

# **Internship Project Report**

**Submitted to the  
Food Safety and Standards Authority Of India  
(FSSAI)**

**1.Codex Division**

**2. Imports Division**



**By,**

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Organization attached with: Food Safety And Standards Authority Of India

Period of Visit: May 15<sup>th</sup> , 2019 to 19<sup>th</sup> August, 2019

S.No	Projects assigned	Division	Reporting officer
1.	Amendment of Code of Practice for the prevention and reduction of Aflatoxin contamination of peanuts	Codex	Ms. Pushpinder Jeet Kaur Assistant Director
2.	Development of Codex Document for code of practices for the prevention and reduction of Aflatoxin contamination for India		
3.	Draft on food additives for their addition and deletion under FSSR,2011		
4.	Proposal for the initiative, Surakshit Khadya Aayat Bharat(Foreign Supplier Verification Programme)	Imports	Dr.Ajay Garg Deputy Director
5.	Studying Food import regulating bodies of Foreign countries		

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Last, but not least, I would like to thank all employees of the organization for sharing their experience and giving their time to us during the course of my projects.

## **CERTIFICATE**

This is to certify that Ms. Bhumika H N, a student of College of Agriculture, Hassan has completed the internship projects “Development of Codex Document for code of practices for the prevention and reduction of Aflatoxin contamination for India” , “Proposal for the initiative, Surakshit Khadya Aayat Bharat(Foreign Supplier Verification Programme)” and “Amendment of Code of Practice for the prevention and reduction of Aflatoxin contamination of peanuts “ successfully. To the best of my knowledge and as per her declaration, the report is an authentic work on the issue carried out at Food Safety and Standards Authority Of India. It is undertaken that to the best of my knowledge, industry interests are protected and no confidential information of the industry is being revealed in this report.

**Signature:**

**(Intern)**

Name: Bhumika H N

**Signature:**

**(Assessing Officer)**

Name: Shri. P. Karthikeyan

Deputy Director(Codex and Regulation Division)

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### **1. Food Safety And Standards Authority Of India**

## 1.1 FSSAI and its functions

Food Safety and Standards Authority of India (FSSAI) is an autonomous body established under the Ministry of Health & Family Welfare, Government of India. The FSSAI has been established under the Food Safety and Standards Act, 2006 which is a consolidating statute related to food safety and regulation in India. FSSAI is responsible for protecting and promoting public health through the regulation and supervision of food safety.

The FSSAI is headed by a non-executive Chairperson, appointed by the Central Government, either holding or has held the position of not below the rank of Secretary to the Government of India. Ashish Bahuguna is the current Chairperson for FSSAI and Pawan Kumar Agarwal is the current Chief Executive Officer for FSSAI.

The FSSAI has its headquarters at New Delhi. The authority also has 6 regional offices located in Delhi, Guwahati, Mumbai, Kolkata, Cochin, and Chennai. 14 referral laboratories notified by FSSAI, 72 State/UT laboratories located throughout India and 112 laboratories are NABL accredited private laboratories notified by FSSAI

FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

FSSAI works through 11 divisions:-

- ✓ Standards Division
- ✓ Regulation / Codex Division
- ✓ Regulatory Compliance / Surveillance Division
- ✓ Quality Assurance / Surveillance Division
- ✓ Human Resource, Vigilance and Training Division
- ✓ Finance Division
- ✓ Imports Division
- ✓ Risk Assessment and R&D Division
- ✓ FSMS Division
- ✓ General Administration Division
- ✓ Legal Division

## 1.2 Key functions of FSSAI:

- Framing of Regulations to lay down the Standards and guidelines in relation to articles of food and specifying appropriate system of enforcing various standards thus notified.
- Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses.
- Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories
- To provide scientific advice and technical support to Central Government and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition.
- Collect and collate data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, residues of various, contaminants in foods products, identification of emerging risks and introduction of rapid alert system.
- Creating an information network across the country so that the public, consumers, Panchayats etc receive rapid, reliable and objective information about food safety and issues of concern.
- Provide training programmes for persons who are involved or intend to get involved in food businesses.
- Contribute to the development of international technical standards for food, sanitary and phyto-sanitary standards.
- Promote general awareness about food safety and food standards

## **2. Projects**

## **2.1 CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF AFLATOXIN CONTAMINATION IN PEANUTS**

**Title:** Suggestion for the amendment of Code of Practice for the prevention and reduction of aflatoxin contamination in peanuts intended for human consumption

<b>CONCEPT</b>	<b>EXISTING IN CODEX</b>	<b>PROPOSAL</b>	<b>REASON</b>
1. Pre harvest	a. In semi-arid environments, populations of <i>Aspergillus</i> may be very high, and crop rotations may have little influence on the fungal activity. Cropping systems in some regions involve varied cultivation and fertiliser practices that individually or taken together	Early planting concept	It favours plants to escape end of season drought that in general predisposes pods to cracking and entry by <i>A.flavus</i>



	may affect survival or build-up populations of the toxigenic fungi.		
	b. There is evidence that peanuts grown in different soil types may have significantly different levels of infection by the moulds. Light sandy soils, for example, favour rapid proliferation of the fungi, particularly under dry conditions. Heavier soils have a higher water-holding capacity and, therefore,	Use of tied ridges(box ridges)	It can improve water penetration into the soils, thereby reducing exposure of the developing crop to <i>A. flavus</i> infestation.

	<p>there is less likelihood of drought stress occurring, which may be partly responsible for the lower than average levels of aflatoxin contamination in peanuts grown on such soils.</p>		
	<p>c. No fungicide, or combinations of fungicides, or other chemical treatments appear to have been adopted for the practical control of <i>A. flavus</i>/<i>A. parasiticus</i> infection and subsequent aflatoxin</p>	<p>1. Application of lime</p>	<p>It supports development of strong shells (pod resistance which provide the first line of defence against pest and fungal attack</p>

	<p>contamination of peanuts pre-harvest. The results of studies on the application of fungicides on freshly harvested or windrowed peanuts are equivocal</p>		
		<p>2. Application of Gypsum and FYM</p>	<p>Gypsum application reduced aflatoxin contamination by 40% in groundnut crop when applied at flowering. Besides yield enhancement, high quality kernels have been reported with gypsum application. Further, both gypsum and FYM application were found to be synergistic with bio agents in</p>

			reducing aflatoxin contamination
	----	Bio control measures	Using non toxigenic biocontrol strains of <i>A.flavus</i> effectively reduces aflatoxin contamination through competition
2. Harvest	Make sure that all equipment, which is to be used for harvesting and storage of crops, is functional. A breakdown during this critical period may cause peanut quality losses and enhance aflatoxin formation. Keep important spare parts available on the farm to minimize time loss from repairs.	Calibration/validation and Verification	Product safety
3. Post harvest	Drying	Ozone Fumigation	Detoxification of aflatoxins. Ozone fumigation during air drying of peanuts to reduce aflatoxin.

<p>4. Storage</p>	<p>For bagged peanuts, ensure that bags are clean, dry, and stacked on pallets or incorporate a water impermeable layer between bags and the floor.</p>	<p>PICS(Purdue improve crop storage)</p>	<p>A triple bagging hermetic technology with 2 inner lines made of HDPE and an outer layer woven Polypropylene. A study showed the efficacy of the PICS bags for protecting groundnut from quality deterioration and aflatoxin contamination caused by <i>Aspergillus flavus</i> and found that there was less toxin production in PICS bags compared to cloth bags under similar conditions.</p>
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**2.2 Title: Development of Codex Document for code of practices for the prevention and reduction of Aflatoxin contamination for India**

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<b>SL NO</b>	<b>NAME</b>
1.	Scope
2.	Definition
3.	Capacity Building
4.	Before storage a. Pre cleaning b. Drying c. cleaning
5.	Storage
6.	Transportation
7.	Good Manufacturing Practice(GMP)
8.	Segregation of Aflatoxin contaminated lots
9.	Control in the Production link
10.	HACCP – Complimentary system

**Scope**

The Standard specifies basic requirements and management rules for controlling aflatoxin in peanuts in harvest, storage and processing processes.

**Definitions**

2.1 “Safe water activity” means a water activity of in-shell peanuts and shelled peanuts that will prevent growth of micro-organisms normally present in the harvesting, processing, and storage environment.

2.2 Water activity (aw), is a measure of free moisture in a product and is the water vapour pressure of the substance divided by the vapour pressure of pure water at the same temperature. Water activities above 0.70 at 25 degrees Celsius (77 ° Fahrenheit) are ‘unsafe’ as far as growth of *Aspergillus flavus* and *Aspergillus parasiticus* and possible aflatoxin production are concerned.

### **3. Capacity Building**

3.1 Harvesting personnel should receive training on personnel hygiene, sanitation and operation.

3.2 Before harvesting, inspect the equipment and facility for harvesting and storage to ensure their proper operation; remove the residues on the equipment to prevent contamination to the subsequently harvested crops by the potential contaminants; during harvest, when having equipment breakdown that may possibly lead to damage to crops, the harvesting equipment should be repaired immediately, and the repair time should be as short as possible.

3.3 When harvesting, transporting, drying and storing crops, the conveyances used should be clean and dry and have no insects or mildew.

3.4 Ripe crops should be harvested in time; avoid harvesting immature crops. Ensure that crops with similar ripe degree are harvested at the same time as possible.

3.5 Separately harvest crops that are damaged or dead due to diseases or insect attack.

3.6 Avoid harvesting crops in an overly humid environment; if crops are harvested in the wet environment, they should be dried immediately after harvest.

3.7 During harvest, avoid mechanical damages to crops as possible, prevent invasion of fungi that produce aflatoxin, such as *Aspergillus flavus* and *Aspergillus parasiticus*.

3.8 After harvest, reduce the harvested crops' contact with soil; remove the residues of soil and straws to prevent invasion of fungi that produce aflatoxin, such as *Aspergillus flavus* and *Aspergillus parasiticus*.

3.9 In harvest, water content of crops harvested in different locations in the same farmland also vary significantly. Therefore, water content of each batch of crops should be determined synthetically by water content of multiple sampling points; determine subsequent storage of the crops based on the water content.

## **4. Before Storage**

### **4.1 Pre-cleaning**

Pre-cleaning could remove a large amount of straws and other plant residues which may carry molds or mold spores. Wind separation and sorting can be adopted to clean food materials. If there is cleaning equipment, it is recommended to use the mechanical methods to remove foreign matters, other crops' seeds and residues before the food materials are transported to the warehouse. However, such cleaning should not cause damages to food materials.

### **4.2 Drying**

4.2.1 Newly harvested food materials should be dried with such methods of air-drying in the sun and forced air circulation as soon as possible; reduce the storage time before drying so as to reduce the risk of mold growing.

4.2.4 In field, dry peanuts under sunshine to some extent and harvest them as fast as possible; avoid severe knock, squeeze and stacking in harvest. The harvested peanuts should be winnowed initially, and then be spread out on drying yards; the harvested fresh peanuts should be dried rapidly (within 3 ~ 5 days) to control the water content below 10%. While drying in sunshine, avoid damages to the peanuts caused by rain, insects, rats, and birds. Fresh peanuts should not be piled up before their water content is reduced to 8% ~ 10%.

4.2.3 During drying, water content should be reduced to a safe range for storage while minimize damages to food materials. During drying, avoid excessive drying or excessive high drying temperature to preserve nutritional values and ensure the crops are suitable for milling or other processing. Meanwhile, before storage, drying capability should be fully considered; ensure the crops to be stored could be dried within a reasonable period of time. During drying, water content should be tested in a timely manner; the samples used for water content testing should be representative. To avoid change of water content due to mixing and storage of the same batch of food materials before and after drying, the dried materials should be stored separately.



4.2.3 When necessary, “warehouse drying” can be adopted. Food materials can be placed in warehouses with mechanical ventilation. Food materials with high water content can be dried by using natural air or slightly heated air as drying means, and then be directly stored the dried crops in the warehouse.

4.2.4 If mechanical drying is not available, food materials should be placed on clean flat surfaces outdoors for air drying in the sunshine as possible. During drying, avoid contamination by rainfall, dews, soil, insects and other contaminants. For even and fast drying, food materials should be spread out into thin layers and be stirred frequently to accelerate evaporation of water and reduce the time of drying in the sun. Unable to dry the food materials under the sun, the food materials harvested could be placed in the shade for drying, ensure necessary ventilation in the drying sites.

4.2.5 Before storage, ensure that the water content of peanuts are reduced to the safe level (below 10% for peanuts with shells, and 9% for peanut kernels); screen the peanuts, remove immature fruits, damaged pods, moldy peanuts and foreign matters.

### **4.3 Cleaning**

After drying, clean the food materials and remove damaged kernels and foreign matters damaged by broken/insect bites/germinated/moldy and unripe. If using gravity separation or other approaches to remove kernels that are easy to be contaminated; if using mechanical approaches to remove foreign matters, avoid mechanical damages to food materials.

## **5. Storage**

### **5.1 General Requirements of Storage Sites**

5.1.1 Storage sites should be kept dry and ventilated; avoid the storage site to be affected by rainfall, snowfall, groundwater and vapor condensation, or invasion by rodents, birds and insects. The storage facilities should be in good conditions with good drying and ventilation facilities. The warehouse site and storage facilities/equipment should meet relevant requirements by FSSAI; environment

of the warehouse and storage facilities/equipment in the processing plants should meet relevant requirements of FSSAI

5.1.2 Before accepting crops, the warehouse and the storage facilities should be cleaned to reduce or remove foreign matters and contamination sources, such as dust /fungal spores/material residues/ animals' and insects' excrement /soil/ insects/ stones/ metal/cullet.

## **5.2 Storage and Management Measures**

5.2.1 Check the temperature and humidity in storage facilities on a regular basis. Abnormal rise in temperature probably means microbial growth and/or occurrence of insects. If there is abnormal rise in temperature or water content, the reasons should be found and reasonable measures should be taken to maintain the temperature in the reasonable and even range.

5.2.2 During storage, food materials may also be moved from one warehouse to another to facilitate fore ventilation and avoid occurrence of potential hot spots.

5.2.3 Finding deteriorating or mold growth in food materials, the food materials that have obviously been contaminated should be isolated and appropriately take samples for aflatoxin testing. While removing the contaminated food materials, avoid mixing the deteriorated materials with the remaining materials that seems to be in good condition. A small amount of severely contaminated food materials could significantly increase the aflatoxin content in food materials. After removal of deteriorated food materials, if necessary, use ventilation to reduce temperature and water content of the remaining stored materials to a reasonable level.

5.2.4 Establish the facility management plan to minimize the risk of rodents, insects and fungi invasion. For example, follow the comprehensive insect/fungi prevention plans' guidance and use the proper and registered pesticides/fungicides or other alternative measures. Use pesticide and fungicide that will not affect safety of the food materials' final intended use, strictly control the dosage, and follow the instructions in use. Using antimildew agents (such as propionic acid, a kind of organic acid) is beneficial for safe storage of food materials.

5.2.5 Install necessary testing devices for aflatoxin testing. Aflatoxin should be tested when food materials enter and exit warehouses, separately. If using the rapid testing methods and devices, proper rules for testing results analysis should be developed.

5.2.6 Food materials which are contaminated with aflatoxin should be separated from those that are not contaminated in storage.

5.2.7 Peanuts should be piled up in bags. Peanuts which have been not been dried or cleaned should be packed in such packing materials that do not cause vapor condensation (such as sacks). Peanuts which have been dried and cleaned should be packed in composite polyethylene film bags.

5.2.8 Leave proper distance between peanuts and walls/floor for air circulation, moving the bags and cleanliness inspection.

5.2.9 Generation of aflatoxin during storage and transport is closely related to the storage temperature, water content and hygienic conditions. An environment with the water activity less than 0.7, the relative humidity under 70% and the temperature lower than 15 °C is adverse for fungi growth and aflatoxin generation, and such environment is conducive for long-term storage of peanuts.

5.2.10 Check the temperature and humidity of warehouse twice a day. Peanuts should be stored at a minimum temperature which is consistent with the ambient environment as possible, though the temperature should not be close to the freezing point. When possible, use air circulation in the storage areas for ventilation of the stored peanuts, which will maintain the proper and even temperature in the whole storage area.

When the water content of peanuts exceeds 10%, dry the peanuts under the sun until the water content is reduced to below 10%. During storage, the temperature and humidity should be controlled to prevent peanuts from being bitten by insects, which will cause contamination of aflatoxin and toxic fungi.

### **5.3 Monitoring Requirements**

Properly record all steps of harvest, drying, cleaning and storage in each harvest season; items to be recorded include measurement values (such as ambient

temperature, water content of materials, ambient humidity) and any changes other than traditional practice; such records shall be documented. Such records can be used to explain reasons of aflatoxin occurrence each year and avoid occurrence of similar situation in the future. If possible, verified prediction models can be used to for management and prevention measures to control fungi growth and aflatoxin generation in the above steps.

## **6. Transportation**

6.1 Containers, vehicles and vessels that transport food materials should be dry, and free from materials that may contaminate the transported crops (such as food material kernels, dust, bacterial plaque, mold odor, insects, etc.) If necessary, the containers for transport should be cleaned and sterilized before use; however, the clean and sterilization should not contaminate the carried crops.

6.2 Proper measures should be taken to protect the transported crops, such measures include using sealed containers and water proof canvas. Minimize temperature fluctuation, and avoid vapor condensation.

6.3 During transport, avoid damages caused by insects, birds and rats. Relevant provisions should be followed when chemicals are used.

6.4 Crops which are contaminated by aflatoxin should be transported separately.

## **7. Segregation of Aflatoxin contaminated lots**

7.1 The distribution of aflatoxin in peanuts has been thoroughly investigated. The results from the investigations indicate that sorting for quality removes a large part of the aflatoxin present at harvest. The distribution of aflatoxins is very heterogeneous in a lot of peanuts and consequently the sampling plan used is critical.

## **9. Good Manufacturing Practice(GMP)**

9.1 Choose to procure peanuts in regions with lower contamination levels as possible.

9.2 When receiving peanuts from farmers, (the buyer) need to ask origin of each batch of peanuts. Inspect vehicles that transport the peanuts. Observe the general appearance of peanuts when the cargos are discharged. If the unloaded peanuts feel wet, they should be stored separately and dried as soon as possible.

9.3 Before receiving peanuts into warehouses, take certain measures to remove abnormal peanuts that are moldy, damaged, insects-bitten, having wrinkled skins and changed colors.

9.4 The warehouse should be cleaned before receiving peanuts, leaving no residues; warehouses should have proper facilities for insect, moisture and microbial multiplication prevention.

9.5 Inspect materials before they enter factories. Before shelling, the water content of peanuts should be under 10%, water content of peanut kernels should be under 9%, and the rate of moldy peanuts should be less than 1%.

9.6 If a factory has color sorters, the color sorters could be used to remove imperfect kernels that are moldy, damaged, broken or immature, which will reduce contamination of aflatoxin to peanuts.

9.7 If a factory does not have color sorters, workers could pick out imperfect kernels, foreign matters, discolored kernels and damaged kernels along the conveyor belts; this will remove imperfect kernels that are moldy, damaged, broken or immature, which will reduce contamination of aflatoxin to peanuts. Manual sorting stations should have bright lights, control the conveyor belt's speed and material thickness (peanuts are in single layer; avoid stacking of peanuts, which will affect the sorting efficiency; the conveyor speed should allow workers to effectively remove foreign matters and inferior peanuts; workers in the selection stations and the loading stations should have pre-job training.

9.8 The aflatoxin content of edible parts of peanuts after sorting should conform to provisions of FSSAI. Unqualified peanuts picked out during the sorting process should not be directly used for food; they may be used for non-food purposes or be destroyed; they should be separated from edible foods.

9.9 Before shelling, sort the peanuts, remove the moldy/sprouting/insect-bitten kernels, and at the same time remove foreign matters (such as iron pieces, clods, stones and plant stems/leaves). The processing equipment should be clean and tidy, without peanuts with shells, peanut kernels or broken kernels left behind.

9.10 If conditions permit, peanuts should be stored with shells and be shelled before use.

9.11 Control the original water content of peanuts during shelling under the safe water content level; it is prohibited to add/spray water in shelling peanuts.

9.12 Keep the workshops and machines clean. Workshops and shelling machines should be cleaned the same day they are used; no peanuts or broken kernels should remain in the shelling machine to avoid mildew from contaminating products.

9.13 Use the proper shelling methods to avoid damages to the materials.

## **10. Control in the Production Link**

10.1 During processing of peanut products, test the procured peanuts for aflatoxin to ensure each batch of materials procured comply with requirements by relevant standards; regularly clean the facilities and equipment for materials storage, and ensure they comply with relevant requirements. For different varieties, the items to be checked for acceptance include: purity rate, mildew, scab rate, foreign matters, water content, smell, vehicle cleanliness; the aflatoxin content should comply with provisions in FSSAI, the water content should be  $\leq 9.0\%$ , and no mildew should be detected.

10.2 For different varieties, check their purity rate, mildew rate and scab rate; the aflatoxin content should comply with provisions in FSSAI.

10.3 Peanuts from different regions should be processed separately to avoid water transfer and subsequent mildew.

10.4 Clean the surface of equipment and operation panels that have contact with food daily; leave no peanut kernels or mills in the equipment to prevent aflatoxin generation caused by damp and mildew, or insect contamination.

10.5 Reduce the retention time of semi-finished products between different stages of production to avoid microbial multiplication and other contamination.

10.6 Peanuts baked should be cooled before packaged; the cooling step will further reduce temperature and to volatilize the moisture; the cooled peanuts should be packaged in plastic bags which should be sealed and packaged in the outer bags for protection. The peanuts should be used as soon as possible.

10.7 The relative humidity for storage should be lower than 50% and the temperature for storage under 15°C; other warehouse management rules should be followed.

10.8 Test the finished products for aflatoxin to prevent aflatoxin contaminated products to enter the market. Finding positive testing results, traceability analysis should be conducted using the batch number to determine causes leading to the problems, and take rectification measures accordingly.

10.9 While producing peanut oil, without sacrificing nutrition and flavor, adopt safe and effective physical, chemical and biological techniques/technologies to remove aflatoxin in peanut oil (such as alkali refining, absorption, ozone, ultraviolet irradiation, etc.), reduce the content of aflatoxin in finished peanut oil as much as possible.

## **11. Complementary Management System to consider**

11.1 The Hazard Analysis Critical Control Point (HACCP) system is an all encompassing integrated food safety management system that is used to identify and control hazards within the production and processing system. The general principles of HACCP have been described in several documents.

11.2 When properly implemented, this system should result in a reduction of the levels of aflatoxins in peanuts. The use of HACCP as a food safety management system has many benefits over the types of management control systems in some segments of the food industry. At farm level there are many factors that influence the aflatoxin contamination of peanuts most of which are environmentally related, such as weather and insects, and these are difficult, if not impossible, to control. Particular attention should be paid to the soil population of the fungus, the health of seed material, soil moisture deficit stress at the pod formation and pod maturity stages, and rains at harvest. The critical control points often do not exist at the pre-harvest level. However, after harvesting, the critical control points may be identified for aflatoxins produced by fungi during drying and storage. For example a critical control point could be at the end of the drying process and one critical limit would be the water content/water activity.

## **2.3. TITLE: DRAFT ON FOOD ADDITIVES FOR THEIR ADDITION AND DELETION UNDER FSSR, 2011**

### **A. ADDITION AND DELETION OF FOOD ADDITIVES FROM FSSR,2011**

1. The food additives tabulated below are allowed to use under Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 but these additives are not specified in CODEX GL 36 and General Standard For Food Additives.

**Table 1. Food additives allowed to use under FSSR, 2011 but are absent in CODEX GL 36 and GSFA**

<b>SL NO</b>	<b>INS NO.</b>	<b>FOOD ADDITIVE</b>	<b>TECHNOLOGICAL PURPOSE (FSSAI)</b>	<b>PRODUCT</b>	<b>LEVEL</b>	<b>CODEX GSFA/ GL36</b>
1.	938	Argon	Packing gas	***	GMP	The Packing gas is mentioned neither in GL 36, CODEX nor GSFA
2.	924b	Calcium bromate	Flour treatment agent	***	***	Absent
3.	939	Helium	Packing gas	***	***	The Packing gas is mentioned neither in GL 36, CODEX nor GSFA
4.	1443	Hydroxyl propyl distarch	Stabilizer, thickener	***	***	Absent



		glycerol				
5.	306	Mixed tocopherols concentrates	Antioxidant	Lard,tallow, fish oil and other animal fats(Edible Fats)	GMP	Absent
6.	472f	Mixed tartaric, acetic and fatty acid esters of glycerol	Emulsifier, stabilizer, sequestrant	***	***	Absent
7.	948	Oxygen	Packing gas	***	***	The Packing gas is mentioned neither in GL 36, CODEX nor GSFA
8.	924a	Potassium bromate	Flour treatment agent	Maida	20ppm	Absent
9.	952	Potassium salt of cyclamic acid	Sweetner	***	***	Absent
10.	1421	Starch acetate esterified with vinyl acetate	Stabilizer, thickener	***	***	Absent

Levels of use and food categories concerned are not specified

1.a The food additives Zeaxanthin, synthetic(INS161h(i)),Lauric arginate ethyl ester(INS 243), Octenyl succinic acid(OSA)modified gum arabic(INS 423), Advantame (INS 969 ), Polyvinyl alcohol-Polyethylene glycol(PEG) graft copolymer(INS 1209) are standardized and specified under General Standard For Food Additive(GSFA) and can be recommended to be used in India.

**PROPOSAL:**

The **addition** of food additives Zeaxanthin, synthetic(INS161h(i)),Lauric arginate ethyl ester(INS 243), Octenyl succinic acid(OSA)modified gum arabic(INS 423), Advantame (INS 969 ), Polyvinyl alcohol-Polyethylene glycol(PEG) graft copolymer(INS 1209) to the Food Additives List under FSSR, 2011. The table is as follows:

**Table 1.a Food additives to be added to FSSAI**

INS NO	FOOD ADDITIVES	TECHNOLOGICAL PURPOSE	FOOD CATEGORY	LIMITS	REMARKS
161 h(i)	Zeaxanthin, synthetic	Colour	Flavoured fluid milk drinks	100ppm	<a href="#">GSEFA Notes.html</a>
243	Lauric arginate ethyl ester	Preservative	GSFA standards		
423	Octenyl succinic acid(OSA) modified gum arabic	Emulsifier	GSFA standards	GMP	
969	Advantame	Flavour enhancer, color	GSFA standards		There are currently no provision

					s for advantam e in CODEX- GSFA
1209	Polyvinyl alcohol- Polyethylene glycol(PEG) graft copolymer	Glazing agent, stabilizer	Food supplement s	1,00,0 00 ppm	

1.b. The standards for food additives Calcium bromate(INS 924b), Hydroxy Propyl distarch glycerol(INS 1443), Potassium cyclamates(INS 952), Starch acetate esterified with vinyl acetate(INS 1421), are not specified in CODEX. JECFA evaluation has not been done for Calcium bromate(INS 924b), Potassium cyclamates(INS 952), Starch acetate esterified with vinyl acetate(INS 1421). The JECFA evaluation has been carried out for Hydroxy Propyl distarch glycerol(INS 1443). The food category and respective limits for the mentioned food additives is not standardized under FSSR Food Additive List.

**PROPOSAL:**

The food additives Calcium bromate(INS 924b), Potassium cyclamates(INS 952), Starch acetate esterified with vinyl acetate(INS 1421), Hydroxy propyl distarch glycerol(INS 1443) can be recommended for **deletion** from FSSR food additive list. The table is as follows:

**Table 1.b. Deletion of Food additives from FSSAI**

INS NO	FOOD ADDITIVE	TECHNOLOGICAL PURPOSE	JECFA EVALUATION STATUS	REMARKS
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924(b)	Calcium bromate	Flour treatment agent	Not evaluated	
952	Potassium cyclamates	Sweetner	Not evaluated	Banned in USA, EU standards only for sodium and calcium cyclamates
1421	Starch acetate esterified with vinyl acetate	Stabilizer, thickener	Not evaluated	
1443	Hydroxy Propyl distarch glycerol	Stabilizer, thickener	Evaluated but no ADI allocated.	The additive not to be removed but held for future reference since there are no standards in CODEX

**B.ADDITION OF FOOD ADDITIVES TO GENERAL STANDARD FOR FOOD ADDITIVE(GSFA).**

1. The food categories and their permissible limits are not specified for the food additives except mixed tocopherol concentrates(INS 306). Mixed tocopherol concentrates can be used in Lard,tallow,fish oil and other animal fats(Edible Fats) under GMP as per FSSR,2011. But the additive is not specified in CODEX GL 36 and GSFA. The food additives Argon(INS 938), Helium(INS 939) and oxygen(INS 948) as packing gases is not specified in GSFA.

**PROPOSAL:**

The additives Mixed tocopherol concentrates(INS 306),Argon(INS 938), Helium(INS 939) and oxygen(INS 948) can be recommended for their **addition** to GSFA. The table is as follows:

**Table 1 Addition of food additives to GSFA**

INS NO	FOOD ADDITIVE	TECHNOLOGICAL PURPOSE	JECFA EVALUATION STATUS	REMARKS
306	Mixed tocopherol concentrates	Antioxidant	Evaluated	
938	Argon	Packing gas	Evaluated	
939	Helium	Packing gas	Evaluated	
948	Oxygen	Packing gas	Evaluated	

## **2.4 TITLE : A STUDY OF IMPORTING REGULATIONS OF DIFFERENT COUNTRIES**

Objective: To study the import regulating bodies of different countries.

### Introduction

#### 1. USA:

FDA and CBP(Customs and Borders Protection) together monitor the food imports into USA. Under provisions of the U.S. law contained in the U.S. Federal Food, Drug and Cosmetic Act, importers of food products intended for introduction into U.S. interstate commerce are responsible for ensuring that the products are safe, sanitary, and labeled according to U.S. requirements. (All imported food is considered to be interstate commerce.)

FDA is not authorized under the law to approve, certify, license, or otherwise sanction individual food importers, products, labels, or shipments. Importers can import foods into the United States without prior sanction by FDA, as long as the facilities that produce, store, or otherwise handle the products are registered with FDA, and prior notice of incoming shipments is provided to FDA.

Imported food products are subject to FDA inspection when offered for import at U.S. ports of entry. FDA may detain shipments of products offered for import if the shipments are found not to be in compliance with U.S. requirements. Both imported and domestically-produced foods must meet the same legal requirements in the United States.

#### 2. United Kingdom:

Port health authorities are responsible for monitoring food imports, checks and inspect high risk food at UK borders, fees and documentation of importers. The work is carried out by Port Health Authorities(specialist environmental health officers) and veterinarians, who are employed by the local authority or Port Health Authority. The Food Standards Agency(FSA) and the Department for Environment, Food and Rural Affairs(DEFRA) are responsible for the overall policy in the area of public and animal health for food and feed.

### 3. Canada:

Canadian Food Inspection Agency is the regulatory body dedicated to the safeguarding of food, animals and plants. It was formed in April 1997 under the ministry of health, government of Canada. CFIA along with others monitor the import standards and regulations. Exporters can get import license from the website *My CFIA*, which will be valid for 2 years. Other government bodies regulating import of food are,

- a. Canada Border Service Agency(CBSA) – it looks after custom duties and admissibility requirement
- b. Canada Revenue Agency(CRA)- Exporters can obtain business no. or import-export program account from CRA
- c. Global Affairs Canada (GAC)- it issues import permits for goods on Import Control List under Exports and Imports permit Act. Ex., Pork, Margarine, Peanut butter.

CBSA AND CFIA must be notified of all food shipments imported into Canada. They are responsible for monitoring and enforcing the import requirements. CBSA and CFIA together operates National Import Service Centre(NISC). NISC processes import request documentation/ data sent by the importing community across Canada. Staff review the information and return the decision electronically to the CBSA, which then relays it to the client or the broker/importer. In addition, NISC staff handle telephone enquiries regarding import requirements for all commodities regulated by the CFIA and when necessary coordinate inspections for import shipments. Automated Import Reference System(AIRS) is the reference tool for importers and exporters

### 4. Australia:

All Imported foods are monitored according to Biosecurity Act 2005 and Import Food Control Act 1992 and Food Inspection Scheme(IFIS). Food Standards Australia New Zealand(FSANZ) develops and maintain Australia New Zealand Food Standards Code. IFIS classifies foods into Risk food and Surveillance Food. Risk food as assessed by FSANZ as posing medium to high risk to public health, Surveillance food which pose low risk. Biosecurity Imports Condition System(BICON) is an inline

platform to determine whether the commodity intended for import into Australia is permitted, subject to import conditions, requires supporting documentation, requires treatment or needs an import permit.

#### 5. Sweden:

The responsibility for the safety of food and agricultural products in Sweden is shared between 3 Swedish Authorities, The Swedish Board of Agriculture, The National Food Agency (NFA) and, to a lesser degree, the Swedish Agency for Marine and Water Management. The NFA is the central supervisory authority for imports.

#### 6. Pakistan:

Pakistan's food imports are generally regulated by the federal government and food standards are regulated by the provincial governments. Pakistan does not have an integrated legal framework but has a set of laws, which deals with various aspects of food safety. Food standards were established in the Pakistan Pure Food Laws (PFL) of 1963. The PFL is the basis for the existing trade-related food quality and safety legislative framework. It covers 104 food items falling under nine broad categories: milk and milk products, edible oils and fat products, beverages, food grains and cereals, starchy food, spices and condiments, sweetening agents, fruits and vegetables and miscellaneous food products. These regulations address purity issues in raw food and deal with additives, food preservatives, food and synthetic colors, antioxidants, and heavy metals.

Pakistan's Hotels and Restaurant Act of 1976 applies to all hotels and restaurants in Pakistan and seeks to control and regulate the rates and standard of service(s) by hotels and restaurants.

The Pakistan Standards and Quality Control Authority, under the Ministry of Science and Technology, is the national standardization body. In performing its duties and functions, PSQCA is governed by the PSQCA Act, 1996. PSQCA is a member of International Organization for Standardization (ISO) and is the apex body to formulate or adopt international standards.

PSQCA also serves as:

Focal point for national, regional and international organizations & institutions such as ISO, IEC, Codex Alimentarius and WTO.



National Enquiry Point (NEP) for WTO Agreement on Technical Barrier to Trade (TBT).

Introduce measures through standardization regarding consumer safety and health.

Establish procedure to conformity assessment compliant with national & international standards.

#### 7. Sri Lanka:

Sri Lanka Standards Institute is the apex body for the country's Food Control Administration whose headquarters is in Colombo. Ceylon Standards Act 1964 was repealed and renamed as Sri Lanka Standards Institution Act 1984. Food Control Administration (FCA) under Ministry of Health monitor the country's food import and regulations.

The importer is required to declare details about the import cargo which is known as Customs Goods Declaration (CUSDEC). The importer is required to make customs declaration through Direct Trader input (DTI) for the import cargo. The automation of processing has been now fully implemented through "ASYCUDA world" to facilitate the importers to process the CUSDEC without delay.

#### 8. Maldives: MALDIVES FOOD AND DRUG AUTHORITY (MFDA)

Maldives Food and Drug Authority is the statutory body responsible for safe food and health of the public. Food Import and Local Production Regulation under Ministry of Health, Health Protection Agency regulates food import and export, hygiene in hotels and restaurants.

#### Afghanistan:

Food is controlled through Multi-organizational approach. Afghanistan still doesn't have an enacted food law. 3 main state agencies that regularly monitor and inspect food commodities are

- a. Ministry of Public Health
- b. Ministry of Agriculture
- c. Ministry of Irrigation, Livestock and municipalities.

9. Bhutan: BAFRA ( THE BHUTAN AGRICULTURE AND FOOD REGULATORY AUTHORITY)

The BAFRA, Ministry of Agriculture and Forests is the competent authority for biosecurity and food safety system to promote the quality and safety of food and agriculture related products.the head office is located near Tashichhodzong.

Import of food products into Bhutan is regulated as per the Plant Quarantine Rules and Regulations (2003), Food Act of Bhutan (2005), Seed Rules and Regulations (2006), the Food Rules and Regulations of Bhutan (2007) and Livestock Rules and Regulations of Bhutan (2008). Prior approval in the form of an import permit to import food commercially into Bhutan must be obtained from the Bhutan Agriculture and Food Regulatory Authority (BAFRA) of the Ministry of Agriculture and Forests.

The application for import permit must be processed two weeks prior to the import of the consignment.

10. Nepal: DFTQC(Department of Food Technology and Quality Control)

The Department of Food Technology and Quality Control, Government of Nepal. It was established in 1961 A.D as Department of Food, currently the present department is known as Department of Food Technology and Quality Control(DFTQC) in 2000. It is the apex organization responsible for the enforcement of food act and regulations.

Documents required for shipment to Nepal include a commercial invoice, a customs declaration form (CDF), clearly marked and labeled packaging, and a certificate of origin. Similarly, exported items sent by air require a CDF, a copy of the export license (if applicable), a commercial invoice, a certificate of origin, a copy of the letter of credit or advance payment statement from a bank, a foreign exchange declaration form, a packing list, a photocopy of the income tax registration certificate, an airway bill, and an authorization letter. Traders need to show their general export/import permits and taxpayer's certificate to import goods. If the end user – for example, a project office, company, or institution - is importing goods directly, it will have to produce a copy of its corporate registration certificate and

taxpayer's certificate in order to obtain both foreign currency approval from Nepal Rastra Bank (Nepal's central bank) and customs clearance of the consignment.

#### 11. BANGLADESH: BANGLADESH FOOD SAFETY AUTHORITY(BFSA)

1. Importer and exporter confirm the transaction by exchanging price quotation(s) and terms of the contract.
2. Importer applies for an import permit from the appropriate ministry (Agriculture or Fisheries and Livestock). Import permit for plant-based agricultural product is issued by the Plant Quarantine Wing, Dhaka Office. Import permit for fisheries or livestock product is issued by the Department of Fisheries and Department of Livestock respectively.
3. Exporter sends Pro-forma Invoice/Commercial invoice to the importer
4. Importer opens Letter of Credit (L/C) in a local bank. For opening the L/C, the importer provides the following documents to the bank:
  - a) Pro-forma Invoice (PI)/Buyer and Seller Agreement 13
  - b) Import Registration Certificate
  - c) Tax Identification Number (TIN) Certificate
  - d) Membership certificate of recognized chamber of commerce and industries or registered trade association
  - e) Insurance cover note with money receipt
  - f) Value added tax (VAT) registration certificate
5. Importer's bank sends L/C to exporter's bank
6. Exporter's bank sends confirmation letter of L/C to the importer's bank
7. Exporter sends the shipment of documents to the importer's bank
8. Exporter's bank sends a package of documents to the importer's bank as per listed in L/C (depending on product type)
  - a. Bill of exchange (invoice of the product)
  - b) Certificate of analysis (description of product)

- c) Country of Origin Certificate issued by any trade association of the exporting country
- b) d) Health Certificate i.e. (Fit for Human Consumption) for any kind of food
- e) Radiation Certificate issued by competent laboratory of exporting country
- f) Phyto-Certificate issued by agricultural department of the exporting country
- g) Animal Health Certificate for live animals
- h) Certificate of weight and quality condition
- i) Packing list/container list
- j) Insurance Certificate
- k) Others may be needed also depending on the product type, such as Fumigation certificate, Technical datasheet of Description of product

9. The bank releases the document package to the importer after receiving full payment of exporter's bills.

10. After the arrival of the shipment at seaport, the importer authorizes clearing and forwarding (C&F) agent to complete all activities required for customs clearance and seaport release.

11. The shipping agent submits the Import General Manifest (IGM) (containing description of imported goods by ship) online.

12. Assistant Commissioner, customs checks the manifest online and approves the manifest, and enters information into the ASYCUDA World system.

13. The C&F agent completes 'noting' which is entering all the required information to the ASYCUDA World system to submit Bill of Entry (BE). Documents submitted to the customs house:

- a) Letter of power of attorney of the C&F agent issued by the importer
- b) IMP form
- c) Import permit
- d) Bank endorsed Letter of Credit Authorization for customs copy
- e) Bank endorsed Letter of Credit for customs copy
- f) Bank endorsed invoice/PCI invoice
- g) Bank endorsed packing list
- h) Bank endorsed copy of CRF certificate of bank

- i) Bank endorsed original copy of Bill of Lading
- j) Insurance cover note and insurance policy document 14
- k) Bill of exchange (invoice of the product)
- l) Certificate of analysis (description of product)
- m) Country of origin certificate issued by any trade association of the exporting country
- n) Certificate of weight and quality condition
- o) Packing list/container list
- p) Others may be needed also depending on the product type: Other types of special documents are submitted as per the product type , 1) Data sheet duly signed by the C&F agent 2) Health certificate (Fit for Human Consumption) for any kind of food 3) Radiation certificate issued by competent laboratory of exporting country 4) Phyto certificate issued by agricultural department of the exporting country 5) Animal health certificate for live animal 6) Fumigation certificate 7) Conformity certification

14. The customs house reviews and approves the Bill of Entry (BE) and put a C number (Registration number/noting) into the system.

15. The agent submits the printed copy of the BE to the product wise customs group or section Assistant Revenue Officer (ARO), Customs House, Chattogram (CHC) for preliminary assessment.

16. The ARO section of the customs house assesses all the information, as per the BE and supporting documents. The ARO takes the official approval of physical examinations, informs the customs officer for tariff assessment.

17. The customs officer assesses the tariff of the product as per the BE and approves the tariff assessment notice online. The officer sends the section and gives the tariff assessment report to the C&F agent.

18. The C&F agent manages the containers to be ready for physical assessment at the port.

19. With the help of the C&F agent, the examining inspector conducts physical examination, and the C&F agent collects samples for in country testing and certification.

20. The C&F agent submits a sample to the respective laboratories of government agencies for conducting laboratory testing and gives certificates to the agent and customs house. The following certificates are generated in country (based on product type). a) Radiation certificate from Bangladesh Atomic Energy Commission. b) Quarantine certificate, fumigation certificate from plant quarantine office (for cotton and where necessary). c) Formalin test certificate from BSTI. d) Bangladesh standard certificate from BSTI.

21. After assessing all the supporting certificates, the examining officer gives the approved physical assessment notice/report.

22. The C&F agent pays the tariff to the authorized bank as per the tariff assessment notice.

23. The bank gives a red mark in the ASYCUDA World system after receiving the tariff payment and sends release order to the Treasury Speed Section.

24. After confirmation of tariff payment through the ASYCUDA World System, the treasury section gets the receive number and writes on the bill of entry. With the taxed bill of entry 15 and assessment notice, the C&F agent gives deliver order to the One Stop Service section of Seaport authority.

25. The One Stop Section of seaport assesses IGM, prepares bill payable to the port authority, receives bill payment, endorses bill and gives delivery order. Usually, it takes two days to deliver in a full container load and one day for less than a container load.

## **2.5 Proposal for the initiative, Surakshit Khadya Aayat Bharat(Foreign Supplier Verification Programme)**

### 2.5.1. Review of Foreign Supplier Verification Programme of Different Countries

#### **UNITED STATES OF AMERICA**

##### **1. Foreign Supplier Verification Programs(FSVP) for Importers**

As part of the US Food Safety Modernization Act(FSMA), 2011 directs the Food and Drug Administration(FDA) as the food regulatory agency of the U.S. Department of Health and Human services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. On November 27, 2015 FDA published the final rule Foreign Supplier Verification Programs for Importers of food for Humans and Animals(FSVP regulation). This regulation became effective on January 26,2016. It creates new requirements for importers of food for humans and animals.

The FSVP regulation establishes requirements relating to:

- Use of qualified individuals to conduct FSVP activities
- Hazard Analysis
- Food and supplier evaluation
- Foreign supplier verification
- Corrective actions
- Record keeping and
- Importer identification for a food offered for entry into U.S ( FDA has recognized the DATA UNIVERSAL NUMBERING SYSTEM(DUNS) number as an acceptable unique facility identifier(UFI) for FSVP)

#### **Special provisions under FSVP:**

Modified Requirements: Importers do not have to conduct hazard analyses or evaluate the food and foreign supplier. The FSVP regulation includes modified requirements for,

1. Very small importers(VSIs) – With respect to the importation of human food, an importer(including subsidiaries and affiliates) averaging less than

\$1,000,000(adjusted for inflation) – in both sales of human food plus the market value of human food that is imported, manufactured, processed, packed, or held without sale or less than \$2,500,000(animal food)

2. Small foreign suppliers - Importers of dietary supplements and dietary supplements, components

Documentation of eligibility to modified FSVP requirements: Written assurance (atleast every 2 years) that the foreign supplier meets the criteria for a type of small foreign supplier.

The U.S. owner or consignee is the person in the U.S. who, at the time of entry, owns the food, has purchased the food, or has agreed in writing to purchase the food. It may seem pretty straightforward and simple, but it can get complex and convoluted. For example, if there is no U.S. owner or consignee at entry, the importer is the U.S. agent (Note: there must be an agent if you import into the U.S.) or representative of the foreign owner or consignee, as confirmed in the signed statement of consent.

Exclusions include: juice (subject to HACCP),seafood(subject to HACCP),research use only, food used only for personal consumption, trans shipped foods, foods imported for processing and export, meat and poultry products subject to USDA regulation at import, alcoholic beverages(ATTB currently retains jurisdiction), low acid canned foods(micro hazards only).

Modified Requirements: There are some modified requirements that are narrow and require analysis. These modified requirements include: Dietary Supplements(Finished dietary supplements are subject to most of FSVP, whereas bulk/components are subject to Part 111 with a little FSVP), Very small supplier or importer, FDA approved country(This refers to a list of approved countries that have an equivalently robust food safety system).

Exemptions: As with each FSMA rule, there are some exemptions that exist as well. These exemptions for foreign suppliers include: Food that does not require a control (e.g., vinegar), Food that cannot be consumed in the absence of a control (e.g., coffee beans), Food that is shipped with an adequate disclosure statement, Food in which controls will be applied within the U.S. by the importer or customer. Foreign suppliers under oversight of a comparable food safety system, Very small



suppliers with less than \$1,000,000 in human food sales, Very small suppliers with less than \$2,000,000 in animal food sales ,Food shipped from Qualified Facilities or suppliers not covered by FSMA.

Use of qualified individuals to conduct FSVP activities.

The FDA defines the Qualified Individual as someone who must have the education, training or experience necessary to perform activities as per 21 CFR 1.503. These Qualified Individuals will develop the FSVP and those activities such as hazard analysis, supplier approval, verification activities and frequency, corrective actions, and other activities for the FSVP. These personnel must be able to read and understand the records to be reviewed for this program. This means they must know English and may also need to know the local language at the point of product manufacture or farming. If the foreign supplier is conducting a hazard analysis on behalf of the importer, they should ensure a Qualified Individual will be performing that work.

### **FSVP – 6 STEP APPROACH**

1. Determine the type of food/food categories to be included in the FSVP
2. Assigning responsibilities
3. Implement QI responsibilities
4. Determine the applicability of other food safety requirements
5. Communicate effectively
6. Be “FDA inspection ready”

### **FSVP – IMPLEMENTATION**

#### **1. Hazard Analysis:**

The hazard analysis is at the heart of the FSVP rule, and requires the evaluation of any known or reasonably foreseeable hazards relating to the imported food. This includes biological, chemical—which includes radiological—and physical hazards. Importers also may assess their foreign

supplier's hazard analysis to determine the hazards for the imported foods, and to determine whether the hazard analysis was conducted by a Qualified Individual. The analysis should be based upon experience, illness data, scientific reports, and other information.

Basically, a hazard requiring a control is a hazard that a person knowledgeable about food safety would establish controls or measures to significantly minimize. Because the foreign supplier is the expert regarding their own facilities, it's helpful to have them involved in this portion. They can provide the most accurate information regarding facility and equipment design, raw materials, product formulation, packaging and labeling, storage and distribution, intended or reasonably foreseeable use, and more.

## **2. Evaluation of Food risk and supplier performance**

After conducting hazard analysis, the next step is to evaluate the food and foreign supplier. A supplier performance evaluation is a culmination of the details of, foreign supplier's procedures, processes, and practices related to the safety of the food. Any information relevant to the supplier's compliance with relevant FDA food safety regulations, including, but not limited to, FDA warning letters, import alerts, or other FDA compliance actions. The foreign supplier's food safety history, including results from testing of foods for hazards, audit results relating to food safety, responsiveness in correcting problems, etc.

## **3. Foreign supplier verification**

The verification activities are those activities necessary to make sure the foreign supplier is actually controlling the hazards identified within the hazard analysis. Based on the evaluation of risk conducted, the importer needs to establish and follow written procedures to ensure they only import from approved foreign suppliers (in most instances). The importer also must conduct appropriate supplier verification activities.

Note: Annual on-site audits are required for foods deemed SAHCODHA (Serious Adverse Health Consequences or Death to Humans or Animals).

#### **4. Corrective actions**

The corrective actions will inform individuals on what to do should there be a deviation in the verification activities. These corrective actions may include the discontinued use of the supplier until corrections can be made, or disqualifying the foreign supplier altogether. Importers are required to reevaluate the plan and their foreign suppliers every three years or when new food safety concerns arise.

An importer is also required to promptly determine whether it's appropriate to continue importing food from that foreign supplier, and whether the verification activities need to be revised. This is an obligation to continuously reassess and reevaluate the programs and the approval of suppliers (periodic assessment).

#### **5. Recordkeeping**

All elements of the hazard analysis and foreign supplier verification activities must be documented, and must be maintained and made available to the FDA within 24 hours upon the FDA's request.

Note: The FSVP rule allows importers to hire a third party to perform the hazard analysis and risk evaluations, set up their food safety plan, and even monitor them. Still, the importer is ultimately responsible for ensuring that the proper evaluations are conducted and for reviewing the documentation from these tasks.

#### **6. Unique facility number**

Importer identification for a food offered for entry into U.S ( FDA has recognized the Data Universal Numbering System (DUNS) number as an acceptable unique facility identifier (UFI) for FSVP). The DUNS number is currently the only UFI approved by the FDA. It is a unique nine-digit identifier for business, assigned to a specific business location. The DUNS number is assigned by Dun & Bradstreet.

## **AUSTRALIA**

### **1. FICA – Food Import Compliance Agreements**

Food importers enter into a Food Import Compliance Agreement, known as a FICA, with the Department of Agriculture and Water Resources (the department) under the *Imported Food Control Act 1992*.

Many food importers have documented food management systems for sourcing and importing food. Under a FICA these systems may be recognised, offering an alternative to the routine inspection and testing of food products under the Imported Food Inspection Scheme (IFIS).

Food products imported under a FICA are not subject to potential delay and costs associated with inspection and testing under the IFIS. Instead, food products imported under a FICA are handled by the importer's food management system which is audited by the department. Compliant importers are audited on an annual basis with the audit frequency dependent upon previous audit performance.

All goods imported into Australia, including food imported under a FICA, are subject to Australian biosecurity requirements in accordance with the *Biosecurity Act 2015* and its subordinate legislation.

### **Requirements of FICA**

1. An importer must have a documented food management system that contains specific elements before the department will consider entering into a FICA. The food safety and compliance system criteria are based on;
  - Australian Standard - ISO 22000:2005 (Food safety management systems - requirements for any organization in the food chain),
  - Australia New Zealand Food Standards Code - Part 3.2 (Food Safety Requirements), and
  - consideration of other food management systems in Australia.

The food safety and compliance system criteria include requirements for manufacturer assurance, food safety assessment, traceability and verification. As a voluntary arrangement, importers must submit an application to the department to enter into a compliance agreement. Any food imported under a compliance

agreement is still subject to Australia's biosecurity requirements under the *Biosecurity Act 2015* and its subordinate legislation.

## **2. FICA application process**

A completed FICA application is required to be submitted, along with an application levy if the importer is not operating under an existing department arrangement. Additional fee for service charges are applied to cover the cost of an assessment of the applicant including a desk audit and an initial site audit to determine suitability to enter into a FICA with the Commonwealth

### **Suitability assessment for FICA applicants**

As part of the FICA application process, the Department of Agriculture and Water Resources will review information to determine the suitability of all listed persons who are in management and control of the FICA

The FICA application form contains a self-assessment checklist. The self-assessment must be completed by linking the relevant section of the importer's food management system to the corresponding requirement in the FICA document.

On receipt of a completed FICA application form, the importer's history of compliance is checked including a review of:

- the importer's record of compliance under the Imported Food Inspection Scheme (IFIS)
- the importer's compliance with other department areas, such as Approved Arrangements and Export Registration
- the importer's payment history and any outstanding debt to the Commonwealth.

If the compliance checks are acceptable, a desk audit of the importer's food management system is done and then conducting an audit at the nominated primary warehouse location to verify that the documented food management system is effectively implemented and satisfactorily addresses the requirements for an FICA.

## **3. FICA notification**

FICA importers must notify the department, using the FICA notification form in the following circumstances:

- detection of non compliant food or initiation of a food recall
- change of the FICA importer's representative or senior management

- variation to the importer's food safety and compliance system
- change to the importer's FICA warehouse register
- an insolvency event.

#### 4. FICA Audit Regime

- All importers that enter into a FICA will receive two probation audits within 180 days after commencement of a FICA. Following the probation audit period, the frequency of scheduled audit is once per year, based on previous audit performance.
- The probationary audit rate commences from the day of approval of a new FICA (or the day of reinstatement following a period of suspension). In the event of a failed audit, the probationary audit rate commences from the date of the failed audit.
- In order to progress from the probationary audit rate to the low scheduled rate of once per year the importer must pass two consecutive probationary audits. If the importer fails any one of the probationary audits, the six monthly period immediately restarts and continues until the importer passes two consecutive probation audits within six months.
- Importers operating under a FICA will progress to the low audit rate upon passing of two probation audits without waiting for the six month period to pass.
- Audit outcome
  - a. **Critical** – a noncompliance that results, or is likely to result, in the release/distribution of food that poses a risk to human health.
  - b. **Major** – a noncompliance that may result in the failure to identify food which is noncompliant with the Australia New Zealand Food Standards Code or the distribution of food that is known to be non compliant.
  - c. **Minor** – a noncompliance that is unlikely to result in the distribution of noncompliant food.

## **CANADA**

### **Foreign Food Safety Systems Recognition Framework**

#### **Introduction**

The Canadian Food Inspection Agency (CFIA) has embarked on a change agenda designed to strengthen how food commodities are regulated in Canada. Initiatives include the new Safe Food for Canadians Act (SFCA), regulations to be made under the *Act*, and the Integrated Agency Inspection Model. The SFCA, when fully in force, establishes a modern legislative framework for food safety. Recognizing the challenging import environment, the SFCA significantly strengthens import oversight authorities and proposed SFCA regulations will require importers to be licensed, develop and maintain a preventive control plan and have a fixed place of business in Canada, except where the Minister has recognized a foreign system

Canada currently uses a range of tools and approaches for import control, based on its legislative and regulatory framework, to target inspection resources and to verify compliance with requirements, in line with international rights and obligations.

These include:

1. pre-border activities (e.g. arrangements with an exporting country; certification; equivalence determination),
2. at border activities (e.g. admissibility of shipments),
3. post-border activities (e.g. inspection, sampling and testing), or a combination thereof.

As the CFIA modernizes its food safety regulatory system, it has an opportunity to make greater use of tools that could optimize its risk management activities for imports. Many of Canada's trading partners have mature domestic food safety systems with public health outcomes that are broadly comparable to Canada's system. Others have commodity specific control programs and oversight which can provide confidence that Canadian requirements will be met. The CFIA can leverage these systems, programs and oversight in its risk management approaches for imports using tools such as recognition of foreign food safety systems and programs.

## **Objective and Scope**

This framework elaborates on the use of recognition of foreign food safety systems and commodity specific food safety control programs and systems of inspection as a Canadian import control tool and identifies benefits, guiding principles and a process to guide implementation. It applies to the following situations:

Where trade between Canada and an exporting country is ongoing and existing knowledge, confidence and experience suggest that the national food control systems of the two countries achieve comparable outcomes.

Where trade in a specific commodity is ongoing and where knowledge, confidence and experience suggest that the foreign country's export control program for that commodity achieves the equivalent level of protection and outcomes as Canada's requirements.

Where Canada has established equivalence of a foreign country's food safety controls and inspection system as a prerequisite for import of a commodity.

The framework applies to food safety controls and oversight. It would not normally apply to requirements such as labelling, grades or compositional standards or to standards set by Health Canada such as maximum residue limits and microbiological criteria.

Animal and plant health import requirements are also not within the scope of this framework, and must be met in order for food products to be imported into Canada. CFIA's existing bilateral arrangements remain in effect as per the conditions of each arrangement. They are subject to regular reviews to determine that they are operating as originally intended and that they remain effective.

## **Categories of Recognition**

**Foreign food safety systems recognition (FFSSR):** A recognition that the design and operational performance of two countries' national food control systems provide comparable public health outcomes, legislative frameworks, implementation and oversight programs, and monitoring of regulatory performance. Systems recognition will be limited to exporting countries with mature national food control system taking into account experience, knowledge and



confidence, and a high level of compliance history. The scope will generally include all elements of a domestic food safety control system and all, or most, food commodities.

**Commodity specific recognition:** Recognition by Canada that an exporting country's food safety control program for a specific commodity is designed, implemented and verified such that Canadian requirements are met. Prior to entering into an assessment, the CFIA would take into account the experience, knowledge and confidence developed with the exporting country based on a history of trade and high level of compliance.

**Recognition of systems of inspection as a pre-requisite to trade:** Canadian legislation requires a foreign country's meat or molluscan shellfish systems of inspection to be evaluated and recognized to ensure that Canadian requirements are met before export can be initiated.

### **Recognition Process**

The scope of a proposal for determination of recognition is agreed upon between Canada and the exporting country. It may include all elements which make up a domestic food safety control system (foreign food safety systems recognition) or may be limited to those elements as applicable to a food commodity (recognition of a country's commodity specific food safety control program or systems of inspection) as agreed between Canada and the exporting country.

Discussions towards a food safety recognition process can be initiated by either the CFIA or the exporting country, and can be one way or reciprocal. In reciprocal agreements each country would assess the other concurrently against their food safety systems or commodity specific food safety control program. The CFIA will engage with its partners, as appropriate, in the undertaking of a recognition arrangement, e.g. other relevant Government of Canada departments and agencies. Further, capacity to enter into a recognition arrangement will be influenced by availability of resources and overall benefit to Canada.

The process for entering into recognition arrangement discussions is based on the Canadian Assessment Standards Tool, and includes:

1. Pre-assessment
2. Assessment
3. Maintenance

## **1. Pre-assessment**

A pre-assessment against clear established criteria is conducted to determine whether there is an adequate basis to enter into discussions towards a recognition arrangement. Criteria include, as applicable:

- whether there is significant trade between the exporting and importing countries for the products proposed in the scope of an arrangement, where trade is ongoing, or potential for trade where recognition is a pre-requisite to trade;
- the level of experience, knowledge and confidence in an exporting country's food control system or commodity specific program and oversight;
- whether Canada's food safety resources could be optimized as a result of the arrangement;
- the exporting country's compliance history, where trade is ongoing.
- For meat and molluscan shellfish, where assessment and recognition of the exporting country's systems of inspection is a pre-requisite to trade, criteria to be considered in the pre-assessment/prioritization include the potential volume of imports into Canada, animal health controls, and availability of resources to initiate an assessment.

## **2. Assessment**

If Canada and the exporting country decide to engage in a food safety recognition process, the assessment includes a documentation review, iterative exchanges with the foreign competent authority to ensure understanding and completeness of the documentary evidence, followed by in-country assessments in the exporting country to verify implementation. The assessment focuses on pre-requisite elements which make up a strong regulatory domestic food safety control system, commodity specific food safety program, or systems of inspection including:

- the legislative/regulatory foundation of the system or the commodity;

- organizational details (e.g. structure of the Competent Authority (ies));
- food inspection program(s);
- program assessment(s) and inspection audit(s);
- food-related illness and outbreaks;
- compliance and enforcement;
- scientific capacity, including laboratories, personnel, systems, evaluation and/or accreditation;
- competency and training of personnel;
- program resources;
- transparency and engagement with stakeholders;
- international communications and harmonization; and/or,
- any other element that may be identified by the Minister.

### **3. Maintenance**

Food safety recognition arrangements will be maintained based on regular reviews to verify continued effectiveness and performance, and ongoing information exchanges with the foreign competent authority.

Where CFIA determines the recognition arrangement with a foreign competent authority is no longer effective as an import control tool or where the CFIA no longer has confidence that the recognition arrangement meets its intended objectives, the status of the recognition will be re-assessed.

For certain food commodities, only specific foreign establishments or suppliers are permitted to export to Canada. CFIA's approval of their country's inspection system. Non resident importers who are subject to oversight by these food safety systems are eligible to hold an import license but only for specific food. Imported food must have been manufactured, prepared, stored, packaged and labeled in a manner and under conditions that provide at least the same level of protection as provided by the preventive control

## **EUROPEAN UNION**

European union classifies food into 3 categories.

- Food of animal origin
  - Food of non animal origin
  - Shelf stable, composite food
1. Food of animal origin: The category includes raw foods like meat, fish, eggs and processed products like ham)
    - Positive lists of eligible countries and business
    - Countries listing based on compliance or equivalence
    - Initial audit by FVO(Food and Veterinary office); Reinspections on risk basis
  2. Food of non-animal origin: The category includes fruits, vegetables, cereals, tubers, drinks, minerals(salt)
    - No country listing
    - Importer is liable for safety(general food law)
    - Import without certification via any port of entry
    - Exceptions apply for high risk foods(aflaoxins)

### **Country listing by EU:**

- Competent veterinary authority is organized and equipped in-line with the regulation 882/2004
- Animal health and zoonoses requirements met
- Approved businesses meet EU hygiene requirements and are regularly inspected
- A monitoring system for residue is in place
- Confirmatory inspection of the FVO
- Official certification agreed
- Member states agree in standing committee

## **Food business listing:**

- Country listing establishes a relationship of trust between EU and the exporting country
- Yearly submission of residue monitoring plan
- Exporting country can list further business after inspection by their own competent authority
- 4 weeks commenting period, and then automatic inclusion on EU list of approved establishments; establishment is then eligible for imports. FVO re-inspects occasionally or “for reason”

## **2.5.2 INDIA**

- Implementation of SURAKSHIT KHADYA AAYAT BHARAT(Safe Food Imports) program , the establishment of a modern legislative framework for food safety.
- Proposal for a regulatory system which will require foreign suppliers to have documented food management system for sourcing, to be verified, licensed and periodically assessed for their competence with the country’s food management system.
- Food products imported under the said program are not subjected to potential delay and costs associated with inspection and testing offering an alternative to the routine inspection and testing under FICS

### **1. Approach**

- a. Determination of foods to be covered under SKAB
- b. Establishment of a proper management system with qualified officers
- c. A guidance document for the importers to understand SKAB program
- d. Comparison with other countries food management system

### **Benefits**

SKAB represents a sea change for food safety, not only in India but also globally. It will have a dramatic effect on the safety of the food supply in India. The importers have the flexibility to determine the appropriate

verification measures for the foods they import based on food and supplier risks

Participating importers face benefits like limiting of examination and sampling of approved foods except in situations of suspected potential risk to public. If FSSAI intend to examine or sample an approved SKAB food, laboratory processing of such samples would be expedited, the location of such sampling to the extent possible, be at a location chosen by the importer.

Reduction of unnecessary delays at the entry points thereby saves time.

Requirements: 5 step approach

1. Use of Import officer to conduct SKAB activities

The Import officer(SKAB officer) plays a pivotal role wherein he is responsible for all the SKAB activities and their effective implementation. He communicates basic information, notices, test results etc., to foreign suppliers and will be in harmony. He communicates the same with the concerned FSSAI authorities.

2. Hazard analysis

The evaluation of any physical, chemical or biological hazards concerning food safety to be done by qualified authority. The analysis should be based upon experience, illness data, scientific reports, and other information.

The foreign supplier is the expert regarding their own facilities, it's helpful to have them involved in this portion. They can provide the most accurate information regarding facility and equipment design, raw materials, product formulation, packaging and labeling, storage and distribution, intended or reasonably foreseeable use, and more

3. Food and foreign supplier identification and verification by qualified FSSAI officers/ FSSAI accredited third- party certification.

The suppliers are periodically audited by FSSAI licensed auditors followed by documentation. A fixed audit regime to be followed by the qualified authority. The exporters are verified and licensed with a unique identification number.

The merchandise imported from verified exporters are made to pass the customs with minimum delay

4. Documentation and record keeping

21<sup>st</sup> century is the Digital age where everything becomes digital. The establishment SKAB technology wherein the information of foreign suppliers are documented contributing to the transparency of the system. It aids in better traceability of the merchandise. For instance, if a specific batch is found to be affected/non-conforming, one can access the portal, check the lot number and retrieve it back or had it replaced. The information exchange between the foreign suppliers and the competent authorities will be more flexible, transparent and reliable without under-hand transactions.

5. Effective communication

Communication is the key. Notification regarding,

1. A detection of non compliant food or initiation of a food recall.
2. change of the importer's representative or senior management.
3. variation to the importer's food safety and compliance system

should be relayed to the competent authority. Effective flow of information between verified suppliers and importing bodies to be followed to avoid any mishaps resulting in cancellation of licence or worse.

- The foreign suppliers should apply for the license along with other requisite documents under SKAB regulation. The application will be scrutinized on various grounds like the other country's food safety management system, disease outbreak records, reliability and traceability.
- After the approval of the application, the qualified authority will conduct a pre-assessment audit checking the foreign establishment and food to be compliant under FSSAI standards.
- If found compliant, there will be another assessment audit followed by a periodic audit every 6 months or a year depending upon the harmony between supplier and importer. An importer is also required to promptly determine whether it's appropriate to continue importing food from that

foreign supplier, and whether the verification activities need to be revised. This is an obligation to continuously reassess and reevaluate the programs and the approval of suppliers (periodic assessment).

### **3.Miscellaneous**

Training programme for 10 days at National Food Laboratory

Training Highlights:

- Basics of Chromatography and Mass spectroscopy
- Understanding and working of H-ESI II probe
- Understanding and working of Triple Quadrupole Mass spectrometer
- Optimization of Antibiotic residues(Kanamycin, Chloramphenicol) for determining RF value for new method development.

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