

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO.4535
TO BE ANSWERED ON 19TH JULY, 2019**

REGULATION UNDER FOOD SAFETY AND STANDARDS ACT

4535. DR. SHASHI THAROOR:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government has notified all regulations as required by the Food Safety and Standards Act, if so, the details thereof and if not the reasons therefor along with the time by which the said regulations is likely to be notified;
- (b) whether the Government is aware that majority of Food Business Operators have license despite incomplete documentation;
- (c) if so, whether the Government has taken steps to review, cancel or reissue these licenses and if so, the details thereof;
- (d) whether the Government is aware that majority of State Food Laboratories (SFL) are not accredited by National Accreditation Board for Testing and Calibration Laboratories; and
- (e) if so, whether the Government has taken steps to accredit these SFLs, if so, the details thereof and if not, the reasons therefor?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

- (a): Government has notified all major regulations and guidelines required in implementation of Food Safety and Standards Act , 2006 which are detailed at **Annexure**.
- (b) & (c): The Food Business Operators, while applying for Food Safety and Standards Authority of India (FSSAI) license are required to submit certain mandatory documents as prescribed under Annexure-2 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 as applicable to their Kind of Business(es). The Licensing Authorities responsible for issuance of State/Central License issued license after verification of the documents submitted by the Food Business Operators.
- (d) & (e): Yes. A Central Sector Scheme for “Strengthening of Food Testing System in the Country Including Provision of Mobile Food Testing Labs” has been rolled out by the Food Safety and Standards Authority of India (FSSAI) with an outlay of Rs. 481.95 Crore for the period 2016-17 to 2018-19. One of the components of the Scheme is Capacity Building of Food Testing Laboratories so as to ensure that all the State Food Testing laboratories attain NABL accreditation and bring them at par with international standards. So far, 8 Capacity Building Programs have been organised in different locations so as to cover all State Food Testing Laboratories in which 264 laboratory personnel have participated. A panel of experts has also been constituted and shared with States/UTs to help them about NABL accreditation process. This has raised the total number of NABL accredited State Food Testing Laboratories from 8 to 16.

AREAS OF REGULATIONS UNDER THE FOOD SAFETY AND STANDARDS ACT, 2006

1. Regulations framed

Section 92 (2) of the Act			Related Regulations framed and notified.
Sr. No.	Reference Section	Suggested areas	
1.	92 (2) (a)	Salaries and other conditions of service of officers and other employees of the Food Authority under sub-section (3) of section 9;	Food Safety and Standards Authority of India (Salary, Allowances and other Conditions of service of Officers and Employees) Regulations, 2013
2.	92 (2) (b)	Rules of procedure for transaction of business under subsection (5) of section 11	Food Safety and Standards Authority of India (Procedure for Transaction of Business of Central Advisory Committee) Regulations, 2010. (2 Amendments)
3.	92 (2) (c)	Other functions of Central Advisory Committee under sub-section (2) of section 12	
4.	92 (2) (d)	Procedure of Scientific Committee and Panels under subsection (4) of section 15;	Food Safety and Standards (Transaction of Business and Procedures for the Scientific Committee and Scientific Panels) Regulations, 2016
5.	92 (2) (e)	Notifying standards and guidelines in relation to articles of food meant for human consumption under sub-section (2) of section 16;	Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. (57 Amendments)
6.	92 (2) (f)	Procedure to be followed by Food Authority for transaction of business at its meeting under sub-section (1) of Section 17	Food Safety and Standards (Transaction of Business) Regulations, 2010.(1 Amendment)
7.	92 (2) (h)	Limits of additives under section 19;	Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011
8.	92 (2) (i)	Limits of quantities of contaminants, toxic substance and heavy metals etc. Under section 20;	Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011. (14 Amendments)
9.	92 (2) (j)	Tolerance limit of pesticides, veterinary drugs residues, etc under section 21;	
10.	92 (2) (k)	The manner of marking and labelling of foods under section 23;	Food Safety and standards (Packaging and Labeling) regulation. 2011. (8 Amendments) Revised Food Safety and Standards (Labelling and Display)

Section 92 (2) of the Act			Related Regulations framed and notified.
Sr. No.	Reference Section	Suggested areas	
			Regulations, 2019 has beendraft notified)
11.	92 (2) (l)	Form in which guarantee shall be given under sub-section (4) of section 26;	Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011-covered under sub-regulation 2.1.14 (form E)
12.	92 (2) (m)	Conditions and guidelines relating to food recall procedures under subsection (4) of section 28;	Food Safety and Standards (Food Recall Procedure) Regulations, 2017
13.	92 (2) (n)	Regulations relating to functioning of Food Safety Officer under subsection (5) of section 29;	Food Safety and Standards Rules, 2011
14.	92 (2) (o)	Notifying the registering authority and the manner of registration; the manner of making application for obtaining license, the fees payable therefore and the circumstances under which such license may be cancelled or forfeited under section 31;	Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011 (3 Amendments)
15.	92 (2) (p)	The respective areas of which the Designated Officer shall be in-charge for food safety administration under subsection (1) of section 36;	Orders issued by FSSAI and State Authorities from time to time for respective areas.
16.	92 (2) (q)	Procedure in getting food analysed, details of fees etc., under sub-section (1) of section 40;	Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011, (1 Amendment)
17.	92 (2) (r)	Functions, procedure to be followed by food laboratories under sub-section (3) of section 43;	
18.	92 (2) (s)	Procedure to be followed by officials under sub-section (6) of section 47;	<ul style="list-style-type: none"> • Food Safety and Standards Rules, 2011 and • Food Safety and Standards (Import) Regulations, 2017.
Section of 22 the Act			Related regulations framed and notified.
Sr. No.	Reference Section	Suggested areas	
19.	22(1)	Foods for special dietary uses or functional foods or Nutraceuticals	Food Safety and Standards (Health Supplements,

Section 92 (2) of the Act			Related Regulations framed and notified.
Sr. No.	Reference Section	Suggested areas	
		or health supplements	Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016
20.	22(2)	Genetically engineered or modified food	Food Safety and Standards (Genetically Modified and Engineered Foods) Regulations, 2019 (Currently under process of draft notification)
21.	22(3)	Organic Food	Food Safety and Standards (Organic Food) Regulations, 2017
22.	22(4)	Proprietary and Novel food	<ul style="list-style-type: none"> • Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011. • Food Safety and Standards (Health Supplements, Nutraceuticals, and Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016. • Food Safety and Standards (Approval for non-specified food and food ingredients) Regulations, 2017
Section 16 (2) of the Act			Related Regulations framed and notified.
Sr. No.	Reference Section	Suggested areas	
23.	16(2) (a)	The standards and guidelines in relation to articles of food and specifying an appropriate system for enforcing various standards notified under this Act;	[Remarks: Area already covered in Section 92(2)(e)]
24.	16 (2) (b)	The limits for use of food additives, crop contaminants, pesticide residues, residues of veterinary drugs, heavy metals, processing aids, myco-toxins, antibiotics and pharmacological active substances and irradiation of food;	[Remarks: Already covered in Sections 92(2)(h), 92(2)(i) and 92(2)(j)]
25.	16 (2) (c)	The mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety	Food Safety and Standards(Food Safety Auditing) Regulations, 2018

Section 92 (2) of the Act			Related Regulations framed and notified.
Sr. No.	Reference Section	Suggested areas	
		management systems for food businesses;	
26.	16 (2) (d)	The procedure and the enforcement of quality control in relation to any article of food imported into India	Food Safety and Standards (Import) Regulations, 2017. (1 Amendment)
27.	16 (2) (e)	The procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories;	Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2018.
28.	16 (2) (f)	The method of sampling, analysis and exchange of information among enforcement authorities;	<ul style="list-style-type: none"> • Food Safety and Standards Rules, 2011. • Manuals of the Methods of Analysis and Sampling approved by the Food Authority
29.	16 (2) (h)	Food labelling standards including claims on health, nutrition, special dietary uses and food category systems for foods;	<p>[Remarks: Labelling already covered in Section 92(2)(k)]</p> <ul style="list-style-type: none"> • Food Safety and Standards (Advertising and Claims) Regulations, 2018 and • Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011

2. Regulations not framed

Sections 16 and 92 of the Act			Remarks
Sr. No.	Reference Section	Suggested areas	
30.	16 (2) (g)	Conduct survey of enforcement and administration of this Act in the country	Regulations need not to be framed as this section envisaging about the process of conducting survey of enforcement and administration of this Act in the country. The same is proposed to be deleted in the proposal of amendment in the Act.
31.	92 (2) (g)	Making or amending regulations in view of urgency concerning food safety or public health under clause (d) of sub-section (2) of section 18.	The Law Ministry suggested that there is no necessity to frame regulations under this clause as the power has already been given in section 18 (2) (d).
32.	92 (2) (t)	Financial regulations to be adopted by the Food Authority	This would be taken up after amendment of the Act so as to

		in drawing up its budget under sub-section (2) of section	provide for creation of corpus.
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3. Regulations framed in other areas

Sections 16 and 92 of the Act			Remarks
Sr. No.	Reference Section	Suggested areas	
33.	92 (2) (v)	Any other matter which is required to be, or may be, specified by regulations or in respect of which provision is to be made by regulations.	<ul style="list-style-type: none"> • Food Safety and Standards (Prohibition and Restriction for sale) Regulations, 2011. (5 Amendments) • Food Safety and Standards (Approval for non-specified food and food ingredients) Regulations, 2017 • Food Safety and Standards (Packaging) Regulations, 2018 • Food Safety and Standards (Recovery and Distribution of Surplus Food) regulations, 2019 (currently under process of final notification) • Food Safety and Standards (Safe and Wholesome Food for School Children) Regulations, 2019. (currently under process of draft notification)

4. Guidelines/ orders issued

Sections 16 and 92 of the Act			Related guidelines/ Orders framed and notified.
Sr. No.	Reference Section	Suggested areas	
34.	16 (2) (i)	The manner in which and the procedure subject to which risk analysis, risk assessment, risk communication and risk management shall be undertaken	<ul style="list-style-type: none"> • Manual for development of food regulations have been framed. • FSS (Import) Regulations, 2017. Covers Risk Management system in Food import clearance (Operational in ICEGATE)
35.	92 (2) (u)	Issue guidelines or direction for participation in Codex meeting and preparation of response to Codex matters;	Guideline for preparation of national response or national view point to codex and participation in codex meeting & guidelines for codex contact point, national codex committee, and nation shadow committee issued by FSSAI.