

Food Safety and Standards Authority of India
The Food Safety and Standards (Food Import) Regulations, 2016
Draft regulations
Notification No: F.No.1/2008/Import Safety/FSSAI
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Chapter – I
Preliminary

1. Short title and commencement:- (1) These regulations may be called the **Food Safety and Standards (Import) Regulations, 2016**.

2. Definitions:- (1) In these regulations unless the context otherwise requires,-

- (a) "Act" means the Food Safety and Standards Act, 2006 (34 of 2006);
- (b) "Authorised Officer" means a person appointed as such by the Chief Executive Officer of the Food Safety and Standards Authority of India by an order for the purpose of performing functions under section 25 of the Act;
- (c) "Balance shelf-life" means the period between the date of import (Import General Manifest) and "Best Before" or "Date of expiry" as the case may be;
- (d) "bill of entry" means the bill of entry filed by the Importer under the provisions of section 46 of the Customs Act, 1962 (52 of 1962);
- (e) "Custodian" means an officer appointed by Commissioner of Customs under whose custody the imported goods shall remain until they are cleared from the customs area for home consumption or are ware housed or are transhipped as provided in the law.
- (f) "customs airport" means any airport appointed under clause (a) of section 7 of the Customs Act, 1962 (52 of 1962);
- (g) "customs area" means the area of a customs station and includes any area in which imported goods or export goods are ordinarily kept before clearance by customs authorities;
- (h) "Custom House Agent" shall have the meaning assigned to it in clause (c) of section 2 of the Custom House Agent Regulation, 2004;
- (i) "customs port" means any port appointed under clause (a) of section 7 of the Customs Act, 1962 (52 of 1962) to be a customs port and includes a place appointed under clause (aa) of that section to be an inland container depot;
- (j) "fees" means the charges specified by food authority for clearance of imported food consignments;
- (k) "Food Analyst" means a person appointed under section 45 of the Act to analyse the food sample;
- (l) "Food Importer" means a Food Business Operator importing or desirous of importing Food into Indian territory, who is duly licensed as Importer under the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 made under the Act;
- (m) "Import" means bringing into India any article of food by land, sea or air;
- (n) "non-conformance report" means a report issued to the customs authorities and the food importer by the Authorised Officer, or any other officer specifically authorized for this purpose, by the Food Authority, for non compliance of the provisions of the Act and the rules and regulations made thereunder, of the consignment of the Food Importer;
- (o) "no objection certificate" means a certificate issued to the customs authorities and the food importer by the Authorised Officer, or any other officer specifically authorised for this purpose, by the Food Authority for conformance with the provisions of the Act

and the rules and regulations made thereunder, of the consignment of the Food Importer;

(p) "packing list" means the itemised list of articles of food giving the description, quantity and weight of each imported articles of food;

(q) "pre-arrival document scrutiny" refers to the scrutiny of documents submitted by the Food Importer to the Authorised Officer in advance, before the actual arrival of the articles of food to facilitate faster clearance of articles of food imported at the customs port;

(r) "prohibited food" means that articles of food as declared by the Food Authority from time to time and published on the website of the Food Authority;

(s) "prohibited sources" means the particular locations for which conditional or absolute restrictions are specified by the Food Authority on its website for import of articles of food;

(t) "review application fee" means the fee levied by the Food Authority towards disposal of review application submitted by the Food Importer against the order of Authorised Officer pertaining to clearance of Import of articles of food;

(u) "Review Officer" means the Chief Executive Officer or an officer authorised by the Chief Executive Officer of the Food Authority for review of the orders of the Authorised Officer;

(v) "risk based random sampling" means the activity of drawing samples randomly based on the risk criteria identified and the compliance history of the importer;

(w) "shelf life" means the period between the date of manufacture and the "Best Before" or "Date of expiry" whichever is earlier as printed on the label;

(x) "Single Window Interface for Facilitating Trade" means the provision of single window system provided by the Customs to the importer and Custom House Agent to apply for import clearance;

(y) "stuffing list" means a list of food items and its actual physical arrangement inside the container or cartons or pallets or skids;

(z) "Transit Country List" means the list of countries through which the imported articles of food transits before it reaches the Indian territory;

(aa) "unclaimed food" means an imported articles of food consignment not having a claimant or bill of entry or both;

(ab) "un-cleared food" means an imported articles of food consignment of which the delivery is not taken by the importer within the period specified in the no objection certificate issued by the Food Authority;

(ac) "visual inspection" means the process of inspection by the authorised officer or an officer deputed by him for the purpose by which the physical condition of the food consignment, scrutiny of documents and compliance of packaging and labeling regulations are ascertained for the Food Safety compliance prior to drawing of samples.

(2) The words and expressions herein but not defined shall have the same meaning as assigned to them in the Act, and the rules and regulations framed thereunder and the Customs Act, 1962 (52 of 1962).

Chapter – II

Licensing of Food Importers and Food Business Operators

3. (1) No person shall import any article of food without an import license from the Central Licensing Authority in accordance with provisions of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

(2) No article of food shall be cleared from the custom unless it has sixty per cent shelf life at the time of its clearance from the customs.

(3) For the purposes of sub – regulations (1) and (2), the Food Importer shall register himself with the Directorate General of Foreign Trade and possess valid Import-Export Code.

4. Suspension or cancellation of license:- (1) The Food Import license granted under regulation 3 may be cancelled or suspended for contravention of the provisions of these regulations or the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

(2) Notwithstanding anything contained in regulation 3, the Licensing Authority may cancel the Food Import license granted under any other regulations made under the Act, if the Designated Officer or Authorised Officer or any officer Authorised by the Food Safety and Standards Authority of India have reasons to believe that,-

(a) there is sufficient ground to believe that the Food Importer has attempted to import unsafe articles of food, prohibited articles of food or articles of food from prohibited sources, directly or indirectly, including re-channeling or re-packing;

(b) the Food Importer fails to comply with the conditions of the license, these regulations, or the undertaking of intended end use.

(3) The Food Importer shall inform the Central Licensing Authority and the Authorised Officer of any suspension, revocation or cancellation of the certificate of Importer-Exporter Code, granted in its favour by the Directorate General of Foreign Trade within twenty four hours and not later than three working days from the date of such order of suspension, revocation or cancellation.

(4) When the certificate of Importer – Exporter code granted by the Director General of Foreign Trade is suspended, revoked or cancelled, the import license granted under the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 shall be deemed to have been cancelled.

(5) Any license that has been cancelled by the Licensing Authority under the Act, as a consequence of the suspension, revocation or cancellation of certificate of Importer-Exporter Code granted by the Directorate General of Foreign Trade may be reconsidered and granted afresh within seven days of an application made by the importer for a License if the suspension, revocation or cancellation of the importers certificate of Importer-Exporter Code granted by the Directorate General of Foreign Trade has been withdrawn or set aside or a fresh certificate of Importer-Exporter Code has been issued to the said Importer by the Directorate General of Foreign Trade.

Chapter – III

Clearance of Imported Food by the Food Authority

5. (1) Upon arrival of the food consignments at the airport, the importer or Custom House Agent shall file an Integrated Declaration Form in the Customs Single Window Integration for Facilitating Trade.

(2) The Form forwarded from Single Window Integration for Facilitating Trade to the Food Import Clearance System shall be processed in the following manner, namely:-

(a) the Authorised Officer shall scrutinise the Form and may seek clarification if required;

(b) upon satisfactory scrutiny, the applicant shall pay the fees as specified by the Food Authority for scrutiny of documents, visual inspection and drawing of sample;

(c) where a single bill of entry is made up of articles of food consignment consisting of multiple categories of articles of food, inspection fee shall be paid for each category of articles of food;

(d) the Food Authority shall specify and review the inspection fee from time to time;

(e) on receipt of the fees, the Authorised Officer shall intimate the details of date and time of inspection to the Food Importer to facilitate the presence of the Food Importer or his Custom House Agent at the time and place of inspection.

(3) The applicant shall remain present at the customs area at the appointed time to participate and facilitate visual inspection, assist in drawing of samples, if required, assist in the import clearance proceedings as instructed by the Authorised Officer or his representative and witness proceeding, sealing of samples by the Authorised Officer or his representative and affix his counter signatures on the sealed samples.

(4) The Food Importer shall facilitate the visual inspection and collection of sample from the consignment as per the stuffing list.

(5) The Authorised Officer shall direct the customs authorities to issue an order for de-stuffing the container and Custom House Agent or Food Importer shall also assist in de-stuffing the container if required.

(6) If the Food Importer or his Custom House Agent is not present to facilitate the inspection and sampling in spite of two opportunities having been granted, the Authorised Officer may refuse to grant further opportunity for inspection and sampling of the food consignment:

Provided that any further opportunity in this behalf may be granted by the Chief Executive Officer or his authorised representative after levy of suitable penalty on the Food Importer as may be specified by the Authority from time to time.

(8) The report of the visual inspection shall be submitted in FORM – 1.

6. Compliance with standards for packaging and labeling:- (1) No Food Importer shall import articles of food that is not transported, or stored in optimal storage conditions of temperature and hygiene, packaged and labeled as per the regulations applicable to that particular article of food at that time.

(2) Every consignment of food sought to be imported into India shall be packed in containers in such a manner that it would facilitate the inspection and collection of samples from the consignment.

(3) Any consignment of multiple foods or food falling under different categories packed in a single container or carton or pallet or skid, shall be packed in such a manner that the Authorised Officer has easy access to all of them for inspection and sampling.

(4) In the absence of a proper stuffing list, the Authorised Officer shall direct the customs officer to issue an order for de-stuffing the container and facilitate the de-stuffing, in order to facilitate inspection and sampling.

(5) In case of imported food consignments, the following special dispensation on labeling shall be complied with, namely:-

(a) name and address of the importer;

(b) Food Safety and Standards Authority of India Logo and license number, Non-Veg or Veg Logo affixed by the Importer and Custom House Agent as rectifiable labeling deficiencies upon arrival of imported food consignments in the custom bonded warehouse;

(c) rectifiable deficiency by affixing a single non detachable sticker or by any other nondetachable method next to the principle display panel.

(6) In respect of the rectifiable labelling deficiencies referred to in sub – regulation (5), the Authorised Officer may pass an order directing the Food Importer or his authorised

agent to carry out the permissible labelling rectifications, within a specified time in the customs area without altering or masking the original label information in any manner.

(7) On rectification by the Food Importer, the Authorised Officer shall carry out a re-inspection of the articles of food and if satisfied, draw the sample, subject to all other conditions being fulfilled by the Food Importer.

(8) In case the Food Importer fails to rectify the permissible defects referred to in sub – regulation

(5), within the specified time, the Authorised Officer may pass an order refusing clearance of such imported articles of food and issue a non conformance report.

(9) If the Authorised Officer is satisfied that the Food Importer has complied with the provisions of this regulation, the Authorised Officer or his representatives shall draw two parts of food sample from the imported articles of food in the customs area in the presence of Food Importer or his Custom House Agent for testing the samples.

(10) If the food analyst seeks additional information on ingredients or on any other parameters after receipt of the food sample, the Authorised Officer shall direct the Food Importer to provide such information duly supported by documentary evidence.

(11) The consignment not complying with the provisions of Labeling and Packaging Regulation, 2011 shall be rejected at the visual inspection and no samples shall be drawn from the consignment

Chapter – IV

Food Import Clearance for Specific Purposes

7. (1) Nothing contained in these regulations shall apply to any person bringing in any article of food for his personal use provided that the value of such article of food shall not exceed the amount as allowed by custom from time to time.

(2) The person carrying the imported articles of food for personal consumption shall submit the declaration in the Single Window Integration for Facilitating Trade.

(3) Unless otherwise specified, the customs authority may not be required to refer the imported articles of food to Food Authority for clearance if such articles of food is meant for –

(a) export as per the extant Government instructions and export rejected or reimported articles of food meant for re-export;

(b) the articles of food or ingredients or additives which are being imported by the manufacturers or processors for their captive use or production of value added products for hundred per cent exports; or the consignments of articles of food or ingredients or additives imported by the firms or companies for use of their sister concerns or wholly owned subsidiary companies, to be used for hundred per cent export production subject to a defined relationship agreement between the two entities in this behalf;

Explanation:- For the purposes of clause (b) of sub – regulation 3, the importer shall declare in the Single Window Integration for Facilitating Trade regarding the captive or end use of the imported product to the Customs Department at the time of filing the bill of entry, declaring that the imported articles of food is meant to be used by the importer for hundred per cent export or re-import of articles of food for export again as the case may be, and that no part thereof shall be supplied for domestic consumption.

(c) The facility under clause (b) of sub – regulation 3 of shall not be applicable in the case of trading entities, which do not import such items for their captive use in view of the problems associated with traceability of the end-use of such items.

(4) The clearance of Food Imports shall be dealt in accordance with the provisions of Vienna Convention on Consular Relations, 1963 (Article 50 of the Vienna Convention on Consular Relations, 1963).

(5) The clearance of food import for the purposes of research and development may be allowed subject to –

(a) the import being undertaken by a licensed Food Importer;

(b) declaration by the Food Importer and the Food Importing Agency in the Single Window Integration for Facilitating Trade to the effect that the imported articles of food shall be utilised for aforesaid purpose only;

(c) not released into the domestic market or used for test marketing or market research purposes.

(6) There shall be following procedure for clearance of food imported for exhibition purposes, namely:-

(a) the exhibitor shall comply with the requirements, if any, specified by the custom and the exhibitor shall declare in the Single Window Integration for Facilitating Trade;

(b) in case the articles of food are proposed to be used for tasting purposes, the importing exhibitor or entity shall also submit a copy of the food safety certificate issued by the Food Regulatory Authority of the country of origin;

(c) food products, included in the list of prohibited items for import, of the Directorate General of Foreign Trade or specified by the Authority from time to time, shall not be allowed to be imported for exhibition or tasting purposes;

(d) all products for exhibition shall bear an additional non-detachable label or sticker stating:

“For Exhibition purpose only” and “Not for sale”;

(e) the importing entity may be permitted to affix additional label in the custom-bonded warehouse, if not already affixed;

(f) The importing exhibitor shall maintain the bills of material-

(i) of the items imported for exhibition;

(ii) the items consumed for tasting purposes or destroyed;

(iii) the items for re-export to the country of origin at the end of the exhibition, fair or event and shall be liable to submit such details on demand by the Authorised Officer;

(7) A placard shall be prominently displayed at the place of exhibition of such food items stating ‘For Tasting Only’.

(8) The unconsumed portion of the articles of food, which have been opened for tasting, shall be destroyed after the exhibition by the Food Importer as per the procedure.

(9) The unopened and unconsumed articles of food shall be re-exported in securely packed condition under intimation to the Authorised Officer by the Food Importer.

(10) The Food Authority may allow the clearance of food imports from a foreign country, exclusively meant for consumption by the sportspersons of such exporting country.

(11) The quantity of imported articles of food in such cases shall not exceed the bona fide requirements for captive use or consumption by the persons concerned of such exporting country for the duration of their stay or event, whichever is earlier and the balance unconsumed articles of food shall be re-exported to its country of origin by the Authorised member of the delegation under intimation to the Authorised Officer.

(12) The importer shall submit the declaration in the Single Window Integration for facilitating trade for clearance of imported food consignment.

(13) In case of contravention of any of the conditions stated in these regulations, the Food Importer or any person or entity concerned shall be debarred from any concessions or facilities set out, in future, in addition to the consequences in accordance with the provisions of the Act and the rules and regulations made thereunder.

(14) Where any article of food is received gratis from other countries in case of any disaster or emergency situations in any part of the country, the quality or safety of imported articles of food shall be ensured through safety certificates issued by the competent authority of the donor country or agency through inspection.

Chapter – V

Storage, Inspection and Sampling of Imported Food

8. Storage facilities for Food Imports – (1) No consignment of articles of food articles shall be stored in a manner that articles of one consignment come in contact with other articles of food.

(2) The imported articles of food shall be stored in accordance with the specified storage conditions in the custom warehouse before clearance, failing which, the concerned Authorised Officer may refuse to grant no objection certificate for import clearance of the food consignment.

9. Storage facilities for Food Imports – (1) The port authorities and Custodian of freight stations shall ensure adequate and conducive storage infrastructure meeting the safe storage of various types of imported food consignments in the customs area till the imported articles of food is cleared by the custom authority.

(2) In case of imported food items which require special storage condition, the Authorised Officer shall verify the true storage conditions required for the consignment.

(3) The Authorised Officer shall confirm from the air cargo operator or Custodian of freight stations regarding the availability of desired special storage facilities at the custom bonded area at the port or airport.

(4) In case of non-availability of storage facility, the Authorised Officer shall –

(a) confirm from the department of custom their no objection to treat importers warehouse as custom bonded area,

(b) direct the applicant to declare the same in the Single Window Integration for Facilitating Trade, and upon acceptance, the Authorised Officer shall allow the issue of provisional clearance certificates to the importer to move the food consignment to a well-equipped storage facility.

(5) In case of non-compliance of any of the conditions, the importer shall not be eligible to avail any facility in future and also liable for other appropriate actions as per the prevailing law, rules and regulations.

(6) The Authorised Officer may issue a no objection certificate subsequent to the analysis report conforming to standards.

(7) The importer or customs shall ensure sale only after clearance based on no objection certificate.

(8) The Food Authority may review the risks associated with articles of food imports from time to time and, accordingly, specify the sampling frequency to be conducted for the import of different categories of food products keeping in view the safety record of the exporting country, exporter, importer, risk attached to the imported product and other matters.

(9) The Authorised Officer or his representative shall comply with the Labelling and Packaging Regulation, 2011 and with a valid balance shelf life in the following manner, namely:-

(a) shall draw two parts of food sample of each description or measures (except for aseptic sealed packages);

(b) shall forward to the food analyst such quantity of sample as specified under the Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011;

(c) seal the samples;

(10) (a) In cases where the imported articles of food are packed in sealed bulk containers by the manufacturer in order to maintain aseptic or hygroscopic conditions that are required to retain the character of the article of food, the manufacturer shall provide two representative sealed samples from the same batch along with a declaration by the manufacturer stating that the articles of food in the sealed container match with the representative samples placed in the sample containers.

(b) In all cases wherever the representative sealed samples referred to in clause (a) with the manufacturers undertaking is not provided by the Food Importer, the Authorised Officer is empowered to break open the seal and collect a sample for lab analysis.

(c) The Authorised Officer may exercise his discretion to collect a representative sample from the sealed container, wherever the sealed representative samples provided appears to be doubtful.

(11) In respect of imported articles of food having shelf-life less than seven days, the applicant shall declare the same in the Single Window Integration for Facilitating Trade allowing the Authorised Officer to draw sample and issue provisional no objection certificate to the customs, without waiting for the analysis report from laboratory.

(12) On receipt of the report analysis from the laboratory, the Authorised Officer shall communicate to the customs along with no objection certificate if products conform to the standard.

(13) In case of non – conformance of the sample, the Authorised Officer shall immediately inform the Importer or Custom Brokers, to recall that consignment and submit a compliance report within twenty four hours to the Authorised Officer and the Food Authority shall alert all import points to maintain vigil on imports of products manufactured by the same company or similar products imported by the same importer or Custom Brokers.

(14) The sealed sample of imported articles of food shall bear the following information on the Label, namely:-

(a) code number of the sample;

(b) date and place of collection;

(c) quantity of sample;

(d) name of articles of food;

(e) name and quantity of preservative added while drawing the sample, if any;

(f) name and signature of the Food Importer or his Custom House Agent and;

(g) name and signature of the sender with official seal.

(15) The Authorised Officer shall forward one part of the sealed and labelled articles of food to the Food Analyst who shall cause it to be analysed by a notified laboratory for imports under regulation 2.1 of the Food Safety and Standards (Laboratory and Sample Analysis), 2011.

(16) The remaining parts of the food sample after forwarding one part of the sealed and labeled articles of food referred to in sub – regulation 15, shall be stored in appropriate conditions by the Authorised Officer or his authorised representative.

(17) On the sample being found to be safe, the remaining sample shall be returned to the food importer.

(18) If the sample found to be unsafe, on any appeal received from Food Importer, the second sample may be forwarded to the Referral Laboratory for analysis.

(19) The rejected export consignments by foreign countries that have been returned to India as the country of origin shall be subject to these regulations except that the packaging and labeling requirements shall be in accordance with the country of export.

(20) The importer shall submit rejection documents of the country of export.

(21) The samples of imported articles of food forwarded by the Authorised Officer to the Food Analyst who shall analyse or cause an article of food to be analysed by a notified laboratory as per the parameters specified in the Act and the regulations made thereunder and shall forward his report within five days to the Authorised Officer whether the product is conforming or nonconforming.

(22) If the sample cannot be tested by the laboratory within the specified time it shall state the reasons for the same in writing to the Food Analyst.

(23) The report of analysis shall be signed by the Food Analyst.

Chapter – VI

Laboratory – Analysis of Samples of Imported Articles of Food

10. Food Analysis:- (1) The sample of imported articles of food forwarded by the Authorised Officer shall be caused to be analysed by the laboratories notified by the Food Authority.

(2) The fees payable for analysis of imported articles of food by referral or notified laboratory shall be as specified by the Food Authority from time to time.

(3) The Authorised Officer shall forward the first part of the sample of imported article of food for laboratory analysis to a Food Analyst of a laboratory notified by the Food Authority under subsection (1) of section 43 of the Act and Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011.

(4) The notified or referral laboratory shall follow the following procedure for food analysis, namely:-

(a) on receipt of the sample of food from the Authorised Officer, the notified or referral laboratory shall immediately conduct a preliminary inspection of the sample to ascertain whether all the information required for testing is available or on the sufficiency of the sample quantity, and if there are any deficiencies, the laboratory shall immediately inform the Authorised Officer of the deficiency;

(b) the notified or referral laboratory shall comply with the test methods specified by the Food Authority with regard to the tests to be performed and the equipment to be used, for testing samples of different categories of articles of food:

Provided that in cases where the test method has not been specified by the Food Authority, the notified or referral laboratory shall comply with the specifications for testing that have been specified by the Codex Alimentarius Commission or the International Organisation for Standardization or Director General Health Services, Ministry of Health and Family Welfare, Government of India;

(c) the notified or referral laboratory shall bring to the notice of the Food Authority any new tests or methods of testing that it may seek to conduct on samples of any specific article of food, or any new equipment that it may seek to use but shall not commence using the tests or methods of testing or equipment unless so permitted by the Food Authority.

(5) The notified laboratory or referral laboratory, as the case may be, shall provide the laboratory analysis report duly signed by its Food Analyst in FORM - 2 within five days from the date of receipt of the sample.

(6) An importer shall file an appeal against the result of notified laboratory within fifteen days of issuance of the Non Conformance Certificate by the Authorised Officer.

- (7) Upon appeal by the Food Importer, the Authorised Officer shall forward the second sample of imported articles of food for laboratory analysis to the specified referral laboratory notified by the Food Authority under sub-section (2) of section 43 of the Act and the Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011.
- (8) Whenever laboratory analysis of a food sample reveals presence of contaminants and presence of microbiological organisms which may pose a serious hazard to the safety and health of the consumer, the Food Analyst shall inform the same to the Authorised Officer for initiating suitable action.
- (9) In case the Authorised Officer has sufficient reason to believe that the imported articles of food consignment poses a serious hazard to the safety and health of the consumer, he shall suo motu refer the second sample to the referral laboratory for retesting to seek the confirmation of the findings of the notified laboratory.
- (10) The retesting referred to in sub – regulation (10) of regulation 10 shall be immediately brought to the notice of the Food Authority by the Authorised Officer.
- (11) The samples, if found to be hazardous shall be destroyed by a specified procedure following biohazard guidelines, and all the imported articles of food to which the samples related, shall be destroyed or re-exported to the country of manufacture or origin by the Food Importer within seven days of being directed to do so by the Food Authority, failing which, the Food Importer and his Custom House Agent shall be jointly and severally liable to a penalty of ten times the value of the imported articles of food and the Food Importers license shall be deemed to have been cancelled.

Chapter – VII

Scheme for Risk based Food Import Clearance

- 11. Risk Based Framework:-**(1) The Food Authority, may adopt a risk-based framework and risk based inspection process for clearance of imported articles of food.
- (2) For the purposes of sub – regulation (1), the Food Safety and Standards Authority of India shall profile the Importer, Custom House Agents, imported product, manufacturer of the imported product, country of origin, source country of the consignment, port of entry, compliance history and any other parameters deemed fit for profiling the risk associated with the commodity.
- (3) The Authority may introduce Pre- Arrival Document Review for regulating the imports.
- (4) The Food Authority in consultation with the concerned Ministry as it deems fit may enter into Memorandum of Agreement with relevant agencies in exporting countries on reciprocal basis to facilitate ease of doing business and accelerated clearance of food imports from the countries referred to in sub – regulation (2).
- (5) The Food Authority may identify laboratories in exporting countries for prior testing of food samples before the articles of food are imported into India.
- (6) The Food Authority may from time to time issue food alert notifications, including time bound prohibited articles of food or prohibited source or recalls, based on the risk associated with the articles of food.
- (7) All importers shall submit a recall plan describing the detail of contingency plan of ensuring the traceability of the products in case of any eventuality of risk associated with the food consignments, and if he fails to do so, it may result in cancellation or suspension of his licence.
- (8) The food alert notifications shall immediately be informed to the Risk Management System of the customs department.

(9) The alert notification shall remain in force until the Food Authority is satisfied that the risk is no longer prevailing or that control measures are in place to prevent the continuation of the risk and confirmed by test reports.

(10) During the pendency of alert notification, the Food Authority may order for additional tests at the point of entry, mandatory certification from the exporting countries or channelisation till such time as the Food Authority may deem fit.

(11) The Government agencies shall conduct post clearance surveillance of all food imports including -

(a) random checks on the imported food items,

(b) providing relevant documents to support the declarations and information provided by the importer or Custom House Agent in the Customs Single Window Integration for Facilitating Trade.

Chapter – VIII

Prohibition and Restrictions on Food Imports

12. Power of the Food Authority to issue orders for prohibition and restriction on import of food:-

(1) The Food Authority may prohibit or restrict import of any article of food based on risk perception or outbreak of disease and issue orders as it deems fit in this regard.

(2) The Food Authority may issue order or advisory or guideline as it deems fit from time to time for ensuring the safety and wholesomeness of articles of food imported into India and such prohibitions and restrictions shall be informed to the customs immediately.

(3) Every Food Importer to whom any order or direction is issued in pursuance of any provisions of these regulations shall comply with such order or direction and if the Food Importer fails to comply with such direction or order, the Food Authority may cancel the import license issued to the Food Importer.

(4) The customs authorities, port authorities or any other agency involved in the clearance, rejection, auction or destruction of imported articles of food in the customs area shall provide all such statistics to the Food Authority on a quarterly basis.

Chapter – IX

Officers of the Food Authority

13. (1) The Food Safety and Standards Authority of India shall notify the officers for the purpose of food import clearance to ensure compliance of the provisions of the Act, and it may also notify officers from other government agencies to maintain the standard operating procedure for food import clearance.

(2) The Authorised Officer shall have the following powers and duties, namely:-

(a) to receive applications for food import clearance;

(b) to make such inquiry and inspection as may be necessary to verify that the import of articles of food is not in contravention of any provision of the Act, rules and regulations made thereunder;

(c) to refuse inspection and intimate the customs, if the articles of import are misclassified as food based on end use declaration;

(d) to ensure compliance of all the conditions set out in sub - regulation (13) of regulation 7;

(e) to take photographs of imported food consignment for review and documentation;

- (f) to draw samples for testing of the imported food, if all the conditions specified in regulation 6 are complied with;
- (g) to collect additional sample of imported articles of food on payment of invoice value of the articles of food;
- (h) to re-seal any package opened for drawing of samples and certify that the same had been opened and sealed;
- (i) to forward the samples to a food analyst of a notified laboratory in proper manner for analysis and receive the report of the laboratory analysis;
- (j) to order additional tests on the food sample of imported food based on visual inspection, risk potential and instructions issued from time to time by the Food Authority;
- (k) to inform the Food Authority of any new variety of food or food ingredients, previously unknown hazards, or any other technical difficulties;
- (l) to maintain record of food imports, inspection, sampling and related activities, action taken, review process within the jurisdiction of customs ports assigned to him and any other such duties assigned by the Food Authority from time to time in writing and by photographs and audio - videography;
- (m) to report to the concerned Licensing Authority on any violation of any conditions of licensing by the Food Importer;
- (n) to recommend destruction or re-export of imported articles of food with necessary conditions as he may deem fit and ensure compliance of the same;
- (o) to inform the laboratory immediately on receipt of advance notice of arrival from the importer under the Pre-Arrival Document Review of the articles of food;
- (p) to ensure that the laboratories authorised by the Food Authority complies with all the specified procedures and perform all parameters of testing as specified in the regulations or permissions accorded by the Food Authority;
- (q) to ensure that the laboratories authorised by the Food Authority shall maintain records of laboratory analysis of the imported articles of food in the format as specified by the Food Authority;
- (r) to present all the related facts and documents before the Review Officer during the review process;
- (s) to seek data or information on imported articles of food consignment from the customs authorities;
- (t) to store the remaining parts of the food sample in appropriate conditions for re-analysis at referral food laboratory on the basis of appeal request received from the Food Importer or return to the Food Importer or Food Business Operator with acknowledgement, after issue of no objection certificate;
- (u) to issue no objection certificate or non-conforming certificate, as the case may be to the customs authorities and Food Importer;
- (v) to carry out any other duties as assigned by the Food Authority from time to time.

Chapter – X

Orders by the Authorised Officer

- 14. No Objection Certificate:-**(1) The Authorised Officer shall issue a 'no objection certificate' in FORM – 3, after assessing the safety of food being imported based on these regulations under his seal and signature for allowing import of food, and shall communicate such order in a specified manner to the customs and the Food Importer.
- (2) The no objection certificate permitting the import of food shall state the period of validity within which the articles of food have to be taken out by the Food Importer from

the customs area and the period of validity of no objection certificate for various types of articles of food shall be reviewed by the Food Authority from time to time.

(3) The Food Importer shall take effective steps to get the articles of food released from the customs area within the period of validity stated in the no objection certificate issued by the Authorised Officer failing which they shall be deemed to be Un- cleared articles of food.

(4) A copy of the report of the laboratory analysis shall be forwarded to the Customs and the Food Importer, wherever the no objection certificate is issued based on the report of the laboratory.

(5) The Authorised Officer shall issue a non conformance report in FORM – 4 specifying the grounds mentioned in these regulations for refusal, wherever the clearance of the imported food is refused, under his seal and signature, and shall communicate such order in a specified manner to the customs, Food Authority and the Food Importer.

(6) A copy of the report of the laboratory analysis shall be forwarded to the customs, Food Authority and Food Importer, wherever the report is issued based on a non-conformance laboratory Analysis Report.

(7) Based on the findings and recommendations in non- conformance report of the laboratory analysis and subsequent confirmation from the referral laboratory, if contamination or presence of microbiological organisms is likely to pose a significant risk to public health, the Authorised Officer, with the prior approval the Food Authority shall pass necessary orders for mandatory destruction of articles of food in FORM- 5.

(8) The customs shall provide a report to the Authorised Officer informing all the pertinent details of the destruction and the same shall be provided every quarter of the financial year.

Chapter – XI

Review Process

15. Reviewable orders:- (1) Any Food Importer aggrieved by one or more of the following orders of the Authorised Officer may file a review application to the Review Officer or Committee constituted in this behalf against such order-

(a) rejecting the clearance of the imported articles of food on the non-compliance with any of the conditions specified in sub – regulation (13) of regulation 7;

(b) any order directing the Food Importer to rectify the labeling of the articles of food; and

(c) report of rejection issued on receipt of a non-conformance report from Food Analyst.

(2) (a) The review application shall be in FORM-6 and shall be accompanied by such fee as may be specified by the Food Authority from time to time;

(b) The review application shall be presented to the Review Officer along with the required documents within seven working days from the date of communication of the report of rejection to the Food Importer;

(c) The Review Officer may admit a review application after the expiry of the said period for an extended period of seven working days, if he is satisfied that the Food Importer had sufficient cause for not presenting it within that period.

(3) (a) The Review Officer shall consider the facts and dispose of the review application in accordance with the provisions of the Act, the rules and regulations made thereunder and advisories or notifications issued by the Food Authority from time to time;

(b) On receipt of the completed application for review along with all documents, the Review Officer, if he deems fit may, fix the date, time and venue of hearing the representation of the Food Importer;

(c) The Food Importer, either in person or by a representative, and the Authorised Officer, either in person or through an authorised representative, shall have the right to be heard at the hearing of the review application;

(d) If either the Food Importer or the Authorised Officer fails to appear themselves at the hearing of the review application, the Review officer shall have the power to proceed to decide the review on merits;

(e) The Review Officer shall dispose of all review applications within a period of seven days, after filing of the review application by the Food importer and the reply of the Authorised Officer thereof:

Provided that the Review Officer may allow further evidence or material, if he deems necessary and also forward a part of the sample for analysis to the referral laboratory;

(f) The Review Officer may, before disposing off any review application, make such further enquiry as he may think fit or direct the Authorised Officer to make such further enquiry and report the result of the same;

(g) The Review Officer may, at the time of hearing of the review application, go into any ground not specified in the grounds for review, if the Review Officer is satisfied that the omission of that ground was not willful or unreasonable;

(h) The order of the Review Officer disposing off the review application shall be in writing and shall state the points for determination, the decision thereon and the reasons for such decision; and

(i) On the disposal of the review application, the Review Officer shall communicate the order passed in the review application to the Food Importer, customs and the Authorised Officer.

Chapter – XII

DISPOSAL OF REJECTED FOOD CONSIGNMENTS AND FOOD SAMPLES

16. Rejection of imported food consignments:- (1) (a) On receipt of the non-conformance report, the Custodian or importer shall dispose of the imported Food consignment in accordance with the provisions of the Customs Act, 1962 (52 of 1962):

Provided that the actual disposal shall be undertaken only after the period of limitation is over provided under these regulations for filing of review application by the Food Importer against the order of the Authorised Officer:

Provided further that in cases of storage of articles of food, the cost and expenses incurred in the storage of the articles of food, in such cases, shall be borne by the Food Importer;

(b) The Authorised Officer shall return the remaining sample to the Food Importer or his Custom House Agent with acknowledgement within a period of ten days from the date of issue of no objection certificate keeping one part of the sample till expiry;

(c) If the Food Importer fails to collect the remaining parts of the sample, by the Food Business Operator or Food Importer or his Custom House Agent the Authorised Officer shall dispose of the sample in the manner specified by the Food Authority;

(d) On receipt of non-conformance report, the remaining parts of the sample shall not be released to the Food Importer or his Custom House Agent and the same shall be retained in the safe custody of the Authorised Officer for a period of thirty days:

Provided that if any review application or any legal processing is filed by the Food Importer or Food Business Operator against the non-conformance report and the same is pending, then the second part of the sample shall remain with the Authorised Officer until the review application or any legal proceeding is disposed of;

- (e) In case no review is filed and the sample may pose risk to the public health the sample shall be disposed of as provided in sub – regulation (7) of regulation 14; and
- (f) If no review application is filed by the Food Importer within the specified period under these regulations, from the date of issue of the non-conformance report or if the review is disallowed, the Authorised Officer shall dispose of the remaining part of the sample in the manner specified by the Food Authority.

Chapter – XIII
Treatment of Uncleared and Unclaimed Food

- 17. Uncleared Food:-** (1) (a) If the Food Importer fails to take out the food import consignment from the custom area within the period of validity specified in the no objection certificate issued by the Authorised Officer, the food import consignment shall be deemed to be uncleared articles of food.
- (b) The Authorised Officer shall follow the procedure of inspection, sampling, testing and clearance laid down under these regulations, for disposal of all cases of uncleared articles of food.
- (2) The Authorised Officer shall, on receipt of request made by the Custodian and after ensuring that the requisite fees has been paid, issue either a no objection certificate or non conformance report after assessing the safety of Unclaimed food consignment based on due inspection and laboratory analysis.

FORM – 1
[See sub - regulation (8) of regulation 5]
Visual Inspection Format

The seal on the container was inspected, it reads as ----- and the same was found to be intact.

The seal was broken by the Authorised Officer or his representatives in presence of the following:

- 1.
- 2.
- 3.

BREAK OPEN SEAL FORMAT
 Food Safety and Standards Authority of India
 Port of Entry: _____

This Package is opened and a sample taken by the Authorised Officer of FSSAI, to have the same analyzed by a notified laboratory.	Location: _____ Sample ID: _____ Signature: _____ Name _____ of _____ officer: _____ Date: _____ Time: _____	This package has be resealed in my presence Initials _____ of Customs House Agent
-----------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------

- (Please tick the applicable)
- Nothing was stored in the container.
- The following were found stored, in the container:
- 1.
 - 2.

3.

The food articles were stored in a clean and hygienic condition and were free of:

1. Living/dead/fragments of insect
2. Rodent contamination
3. Moulds
4. Unwanted odour taint or mustiness
5. Any other substance, which can influence the safety of the food.

The packaging material was inspected and the following was observed;

The package prima facie appeared to be compliant to the packaging and labeling requirements as per the (Packaging and Labeling) Regulations, 2011

The package of the food consignment was inspected and the following was observed:

1. Size
2. Material used
3. Securely packed and sealed
4. Free from major dents, rust, perforation, seam distortion, leaks etc.

Brief description of the package:

Photograph of the Label

Observation:-The Food consignment is in compliance with the provisions of Food Safety and Standards (Packaging and Labeling) Regulations, 2011. Food article was found to be fit/not found fit for drawing sample and therefore the sample was drawn/not drawn.

SD/

Authorised Officer

The process has been carried out in the presence of all the signatories who have signed the present memo in token of their acknowledgement of the correctness of the proceeding.

- 1.
- 2.

FORM – 2

[See sub-regulation (6) of regulation 10]

LABORATORY ANALYSIS REPORT

Name of Laboratory Address

Test _____ Certificate _____ No _____
: _____ Date :

Laboratory Analysis Report

1. Sample Identification : Sample No:
2. Ref No :
3. Sample received from :
4. Sample Particulars : Brief description of sample material
5. Volume / Weight :
6. Sample received Date and Time : Time: _____ on _____
7. Lot / Batch No :
8. Date of Manufacture : _____ (mmyyyy)
9. Fee Received : Yes
10. Lab Code No : code assigned by laboratory for its records
- A. Physical Examination
11. Type of Packaging :
12. Condition of Package :
13. Physical Appearance of sample :

14. Labelling – Details sufficient : Yes No
 15. If condition of packaging or sample or details provided in the label is not acceptable, provide reason:
 B. Laboratory Analysis
 16. Analysis date of starting: Analysis date of completion:

Test results

S No:	Quality characteristics	Specified value	Name of the method	Test results (value)

C. Conclusion:

The sample conforms to the specification laid down in the Act and the rules and regulations made thereunder.

The sample does not conform to the specification laid down in the Act and the rules and regulations made thereunder.

Requires mandatory destruction: Yes No

If yes, provide comments:

1. _____

2. _____

Place

Signature

Date

Name and Seal and Designation

FORM – 3

[See sub-regulation (1) of regulation 14]

No Objection Certificate

No objection certificate

No: _____ Date: _____

Port of Entry/Location: Import General Manifest No. and date:

Bill of entry number and date:

To,

The Assistant/Deputy Commissioner of Customs

Sir,

Product as per the bill of entry	Sample ID	Exporting country

Remarks: Conforming

Balance shelf life of the product, on the date of issue of this no objection certificate:

This office has no objection if the above mentioned articles of food is released or cleared from this port before (Validity period of the no objection certificate), as the result of the inspection or analysis that the sample conform to the specifications provided under the Food Safety and Standards Act 2006, and the rules and regulations made thereunder.

This is for your information and necessary action please.

Date: _____ Name/Signature with Seal of the Authorised Officer

Place:
Copy to:
Name of the Importer and Import Export Code:
Address of Importer:
Food Safety and Standards Act License Number of the Importer:
Name of the Custom Brokers:

ENCL: Report/Certificate of Laboratory.

FORM – 4

[See sub–regulation (5) of regulation 14]

Non–Conformance Report

Non
No: conf
e: Dat

Port of Entry/Location: Import General Manifest No. & date:
Bill of entry number & date:

To,
The Assistant/Deputy Commissioner of Customs
Sir,

Product as per the bill of entry	Sample ID	Exporting country

The consignment is rejected on following grounds:

1.
2.
3.

This office is of the opinion that the consignment is not to be released/cleared from this port for the reasons mentioned above.

This is for your information and necessary action please.

Date: Name/Signature with Seal of the
Authorised Officer

Place:

Copy to:

Name of the Importer and Import Export Code:
Address of Importer:
Food Safety and Standards Act License Number of the Importer:
Name of the Custom Brokers:

ENCL: Report/ Certificate of Laboratory.

FORM - 5

[See sub–regulation (7) of regulation 14]

Mandatory Destruction Order

Food Safety and Standards Authority of India Authorised Officer

To,

Date:

The Asst. Commissioner of Customs

Food Article imported by :

Importer License No:

Vessel Name: _____
Import _____ General _____ Manifest _____
Number: _____ Dated: _____
BE: _____
Dated: _____
Index No: _____
Custom Brokers License No: _____
Custom Brokers Name _____

Sir,
1. The above mentioned food consignment imported by _____ was inspected on _____

by the Authorised Officials of Food Safety and Standards Authority of India and samples have been analysed by the Notified laboratory.

2. This office requests you to reject the clearance of import of this article of food and not to release it from this port as the result of the inspection and analysis of the sample of the articles of food does not conform to the specifications specified under the Food Safety and Standards Act, 2006 (34 of 2006) and Rules and Regulations made thereunder.

3. Based on the findings and recommendation in Non-Conformance Laboratory Analysis Report and subsequent confirmation from the Referral Laboratory, the contamination and presence of microbiological organisms in the food sample is likely to pose a significant risk to public health. The lab analysis reports are enclosed.

4. This office requests you to reject the clearance of import of this consignment and not to release it from this port and recommends for mandatory destruction of the articles of food of this consignment owing to the significant risks to the Public Health.

This is for your information and necessary action please

Yours Faithfully,
(Name and Seal of Authorised Officer)

Copy of Lab Analysis Report attached

FORM - 6

[See clause (a) of sub - regulation (2) of regulation 15]

Review Application to the Review Officer

Name and address of the petitioner: _____

~~Registration No. as Food Business Operator:~~ _____

Importer's License No.: _____

Import Details

Date of Import: _____ Bill of Entry No: _____

Point of import: _____

Name of Article of Food under consideration: _____
Product Type: _____

Invoice Value of Articles of Food: _____

Perishable: _____

Yes/No _____

Balance Shelf life of the item: _____

End Usage: _____

Rejection Report Details

Date of Rejection Report sought to be reviewed: _____ Order passed by:

(Authority) (Place)
Food Safety and Standards (Food Import) Regulation, 2012 under which the Rejection Report was passed: _____

Relief claimed in appeal: _____

Statement of Facts:

Grounds of Appeal

- 1.
- 2.
- 3.

Date:.....

Place:.....

Signed
(Appellant)

Form of verification

I,....., the petitioner herein/ the authorised representative of the petitioner herein, do hereby declare that what is stated in the accompanying Form I dated.....is true to the best of my knowledge, information and belief.

Place.....

Date.....

(Appellant)

PAWAN AGARWAL,
Chief Executive Officer
[ADVT:-III/4/Exty..281(187)]