

**Voluntary Report** – Voluntary - Public Distribution

**Date:** October 24, 2022

**Report Number:** IN2022-0086

**Report Name:** India's FSSAI Requires Mandatory Registration of Foreign Food Manufacturing Facilities for the Import of Certain Categories of Foods

**Country:** India

**Post:** New Delhi

**Report Category:** FAIRS Subject Report

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**Report Highlights:**

On October 10, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued Order F. No. TIC-B02/2/2022-IMPORTS-FSSAI. The FSSAI order requires the mandatory registration with the competent authority of jurisdiction of the country of export, of all foreign food manufacturing facilities intent on exporting milk and milk products; meat and meat products; egg powder; infant food; and nutraceuticals to India. The order requires the competent authorities of all exporting countries to email to the FSSAI, a list of existing manufacturers, and of those intent on exporting milk and milk products; meat and meat products; egg powder; infant food; and nutraceuticals to India in the mandated FSSAI format. The effective implementation date of the FSSAI order is February 1, 2023. The published order is yet to be notified to the World Trade Organization (WTO).

**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 Foreign Agricultural Service (FAS) Office of Agricultural Affairs at the U.S. Embassy in New Delhi, 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 October 10, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued **Order F. No. TIC-B02/2/2022-IMPORTS-FSSAI** (see, Appendix I). The FSSAI order requires the mandatory registration with the competent authority of jurisdiction of the country of export, of all foreign food manufacturing facilities intent on exporting milk and milk products; meat and meat products; egg powder; infant food; and nutraceuticals to India,

Additionally, the order requires the competent authorities of all exporting countries to email to the FSSAI, a list of existing manufacturers, and of those intent on exporting milk and milk products; meat and meat products; egg powder; infant food; and nutraceuticals to India in the mandated FSSAI format specified within **Order F. No. TIC-B02/2/2022-IMPORTS-FSSAI**. The FSSAI will subsequently vet the submissions and incorporate accordingly to its online portal. The email addresses to remit the listing of registered manufacturers provided is [dramit.sharma@fssai.gov.in](mailto:dramit.sharma@fssai.gov.in) (Director of Trade and International Cooperation) and [import@fssai.gov.in](mailto:import@fssai.gov.in).

From the reading of the order, and its interpretation, it is unclear as to who would be the competent authority in the country of export that would be charged on the behalf of FSSAI with registering, collecting, and conveying this information to an Indian government authority. There is no clarification as to what registration entails, the operationalization of the procedures, or as to even as how often to renew the list. The intent of the FSSAI order is being perceived already by India’s trade partners and bemoaned as being another new trade restrictive measure, a trade barrier meant to restrict, slow the flow of foreign-origin imports to help protect and build up India’s domestic producers.

The United States for its part also maintains a “Food Facility Registration requirement” via the Food Safety Modernization Act (FSMA) that identifies facilities that manufacture/process, pack, or hold food for consumption in the United States. By contrast, however, the FSMA Food Facility Registration requirement stipulates that the owner, operator, or agent in charge of either a domestic or foreign facility engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the United States, must register with the Food and Drug Administration (FDA).<sup>1</sup> Foreign facilities exporting to the United States are only required to provide “activity type” information about food that

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<sup>1</sup> A “competent authority” or foreign government representative engaging in facilities registration through FSMA may conflict with the duties of foreign government representatives. Whether it is proper for a foreign government representative to act as a U.S. agent is a fact-specific inquiry, depending on the title and status of the foreign government representative and the functions that the representative assumes as a U.S. agent. According to FDA, it will consider such situations on a case-by-case basis in consultation with the U.S. State Department. See, Questions and Answers Regarding [Food Facility Registration \(Seventh Edition\): Guidance for Industry](#).

the facility manufactures/processes, packs, or holds for consumption in the United States. Entities register through the Food Facility Registration Module ([FFRM](#)) and receive a unique facility identifier. Facilities that manufacture/process, pack, or hold food entering the United States solely for the purpose of exportation or trans-shipment to another country are not required to register. As of September 2022, FDA has reported over 138,000 foreign facility registrations in FFRM, including 5,160 from India.<sup>2</sup>

The effective implementation date of the FSSAI order is February 1, 2023. The published order is yet to be notified to the World Trade Organization (WTO).

The full text of the FSSAI **Order F. No. TIC-B02/2/2022-IMPORTS-FSSAI** is accessible on the FSSAI website located at:

[https://fssai.gov.in/upload/advisories/2022/10/6343da0a0f78fOrder\\_Foreign\\_Food\\_10\\_10\\_2022.pdf](https://fssai.gov.in/upload/advisories/2022/10/6343da0a0f78fOrder_Foreign_Food_10_10_2022.pdf)

### **Background:**

On November 3, 2021, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India 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, [GAIN-INDIA | IN2021-0136 | India’s FSSAI Amends Its Food Import Regulations](#)).

The FSSAI (authority) notified 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 would also be subject to the inspection of their (overseas) manufacturing facilities by Indian regulatory officials. The authority, however, did not then define the scope of the product categories covered under this regulatory framework. The implementation date for this amendment nonetheless was set for June 1, 2022. Previously on November 18, 2020, the FSSAI had then proposed in its draft notification the inspection of food imports based on the specific risk categories of imported food products. Media sources were then reporting that the final regulation was being notified following a year-long consultation process with industry stakeholders.

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<sup>2</sup> FDA [Food Facility Registration Statistics](#); September 22, 2022.

**APPENDIX I: ORDER F. NO. TIC-B02/2/2022-IMPORTS-FSSAI – REQUIREMENT OF REGISTRATION OF FOREIGN OF FOREIGN FOOD MANUFACTURING FACILITIES**

**F. No. TIC-B02/2/2022-IMPORTS-FSSAI**  
**Food Safety and Standards Authority of India**  
(A Statuary Authority established under the Food Safety and Standards Act, 2006)  
(Trade & International Cooperation Division)  
**FDA Bhawan, Kotla Road, New Delhi-110002**

Dated: The 10<sup>th</sup> October, 2022

**ORDER**


**Subject: - Requirement of Registration of foreign food manufacturing facilities as per Food Safety and Standards (Import) First Amendment Regulations, 2021 dated 03.11.2021 -reg.**

In exercise of the provisions of Food Safety and Standards (Import) First Amendment Regulations, 2021, it has been decided that registration of **foreign food manufacturing facilities falling under following food categories, who are intended to export these food products shall be mandatory: -**

- i) Milk and Milk Products;
- ii) Meat and Meat Products including Poultry, Fish and their products;
- iii) Egg powder
- iv) Infant Food;
- v) Nutraceuticals.

In view of the above, the Competent Authorities of all the exporting countries are requested to provide the list of existing manufacturers and of those who are intended to export such food products to India as per the format attached at email id: [dramit.sharma@fssai.gov.in](mailto:dramit.sharma@fssai.gov.in) and [import@fssai.gov.in](mailto:import@fssai.gov.in) . Based on the list provided by the Competent Authority of exporting country, the registration of such facilities will be done by the Food Safety and Standards Authority of India at its portal.

This order will be effective from 1<sup>st</sup> February, 2023. This issues with the approval of the Competent Authority.

  
(Dr. Amit Sharma)  
Director (Trade and IC)

**Attachments:**

No Attachments.