and pose a serious health threat to humans and livestock. (Source: [https://www.who.int/foodsafety/FSDigest\\_Aflatoxins\\_EN.pdf](https://www.who.int/foodsafety/FSDigest_Aflatoxins_EN.pdf) (13/3/2019, 14:30 hours).

### 5.3 'Regulating our Future' – FSA's Future Plans

By 2020, FSA intends to have a new regulatory model for food safety, which will be based on a modern, risk-based, proportionate, robust and resilient regulatory system. The current 'one-size-fits-all' is not well suited for the ever-evolving needs of the food industry. Moreover, it is felt that with the advent of new players in the national and global food safety landscape – online retailers, food delivery services, private auditors, independent food safety certification schemes – the dynamics of the food industry will change. Hence, FSA realised that it needs a model that is flexible enough to adapt to the changing food environment.

As part of its 'Regulating Our Future', the FSA intends to make the registration process easier for FBOs. In future, FSA intends to follow a 'digital approach', by developing a solution for real time access to registration details of all food businesses in England, Wales and Northern Ireland. The resulting data will be used to categorise businesses and determine appropriate regulatory intervention frequencies. As part of its reforms, FSA also intends to introduce a new risk management framework for determining the nature, intensity and frequency of the controls on food businesses. The new risk management framework will try to capture more information about the business through registration and other sources. For instance, the compliance history of a food business in other regulatory areas beyond food safety might also reflect on the overall compliance behaviour of the business.

- Recommendation 7 – FSSAI should have a nuanced approach to compliance vis-à-vis segment and size as well as the evolving nature of the food industry. That is possible with a robust surveillance system in place. Such a surveillance system would not only help in more nuanced, risk-based inspections, but also help identify FBOs that need support in terms of compliance. In India, with limited awareness and resources among SMEs, a proactive and promotive approach to compliance by the regulator is essential.

### 5.4 Government-wide Regulatory Reforms in the UK

The Better Regulation Executive (BRE), a unit within the Department for Business, Energy and Industrial Strategy (BEIS), leads government-wide regulatory reforms in the UK. The BRE works with all government departments to monitor the measurement of regulatory burden and co-ordinate

to reduce it and to ensure that the regulation that remains is smarter, better targeted and less costly to business.<sup>52</sup> From the perspective of ease of doing business, 'One in, two out'<sup>53</sup> and the 'Red Tape Challenge' (RTC)<sup>54</sup>, are among the well-known regulatory principles of BRE in which the public (consumers) was also included as a stakeholder to help cut-down unnecessary regulations.

Another department that is of relevance for regulatory reforms in the UK is the Office for Product Safety and Standards (OPS&S), a unit within BEIS. OPS&S was established in 2018. This department aims to ensure 'ease of doing business' – especially supporting small business growth – and simplifying regulation. OPS&S works closely with businesses, local and national regulators and consumers to improve regulatory protections and support compliant businesses. OPS&S coordinates with LAs, including PAs,<sup>55</sup> in the UK, while also sharing expertise and technical assistance with other countries. For the operation of PAs, OPS&S exercises the statutory responsibility including nominating partnerships, issuing guidance and resolving concerns on behalf of the Secretary of State. It also manages the Primary Authority Register that contains details on every partnership, provides a forum for communications and allows PAs to make important documents and business information readily available to local regulators.<sup>56</sup> In India, OPS&S engages with the Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry.

OPS&S also looks after to ensure the effective implementation of the *Regulators' Code*, a statutory measure, which came into effect on April 6, 2014 as part of the *Legislative and Regulatory Reform Act 2006*. The Regulator's code provides a principles-based framework for how regulators should engage with those they regulate. The first code mandates

52. <https://www.gov.uk/government/groups/better-regulation-executive> (13/3/2019, 13:06 hours).

53. <https://www.gov.uk/government/collections/one-in-two-out-statement-of-new-regulation> (13/3/2019, 13:06 hours).

54. <https://www.gov.uk/government/news/red-tape-challenge>. (13/3/2019, 13:06 hours).

55. UK's Regulatory Enforcement and Sanctions Act 2008 is quite pertinent: it made provision for the establishment of the Local Better Regulation Office (LBRO), for the coordination of regulatory enforcement by local authorities and introduced into law the principle of the PA to ensure greater consistency in local enforcement – one of the major challenges for FSSAI in terms of dealing with state/UT food safety authorities and burden for FBOs.

56. <https://www.gov.uk/guidance/local-regulation-primary-authority> (13/3/2019, 13:06 hours).

that “regulators should carry out their activities in a way that supports those they regulate to comply and grow”, avoid imposing unnecessary regulatory burdens.<sup>57</sup> FSA also follows the Regulator’s Code.

As part of statutory obligation of the Small Business, Enterprise and Employment Act (SBE) 2015, business impact target (BIT) is carried out. A progress

report of BIT is published for the Parliament by the BEIS. It highlights the information on regulatory provisions that have come into force or ceased to be in force during the parliamentary year and an assessment of the economic impact on business of such regulatory provisions. FSA also has to report qualifying regulatory provisions (if there are any such provisions).<sup>58</sup>

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57. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/300126/14-705-regulators-code.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf) (13/3/2019, 13:06 hours).

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58. Between 9 June 2017 and 20 June 2018, FSA did not introduce any qualifying regulatory provisions under the BIT.

# 6

## Further Recommendations

### 6.1 Recommendations for Systemic Reforms

#### 6.1.1 Substantive, Goal-oriented Compliance

To a lot of businesses, the term ‘compliance’ may imply that they have to simply conform to certain directives instead of proactively dealing with their legal, social, environmental and ethical responsibilities. Goal-oriented regulations lay emphasis on attaining substantive goals, while rule-oriented regulatory policies focus on simplistic obedience to guidelines. Substantive compliance systems focus on internalised commitment to achieve socially desirable goals and not mere subservience to rules or ticking a set of boxes (Parker 2002: 27).

Our interactions with FBOs revealed that FSSAI’s regulations excessively focus on achieving specific regulatory objectives that are often formulated without any systematic consultation with FBOs. Dynamic engagement of regulatory authorities with FBOs and vice-versa is crucial. This is also important to ensure that FBOs gradually adopt rigorous measures to strengthen self-compliance.

#### 6.1.2 Institutionalisation of Consultative and Rational Rule-making

Institutionalizing rule-making fosters transparency, enhances compliance and reduces costs for businesses. Moreover, a dynamic consultative rule-making process is required to ensure that regulations move in tandem with the evolving industry and there are no abrupt changes without due consultation.

To understand the rationality of compliance requirements, there is need to assess if existing ones

are proportionate vis-à-vis the regulatory objectives. In this regard, the case of the USA offers insights on the detailed process of rule-making and RIAs of rules and regulations thereafter. The Office of Information and Regulatory Affairs (OIRA), established by the US Congress under the 1980 Paperwork Reduction Act, is a dedicated federal office (similar to the BEIS in UK). It is responsible for reviewing regulations. OIRA is a part of the Office of Management and Budget (OMB), an agency within the Executive Office of the President.

- The Executive Order (12866 - ‘Regulatory Planning and Review’ signed by President Bill Clinton in September 1993), *inter alia*, emphasised the need ‘to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public’. Toward this end, the Executive Order laid down certain principles that agencies should follow in rule-making, including consideration of alternatives and cost-benefit analyses, and describes OIRA’s role in the rule-making process. It may be noted that not all regulatory actions qualify for a review. According to the Executive Order mentioned above, OIRA is responsible for determining which agency’s regulatory actions are ‘significant’, and hence subjected to an inter-agency review.
- Later, in 2011, the Executive Order 13563 (‘Improving Regulation and Regulatory Review’, issued by President Barack Obama) stressed that the regulatory system should protect public health, safety and



environment while promoting economic growth, innovation, competitiveness and job creation. It also highlighted the need for using the least burdensome tools for achieving regulatory ends and enhancing predictability to ensure certainty. Focusing on curtailing regulatory costs, the Executive Order stressed the need for regulatory agencies to ‘use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible’, and qualitatively address the values that are difficult to quantify – viz. equity, human dignity, fairness, and distributive impact.

- More recently, President Donald Trump, in Executive Order 13771 (‘Reducing Regulation and Controlling Regulatory Costs’) directed a two-fold approach to regulatory reforms – ‘agencies eliminate two regulations for each new significant regulation’ and ‘offset any new regulatory costs’.

### 6.1.3 Regulatory and Prospective Impact Assessments (RIAs and PIAs)

While lack of transparency and corruption adversely affect all businesses, they are particularly detrimental to the functioning of SMEs, which are often unequipped to deal with the opacity of public sector or develop strategies to participate proactively in the decision-making process. High compliance costs and the complexity of the compliance regime may further add to the woes of young FBOs. Conducting Prospective Impact Assessments (PIAs) can be used to assess the possible implications of new regulatory measure. By analysing the impact of regulations, RIAs and PIAs can also help the FSSAI to consider regulatory options that are viable for SMEs. For instance, in the European Union (EU), the ‘Think Small Principle’ is implemented by assessing the possible impact of EU legislative proposals on SMEs through:

- Consultation with SME stakeholders;
- Identification of affected businesses;
- Evaluation of impact of legislations on SMEs (cost-benefit analysis); and
- Analysis of substitute mechanisms and mitigating measures (OECD 2018).

In order to improve the quality and relevance of EU’s legislative framework, the European Commission (EC), along with the European Parliament, Council, Member States, and other stakeholders, applies a ‘smart regulation’ framework, which requires

impact evaluation of legislation during its entire cycle starting from designing to implementing and subsequent revisions. In EC, in furtherance to its better regulation programme, the regulatory fitness and performance (REFIT) aims to ensure that EU legislation is implemented efficiently and at minimum cost and effectively benefit citizens and businesses. For the existing EU legislation, REFIT focuses on ‘tackling unnecessary costs and eliminating regulatory burdens without compromising policy objectives’ and ‘making legislation simpler in order to improve implementation and enforcement by reducing its volume and complexity’ (EC 2018). EC is working towards simplifying legislations by evaluating several policy areas to judge their fitness and concomitant purpose of the existing legislation. REFIT Platform has adopted 11 opinions in the domain of health and food safety including food contact materials, monitoring of residues of veterinary medicinal products and other substances in food of animal origin, definition of ‘vegan’ and ‘vegetarian’, traditional herbal medicines products directive, vitamins and minerals, protection of animals during transport and related operations, hygiene package, nutrition and health claims, and registration of feed business operators (EC 2018: 75). The ongoing evaluation of the applicable legislative frameworks will take into account the recommendations of the REFIT Platform on most of these issues and are expected to be finalised by early 2020.

### 6.1.4 Third Party Assessments (TPAs)

As the name suggests TPAs are independent assessments by third party, to assess implementation of proposed program as well as evaluating the achievement of stated goals.<sup>59</sup> TPAs are an important tool to assess the implementation of proposed activities and gauge the achievement of specified goals. Third party-evaluation of activities undertaken by FSSAI and state/UT authorities would be an important initiative to determine whether the measures taken by them actually help realise desired outcomes. Alternatively, major RIAs and PIAs could be commissioned to independent third-party agencies. This would help in regulating the regulator.

### 6.1.5 Reimagining FSSAI

FSSAI’s mandate should be clearly focused and outcome-oriented – food safety. It should not focus

59. [https://www.ies.ncsu.edu/solution/third-party-evaluation/\(3/5/2019, 17:00 hours\)](https://www.ies.ncsu.edu/solution/third-party-evaluation/(3/5/2019, 17:00 hours)).

on nutrition or health promotion. Other agencies should deal with these issues. A rational and focused mandate is the first step towards a rational and focused compliance ecosystem.

Secondly, like the FSA (UK), FSSAI should be a non-ministerial government department and work with state/UT food safety authorities to develop a LA and PA sort of system in the country. The contours of such a system for the specific Indian context require thorough and careful consideration, and it is beyond the scope of the present work to develop one. Nevertheless, the FSSAI should consider this and try to develop an in-principle consensus on it at the level of the central and state/UT governments.

## 6.2 Recommendations for Streamlining the Operations of the FSSAI

### 6.2.1 Awareness and Grievance Redressal

To improve awareness and understanding of FSCR among FBOs, a host of measures may be implemented. First, industry associations should assume a more prominent role in terms of enhancing awareness about new/updated regulations among FBOs and facilitating redressal of their grievances. Second, FSSAI should consider revamping its website and provide regulatory information in a more structured way for the convenience of FBOs. FSSAI can consider developing a 'chatbot' to proactively help address grievances of FBOs on a real-time basis. Further, to update FBOs about new or revised regulations, it should also introduce a system of issuing mass alerts by developing a dedicated mobile application. FSSAI can also consider including a feature like an RSS feed in the website through which content can be distributed in real-time, reflective of the latest published content on the website.

### 6.2.2 Strengthening Administrative Capacity and Coordination

The FSSAI's weak administrative capacity was identified as a major barrier to effective enforcement of food safety regulations. First, enhanced co-ordination between FSSAI's zonal and state/UT food authorities is required to apprise FSOs of FSSAI's latest compliance requirements; they should have a co-ordinated approach to surveillance, inspections and other activities. In addition to the food safety manual to facilitate inspections by the FSOs, regular workshops should be conducted to increase uniformity in inspection protocols. Further, although third party auditors are expected to reduce the enforcement burden, FSSAI should consider forming

a sizable cadre of FSOs.

### 6.2.3 Hand-holding of Small and Medium Enterprises

FSSAI may initiate a dedicated guidance program to increase compliance and clarify complex rules and regulations for SMEs. Given the large presence of the informal sector and SMEs in the food sector in India, such a move will help uplift the status of food safety in the country. At present, while most big FBOs either have internal compliance officers/lawyers/ access to external advisory firms and membership of industry association, it is expensive for SMEs/ family-run enterprises to have such a compliance team. Although the training and common service centres (under the eGovernance Programme of Ministry of Electronics and Information Technology) facilitate procedural assistance in registration process to petty food manufacturers, formal mechanisms are required vis-à-vis details of regulations and compliance requirements, grievance redressal, etc. Initiatives can include dedicated discussion portals, simplified standard operating documents as well as a nodal go-to department for SMEs. To understand and prioritise substantive issues faced by SMEs, FSSAI may also conduct focused studies. For instance, in 2015, the FSA (UK) commissioned a research study among small and medium-sized food businesses to measure awareness of and compliance with food safety guidelines and regulations. The study included opinion on attitudes towards regulations, compliance, and sources of food hygiene and safety information, knowledge of new regulations, access to relevant information, perceptions of the website and helpfulness of FSA sources, etc.<sup>60</sup> The EU has an SME Test that includes a cost-benefit analysis of the impact of a regulation on SMEs, 'assessment of alternative mechanisms and mitigating measures' and uses these to help implement the "Think Small Principle" (OECD 2018).

60. This study found out that 86 per cent of SME FBOs are largely confident that they can find and access the information they need on food safety and hygiene regulations. Still, 35 per cent said they would like more help and information on what to do. Perceptions of the FSA were largely positive – 87 per cent stated it is trustworthy, honest and reliable; 73 per cent agreed it makes legislation changes clear to businesses; 73 per cent said they get the information they need to run their business with good food hygiene standards; 22 per cent tried to contact it in the past six months; the most common reason for contacting it was to ask about or check their understanding of regulations; 55 per cent said they would prefer to receive a leaflet from it about legislation changes and 40 per cent would prefer an email. Source: FSA baseline study with SME food businesses, March 2015. <https://bit.ly/2X0871k> (10/4/2019, 17:21 hours).

# 7

## Appendices

### Appendix A – Primary Authority (PA)

#### 7.1 Official Description

The *Regulatory Enforcement and Sanctions Act 2008* established PA as a statutory scheme in which a LA can partner with a business or with a group of businesses, taking on the responsibility of providing regulatory advice and guidance to them and for guiding the way in which they are regulated by LAs. PA covers issues of environmental health, licensing, trading standards and fire safety functions of LAs. PA applies differently in each nation of the UK. PA provides a valuable resource for businesses as well as the enforcing authorities by acting as a key point of contact and source of information. This allows the PA to improve communication, deliver efficiencies and facilitate better relationships. A PA working with an individual business or group of businesses is well-placed to liaise effectively with any national regulator or government department that has a lead role in relation to the legislation with which the business(es) must comply (known as a ‘relevant national regulator’). OPS&S in BEIS works with the LAs, including PAs.

A business that receives advice from its PA (‘Primary Authority Advice’ or PAA) is able to rely on that advice in its dealings with all LAs. An LA that proposes enforcement action against a business is required to first notify its PA. The PA then directs that LA not to take the proposed action if the PA decides that it would be inconsistent with any PAA it has given. This provides certainty for a business that chooses to

receive and follow PAA, giving it the confidence in its approach to compliance.

Source: Primary Authority Statutory Guidance (October 2017), Department for Business, Energy & Industrial Strategy (BEIS)

#### 7.2 Company Perceptions

Following are the perceptions of the companies that we talked to in the UK vis-à-vis the PAs –

- It is not necessary to pick a PA near to companies’ geographical location; it could be somewhere else too. One of the companies surveyed suggested that they chose a PA that had very good food trading standards and practical knowledge of food safety. We were also told that PAs can also be changed later on; however, one needs to have good reasons for that. In this regard, one has to go through BEIS for the PA. The companies would have to approach their LA, make an application through them and then they will submit it to BEIS, which will review whether that particular LA has the necessary competence and human resources.
- In addition to food safety, PA also ensures general ease of doing business.
- There is a set of fees for registration with PA and then the companies pay on time-basis.
- The concept of PA does not mandate that companies have a central compliance team in the company.
- The concept of PA was largely driven by large retailers operating from different sites, as

these retailers wanted a consistent approach to compliance. It may be noted that this does not stop enforcement officers from stepping in if they think there is a breach of regulation. So, the regulation has primacy over assured advice from PA.

- PA makes it more formal if AOs raise objections against practices of a company. If there is assured advice in place and authorised officer challenges that assured advice, then the company has to go through a process to claim a different view. It has led to an improved standardised approach in terms of important things that will grow as more people come into the PA system.
- If there is a new issue, which has not been dealt with before by the PA, then the LA can take a call on that. In such cases, the companies can go to the PA and find a way through triangular conversation (involving PA, LA, and the company) to ensure that it is dealt with.
- One of the companies raised an important concern – in case a company has multiple premises, there is a problem of dissemination of PA's advice/and coordination on food safety measures.' According to this company, this kind of arrangement works for retailers because they replicate their activities on different sites. However, the same is difficult for this particular company because their factories are centres of excellence, so they may have one PA in dairy, one for dry products, etc. in which case, the company will hold the information and then utilise the same when contacted by other sites.

In addition to a direct PA, there are indirect PAs too – for instance, trade associations sign up for PA advice for SMEs. Trade associations would hold that information and then they can disseminate. They can provide training to companies also, depending on their terms of reference and whether they have in-house capacity to do so. They can also appoint members who are approved or certified trainers. For instance, the British Soft Drinks Association (BSDA) is a trade association with a PA. They might have several assured advice on different aspects of food safety through the PA arrangement; they will provide when called upon.

- For risk assessment and everything else, the PA will hold primary authority advice so that it is available to other LAs as well.

Enforcement authorities can access the advice and information held through a central database. Enforcement agencies also look at other sources of information about the premises in addition to food safety.

- As part of 'Regulating Our Future',<sup>61</sup> FSA working on an intelligence-based risk-assessment. FSA intends to have a new regulatory model for food safety, which will be based on a modern, risk-based, proportionate, robust and resilient regulatory system.

## Appendix B – Proposed Regulatory Philosophy Statement for FSSAI

1. Goal – Our regulatory system will be modelled as per the spirit of the United Nations General Assembly Resolution 70/1 (25 September 2015) – “Transforming our world: the 2030 Agenda for Sustainable Development”. It will focus on ‘people, planet and prosperity’ in an ‘integrated and indivisible’ manner so as to ‘balance the three dimensions of sustainable development: the economic, social and environmental’.
2. Regulations would be goal-/outcome- rather than rule-oriented.
3. Regulations should have clear and highly focused objective(s) and all compliance requirements throughout the continuum should be strictly and proportionately justifiable with reference to these objective(s) alone.<sup>62</sup> The objective/justification statements should be publicly available.
4. Regulations should be –
  - a. based on the best available science;
  - b. rational, risk-based, robust, resilient, predictable and flexible (vis-à-vis design);
  - c. consistent and transparent (vis-à-vis implementation);
  - d. use the most innovative and least burdensome tools for achieving regulatory objectives;

61. <https://www.food.gov.uk/about-us/regulating-our-future#regulating-our-future-key-documents> (5/3/2019, 16.54 hours).

62. For instance, a number of documents required for new application for State/Central License in Schedule 2, Annexure 2 of the Food Safety and Standards (Licensing and Registration of Food Businesses), Regulations 2011 are not strictly required from the perspective of food safety per se.

- e. easily accessible/understandable for all, especially the least empowered, stakeholders (written in plain and local languages)
5. Regulations should be well-designed in order to achieve regulatory objectives in a manner that helps minimize complexity and cost to companies.<sup>63</sup>
6. A review – and RIAs, especially with reference to the SMEs – of existing regulations should be conducted from this perspective in particular. These reviews should be made public.
7. There should be a special effort to reduce compliance complexity and costs for new enterprises in particular<sup>64</sup> – without any compromise vis-à-vis the objectives – in order to promote the start-up ecosystem, ease of doing business, formalisation and job creation.
8. Regulators should simplify compliance procedures, particularly through the use of technology. However, the leveraging of technology should be aimed at the achievement of objectives in a cost-effective manner, without creating further complexities/distortions.
9. Regulators should assess alternative mechanisms, especially non-regulatory instruments, with an eye on process simplification and ease of doing business.
10. Wherever possible, regulations/changes should be made following a proactively participative consultative process and adequate reasons for acceptance/rejection of suggestions should be given and made publicly available.
11. An NIS for a risk-based approach to inspections and consistency in enforcement should be developed, widely publicized and followed in letter and spirit by the local inspection/enforcement authorities.
12. Inspection/enforcement authorities should be bound by fair and effective principles of practice.
13. Regulations/regulators should be forward-looking and take into account/evolve with changes in the local, global, technological, etc. landscape, international commitments, etc. They should develop/publish short and long-term strategy documents.

63. “In the UK, over 2011-13, the Red Tape Challenge website promoted open discussion on how the aims of existing regulation can be fulfilled in the least burdensome way possible. Comments were used by the British government to design a package of 3000 reforms to cut red tape” (OECD 2018: 5).

64. “For young firms, which also tend to be small, high compliance costs and complexity ... can exacerbate the resource and cash-flow constraints often experienced in the early stages of business development, and may act as a deterrent to formalisation” (OECD 2018: 7).



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**N**oting interlinkages of food safety with food security, public health, trade, economy, employment and poverty alleviation, the United Nations General Assembly designated June 7th as World Food Safety Day in 2018. On the eve of the first World Food Safety Day, the Hon'ble Prime Minister of India, Shri Narendra Modi, stated that since 'food safety is of prime importance for the well-being and health of our nation as well as its people, particularly women and children', the Government of India 'is focused on implementing the latest and best standards of food safety in the country'.

For streamlining India's food safety compliance ecosystem, this report argues that it should be –

1. based on best available science;
2. rational, risk-based, robust, resilient and predictable (vis-à-vis design);
3. consistent and transparent (vis-à-vis enforcement);
4. easily accessible and understandable for all stakeholders;
5. use most innovative and least burdensome tools for achieving regulatory objectives.



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