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Impact of Food Safety and Standards Regulation on Food Business Operators

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Abstract

The main aim of the study is to understand food regulation and food safety in the Indian context and global aspects. It also explains the major health problem and recent past reports of FSSAI. The primary data were collected from food business operators (mobile food vendors, many small-scale hotels, and local restaurants). It also helps to ensure the knowledge and awareness level of the food business operators. This study is to understand the view of food-business operators in a B-grade city of India "Salem" in Tamil Nadu about the FSSAI regulations and the status of performance of the food safety department in maintaining the safety and quality of food and also to know about the level of awareness among the usage of fortified foods among food-businesses. The Study concludes that the Food and Safety Officers should regularly visit for inspection and monitor the food business operators for the betterment of public health. There should be proper awareness about the ingredients used in fortified food among food businesses to eliminate malnutrition and avoid food adulteration. The future rules and regulations of FSSAI should be strictly implemented all over India and properly monitor the activities of food business operators to fulfil the FSSAI standards.

Keywords: Food-Business Operators, FSSAI, Food Laws & Regulations.
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1. Introduction

Hygienic food is essential for the survival of people so that they can acquire a sustainable and healthy life. Due to unhygienic, they are more than 200 diseases which were caused by various viruses, bacteria, parasites, and also excessive use of chemical substances. Its main causes for cancers, diarrhoea, and other health issues which finally leads to death. Globally estimated that around 582 million people had fallen into various diseases due to unsafe food consumed that causes annually more than 3,50,000 people died due to Escherichia coli infection, Salmonellosis, Gastrointestinal disease and other issues (Monostori, 2014). It is mainly caused by semi-cooked meat, raw seafood containing marine bio-toxins, contaminated fruits, and vegetables, etc. Diarrhoea, vomiting, and stomach pains are common symptoms of foodborne (Arokiaraj, 2015; David, et al., 2018). Annually, there are 600 million cases registered which is related to foodborne illnesses due to unsafe food which was considered the greatest threat to people's health (Anyanwu & Jukes, 2019).

According to the World Health Organization (WHO), it is estimated that one out of ten people was dying due to contaminated and unsafe food (Brettel et al., 2014). It was noted that around 4, 20,000 people were dead. Further, it was quite shockingly recorded by the WHO that around 40% of children had foodborne diseases who are aged under 5 years old. Every year 1, 25,000 children were dying due to foodborne diseases (Lee et al., 2015; Lee et al., 2014).

Food business operators have to need to learn global best practices and also must follow the basic rules and regulations for ensuring the quality of food. The Indian Ministry of Food Processing Industry (MOFPI) is responsible for the food processing industry in terms of rules, regulations, and laws. MOFPI was established in 1988 and was mainly aimed to stimulate hygienically processed food in order to feed the entire Indians with the help of modern technology (David, & Banumathi, 2014_a). The Food Safety and Standards Authority of India (FSSAI) was established in 2006 under the Ministry of Health and Family Welfare (MHFW) which was under the control

of the Government of India (GoI). The main role of FSSAI is responsible for ensuring public health and hygiene food from the food business operators by monitoring the quality of food through strict rules and regulations. Further, it also checks the food quality such as freshness, natural, purity, originality, authentic, genuine, real, and organic (Ryu et al., 2012).

During 2018-19 FSSAI checked the food quality in Tamil Nadu and Uttar Pradesh found that almost one-third of food samples were adulterated and nearly half of the samples failed to meet the standard in the test. During 2016-17, a total of 78,000 samples were collected from the fortified food business operators among that 18,000 samples failed to pass the test. In 2017-18 around 99,000 food business operators' samples were collected among these 24,000 samples failed the test. In 2018-19, around 65,000 samples were collected from food business operators among that 20,000 samples failed the test. During 2018-19 the FSSAI conducted a survey about the safety, quality and hygiene level of milk from all over the States and Union Territories of India. Around 6,432 milk sample was gathered and the result shows that only 41% of milk sample was approved under the safety level parameters and 7% of packed milk contained serious health hazards and the remaining were not at all fall under the safety category. The Minister for Consumer Affairs, Ram Vilas Paswan, pointed out that during 2016-17 and 2018-19 around 8100 people were convicted of food adulteration and contamination and a total fine amount of 43.65 crores were collected. The FSSAI made an investment of USD 65 billion in 2018 for infrastructural development and also the further extension of new food testing sites (Christiansen; Pratheepkumar et al., 2017). It comprises new 62 mobile testing labs and 59 food testing laboratories.

Table 1: Last Three Years Test Conducted by FSSAI

Sl. No.	Year	Food Samples Test (Food Business Operators)	Failed to meet the FSSAI Standard
1	2016-17	78,000 sample	18,000 sample
2	2017-18	99,000 sample	24,000 sample
3	2018-19	65,000 sample	20,000 sample

Source: ISO, 2020

Based on the government data about 40% of food-delivered restaurants failed to meet the FSSAI's rules and regulations. Recently FSSAI has sent a notice to Zomato, Foodpanda, Swiggy, UberEats, FoodCloud, Box8, Fasoos, JustFood, Foodmongo, and LimeTray. The Chairman of FSSAI, Pawan Kumar Aggarwal has set the target for food business operators to restrict 'unsafe food' in the future. He has made a vision by 2022 he wants to eliminate entire unsafe food like adulteration, and containment with less than one percent (David et al., 2019_b, Nambirajan & Prabhu, 2011; Ganeshkumar et al., 2017). On another side, the excessive use of colour, flavours, and additive in food from permissible level also cause cancer and other health-related problems which they wanted to control by Food Product Standards and Food Additives Regulations (Thummula et al., 2019; Ravi et al., 2018).

1.1 Present Scenario

The Indian agricultural product exporters were ranked 15th in the global market. The Indian food industry of the food and grocery market was ranked 6th in the world and contributed 70% of total sales. The UN Food and Agriculture Organization has studied Indian food consumption from 1961 to 2011. These 50 years of studies found that the average calorie consumed by the Indians during 1960 was 2,010 calories which rapidly increased to 2,458 calories in 2011. It indicates that the food consumption pattern of Indians has gradually increased.

At present, food business operators and related businesses have a lot of difficulties in getting certificates and licenses from both the State, Central governments and also at the international level. The Chief Officer of FSSAI has stated that there is always a communication gap between reality and perception about the FSSAI regulations (David, & Banumathi, 2014_a; Srivel et al., 2018). These regulations and standards have been made clear to understand by food business operators and the public.

2. Review of Literature

2.1 Brief International Food Regulations and Standards

The United Nations (UN) and consumer organizations jointly structured consumer protection to safeguard human health (Anyanwu & Jukes, 2019). The UN Government has stressed the importance of food safety and regulation. They insisted there is a requirement to improve food safety, including, inter alia, food standards, dietary requirements, and effective monitoring inspection and evaluation mechanisms (Jongwanich, 2009). The Food and Agricultural Organization (FAO) was established in 1961, the main agenda is to save people from starvation, also food security and rich nutrition (Choudhury et al., 2011). Currently, there are around 821 million people who are suffering from hunger thus made the FAO has set a target by 2030 to bring down to 'Zero Hunger.

The Codex Alimentarius Commission (CAC) was established in Rome, Italy in 1962. It was an intergovernmental agency of the UN which was functions under the Food and Agriculture Organization and the WTO (Ghoshal; Jenkins, 1992). The codex food safety standard has measured the 'Risk Analysis' which gauges the adverse food quality, food additives, hazardous, toxicants, excess drugs, and contaminants (Evenhuis, 1986, Lu, 1970). It is assessed by the Joint Expert Committee of Food Additives term members (JECFA), FAO & WHO. The International Association of Consumer Food Organizations works for the Codex Alimentarius Commission and its subsidiary bodies that deal with health and safety-related issues (Henson & Jaffee, 2006).

2.2 International Organization Standardization (ISO)

ISO 22000 deals with Food Safety Management Systems which will apply to any food industry. The ISO 22000 standard keen to monitor food safety, stresses the prominence to produce high quality and, hygiene to the consumer end. It set a standard for the food-safe, avoiding risk and standard for human consumption (Schmidt et al., 2015). Whereas, ISO 9001 deals with food quality and standards and also ISO 14000 deals with the environmental aspects of food (Arokiaraj, 2015; David & Banumathi, 2015).

China is the leading producer of ISO certificates in the world with a total number of 3, 93,019 (i.e. ISO 22000-Food Safety Management System, ISO 9001-Quality Management Systems and ISO 14001-Environmental Management Systems). In terms of food safety and standards, China is holding the top position (10,535) followed by Greece (1,725), whereas India is placed in the third position (1,684) in the world. But in terms of quality aspects, India is holding the 5th position (27,488) in the world ISO 9001 and ISO 14001 as marked in the sixth position (6,491) in 2018 (David et al., 2019$_a$; Sudhakar, 2017 Ganesh Kumar et al., 2017, Thyagarajan et al., 2018$_a$).

2.3 Indian Food Safety and Standards

Food is an important source of energy for all living beings. In the recent past, India has had massive population growth and the problem of less cultivable land has made a lot of difficulties to feed the entire population and also hygienic food to the consumer (Arokiaraj, 2015; Thyagarajan et al., 2018$_a$). Till the advent of the 21st century, there is no clear regulation about food safety and standard in India. There are a lot of food laws and regulations which was different from state to state (Sengottuvel & Ganeshkumar, 2018). The gist formats the major timeline of the Indian food regulation act as shown below.

Table 2: Timeline of the Food Regulation Act in India

Sl No.	Year	Food Regulation Act in India
1	1860 & 1872	Adulteration of Food and Drink Act
2	1875	Sale of Food and Drugs Act
3	1918	Madras Prevention of Food Adulteration Act
4	1919	Bengal Food Adulteration Act
5	1923	Calcutta Municipal Act
6	1925	Bombay Prevention of Food Adulteration Act
7	1928	Food and Drug Adulteration Act
8	1929	Punjab Pure Food Act
9	1938	Food and Drugs Act
10	1947	Vegetable Oil Products (Control) Order
11	1954	Prevention of Food Adulteration Act & Rules (PFA ACT)
12	1955	Fruit Products Order (FPO)
13	1955	The essential commodities Act

14	1963	The export (Quality Control & Inspection) Act
15	1967	Solvent Extracted Oil, de-oiled mead and edible flour (Control) Order
16	1968	The Insecticides Act
17	1973	Meat Food Products Order (MFPO)
18	1976	Standards of weights and measures act
19	1988	Edible Oils Packaging (Regulation) Order
20	1986	Environment (Protection) Act, 1986
21	1992	Milk and Milk Products Order (MMPO)
22	1998	Edible Oil Packaging (Regulation) Order
23	1998	Vegetable oil product (Control) order
24	2006	Food Safety and Standard Act (FSSA)
25	2012	Guidelines for Proprietary and novel foods
26	2016	Public health food authority implements new regulations

Source: Food Regulation Act in India

India has become a member of CODEX in 1964. As a member of the National Codex Contact (NCC), the Food Safety and Standard Authority of India (FSSAI) was formed in New Delhi in 2006 (Kandampully & Suhartanto, 2000). The Codex Alimentarius has already set the guidelines for quality, safety, nutrition level and other important aspects related to foods. The Indian regulator adopted the models and guidelines which were given by the Codex. The FSSAI was formed and considered a responsible body for ensuring that food quality is being produced and consumed in a safe way by meeting all standards of FSSAI. In order to ensure food quality and hygiene, there is a necessity for monitoring systems to enhance the food process (i.e. Cradle-to-Grave approach) throughout the food lifecycle until it reaches the final consumer (Kumar & Mohan, 2015; Leitão et al., 2016).

The FSSAI has clearly mentioned its standard in protecting food safety, processing, manufacture, sales, distribution, storage, import and wholesome food for human consumption (Taylor, 2008; Prabhu, et al., 2020). Further, it also tests the food ingredients, colours, preservatives, labelling, contaminants, food additives, etc. In order to control unhygienic food, the FSSAI has implemented multiple food laws for food business operators. The State Governments and local bodies will make effective implementation of food laws all over the country (David & Ravi, 2017, Ganesh Kumar, 2017). The primary role was assigned to State Governments and local bodies about verify their license as well as food safety and standard as per the FSSAI regulations. Common platforms and formats are available for license and registration (Goyal, 2007). In this regard, the Senior Officers of the Bureau of Indian Standards (BIS), and the Head of the Food and Agriculture Department (FAD) have stated that "food safety is the condition that ensures that food will not cause any harm to the consumer when it prepared and/or eaten according to its intended use."

Standardization provides benefits to manufacturers, consumers and service providers alike in various ways such as sustainable development. The current legislative requirements as an emphasis on food hygiene, Food Safety Management Systems (FSMS), good manufacturing practices, Critical Control Points (HACCP), hazard analysis and nutritional labelling."

3. Research Methodology

The study was conducted in Tamil Nadu in the region of Salem. Generally, the FSSAI is usually actively working in all metro and cosmopolitan cities, whereas Salem is considered a B Grade city and a Smart city announced by the Government of India (GoI). The migrated people mostly like to take fortified food such as mobile food vendors, many small-scale hotels, and local restaurants, there are around more than 15 thousand fortified food operators in Salem. Among these people the primary data were collected from food business operators (mobile food vendors, many small-scale hotels, and local restaurants) from the study area. The questionnaire was distributed to the 75 local food-business operators in the study area however only 60 respondents were gathered and further proceed to analysis. The collected data was analyzed in SPSS Software and performed descriptive statistics, Independent Sample T-test, and ANOVA. These statistical tools help to identify the role and impact of FSSAI on food safety and awareness level in the study area. The reliability and validity of the collected data was tested which is above > .70. There are around 11 categorical and two interval

scaled questions that helps to identify the role and perception level of food business operators.

The demographic profile of food-business operators in the Salem region is described below in table 3. It explains that around 63.3% of food business operators are successfully running their business in public areas and the city centre. The nature of business ownership was mostly owned by a sole proprietor (66.7%) and they don't have any branches in the studied area (66.7%). The consumers were more preferred to consume vegetarian food by 55%. Around 91.7% of food-business operators were registered under FSSAI, they acquired their license before opening the outlet (46.7%) and after opening their outlet (46.7%). The food-business operators were broadly categories into hotel & restaurant (35%), Small food joint (21.7%), Cafe/ Eatery (16.7%), Tea/ Snack shop (13.3%), 3/Retail outlet (6.7%), and Mobile food vendor (6.7%).

Table 3: Demographic Profile of Food-Business Operators

Food-Business Operators		**% of Respondents**
Business Location	City outer	15.0
	Market area	11.7
	Shopping mall	10.0
	City Centre	25.0
	Public area	38.3
Business Ownership	Partnership	20.0
	Sole proprietor	66.7
	Franchise	13.3
Kind of food you serve	Vegetarian	55.0
	Both	45.0
Number of Branches	No branches	66.7
	Two to five	16.7
	Five to ten	8.3
	More than ten	8.3
Business Registered under FSSAI	Yes	91.7
	No	8.3
FSSAI license Status	Before opening the outlet	46.7
	After opening the outlet	46.7
	License not applied	6.7
Category of Food Business	Hotel/ restaurant	35.0
	Cafe/ eatery	16.7
	3/Retail outlet	6.7
	Small food joint	21.7
	Tea/ Snack shop	13.3
	Mobile food vendor	6.7
FSSAI License	Self	40.0
	Consultancy	16.7
	Municipality	33.3
	No license	10.0
Reason for not having FSSAI License	Not aware of FSSAI	3.3
	Don't know how to apply for the license	1.7
	My outlet doesn't meet FSSAI License requirements	1.7
	I can't afford for getting the license	1.7
	Have license	60.0
	Not applicable	31.7
Opinion about FSSAI Licensing	Voluntary	8.3
	Mandatory	91.7
FSSAI strict regulation	100%	33.3
	75%	38.3
	50%	25.0
	NIL	3.3
Activities & Performance of FSSAI	Very active	51.7
	Active	21.7
	Neutral	16.7
	Less Active	5.0
	Not Active	5.0
Rate FSSAI for future	Very strict	16.7
	Strict	35.0
	Neutral	26.7
	Liberal	10.0
	Not applicable	11.7
Visit of Food Safety Officer	A few days back	43.3
	A few weeks ago	45.0
	Never came for inspection	11.7

Source: Primary

Around 40% of food-business operators have owned their business licenses by themselves. Further, it is also found out the reason why not having FSSAI Licenses and we got responses from them, that it is not

applicable to them (31.1%). The respondent was also given their opinion about the FSSAI license 91.7% mentioned it is mandatory for their business operation and most of the respondents (38.3%) suggested that only 75% of FSSAI regulation is necessary for them. The respondents were asked to rate the performance and activities of FSSAI and they marked very actively (51.7%). Further, they have rated future FSSAI regulation for the food-related business should be strict by 35%. The respondents have also shown that the food safety officers check the quality of food a few weeks ago (45%) and a few days back (43.3%).

The independent sample T-test was performed to understand the role and performance of FSSAI which was considered as a dependent variable and their opinion about FSSAI licensing, Business registered under FSSAI and type of food served to consumers as considered as the independent variables.

Table 4: Independent Sample T-Test for the Role and Performance of FSSAI

Role and Performance of FSSAI	T-value	F-value	P-value	Level of Significant
Opinion about FSSAI Licensing	5.75	0.339	0.001	Significant
Kind of food you serve	0.511	0.037	0.611	Not Significant
Businesses registered under FSSAI	-6.351	0.350	0.000	Significant

Source: Primary

Based on the above table, explains the opinion about FSSAI licensing and business registration under FSSAI. It is found that there is a statistically significant influence on the role and performance of FSSAI. Whereas the food type is not influenced by the role and performance of FSSAI.

The one-way ANOVA was conducted to understand the mean differences between the dependent variable and independent variables individually. The below table helps to understand the role and performance of FSSAI (dependent variable) towards the business location, business ownership, the number of branches, FSSAI license Status, food categories, FSSAI license, the reason for not having FSSAI license, FSSAI strict regulation, visit of food safety Officer and rate the FSSAI for the future consideration as considered as independent variables.

Table 5: One-Way ANOVA for the Role and Performance of FSSAI

Role & Performance of FSSAI	F- value	P-value	Level of Significant
Business Location	8.001	0.000	Significant
Business ownership	0.257	0.775	Not Significant
Number of branches	0.861	0.467	Not Significant
FSSAI license Status	12.22	0.000	Significant
Category of food business	1.060	0.393	Not Significant
FSSAI license	19.68	0.000	Significant
Reason for not having FSSAI License	7.456	0.000	Significant
FSSAI strict Regulation	0.642	0.591	Not Significant
Rate the FSSAI for future	27.27	0.000	Significant
Visit of Food Safety Officer	16.56	0.000	Significant

Source: Primary

The ANOVA result has shown that there are statistically significant differences between the dependent and independent variables. Based on the result, we can identify that the business location, FSSAI license status, FSSAI license, reasons for not having FSSAI license, rate of the FSSAI for future consideration and visit of food safety Officer are major differences with the role and performance of FSSAI. Whereas, the business ownership, number of branches, category of food business and the FSSAI implementation of strict regulation are found to be insignificant.

The Chi-square analysis was performed to understand the statistical association between the dependent variable and independent variables. Again the dependent variable is selected as the role and performance of FSSAI and independent variables are business location, business ownership, type of food serving to consumers, the business registered under FSSAI, the number of branches, FSSAI license status, category of food business, FSSAI license, reasons for

not having FSSAI license, opinion about FSSAI licensing, FSSAI strict regulation, rate the FSSAI for future, and visit of food safety officer.

Table 6: Chi-Square Test for the Role and Performance of FSSAI

Pearson Chi-Square Test	Chi-Square Value	P-Value	Level of Significant
Business Location	38.07	0.001	Significant
Business ownership	9.265	0.320	Not Significant
Kind of food you serving	1.794	0.774	Not Significant
Businesses registered under FSSAI	30.76	0.000	Significant
Number of branches	7.465	0.825	Not Significant
FSSAI license Status	27.05	0.001	Significant
Category of food business	17.21	0.639	Not Significant
FSSAI license	51.09	0.000	Significant
Reason for not having FSSAI License	76.04	0.000	Significant
Opinion about FSSAI Licensing	30.76	0.000	Significant
FSSAI strict Regulation	12.18	0.431	Not Significant
Rate the FSSAI for future	63.25	0.000	Significant
Visit of Food Safety Officer	30.59	0.000	Significant

Source: Primary

Based on the Chi-Square result, it is found that the business location, the business registered under FSSAI, the status of the FSSAI license, FSSAI license, the reason for not having FSSAI license, opinion about FSSAI licensing, rate the FSSAI for future consideration and visit of food safety Officer are statistically associated to role and performance of FSSAI.

4. Discussions of the Study

The outcome of food-business operators has explained the current status of food-business operated in the study area. The collected data were analyzed in the SPSS software with help of the T-Test, ANOVA, and Chi-Square test. Through the questionnaire, it reveals basic information about the name of the outlet, type of ownership, the number of branches operated, usage of clean, processed, water for cooking, the status of the FSSAI License, awareness level about the Fortified Foods and their exposure level of FBO's about the recent amendments of FSSAI. The Food business operators mostly own their business individually and there are located in the city Centre and the public area. Most of them registered their business under FSSAI, and they had their license before and after opening the outlet is mandatory.

5. Conclusion

It is concluded that the FSSAI should take the necessary steps to make crystal clear the process and procedure to apply and proceed for license and registration for their food business. The license and registration have played a vital role in food business operations for the satisfaction of consumers in a healthy life. There should be proper awareness about the ingredients used in fortified food among food businesses to eliminate malnutrition and avoid food adulteration. Finally, the consumers should also understand what they are consuming and the quality of ingredients in the food outlets.

The government should take the necessary steps to control the food business towards food quality and healthiness for a better life. Food and Safety Officers should regularly visit for inspection and monitor the food business operators for the betterment of public health. Officers should encourage the consumers can able to make their opinion or complaints or any queries about the quality of the food which is being served in food outlets. The food-business operators also should make transparent the raw ingredients used in the preparation of foods. The future rules and regulations of FSSAI should be strictly implemented all over India and properly monitor the activities of food business operators to fulfil the FSSAI standards.

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