

Dated, the 29<sup>th</sup> November, 2024

**ORDER**

**Subject: Addition of Food Products under 'High Risk Food Categories' subsequent to the omission of Mandatory BIS Certification-reg.**

Consequent to the omission of sub-regulation 2.3.14 (4), (5), (17) and (18) of the Food Safety and Standards (Prohibitions and Restriction on Sales) Regulations, 2011 (copy of notification is attached), which pertain to mandatory Bureau of Indian Standards (BIS) certification for certain food products, it has been decided that **'Packaged Drinking Water and Mineral Water'** (for which BIS certification was mandatory prior to Gazette notification of Food Safety and Standards (Prohibition and Restrictions on Sales) first Amendment Regulations, 2024 dated 17<sup>th</sup> October 2024) **will be treated under 'High Risk Food Categories'**. It is to be noted that other food products for which BIS certification was mandatory are already identified as high risk categories under FSSAI's Risk Based Inspection Scheduling [RBIS] policy vide order number RCD-02001/9/2021-Regulatory-FSSAI dated 02<sup>nd</sup> May, 2022 (copy of order is attached).

2. Accordingly, following are the amendments to the said RBIS policy:

(a) after point (h) of para I.8 of Annexure-1 of FSSAI order number, the following is inserted –  
**(i) 14.1 - Non-alcoholic ("soft") beverages - Packaged Drinking Water and Mineral Water only**

(b) After the sub-para 2 of para II, following is inserted–

2(a) Further, **inspection of manufacturers/processors for the food products** (for which BIS certification was mandatory prior to Gazette notification of Food Safety and Standards (Prohibition and Restrictions on Sales) first Amendment Regulations, 2024 dated 17<sup>th</sup> October 2024) **is mandatory before the grant of license or registration.**

(c) In sub para 3.1 of Para II relating to - **Frequency of mandatory inspections of Food Business Operators, against serial no. i, in column 2 & 3, after the existing entries, following is being inserted –**

<b>Food product category</b>	<b>Frequency of inspection</b>
14.1 - Non-alcoholic ("soft") beverages - Packaged Drinking Water and Mineral Water only	Once a year

3. It is reiterated that all Centrally Licensed Manufacturers under High Risk Food Categories shall get its business audited by FSSAI recognised third party food safety auditing agency every year. The list of High Risk Food Categories now also includes Packaged Drinking Water and Mineral Water.

4. This issues with the approval of Competent Authority.

Yours sincerely,

(Rakesh Kumar)

**Director (Regulatory Compliance Division)**

To

1. The Commissioners of Food Safety of all States/UTs,
2. All Regional Directors, FSSAI,
3. All Central Licensing Authorities, FSSAI,
4. CTO, FSSAI- For placing the order on FSSAI's website for information and necessary action by the enforcement authorities.

**Copy for information to:**

1. Sr. PS to CEO, FSSAI;
2. All Divisional Heads, FSSAI.



# भारत का राजपत्र The Gazette of India

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असाधारण  
EXTRAORDINARY

भाग III—खण्ड 4  
PART III—Section 4

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 832]  
No. 832]

नई दिल्ली, शुक्रवार, अक्टूबर 18, 2024/आश्विन 26, 1946  
NEW DELHI, FRIDAY, OCTOBER 18, 2024/ASVINA 26, 1946

भारतीय खाद्य सुरक्षा और मानक प्राधिकरण

अधिसूचना

नई दिल्ली, 17 अक्टूबर, 2024

सं. रेग-11027/2/2022-विनियम-एफ एस एस ए आई.—खाद्य सुरक्षा और मानक (विक्रय प्रतिषेध एवं निर्बंधन) संशोधन विनियम, 2023 का प्रारूप खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 का 34) की धारा 92 की उपधारा (1) की अपेक्षा के अनुसार, भारत के राजपत्र, असाधारण, भाग III, खंड 4 में, भारतीय खाद्य सुरक्षा और मानक प्राधिकरण की अधिसूचना संख्या फा. स. रेग-11027/2/2022-विनियम-एफ एस एस ए आई, दिनांक 27 अप्रैल, 2023 द्वारा, प्रकाशित किये गए थे जिसमें उन सभी व्यक्तियों से जिनको उससे प्रभावित होने की संभावना थी उक्त अधिसूचना को अंतर्विष्ट करने वाली राजपत्र की प्रतियाँ जनता को उपलब्ध कराये जाने की तारीख से साठ दिन की अवधि की समाप्ति से पूर्व आक्षेप और सुझाव आमंत्रित किये गए थे।

और उक्त राजपत्र की प्रतियाँ जनता को 28 नवम्बर, 2023 को उपलब्ध करा दी गई थीं;

और उक्त प्रारूप विनियम के सम्बन्ध में जनता से प्राप्त आक्षेपों और सुझावों पर भारतीय खाद्य सुरक्षा और मानक प्राधिकरण द्वारा विचार कर लिया गया है;

अतः अब भारतीय खाद्य सुरक्षा और मानक प्राधिकरण, खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 का 34) की धारा 92 द्वारा प्रदत्त शक्तियों का उपयोग करते हुए खाद्य सुरक्षा और मानक (विक्रय प्रतिषेध एवं निर्बंधन) विनियम, 2011 में और संशोधन करने के लिए निम्नलिखित विनियम बनाता है, अर्थात्:-

### विनियम

1. संक्षिप्त नाम और प्रारंभ.- (1) इन विनियमों का संक्षिप्त नाम खाद्य सुरक्षा और मानक (विक्रय प्रतिषेध एवं निर्बंधन) प्रथम संशोधन विनियम, 2024 है।

(2) यह राजपत्र में इनके प्रकाशन की तारीख से प्रवृत्त होंगे।

2. खाद्य सुरक्षा एवं मानक (विक्रय प्रतिषेध एवं निर्बंधन) विनियम, 2011 में,-

(i) विनियम 2.1 के उप विनियम (2.1.1) में, 'परन्तु यह भी कि विनियम 2.1.1(5) में प्रतिषेध' शब्दों से प्रारम्भ और 'विहित सुसंगत मानकों के अनुरूप हो।' शब्दों पर समाप्त होने वाले तीसरे परंतुक के स्थान पर निम्नलिखित को रखा जाएगा, अर्थात्-

"परन्तु यह भी कि विनियम 2.1.1 (5) में प्रतिषेध, खाद्य सुरक्षा और मानक (खाद्य उत्पाद मानक और खाद्य सहयोज्य) विनियम, 2011 के विनियम 2.2 के उप विनियम 2.2.1 के खंड 24 के अधीन विनिर्दिष्ट बहु-स्रोत खाद्य तेल के संबंध में निष्क्रिय रहेगा और बहु-स्रोत खाद्य तेल को 15 लीटर से अधिक वजन वाले पैकेज में नहीं बेचा जाएगा।"

(ii) विनियम 2.3 में,-

(क) उप विनियम 2.3.8 का लोप किया जायेगा;

(ख) उप विनियम 2.3.14 में,-

(I) खंड (4) और (5) का लोप किया जायेगा;

(II) खंड (11) में, शब्दों "एगमार्क प्रमाण चिन्ह के अधीन" का लोप किया जायेगा;

(III) खंड (13) में, शब्दों "एगमार्क प्रमाण चिन्ह के अधीन ही" का लोप किया जायेगा;

(IV) खंड (17) और (18) का लोप किया जायेगा;

(iii) प्ररूप क का लोप किया जायेगा;

जी. कमलावर्धन राव, मुख्य कार्यकारी अधिकारी

[विज्ञापन-III/4/असा./601/2024-25]

टिप्पण: मूल विनियम भारत के राजपत्र, असाधारण में अधिसूचना संख्याक फा. सं. 2-15015/30/2010 तारीख 1 अगस्त, 2011 द्वारा प्रकाशित किए गए और अधिसूचना संख्याक फा. सं. आरईजी/प्रतिनिधित्व-एमएसईओ/एफएसएसएआई-2021, तारीख 05 सितंबर, 2022 द्वारा अंतिम बार संशोधित किए गए थे।

**FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA****NOTIFICATION**

New Delhi, the 17th October, 2024

**No. REG-11027/2/2022-Regulation-FSSAI.**—Whereas the draft of the Food Safety and Standards (Prohibition and Restrictions on Sales) Amendment Regulations, 2023, were published as required under sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006) *vide* notification of the Food Safety and Standards Authority of India number F.No. REG-11027/2/2022-Regulation-FSSAI dated the 27<sup>th</sup> April, 2023, in the Gazette of India, Extraordinary, Part III, Section 4, for inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official Gazette containing the said notifications were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the **28<sup>th</sup> April, 2023**;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, namely: -

**REGULATIONS**

1. **Short title and commencement.**- (1) These regulations may be called the Food Safety and Standards (Prohibition and Restrictions on Sales) first Amendment Regulations, 2024.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011,-

(i) in regulation 2.1, in sub-regulation 2.1.1, for the third proviso commencing with the words “Provided also that prohibition in regulation 2.1.1” and ending with the words “the relevant standard prescribed by these regulations.”, the following shall be substituted, namely,-

“Provided also that prohibition in regulation 2.1.1 (5) shall remain inoperative in respect of Multi-Source Edible Oil specified under the clause 24 of sub-regulation 2.2.1 of regulation 2.2 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and Multi-Source Edible Oil shall not be sold in a package weighing more than 15 litres.”;

(ii) in regulation 2.3,-

(A) sub-regulation 2.3.8 shall be omitted;

(B) in sub-regulation 2.3.14,-

(a) clauses (4) and (5) shall be omitted;

(b) in clause (11), the words “AGMARK certification mark bearing” shall be omitted;

(c) in clause (13), the words “AGMARK Certification mark bearing” shall be omitted;

(d) clauses (17) and (18) shall be omitted;

(iii) The Form A shall be omitted.

G. KAMALA VARDHANA RAO, Chief Executive Officer

[ADVT.-III/4/Exy./601/2024-25]

**Note.** - The principal regulations were published in the Gazette of India, Extraordinary *vide* notification number F. No. 2-15015/30/2010, dated the 1st August, 2011 and last amended *vide* notification number F.No. REG/Representation-MSEO/FSSAI-2021, dated 5th September, 2022.



**F.No. RCD-02001/9/2021-Regulatory-FSSAI**  
**Food Safety and Standards Authority of India**  
**Regulatory Compliance Division**  
**FDA Bhawan, Kotla Road, New Delhi- 110002**

Dated <sup>nd</sup>02 May 2022

**Order**

FSSAI from time to time, has issued several orders/advisories/instructions with respect to conducting inspections of food businesses, as listed below:

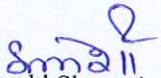
- i. O.M. No. 03-01/2012/Enf-1/FSSAI dated 15.10.2012
- ii. O.M. No. 03-01/2012/Enf-1/FSSAI dated 4.12.2012
- iii. O.M. No. 03-01/Enf-1/FSSAI/2012 dated 22.10.2012
- iv. OM File No.1(5)/Enf-1/FSSAI/2012 dated 12.02.2015
- v. Letter No. 4(35) 2016/U.P./Enf/FSSAI dated 19.07.2017
- vi. Order no. 19(2) 2008/FSA/RCD/FSSAI dated 13.08.2019 & subsequent clarifications dated 24.09.2019 and 29.11.2019

2. It has been decided to review the above advisories/ instructions/ orders to consolidate and update the same and to issue the comprehensive order on inspection/auditing superseding all the above advisories/ instructions/ orders in the matter.
3. Accordingly, an inspection plan has been framed, based on risk associated with the Food Businesses, to enable the authorities to carry out the mandatory inspections of the premises of the Food Business Operators (FBOs) ensuring the safety of high risk food categories in a more systematic and intensive manner. There is also a provision for exemption from the inspection based on the score of Third Party Audit or Hygiene Rating Scheme as applicable.
4. Further, if Commissioner of Food Safety of any State/UT is of the view that more number of inspections needs to be added for a particular Financial Year, he/she may give directions to the Designated Officers in addition to already proposed list of scheduled inspections as per this inspection plan. Also, this plan shall not preclude the Registration or Licensing Authorities from carrying out the inspections of any other Food Business Operator in the situation of the health risk or food safety emergencies. The inspection plan is annexed at **Annexure-I**.
5. All Central Licensed Manufacturer/Processors under High Risk Food Categories as specified in the Annexure –I shall get its business audited by FSSAI recognised food safety auditing agency every year. Also, Third Party Auditing of manufacturers/processors of high risk food categories having State license may be mandated by the concerned Commissioners of Food Safety in their respective States/UTs.
6. The inspection plan shall be reviewed further from time to time by the Food Authority. The provisions of the annexed inspection plan shall be incorporated in the Food Safety Compliance System (FoSCoS) for systematic allotment of inspection to Designated Officers/Food Safety Officers.

7. Commissioners of Food Safety of all States/UTs shall ensure the strict implementation of the inspection plan and shall monitor the progress of inspections conducted. They shall also review the pendency, if any, regularly so that targeted inspections shall be conducted within the timelines as specified.

8. This issues with the approval of Food Authority.

Yours faithfully,

  
(Inoshi Sharma)

Executive Director (Compliance Strategy)

To,

1. Commissioners of Food Safety of All States/UTs
2. Directors of All Regional Offices, FSSAI
3. All Central Licensing Authorities
4. CITO- for making necessary changes in the FoSCoS portal and uploading on website

Copy for information to-

1. All Divisional Heads of FSSAI
2. PPS to Chairperson, FSSAI
3. PS to CEO, FSSAI



**I. General principles for Inspections**

1. As a general rule, inspection should be undertaken with the objective of bringing about systematic improvements rather than in the form of raids/searches and should be undertaken with prior notice to FBO unless the concerned officer has reason to believe/ definite information about serious food safety issues which could be in the contravention of FSS Act or the regulations made thereunder.
2. It is mandatory to use the inspection checklist developed and prescribed by FSSAI for different KOBs.
3. It is also mandatory that all inspections to be carried out only using Food safety compliance through regular inspection & sampling system (FoSCoRIS) developed by FSSAI. In case owing to any reason FoSCoRIS app is not used, the report of inspection must be uploaded on FoSCoS within 24hrs of inspection. Any additional aspect may be inspected/ checked and recorded in the report.
4. As a general rule, all inspections should be accompanied with sampling. In case sampling is not feasible to be carried out along with inspection, the reason for the same must be recorded in writing.
5. Local sensitivities/ festivals/ practices/media reports etc. need to be factored in while scheduling inspections.
6. E-Inspection- When regular inspection is not feasible (reason to be recorded in writing), e-inspection of FBO's premise/unit may be conducted. The authority may record the observations by the way of videos or images submitted by FBO. The mode of submission of videos or images related to the inspection may be through any possible media available including live streaming preferably, if possible. If the facility of downloading of videos or images is available through that media, the concerned authority shall download and keep a copy of these visuals in their electronic devices for future reference.
7. The frequency where ever prescribed for any year, the year should be taken as financial year.
8. FSSAI has identified the following food categories as high risk categories:
  - a) 01 - Dairy products and analogues
  - b) 08 - Meat and meat products including poultry
  - c) 09- Fish and fish products, including molluscs, crustaceans, and echinoderms
  - d) 10 - Eggs and egg products
  - e) 13- Foodstuffs intended for particular nutritional uses
  - f) 16- Prepared Foods
  - g) 18.1- Indian Sweets
  - h) 99.5 – Nutrients and their preparations (Fortified Rice Kernels only)
9. Mandatory Third Party Audit shall be conducted annually only for the Manufacturers/Processors holding Central License for high risk categories mentioned in point I (8) above.



10. The inspection of high risk food categories shall be carried out on priority and other inspections may be conducted only when mandatory inspections of all high risk food categories are exhausted.

## II. Types of Inspections

1. **Pre-License Inspection:** No pre-licensing inspection is required except in case of **Manufacturer/Processors of Milk & Milk products, Meat & Meat products, Fish & Fish products, Fortified Rice Kernels (FRKs) and Slaughter houses**, where inspection is mandatory before grant of license. In other cases, the license may be granted and inspection may be conducted in due course. The timelines given under 2.1.4 of FSS (Licensing and Registration of Food Businesses) Regulations, 2011 for conducting Pre-License Inspection shall be adhered to and any delay in processing of application should be avoided.
2. **Pre-Registration Inspection:** No pre-registration inspection is required except **Manufacturer/Processors of Fortified Rice Kernels (FRKs)** where it is mandatory to carry out inspection before issuing Registration Certificate. The timelines given under 2.1.1 of FSS (Licensing and Registration of Food Businesses) Regulations, 2011 for conducting Pre-Registration Inspection shall be adhered to and any delay in processing of application should be avoided.
3. **Routine Inspection:** Regular inspections for Enforcement and Surveillance are undertaken as per the plans developed by each State on the basis of their respective risk profile and scale of operations of FBOs as reflected in Table 3.1. The Food Safety Officer should carry out inspections of FBOs as per the frequencies and exemptions prescribed below.

### 3.1 Frequency of mandatory inspections of Food Business Operators

The frequency of the inspections has been calculated on the basis of the risk categorisation of the KoBs. The following inspection frequency is valid for both licensed and registered FBOs.

S.No.	Kind of Business (KoB)	Food Product Category	Frequency of Inspection
i	Manufacturer / Processer	1, 8, 9, 10, 13, 16 & 18.1, 99.5(only FRK)	Once a year
		Other than 1, 8, 9, 10, 13, 16, 18.1 & 99.5 (only FRK)	Once in every two years
ii	Food Service Establishments*	All licensed FBOs	Once in every two years
iii	Storage (Frozen, Refrigerated & Controlled Atmosphere)*	All licensed FBOs of Milk and Milk products, Fish and Fish products, Meat and Meat products	Once in every two years
iv	Transporter (Frozen & Refrigerated)*	i.e FPC - 1, 8 and 9	Once in every two years
v.	Other KoBs	5 % of licensed FBOs and 2 % registered FBOs selected randomly or on the basis of the risk profile	Once a year

*\*For Registered FBOs, State may draw their own inspection plan in accordance with the number of the registered FBOs in these categories, number of FSOs/DOs available and scale of operation of FBos*



### 3.2 Exemption from Inspections<sup>###</sup>

S. No.	Eligible KoB	Criteria	Exemption
i.	All KoBs* <sup>#</sup>	Obtaining 80% or above score in FSSAI's Third Party Audit.	2 years (two Financial Years i.e. First FY, in which Third Party Audit is conducted and succeeding FY)
ii.	Food Service Establishments, Meat Retail Shops, Sweet Shops, Bakery Retail Shops	Hygiene Rating 5 Smileys (Excellent)	2 years (two Financial Years i.e. First FY, in which Hygiene Rating Certificate has been awarded is conducted and succeeding FY)

*\*Third Party Audit report shall be used for awarding Hygiene Rating Certificate to FBOs eligible for the same under Hygiene Rating (HR) Scheme (Food Service Establishments, Meat Retail Shops, Sweet Shops and Bakery retail shop). No separate audit will be required to award HR certificate to such FBOs.*

*# Note: Hygiene Rating Scheme cannot replace Third Party Audit in case of KoBs such as High Risk Categories where Third Party Audit has been mandated by the Food Authority or Commissioners Food Safety of States/UTs.*

*## FSSAI, by way of issuing orders from time to time, may also exempt any other Kind of Business from the inspections and/or frequency thereof, on the basis of any other scheme designed to ensure the safety and hygiene of such food business operators.*

**Illustration:** If an FBO "X" has obtained Audit Score of 80% or above in FY 2021-2022 then the inspection by FSO during FY 2021-2022 & FY 2022-2023 will be exempted however, in the next FY i.e. 2023-2024, the inspection by FSO shall be carried out. If the FBO 'X' obtained audit score of 80% or above in the FY 2023-2024 as well then inspection by FSO during FY 2024-2025 will be exempted but shall be carried in the next FY i.e. 2025-2026.

Further, the above exemption from inspections may also be extended to other Kind of Businesses (KoBs) as identified and decided by the Food Authority from time to time.

#### 4. Follow up inspections:

4.1 The FSO undertakes follow up inspection of the FBO's premise in cases where he believes, the reason for the same must be recorded in writing, that it is necessary to follow up to ensure and satisfy himself that FBO has fulfilled all the improvement suggestions provided by the FSO during previous inspection. Such an inspection may be a pre-informed or surprise inspection.

4.2 Similarly, the FSO on the directions of the DO, undertakes follow up inspection of the food establishment of a FBO to ensure and satisfy himself that the FBO has complied with all the suggestions mentioned in the improvement notice issued by the DO either at the time of Pre-License Inspection or Routine Inspection. Follow up inspections must be done within 3 months of previous inspection or issue improvement notice.



4.3 Further, **at least 2% of FBOs** who have undertaken Hygiene Rating in that financial year shall be inspected by FSOs.

5. **Inspection before renewal/modification of license:** Pre-renewal inspection is not mandatory. However, it may be done in select cases for the reasons to be recorded usually based on previous inspection/audit score. In case of modification of the license, inspection is not mandatory unless the modification is to include products type/ kind of business which were not manufactured/processed/ undertaken earlier and require inspection to be done.
6. **Inspection for investigation of complaint:** The Food Safety Officer should investigate any complaint which is made to him in writing in respect of any contravention of the provisions of the Act or Rules & Regulations made there under. This may be pre-informed or surprise inspection. Food businesses shall be inspected as soon as possible on receipt of the complaint, irrespective of any food product category. It should be invariably done within **15 days** of receipt of the complaint.
7. **Inspection in case of food safety emergency:** The FSO will initiate investigation and inspect premises of the FBO as per guidelines laid down by FSSAI for management of food borne illness outbreaks in India. This may be pre-informed or surprise inspection and needs to be done at the earliest.
8. **Inspection in case of report of major non-conformity during Third Party Audit or Hygiene Rating Scheme:** In case of referral of a major non-conformity by an auditor or agency during food safety audit or hygiene rating, an inspection of the premises must be done within **30 days** of receipt of such information.
9. **Inspection of expired licenses:** **At least 1% of FBOs**, whose licenses have expired in a given month, shall be inspected within next succeeding **two months**. For rest of Food businesses whose licenses have expired (remaining 99% or less as the case may be), the DO shall give notices within 15 days from the month. In cases, if there is no response received from the FBO within 15 days from the date of receipt of the notice or if response is found unsatisfactory then the DO shall direct inspection of such food businesses. Appropriate action against the FBO shall be taken as per the provisions of the FSS Act, 2006 and the Rules/Regulations made thereunder on the basis of findings of inspection reports.
10. **Other Inspections:** Any other inspections prescribed by the Food Authority from time to time.

*Note: The expression FSO also refers to Central Food Safety Officer (CFSO) and the expression DO also refer to Central Licensing Authority (CLA)*

**Disclaimer:** This is a suggestive inspection plan to draw a minimum number of food safety inspections to be conducted by any State/UTs. The States/UTs may revise the inspections frequency/numbers on the basis of the number of FBOs per KoB and availability of FSO/DOs.

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