

**Voluntary Report** – Voluntary - Public Distribution

**Date:** November 24, 2021

**Report Number:** IN2021-0136

## **Report Name:** India's FSSAI Amends its Food Import Regulations

**Country:** India

**Post:** New Delhi

**Report Category:** FAIRS Subject Report, Agriculture in the Economy, Policy and Program Announcements

**Prepared By:** Radha Mani, Agricultural Assistant and Mariano J. Beillard, Senior Regional Agricultural Attaché

**Approved By:** Mariano Beillard, Senior Regional Agricultural Attaché

### **Report Highlights:**

On November 3, 2021, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified its Food Safety and Standards (Import) First Amendment Regulations (2021). The amendment notified relates to the inclusion of a new Chapter XIV to the food import regulations titled “Registration and Inspection of Foreign Food Manufacturing Facilities.” The implementation date for this amendment is set for June 1, 2022.

**DISCLAIMER:** The information contained in this report was retrieved from the Food Safety and Standards Authority of India's (FSSAI) website <http://www.fssai.gov.in>. The U.S. Embassy in New Delhi – Foreign Agricultural Service (FAS) Office of Agricultural Affairs (OAA), USDA and/or the U.S. Government make no claim of accuracy or authenticity. The Government of India has not officially endorsed this report. Import approval for any product is subject to local rules and regulations as interpreted by Indian officials at the time of product entry. [Note: Use Google Chrome to access the links that do not open in Internet Explorer. Indian host sites will geo-block site access on a rolling basis].

## GENERAL INFORMATION

On November 3, 2021, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified its Food Safety and Standards (Import) First Amendment Regulations (2021). The amendment notified relates to the inclusion of a new Chapter XIV to the food import regulations titled “Registration and Inspection of Foreign Food Manufacturing Facilities” (see, Appendix I).

The FSSAI (authority) is notifying a new regulatory framework to ensure the food safety of imported food products, mandating that products in certain categories, based on their risk to human health, be registered with the authority prior to export. These products will also be subject to the inspection of their (overseas) manufacturing facilities by Indian regulatory officials. The authority, however, has not yet defined the scope of the product categories covered under this regulatory framework. The implementation date for this amendment nonetheless is set for June 1, 2022.

Previously on November 18, 2020, the FSSAI proposed in its draft notification the inspection of food imports based on the specific risk categories of imported food products. Media sources are reporting that the final regulation is now being notified following a year-long consultation process with industry stakeholders.

A comparison of the draft and final regulation reveals that a provision has been added in the final regulation in Clause 3 18(1) of the Food Import Regulations entitled “Registration and Inspection of Foreign Food Manufacturing Facilities.” All other information remains the same as published in the draft notification. Clause 3, with the additional provision now reads:

- (3) **Inspection of Foreign Food manufacturing facilities-** (a) Foreign Food manufacturing facility (ies) may be inspected, if required in a manner as specified by Food Safety and Standards Authority of India:

Provided that no inspection shall be required in case of such categories of food that are covered under mandatory Bureau of Indian Standards Certification Mark Scheme and where the Bureau of Indian Standards scheme of inspection includes the requirements specified under Schedule 4 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

The full text of the FSSAI notification is available on the FSSAI website located at:

[https://fssai.gov.in/upload/notifications/2021/11/618b4e7b785d6Gazette\\_Notification\\_Inspection\\_Foreign\\_Food\\_10\\_11\\_2021.pdf](https://fssai.gov.in/upload/notifications/2021/11/618b4e7b785d6Gazette_Notification_Inspection_Foreign_Food_10_11_2021.pdf)

# APPENDIX I - FOOD SAFETY AND STANDARDS (IMPORT) FIRST AMENDMENT REGULATIONS (2021)

## FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

### NOTIFICATION

New Delhi, the 3rd November, 2021.

**F. No. 4067/MOC-Trade/Reg-FSSAI/2017 (Part-1).**—Whereas the draft of the Food Safety and Standards (Import) Amendment Regulations, 2020, were published vide notification of the Food Safety and Standards Authority of India number F.No. 4067/MOC-Trade/Reg-FSSAI/2017(part-1), dated the 10th November, 2020, in the Gazette of India, Extraordinary, Part III, Section 4 as required under sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), inviting objections and suggestions from persons likely to be affected thereby, within a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, the copies of the said Gazette were made available to the public on the 16th November, 2020;

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 clause (e) of sub-section (2) of section 92 of Food safety and Standards Act,2006(34 of 2006) the Food Safety and Standards Authority of India, with the previous approval of the Central Government hereby makes the following regulations, further to amend the Food Safety and Standards (Import) Regulations, 2017, namely:—

1. (1) These regulations may be called the Food Safety and Standards (Import) First Amendment Regulations, 2021.  
(2) They shall come into force on the date of their publication in the Official Gazette and Food Business Operator shall comply with all the provisions of these regulations with effect from 1st June, 2022.
2. In the Food Safety and Standards (Import) Regulations, 2017,—
  - (i) after “chapter XIII”, the following shall be inserted, namely,—

#### “Chapter XIV

##### Registration and inspection of Foreign Food manufacturing facilities

- 18 (1) Registration of Foreign Food manufacturing facilities.**—(a) The Food Authority may from time to time based on the risk specify the categories of food products intended for export to India for further regulating control as specified in these regulations.
- (b) Foreign Food manufacturing facilities falling under such categories and desirous to export such article of food to India shall register with the Food Authority before exporting to India:
  - (c) Foreign Food manufacturing facility either directly or through authorised representative may apply for registration in “Form 16” of these regulations along with documents specified in Annexure-1 and fee as specified by the Food Authority.

- (2) **Processing of application for Registration of Foreign Food manufacturing facilities**—(a) If upon scrutiny of the application Food Authority requires any additional information with respect to an application or if the application is incomplete, the Food Authority shall advise the applicant, to furnish such additional information or complete the application, as the case may be, within thirty days from such notice. In case the applicant fails to furnish the required information within the stipulated time of thirty days, the application for Registration of Foreign Food Manufacturing Facility shall stand rejected;
- (b) On receipt of a complete application including the additional information if asked for, the Food Authority may process the application for inspection, if required or issuance of registration or rejection of the application.
- (3) **Inspection of Foreign Food manufacturing facilities**- (a) Foreign Food manufacturing facility (ies) may be inspected, if required in a manner as specified by Food Safety and Standards Authority of India:
- Provided that no inspection shall be required in case of such categories of food that are covered under mandatory Bureau of Indian Standards Certification Mark Scheme and where the Bureau of Indian Standards scheme of inspection includes the requirements specified under Schedule 4 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.
- (b) Foreign Food manufacturing facility may also be inspected after the issuance of registration, as deemed necessary;
- (c) Officials from FSSAI and relevant ministry or organization or department or recognised auditing agency shall be nominated by the Food Authority for the purpose of inspection of Foreign Food Manufacturing Facilities;
- (d) Food Authority, if required may prescribe cost of inspection, which shall be borne by the Foreign Food manufacturing facility.
- (4) **Issuance of registration**.—(a) Foreign Food manufacturing facility found to be in compliance of Food Safety and Standards Act, rules and regulation made there-under shall be registered as Foreign Food manufacturing facilities for a period of two years and their registration number shall be communicated in Form 17;
- (b) Foreign Food manufacturing facility found to not be in compliance of Food Safety and Standards Act, rules and regulation made there-under, the application made for registration shall be rejected;
- (c) Foreign Food manufacturing facility whose application is rejected, after taking remedial action may apply for recognition again, and
- (d) Renewal of registration of Foreign Food manufacturing facility shall be made in Form 16, not later than thirty days prior to the expiry date indicated in the registration.
- (5) **Suspension or cancellation of registration**.—(a) If Foreign Food manufacturing facility or their food products intended for export to India are found not to be in compliance of Food Safety and Standards Act, rules and regulation made there-under, their registration as Foreign Food manufacturing facilities shall be suspended or cancelled. However, Food Authority may review the same after giving opportunity for hearing or clarification, as deemed fit.”
- (ii) after “Form 15”, the following form shall be inserted, namely:—

**“FORM – 16**

*[See regulation 18(1)(b)]*

**Application for Registration/renewal of Registration of Foreign Food manufacturing facilities**

1. Name of the Company/Organisation.....
2. Registered Office Address.....
3. Address of Premise for which Registration is being applied.....

4. license/registration issued by concerned country's government authority for food manufacturing/processing facility.....
5. E.mail .....
6. Contact no.....
7. Product(s) name and description.....
8. All information and particulars furnished here by me are true and correct to the best of my knowledge.

Date.....

Signatures and seal of authorized signatory

Place.....

Name and address.....

**Annexure-1**

List of documents to be enclosed with Application for Registration/renewal of Registration of Foreign Food manufacturing facilities:—

- (1) license/registration or similar document issued by concerned country's government authority for food manufacturing/processing facility;
- (2) Consent of owner of Foreign Food manufacturing facility for inspection by Food Safety and Standards Authority of India officials;
- (3) Detail composition of products;
- (4) Authorisation in favour of authorised representative (if applied through of authorised representative).
- (5) Any other documents/ information as may be required by the food Authority.

**FORM – 17***[See regulation 18(4)(a)]***Registration/renewal of Registration of Foreign Food manufacturing facilities**

1. Name of the Company/Organisation.....
2. Registered Office Address.....
3. Address of authorised premise.....
4. Registration no.....
5. Product(s) name and description .....

Note: This must not be altered in any way. Intentional misuse of this will result in cancellation without prior intimation.

Date.....

Signatures of CEO, FSSAI/representative  
authorised by him

Place.....

Name .....

ARUN SINGHAL, Chief Executive Officer

[ADVT.-III/4/Exty./404/2021-22]

**Attachments:**

No Attachments.