

F.No. 1/2008/Import Safety/FSSAI
Food Safety and Standards Authority of India
(A statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110002

The 13th January, 2017

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding operationalization of Food Safety and Standards (Food Import) Regulations, 2017.

In exercise of the powers conferred under section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), the FSSAI has framed the Food Safety and Standards (Food Import) Regulations, 2017.

2. The draft notification of said regulation was notified in the Gazette of India vide F.No.1/2008/Import Safety/FSSAI dated 25.10.2016 inviting comments and suggestion from the stakeholders. These regulations were operationalised up to 13.01.2017 in exercise of the power vested in the food authority under section 18 (2) (d) read with section 16 (5) of the Food Safety and Standards Act, 2006.
3. After considering the suggestions received from the stakeholders, these regulations are being modified and are in the process of final notification. Since this is likely to take some more time, and it is neither possible to suspend food import nor allow unrestricted food import that may endanger food safety and public health, the competent authority has decided to re-operationalise the draft Food Safety and Standards (Food Import) Regulations, 2017, as enclosed herewith, w.e.f. 14.01.2017 by invoking the provisions under section 18 (2) (d) of the Food Safety and Standards Act, 2006.
4. It is directed that all Authorised Officers/ Officers authorised by Food Authority shall implement the above mentioned Standards till the issuance of final notification in this regard.
5. This issues with the approval of the Competent Authority in exercise of the power vested under Section 18 (2) (d) read with Section 16 (5) of the Food Safety and Standards Act, 2006.



(Sunil Bakshi)
Advisor (Codex/Regulation)

Enclosure: as above

To

1. All Authorized Officers, FSSAI

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI

**Notice for operationalization of Food Safety and Standards (Food Import)
Regulations, 2017**

Chapter - 1

Preliminary

1.1 Short title and commencement

1.1.1 These regulations may be called the Food Safety and Standards (Import) Regulations, 2017.

1.2 Definitions

1.2.1 In these regulations, unless the context otherwise requires:

- (a) **"Act"** means the Food Safety and Standards Act, 2006 (34 of 2006);
- (b) **"Authorized Officer"** means a person appointed as such by the Chief Executive Officer of the Food Authority 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-IGM) to "Best Before" or "Expiry Date" as the case may be;
- (d) **"Bill of Entry (BoE)"** means the Bill of Entry filed by the Importer under the provisions of section 46 of Customs Act, 1962 (52 of 1962);
- (e) **"Customs Airport"** means any airport appointed under clause (a) of Section 7 of Customs Act, 1962 (52 of 1962) to be a customs airport;
- (f) **"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;
- (g) **"Custom House Agent"** means a person defined under Custom house agent Regulation, 2004
- (h) **"Customs Port"** means any port appointed under clause (a) of section 7 to be a customs port and includes a place appointed under clause (aa) of that section to be an inland container depot
- (i) **"Fees"** means the charges prescribed by food authority for clearance of imported food consignments
- (j) **"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 & Registration of Food Businesses) Regulations, 2011 notified under the Act;

- (k) **“Food Analyst”** means an analyst appointed under section 45 of the Food Safety and Standards Act, 2006.
- (l) **“Import”** means bringing into India any article of food by land, Sea or air.
- (m) **“Non-Conformance Report (NCR)”** means a certificate or report issued to the customs authorities and the food importer by the Authorized Officer or any other officer specifically Authorized for this purpose by the Food Authority on account of non-conformance to/with the Act and the rules and regulations made thereunder of the consignment of the Food Importer;
- (n) **“No Objection Certificate (NOC)”** means a certificate or report issued to the customs authorities and the food importer by the Authorized Officer or any other officer specifically Authorized for this purpose by the Food Authority on account of conformance to/with the Act and the rules and regulations made thereunder of the consignment of the Food Importer.
- (o) **“Packing List”** means the itemized list of Food giving the description, quantity and weight of each imported article of food;
- (p) **“Pre-Arrival Document Scrutiny” (PADS)** means and refers to the scrutiny of documents submitted by the Food Importer to the Authorized Officer in advance, before the actual arrival of the article of food in order to facilitate faster clearance of food imported at the Customs Port, the Food Importer may be required to furnish documents as notified by the Food Authority from time to time;
- (q) **“Prohibited Food”** means that article/category(ies) of food as declared by the Food Authority time to time and published on the website of Food Authority
- (r) **“Prohibited Sources”** means the particular locations for which conditional or absolute restrictions are mentioned by the Food Authority on its website for import of food.
- (s) **“Review application fee”** means the fee levied by FSSAI towards disposal of review application submitted by Food Importer against the order of Authorised Officer pertaining to clearance of Food Imports;
- (t) **“Review Officer”** means the CEO or an officer Authorized by the CEO of the Food Authority for review of the orders of the AO. Such Review Officer shall examine any order of the Authorized Officer passed in respect of any import at the Customs Port(s), if the Food Importer approaches the Review Officer in respect of any such reviewable order.

passed in respect of any import at the Customs Port(s), if the Food Importer approaches the Review Officer in respect of any such reviewable order.

- (u) **“Risk Based Random Sampling”** means the activity of drawing samples randomly based on the risk criteria identified and the compliance history of the importer
- (v) **“Shelf Life”** means the period between the date of manufacture and the “Best Before” or “Expiry Date” whichever is earlier as printed on the Label.
- (w) **“Single Window Interface for Facilitating Trade (SWIFT)”** means the provision of single window system provided by the Customs to the importer/CHA to apply for import clearance.
- (x) **“Stuffing List”** means a list of Food items and its actual physical arrangement inside the container or cartons or pallets or skids;
- (y) **“Transit Country List”** means the list of countries through which the imported Food transits before it reaches the Indian Territory;
- (z) **“Unclaimed Food”** means an imported food consignment not having a claimant or Bill of Entry or both;
- (aa) **“Un-cleared Food”** means an imported food consignment of which the delivery is not taken by the importer within the period specified in the No Objection Certificate (NOC) issued by Food Authority;
- (ab) **“Visual Inspection”** means the process of inspection by the Authorized 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 Labelling regulations are ascertained for the Food Safety compliances prior to drawl of Samples.

1.2.2 The expressions used in these Regulations which have not been specifically defined herein shall have the same meaning as ascribed to them in the Food Safety and Standards Act 2006, and the Rules & Regulations framed thereunder and the Customs Act 1962. In the event of a difference between the definitions in The Food Safety and Standards Act 2006, its Rules & Regulations, and that in the Customs Act 1962, the definitions as contained in the Food Safety and Standards Act 2006, and the Rules & Regulations framed thereunder shall prevail. In the event of a difference between the definitions in the present Regulations and that in other Regulations under The Food Safety and Standards Act 2006, the definitions contained in the present Regulations shall prevail.

- 1.2.3 Any change or amendment in the definition of any expression used in these regulations as occurring in the Food Safety and Standards Act, 2006, and the Rules and Regulations framed thereunder; and/ or the applicable guidelines by the DGFT and Customs, shall be construed and understood as such.

Chapter – 2

Licensing of Food Importers/FBOs

- 2.1 No person shall import any food without an import license from the Central Licensing Authority in accordance with the procedure laid down in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011. No food article shall be allowed to be cleared from the custom unless it has 60% shelf life at the time of its clearance from the customs.
- 2.2 In addition to the FBO License for import of food, the Food Importer shall also register himself with the Directorate General of Foreign Trade (DGFT) and possess valid Import-Export Code.
- 2.3 Suspension or cancellation of License**
- 2.3.1 The provisions of these regulations shall be applicable for regulating conditions of license including suspension and cancellation thereof in addition to Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.
- 2.3.2 In addition to the above, the Licensing Authority shall cancel the Food Import license granted under the applicable regulations, if the DO/AO or any officer Authorized by the FSSAI have reasons to believe that;
- (a) There is sufficient ground to believe that the Food Importer has attempted to import unsafe food, prohibited food or food from Prohibited Sources, directly or indirectly, including re-channeling, re-packing etc.;
- (b) The Food Importer did not comply with conditions of the license, these regulations, or the undertaking of intended end use
- 2.3.3 The Food Importer shall be duty bound to inform the Central Licensing Authority and the Authorized Officer about any suspension, revocation or cancellation of the certificate of Importer-Exporter Code, granted in its favour by the Directorate General of Foreign Trade (DGFT) within 24 hours and not later

than three working days from the date of such order of suspension, revocation or cancellation.

- 2.3.4 The suspension, revocation or cancellation of certificate of Importer-Exporter Code granted by the Directorate General of Foreign Trade (DGFT) shall result in automatic and immediate cancellation of the import license granted under the FSS (Licensing and Registration of Food Businesses) Regulations, 2011, without any further notice in this behalf.
- 2.3.5 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 (DGFT) shall be reconsidered and granted within 7 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 (DGFT) 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 (DGFT).

Chapter - 3

Clearance of Imported Food by the Food Authority

- 3.1 Upon arrival of the food consignments at the port, the importer/CHA shall file an Integrated Declaration Form in the Customs Single Window Integration for Facilitating Trade (SWIFT). The applications forwarded from SWIFT to the FICS shall be processed as under:**
- (a) The AO shall scrutinize the application and may seek clarification if required.
 - (b) Upon satisfactory scrutiny, the applicant must pay the fees as prescribed by the Food Authority for scrutiny of documents, visual inspection and drawing of sample(s);
 - (c) Where a single Bill of Entry is made up of food article consignment consisting of multiple categories of food articles, Inspection Fee shall be applicable for each Food Article proposed for batch wise inspection.
 - (d) The Food Authority shall specify and review the inspection Fee from time to time.
 - (e) Upon receipt of the fees, the Authorized 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 CHA at the time and place of inspection.

- 3.2 The applicant must 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 Authorized Officer or his representative and witness proceeding, sealing of samples by the Authorized Officer or his representative and affix his counter signatures on the sealed samples.
- 3.3 The Food Importer shall facilitate the visual inspection and collection of sample(s) from the consignment as per the Stuffing List. The Authorized Officer shall direct the customs authorities to issue an order for de-stuffing the container and also assist in de- stuffing the container if required.
- 3.4 In the event of the food importer or his CHA is not being present to facilitate the inspection and sampling in spite of two opportunities having been granted, the Authorized Officer shall refuse to grant further opportunity for inspection and sampling of the food consignment. Any further appointment in this behalf may be granted by the CEO or his Authorized representative after levy of suitable penalty on the Food Importer as may be prescribed by the Authority from time to time.
- 3.5 The report of the visual inspection shall be submitted as per the format given in **Schedule-1**.
- 3.6 **Compliance with Standards for Packaging and Labeling Regulations**
- 3.6.1 No Food Importer shall import food that is not transported, or stored in optimal storage conditions of temperature and hygiene, packaged and labelled as per the Regulations applicable to that particular food at that time.
- 3.6.2 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.
- 3.6.3 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 Authorized Officer has easy access to all of them for inspection and sampling. In the absence of a proper stuffing list, the Authorized 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.
- 3.6.4 Special dispensation on labeling in case of Imported Food Consignments –Information on:

- (a) Name and address of the importer, and
 - (b) FSSAI Logo and License Number, Non-Veg/Veg Logo can be affixed by the Importer/CHA as rectifiable labeling deficiencies upon arrival of imported food consignments in the custom bonded warehouse. Such deficiency shall be rectified by affixing a single non detachable sticker or by any other non- detachable method next to the principle display panel. No other deficiency in the label is allowed to be rectified.
- 3.7 In respect of the rectifiable labelling deficiencies as set out in Clause 3.6.4, the Authorized Officer may pass an order directing the Food Importer or his authorized agent to carry out the permissible labelling rectifications, within a prescribed time in the Customs Area without altering or masking the original Label information in any manner. Upon such rectification by the Food Importer, the Authorized Officer shall carry out a re-inspection of the Food and if satisfied, draw the sample, subject to all other conditions being fulfilled by the Food Importer.
- 3.8 In case the Food Importer fails to rectify the permissible defects as set out in Clause 3.6.4, within the prescribed time, the Authorized Officer may pass an order refusing clearance of such imported food and issue a NCC.
- 3.9 If the Authorized Officer is satisfied that the Food Importer has complied with the above, the Authorized Officer or his representatives shall draw two parts of food sample (s) from the imported food in the Customs Area in the presence of Food Importer or his CHA for testing the samples.
- 3.10 If the food analyst seeks additional information on ingredients or on any other parameters after receipt of the Food Sample(s), the Authorized Officer shall direct the Food Importer to provide such information duly supported by documentary evidence.
- 3.11 The consignment not complying with the provisions of Labelling and Packaging Regulation, 2011 shall be rejected at the visual inspection and no samples shall be drawn from the consignment

Chapter - 4

Food Import Clearance for Specific Purposes

Nothing contained in this regulation will be applicable to any person bringing in any food article for his personal use provided that the value of such food article(s) shall not

exceed the amount as allowed by custom from time to time. The person carrying the imported food for personal consumption shall submit the declaration in the SWIFT

- 4.1 Unless otherwise specified, the Customs authority may not be required to refer the imported food to Food Authority for clearance if such food is meant for:
- 4.1.1 Export as per the extant Government instructions and export rejected/re- imported food meant for re-export;
 - 4.1.2 The food articles/ ingredients/ additives which are being imported by the manufacturers/ processors for their captive use/ production of value added products for 100% exports; and/ or the consignments of food items/ ingredients/ additives imported by the firms/ companies for use of their sister concerns/ wholly owned subsidiary companies, to be used for 100% export production subject to a defined relationship agreement between the two entities in this behalf;
 - 4.1.3 The importer would have to declare in the SWIFT regarding the captive/ end use of the imported product to the Customs Department at the time of filing the Bill of Entry, declaring that the imported food article is meant to be used by the importer for 100% export or re-import of food for export again as the case may be, and that no part thereof will be supplied for domestic consumption.
 - 4.1.4 The facility under clause 4.1.2 above shall not be applicable in the case of trading entities, who do not import such items for their captive use in view of the problems associated with traceability of the end-use of such items;
- 4.2 **Food imported by Diplomatic Missions** – The clearance of Food Imports shall be dealt in accordance with provisions of Vienna Convention on Consular Relations, 1963 (Article 50 of the Vienna Convention on Consular Relations, 1963).
- 4.3 **Import of Food for the purposes of Research and Development** – The clearance of food import for the purposes of research and development will be allowed subject to the import being undertaken by a licensed Food Importer and declaration by the Food Importer and the Food Importing Agency in the SWIFT to the effect that the imported food shall be utilized for aforesaid purpose only and not released into the domestic market or used for test marketing or market research purposes.
- 4.4 **Import of Food for the purposes of Exhibition and Tasting**
- 4.4.1 The procedure for clearance of food imported for exhibition purposes shall be as under: -

- (a) The exhibitor shall comply with the requirements, if any, prescribed by the custom. The exhibitor shall declare in the SWIFT.
- (b) In case the food is proposed to be used for 'tasting' purposes, the importing exhibitor/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 (DGFT) or specified by the Authority from time to time, will not be allowed to be imported for exhibition and/or tasting purposes;
- (d) All products for exhibition shall bear an additional non-detachable label/ sticker stating: "For Exhibition purpose only" and "Not for sale". The importing entity may be permitted to affix such additional label in the custom-bonded warehouse, if not already affixed;
- (e) 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, AND (iii) the items for re-export to the country of origin at the end of the exhibition/fair/event and shall be liable to submit such details on demand by the Authorized Officer.

4.4.2 A placard shall be prominently displayed at the place of exhibition of such food items stating 'For Tasting Only'.

4.4.3 The unconsumed portion of the food products, which have been opened for tasting, shall be destroyed after the exhibition by the Food Importer as per prescribed procedure. The unopened and unconsumed food product shall be re-exported in securely packed condition under intimation to the Authorized Officer by the Food Importer.

4.5 Import of Food for international sports events – The clearance of Food imports from a foreign country, exclusively meant for consumption by the sportspersons of such exporting country, may be allowed. The quantity of imported Food in such cases shall not exceed the bona-fide requirements for captive use/consumption by the persons concerned of such exporting country for the duration of their stay or event, whichever is earlier and the balance unconsumed food shall be re-exported to its country of origin by the Authorized member of the delegation under intimation to the Authorized

Officer. The importer shall submit the declaration in the SWIFT for clearance of imported food consignment.

- 4.6 In case of non-compliance or violation of any of the conditions stated hereinbefore, the Food Importer/any person or entity concerned shall be debarred from any concessions/ facilities set out hereinabove in future, in addition to the consequences in accordance with the provisions contained in the FSS Act and the rules and regulations thereunder.
- 4.7 Where any food is received gratis from other countries in case of any disaster or emergency situations in any part of the Country, the quality/safety of imported Food shall be ensured through Safety Certificates issued by the competent authority of the donor country/agency through inspection.

Chapter – 5

Storage, Inspection and Sampling of Imported Food

5.1 Storage facilities for Food Imports

- 5.1.1 No consignment of Food articles shall be stored in a manner that articles of one consignment come in contact with other food articles.
- 5.1.2 The imported food articles, shall be stored strictly in accordance with the prescribed storage conditions in the custom warehouse before clearance, failing which, the concerned Authorized Officer may refuse to grant NOC for import clearance of the food consignment.

5.2 Storage facilities for Food Imports –

The port authorities and Custodians 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 food article is cleared by the custom authority.

- 5.2.1 In case of imported food items which require special storage condition, the Authorised Officer will verify the true storage conditions required for the consignment. The Authorised Officer will also confirm from the air cargo operator /custodian regarding the availability of desired special storage facilities at the custom bonded area at the port/airport. In case of non -availability of such storage facility, the Authorised Officer will confirm from the department of custom their no objection to treat importers

warehouse as custom bonded area, the applicant will declare the same in the SWIFT which upon acceptance by the AO will allow the issue of provisional clearance certificates to the importer to move the food consignment to a well-equipped storage facility.

In case of non-compliance of any of the condition, the importer will not be eligible to avail of above mentioned facility in future besides other appropriate actions as per the prevailing law, rules, Regulations & instructions. The Authorised Officer will issue a NOC subsequent to the analysis report conforming to standards. The importer/customs shall ensure sale only after clearance based on NOC.

- 5.3 **Sampling Plan** –The Food Authority may review the risks associated with 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 etc.

5.4 **Sampling of Imported Food**

- 5.4.1 The Authorized Officer or his representative shall draw samples from the food consignments complying with Labelling and Packaging Regulation, 2011 and with a valid balance shelf life in the following manner: -

- (a) two parts of Food Sample (except for aseptic sealed packages) of each description (s)/ measures;
- (b) quantity of Sample(s) to be sent to the food analyst shall be as specified under Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011; (c) seal the samples

5.4.2 **Sampling of Imported food with specialized packing conditions: -**

- (a) In cases where the imported food is 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 food, the manufacturer shall provide two representative sealed samples from the same batch along with a declaration by the manufacturer stating that the Food Articles in the sealed container match with the representative samples placed in the sample containers.
- (b) In all cases wherever such representative sealed samples 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.

5.4.3 In respect of Imported food items having shelf-life less than 7 days the applicant must declare the same in the SWIFT allowing the AO to draw sample and issue Provisional NOC to the Customs, without waiting for the analysis report from lab. Upon the receipt of the analysis report from the lab, the same will be communicated to Customs along with NOC if products conform to the standard.

5.4.4 In case of non- conformance of the sample, the Authorised Officer shall immediately inform the Importer/Custom Brokers, to recall that consignment and submit a compliance report within 24 hours to the Authorised Officer and the Food Authority. Food Authority will alert all import points in to maintain vigil on imports of products manufactured by the same company or similar products imported by the same importer/Custom Brokers.

5.5 The sealed sample of imported Food shall bear the following information on the Label:

- (a) Code number of the Sample;
- (b) Date and place of collection;
- (c) Quantity of Sample;
- (d) Name 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/her CHA;
- (g) Name and signature of the sender with official seal.

5.6 One part of the sealed and labelled Food Sample shall be sent to the Food Analyst who shall cause it to be analyzed by a Notified Laboratory for Imports under Regulation 2.1 of Food Safety and Standards (Laboratory and Sample Analysis). The remaining parts of the Food Sample(s) shall be stored in appropriate conditions by the AO or his authorized representative. On the sample being found to be safe, the remaining sample shall be returned to the food importer. In the eventuality of the sample found to be unsafe, on any appeal received from Food Importer, the second sample may be sent to the Referral Laboratory for analysis whose decision shall be final.

5.7 Rejected export consignments by foreign countries that have been returned to India as the country of origin shall be subject to all the conditions of these regulations except that the packaging and labelling requirements shall be in

accordance with the country of export. The importer shall also submit rejection documents of the country of export.

- 5.8 The samples of imported Food sent by the Authorized Officer to the Food Analyst who shall analyse or cause an article of food to be analyzed by a notified laboratory as per the parameters defined in the Food Safety and Standards Act and the Regulations therein and shall send his report within five days to the Authorized Officer whether the product is conforming or non-conforming. If the Sample cannot be tested by the laboratory within the prescribed time it shall inform the reasons for the same in writing to the Food Analyst. The report of analysis shall be signed by the Food Analyst.

Chapter – 6

Laboratory – Analysis of Samples of Imported Food

6.1 Food Analyst

- (1) The samples of imported food sent by the Authorized Officer shall be caused to be analyzed by the Food Analyst.
- (2) The Food Authority shall appoint one or more Food Analyst for every notified laboratory for the purpose of this regulation.

- 6.2 Fees payable to Laboratory** – The fees payable for lab analysis report per sample of imported food analyzed by referral/notified laboratory shall be as prescribed by the Food Authority from time to time.

- 6.3** The Authorized Officer shall send the first part of the sample of imported food article for laboratory analysis to a Food Analyst of a laboratory notified by the Food Authority under sub-section (1) of section 43 of the Act and Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011.

6.3.1 Procedure to be followed by Notified/Referral Laboratory-

- (a) Upon 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 same.

- (b) The Notified or Referral Laboratory shall follow 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 food:

Provided that in cases where the test methods have not been specified by the Food Authority, the Notified or Referral laboratory shall follow the specifications for testing that have been prescribed by the Codex Alimentarius Commission or the International Organisation for Standardization (ISO) or Director General Health Services (DGHS), 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 food article, or any new equipment that it may seek to use but shall not commence using the above tests or methods of testing or equipment unless so permitted by the Food Authority.

6.3.2 Format of Laboratory Analysis Report—The Notified Laboratory or Referral Laboratory, as the case may be, shall provide the lab analysis report duly signed by its Food Analyst in the format specified in **Schedule-2** of these regulations within the statutorily prescribed outer limit of five days from the date of receipt of the samples as stipulated in the Act.

6.4 Referral Laboratory – An importer must file an appeal against the results of Notified Lab within 15 days of issuance of the Non Conformance Certificate by the Authorised Officer. Upon appeal by the Food Importer, the Authorized Officer shall send the second sample of imported food article 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.

6.5 Whenever lab 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 Authorized Officer for initiating suitable action.

6.5.1 In case the Authorized Officer has sufficient reason to believe that the imported food consignment poses a serious hazard to the safety and health of the consumer, he shall suo *moto* refer the

second sample to the Referral Laboratory for retesting to seek the confirmation of the findings of the Notified Laboratory. Such an incident shall also be immediately brought to the notice of the Food Authority by the Authorized Officer. Such samples, if found to be hazardous must be destroyed by a prescribed procedure following biohazard guidelines, and all the imported food articles to which the samples related, must be mandatorily destroyed/re-exported to the Country of manufacture/Origin by the Food Importer within 7 days of being directed to do so by the Food Authority, failing which, the Food Importer and his CHA will be jointly and severally liable to a penalty being 10 times the value of the imported food and the Food Importers license shall stand cancelled without any further intimation.

Chapter - 7

Scheme for Risk based Food Import Clearance

7.1 Risk Based Framework

7.1.1 The Food Authority, may adopt a risk-based framework and risk based inspection process for clearance of imported food articles. FSSAI for this purpose shall profile the Importer, CHAs, 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. The Authority may also introduce Pre- Arrival Document Review for regulating the imports.

7.2 Agreement with Exporting Countries-

(1) The Food Authority in consultation with the concerned Ministry as deemed 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 such countries.

- (2) The Food Authority may identify laboratories in exporting countries for prior testing of food samples before the food articles are imported into India.

7.3 Alerts

- 7.3.1 The Food Authority from time to time may issue Food alert notifications (including time bound prohibited foods/prohibited source) or recalls, based on the risk associated with the Food article. 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. Failure to do so on the part of the FBO will result in cancellation or suspension of his licence. The food alert notifications shall immediately be informed to the RMS of the customs department.
- 7.3.2 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.
- 7.3.3 During the pendency of alert notification the Food Authority may order for additional tests at the Point of Entry, mandatory certifications from the exporting countries or channelization till such time as deemed fit by the Food Authority.

7.4 Provision for post clearance surveillance and inspection

All food imports are subject to post clearance surveillance by government agencies. These will include:

- a) Random checks on the imported food items,
- b) Requirement to provide relevant documents to support the declarations and information provided by the importer/CHA in the Customs SWIFT.

Chapter – 8

Prohibition and Restrictions on Food Imports

8.1 Power of the Food Authority to issue orders for prohibition and restriction on import of food

- 8.1.1 The Food Authority may prohibit/restrict import of any article of Food based on risk perception or outbreaks of disease, etc. and issue orders as deemed fit in this regard.

8.1.2 The Food Authority may issue advisory(ies)/ guideline(s)/ order(s) as deemed necessary from time to time for ensuring the safety and wholesomeness of Food imported into India. All such prohibitions and restrictions to be informed to the Customs immediately.

8.2 Food Importers to be bound by directions or Order – Every Food Importer to whom any direction or order is issued in pursuance of any provisions of these regulations shall be bound to comply with such directions or order and any failure on the part of the Food Importer to comply with such direction or order shall amount to a contravention of the provisions of the Act and may lead to cancellation of food import license.

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

Chapter – 9

Officers of the Food Authority

The FSSAI shall notify the officers for the purpose of food import clearance. In order to ensure compliance of the FSS Act, 2006 and to maintain the standard operating procedure for food import clearances, the officers from other government agencies can also be notified as Authorised Officers.

9.1 **Qualifications of the Authorized Officer** – The Authorized Officer shall have the same qualifications as that of a Food Safety Officer prescribed under the FSS Rules or such additional qualification as may be specified by the Food Authority;

9.2 Powers and duties of the Authorized Officer – The Authorized Officer shall have the following powers and duties: -

- (a) to receive applications submitted under food import clearance;
- (b) to make such inquiries and inspections as may be necessary to verify, if the import of Food is in contravention of any provision of the Act, rules and regulations made thereunder;
- (c) to refuse the inspection and intimate the Customs accordingly, 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 Clause 4.6;
- (e) to take photographs of imported food consignment for review and documentation;
- (f) draw samples for testing of the imported food; if all the conditions set out in Clause 3.6 are complied with;
- (g) to collect, additional Sample of imported food(s) if required for research purpose(s). The cost of such additional Sample, shall be paid to the FBO by the Food Authority and calculated on the value mentioned in the invoice and duty paid to the customs for the imported food by the FBO;
- (h) to re-seal any package opened for drawing of Samples and certify that the same had been opened and sealed;
- (i) to send the Samples to a Food analyst of a Notified Laboratory in appropriate manner for analysis and receive the laboratory analysis report;
- (j) to order additional tests on the Food Sample(s) 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 all food imports, record of all inspections including sampling and related activities, action taken, review process within the jurisdiction of Port of Customs assigned to him/her 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 licensing conditions by the Food Importer(s);
- (n) to recommend destruction or re-export of imported 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 (PADR) about the Food;
- (p) to ensure that the laboratories authorized by the Food Authority follow all prescribed procedures and perform all parameters of testing as prescribed in the regulations or permissions accorded by the Food Authority;
- (q) to ensure that the laboratories authorized by the Food Authority maintain laboratory analysis records of the imported food in the format as prescribed 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 food consignment(s) from the customs authorities;

- (t) to store the remaining parts of the Food Sample(s) 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/ FBO with acknowledgement, after issue of NOC;
- (u) to carry out any other duties as assigned by the Food Authority from time to time;
- (v) to issue No Objection Certificate (NOC) or Non-Conforming Certificate (NCC) as the case may be to the customs authorities and Food Importer;
- (w) recommend a challenge to the orders passed by the Review Officer.

Chapter – 10

Orders by the Authorized Officer

10.1 No Objection Certificate. —

- (1) The Authorised Officer shall issue a 'No Objection Certificate' in the format specified in **Schedule-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 may state the validity period within which the food has to be taken out by the Food Importer from the Customs Area and the validity period of NOC for various types of food articles shall be reviewed by the Food Authority from time to time.
- (3) The Food Importer shall immediately thereafter take effective steps to get the food released from the Customs Area within the validity period stated in the No Objection Certificate issued by the Authorised Officer failing which they shall be treated as Un- cleared Food Articles.
- (4) A copy of the lab analysis report shall also be sent to the Customs and the Food Importer, wherever the No Objection Certificate is issued based on the lab analysis report.

10.2 Non Conformance Report. —

- (1) The Authorised Officer shall issue a Non Conformance Report in **Schedule-4** citing 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.
- (2) A copy of the lab analysis report shall also be sent to the Customs, Food Authority and Food Importer, wherever the Rejection Report is issued based on a Non-Conformance Lab Analysis Report.

- 10.3 Mandatory Destruction Order**--Based on the findings and recommendations in Non- Conformance Laboratory Analysis Report 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 food as per **Schedule- 5**. The Customs must provide a report to the Authorised Officer informing all the pertinent details of the destruction. The same should be provided every quarter of the financial year.

Chapter - 11

Review Process

- 11.1 Reviewable orders** - Any Food Importer aggrieved by one or more of the following orders of the Authorized Officer may file a review application to the Review Officer/Committee against such order: -
- (a) Rejecting the clearance of the imported food article on the non-compliance with any of the conditions set out in Clause 4.6;
 - (b) Any order directing the Food Importer to rectify the labelling of the food article; and
 - (c) Rejection Report issued on receipt of a Non-Conformance Report from Food Analyst.
- 11.2 Format of review application and limitation: -**
- (a) The review application shall be in the format specified in **Schedule-6 along with the review application fees as prescribed by the 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 Rejection Report 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 (7) working days, if he is satisfied that the Food Importer had sufficient cause for not presenting it within that period.
- 11.3 Procedure of review: -**
- (a) The Review Officer shall consider the facts and dispose of the review application based on the Act, and the rules and regulations made thereunder and advisories or notifications issued by the Food Authority from time to time.

- (b) Upon receipt of the completed application for review along with all documents, the Review Officer, if 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 Authorized Officer, either in person or through an authorized representative, shall have the right to be heard at this hearing.
- (d) If either of the parties does not present 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 will 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 Authorized Officer thereof. Provided the review officer may allow further evidence or material, if deemed necessary. He may also send a part of the sample for analysis to the referral laboratory.
- (f) The Review Officer may, before disposing off any review applications, make such further enquiry as he may think fit or direct the Authorized 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.
- (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 Authorized Officer.

Chapter - 12

DISPOSAL OF REJECTED FOOD CONSIGNMENTS AND FOOD SAMPLES

12.1 Rejection of imported food consignments: -

- (a) Upon receipt of the Non-Conformance Report (NCR), the Custodian/importer shall dispose the imported Food consignment as per the Customs Act, 1962.

Provided, the actual disposal shall be undertaken only after the lapse of period of limitation provided under these regulations for filing of review application by the Food Importer against the order of the Authorized Officer. The cost and expenses incurred in the storage of the Food, in such cases, shall be borne by the Food Importer.

- (b) Authorized Officer shall return the remaining of the Sample(s) to the Food Importer or his CHA with acknowledgement within a period of 10 days from the date of issue of No Objection Certificate (NOC) keeping one part of the sample till expiry. Upon failure to collect the remaining parts of the Sample(s), by the FBO/Food Importer or his CHA the Authorized Officer shall dispose of the Sample(s) in the manner prescribed by the Food Authority.
- (c) On receipt of Non-Conformance Report (NCR) the remaining parts of the Sample(s) shall not be released to the Food Importer or her/his CHA and the same shall be retained in the safe custody of Authorized Officer for a period of thirty days.

Provided, if any review application or court case is filed by the Food Importer/FBO against the Non-Conformance Report (NCR) and the same is pending then the second part of the Sample(s) shall remain with the Authorized Officer until the review application or the court case is disposed of. In case no review is filed and the sample may pose risk to the public health disposal as prescribed in clause 7.5 shall be followed.

- (d) 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 (NCR) or if the review is disallowed, the Authorized Officer shall dispose of the remaining part of the Sample(s) in the manner prescribed by the Food Authority.

Chapter – 13

Treatment of Un-cleared and Unclaimed Food

13.1 Un-cleared Food

- (a) The food imports consignments not taken out by the Food Importer from the Customs Area within the validity period specified in the No Objection Certificate issued by the Authorized Officer shall be treated as Un-Cleared Food.
- (b) The same procedure of inspection, sampling, testing and clearance, as laid down under these regulations, shall be followed for all cases of Un-Cleared Food in case the same is recommended by the Authorized Officer for the purposes of a further risk analysis.

13.2 Unclaimed Food

- (a) The Unclaimed consignments by the Food Importers in the Customs area shall be inspected by the Authorised Officer to ensure safety of food before release by the Custodians to open market through their disposal process.
- (b) The Authorised Officer, upon receipt of examination request made by the Custodian routed through Customs, after ensuring that the requisite fees has been paid, shall issue either a No Objection Certificate or Non Conformance Report after going through routine inspection and lab analysis process to assess the safety of unclaimed food consignment.

Schedule - 1

[See Regulation 3.5]

Visual Inspection Format

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

The seal was broken by the AO/his representatives in presence of the following:

- 1.
- 2.
- 3.

BREAK OPEN SEAL FORMAT



**Food Safety and Standards
Authority of India**

fssai

Port Of Entry: _____

<p>This Package is opened and a sample taken by the Authorised Officer of FSSAI, to have the same analyzed by a notified laboratory.</p> <p>Authorised Officer Seal</p>	<p>Location: _____</p>	<p>This Package has be re-sealed in my presence</p> <p>Initials of Customs House Agent</p>
	<p>Sample ID: _____</p> <p>Signature: _____</p> <p>Name Of Officer: _____</p> <p>Date: _____ Time: _____</p>	

(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 labelling requirements as per the (Packaging and Labelling) Regulations 2011

The Packages 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 Labelling) Regulations, 2011. Food article was found to be fit/not found fit for drawing sample and therefore the sample was drawn/not drawn.

SD/
Authorized 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.

Schedule – 2

[See Regulation 6.3.2]

FORM D**LAB ANALYSIS REPORT (Regulation 46, 48)****Name of Laboratory Address**

Test Certificate No: 0000000000

Date: 0000000000

Lab 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 & Time : Time: 0000 on 000000
7. Lot / Batch No :
8. Date of Manufacture : 000000 (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 are not acceptable, provide reason: _____

B. Laboratory Analysis

16. Analysis start Date:

Analysis completion Date:

Test results

S No:	Quality Characteristics	Specified Value	Name of the Method	Test Results

C. Conclusions:

The sample conforms to the specification laid down in FSS Act and Rules and Regulations made thereunder.

The sample does not conform to the specification laid down in FSS Act and Rules and Regulations made thereunder.

Requires Mandatory destruction: Yes No

If yes, provide comments:

1. _____

2. _____

Place

Signature

Date

Name and Seal and Designation

Schedule - 3

[See Regulation 10.1(1)]

No Objection Certificate

NOC No:

Date:

Port of Entry/Location: IGM 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

Remarks: Conforming

Balance shelf life of the product, on the date of issue of this NOC:

This office has No Objection if the above mentioned food is released/ cleared from this port before (Validity period of the NOC), as the result(s) of the inspection/ analysis that the sample(s) conform to the specifications prescribed under the Food Safety and Standards Act, Rules and Regulations.

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 IE Code:

Address of Importer:

Food Safety and Standards Act License Number of the Importer:

Name of the Custom Brokers:

ENCL: Report/ Certificate of Laboratory.

Schedule - 4

[See Regulation 10.2 (1)]

Non - Conformance Report

NCC No:

Date:

Port of Entry/Location: IGM 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 IE Code:

Address of Importer:

Food Safety and Standards Act License Number of the Importer:

Name of the Custom Brokers:

ENCL: Report/ Certificate of Laboratory.

Schedule - 5

[See Regulation 10.3]

MANDATORY DESTRUCTION ORDER**FSSAI Authorized Officer****To,****Date:**

The Asst. Commissioner of Customs

Food Article imported by :**Importer License No:****Vessel Name:****IGM 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
FSSAI and samples have been analysed by the Notified laboratory.

2. This office requests you to reject the clearance of import of this Food Article and not to release it from this port as the result(s) of the inspection and analysis of the sample of the Food Article does not conform to the specifications prescribed under the Food Safety and Standards Act, 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 Food Articles 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 AO)

Copy of Lab Analysis Report attached

Schedule - 6

[See Regulation 11.2(a)]

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 Food Article under consideration: _____ Product Type: _____

Invoice Value of Food Articles: _____ 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)

FSS (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 authorized 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)

