



***Manual of
Food Safety
Management
System, FSS
Act, 2006***

SCOPE OF THIS DOCUMENT

Section 16(2)(c), of the FSS Act, 2006 provides for the mechanism for accreditation of certification bodies for Food Safety Management Systems and Section 44 of FSS Act provides for recognition of organization or agency for food safety audit and checking compliance with Food Safety Management System required under the Act or the rules and regulations made thereunder.

This document defines the authority's definition on requirements of FSMS to be implemented by Food Business Operators in the country.

The present document aims to assist all players in the food chain to better understand FSMS implementation.

International Scenario on Food Safety

The International Standard ISO 22003 defines **food safety management system (FSMS)** as the set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives, used to direct and control an organization with regard to food safety.

The Key elements of any FSMS are:

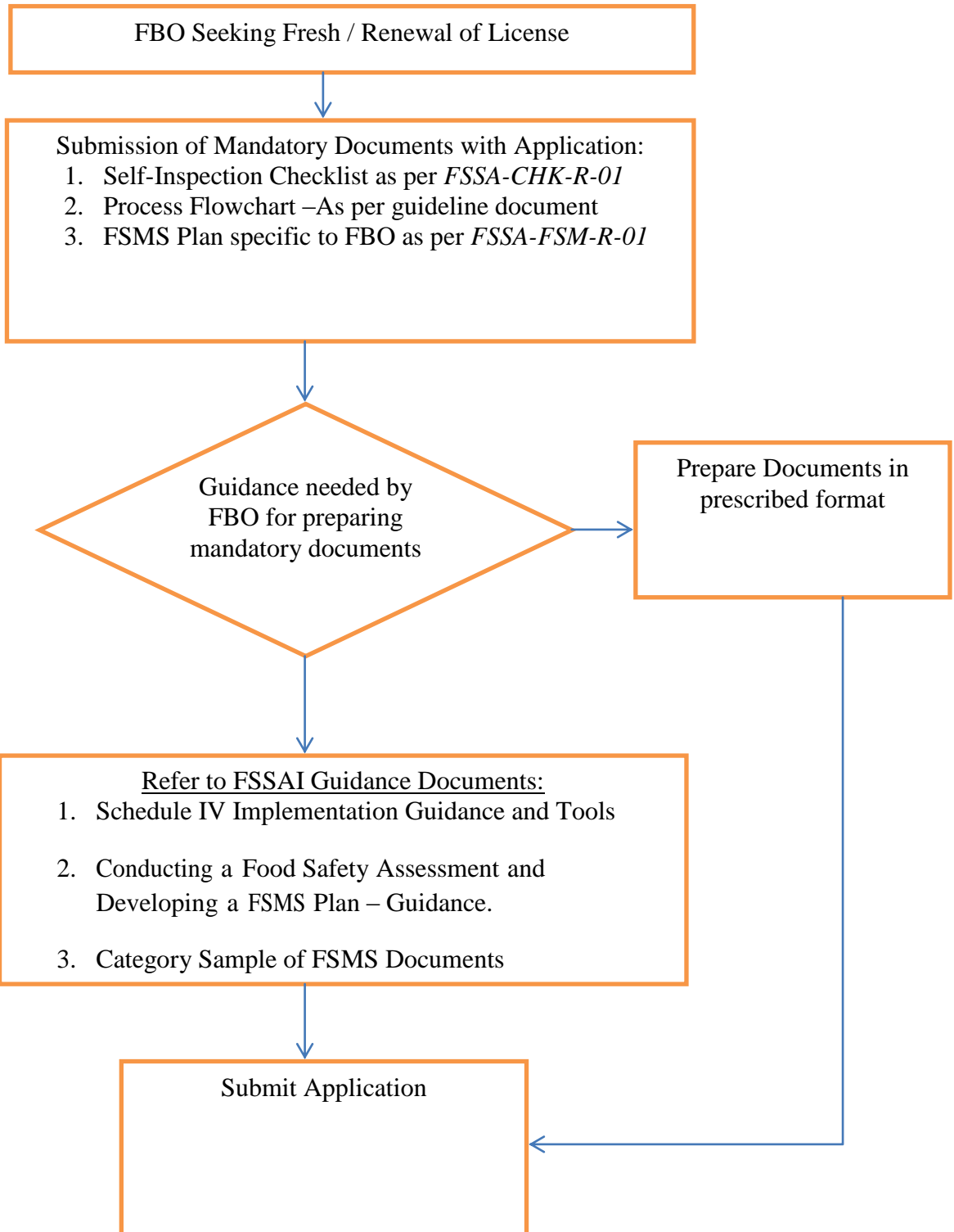
- ✓ Good Practices/ PRPs
- ✓ Hazard Analysis /HACCP
- ✓ Management Element / System
- ✓ Statutory and regulatory requirements
- ✓ Communication

Internationally and even in India, there are many Food Safety Certifications which meets these requirements. These are HACCP, ISO 22000, FSSC 22000 and many more. These are voluntary certifications to strengthen the food safety system.

However, under current Indian regulation defined by the FSS Act 2006, Food Safety Management System (FSMS) means the adoption Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business.

For the purpose of this document and all assessments conducted thereunder, the definition of FSMS shall be read as the above and the requirements for this are taken as that defined under **Schedule IV & Critical Control Points.**

FSMS Documentation by FBO



DEFINITIONS

“Act” means the Food Safety and Standards Act, 2006 (Act 34 of 2006)

“Rules” means the Food Safety and Standards Rules, 2011.

“Adulterant” means any material which is or could be employed for making the food unsafe or sub-standard or misbranded or containing extraneous matter.

“Consumer” means persons and families purchasing and receiving food in order to meet their personal needs.

“Contaminant” means any substance, whether or not added to food, but which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry or veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination and does not include insect fragments, rodent hairs and other extraneous matter;

“Food” means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zk) genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances :

“Food Authority” means the Food Safety and Standards Authority of India established under section 4;

“Food business” means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution of food, import and includes food services, catering services, sale of food or food ingredients;

“Food business operator” in relation to food business means a person by whom the business is carried on or owned and is responsible for ensuring the compliance of this Act, rules and regulations made thereunder

“Hazard” means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect;

“Food safety” means assurance that food is acceptable for human consumption according to its intended use;

“Food safety audit” means a systematic and functionally independent examination of food safety measures adopted by manufacturing units to determine whether such measures and related results meet with objectives of food safety and the claims made in that behalf;

“Food Safety Management System (FSMS)” means the adoption Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business;

“Food Business Operator” in relation to food business means a person by whom the business is carried on or owned and is responsible for ensuring the compliance of the Act, rules and regulations made thereunder

Structure of the FSMS Program

FSMS Program will cover following documents

1. The FSMS Plan (samples are provided as guidance) and
2. Flow chart of for the Process
3. A self-inspection checklist, which is to be submitted as an annexure to the plan.

FSMS guideline document is attached which has detailed the checklist/flowchart and FSMS plan for various categories. The categories which are not covered can use general checklist which is given in guideline document.

These documents will need to be submitted by the FBO as part of application for new license or renewal of license.

Also the FSSAI approved audit agency may inspect the FBOs on basis of this scope.

How prepare the documents

Use guideline documents for preparation of the FSMS program. The guideline document is to be used only for reference purpose - to understand how to make the flow chart and FSMS plan.

Schedule 4 checklists are given category-wise that should be used for self checking purpose.

The categories which are not covered can use general checklist.

For compliance of Schedule 4 & FSMS Plan, the reference documents are attached with the program to facilitate the FBOs in development of individual FSMS Program.

Reference Documents

In order to support the implementation and give clarity to FBOs, the FSMS implementation reference document has been provided which can be used. These documents are for guidance; and some changes may be required depending on type of food business.

These documents has covered following

- Implementing Schedule IV Requirements – Guidance.
- Conducting a Food Safety Assessment and Developing a FSMS Plan – Guidance.

Document and validation:

The Mandatory documents shall be validated by respective Food Safety Officer/Designated officer or he may assign suitable agency/person who is competent to carry out this job.

Record

1. Food Safety Management System (FSMS) Plan Form
2. Self Inspection checklist (Schedule IV)
3. Flow chart

Conclusion

The Food Safety Management System is a continual process and every FBO should aim for improvement and take higher Food Safety objectives for consumer safety.

FAQs

What if FBO already have HACCP/ISO 22000 or other FSMS certification, should they need FSMS Program documentation?

Answer : YES, If the FBO is already certified for advance FSMS systems then also as per FSSAI requirement, he/she needs to comply with Schedule 4 requirements. Thus each FBO needs to submit the FSMS program as per regulation. If FBO is already certified for such system, then it will be very easy for him/her.

For above FBOs, the inspection would be easy since they are already certified.

We are petty manufacturer why such sophisticated system is required for us?

Answer: Food safety is not depend on type or size of business. Under regulation FBO is defined very well. The FSMS program though looks complicated; depending on type of business the actual documentation may be very little.

Viz: For some FBOs the FSMS program may be completed in 4 pages or for some critical FBOS it may run in 20 pages. Basically it covers schedule 4 requirements and FSMS Plan

I do not have any qualified person, how I can implement the FSMS program my own?

Answer: Under regulation, each manufacturing FBOs should have technical qualified person. The program which is given is very simple and all supporting documents are provided. Any technical qualified person will able to implement this requirement depending on type of business within 1 day to 7 days. But implementation of the program will ensure commitment and involvement of top management.

If I do this FSMS Program then should I need to go for HACCP/ISO 22000 or other certificates?

Answer: Under FSS Act, the FSMS system is mandatory. If any FBO over and above wants to go for higher certification, we do not have any restriction. The FSMS system as per FSSAI covers basic things like GMP/GHP/Schedule 4 and Critical control point identification and monitoring only.

SELF- INSPECTION REPORT FORM

Catering and Food Service Establishments

Food Service Establishments - *Includes premises where public is admitted for consumption of any food or drink or any place where cooked food is sold or prepared for sale (Eating houses, Restaurant and hotels, snack bars, canteens, food service at religious places, Tiffin services, Dabbavalas)*

Date of Self-Inspection:	
Name of the Establishment:	
Address of premises:	
Tel. No.:	
Fax No.:	
Category of licence (Central/ State)	
License No.:	
E-mail Address:	
Name of the Manager / Authorized Signatory:	
No. of Shifts:	
No. of Employees:	
Kind of business:	
Type of business ownership:	Limited/ Private limited/ Public sector undertaking/ Co-operative/ Partnership/ proprietorship/other.

Please mark as Status as appropriate

In order

not in order

* If Status is marked not in order, please provide target completion date

Sr No	Area	Status
1	LOCATION AND LAYOUT OF THE ESTABLISHMENT	
a	The Food service establishment is ideally located away from industries which are emitting harmful gases, obnoxious odour, chemical etc.	
b	The Food preparation area walls are smooth, made with impervious material up to a height of not less than five feet and the junction between the walls and floors are curved.	
c	The premises of the food outlet is adequately lighted and ventilated, properly white washed or painted.	
d	Food preparation/ cooking/frying area is equipped with chimney with appropriate suction capacity depending upon kitchen size to avoid smoke	
e	The preparation/ processing/ cooking should be adequate to eliminate and reduce hazards to an acceptable level which might have been introduced at the raw food level.	
2	EQUIPMENT AND FIXTURES	
a	Work surfaces, chopping boards and equipments are thoroughly cleaned before the preparing of food starts and after it has been used	
b	Separate chopping boards and knives for raw fruit/ vegetables/meat/poultry and ready-to-eat food are used	
c	The equipments are made of stainless steel /galvanised iron/ non corrosive materials.	
d	Appropriate facilities for the cleaning and disinfecting of equipments and instruments and preferably cleaning in place (CIP) system are adopted; wherever necessary.	
e	All electrical wires, boards and panels are adequately secured and in a clean state	
f	Any glass fixture including tubelights is appropriately secured with an unbreakable high temperature resistant material	
3	STORAGE SYSTEMS	
a	Appropriate arrangement for storage of food & food ingredients provided and adequately segregated and labeled	
b	Containers used for storage are made of non toxic material.	
c	Veg. foods are stored above non-veg. foods and cooked foods above uncooked foods on separate racks in the refrigerator.	
d	Storage temperature is maintained at -18C for frozen foods and at or	

	below 5C for high risk foods.	
e	Stock Rotation is followed	
f	Raw food /meat/poultry and ready-to-eat foods are kept separate at all times to avoid cross contamination.	
g	Special attention is given while storing high risk foods such as cut fruits and salads, fruit juices, confectionary, meat, poultry, fish, water based sauces and chutneys, gravy foods.	
4	PERSONAL HYGIENE	
a	Food handlers must wear suitable clean clothes and where necessary, shall wear head cover, apron, mask mouth and use gloves etc	
b	Avoidance of unhygienic practices such as chewing tobacco, touching face, mouth, ear or other body parts, Spitting, sneezing, coughing by food handler.	
c	Adequate facilities for toilets, hand wash and footbath, with provision for detergent/bactericidal soap, hand drying facility and nail cutter are provided	
d	Arrangements are made to get the staff medically examined once in six months to ensure that they are free from infectious, contagious and other diseases.	
e	All food handlers are inoculated against the enteric group of micro-organisms	
6	WATER SUPPLY	
a	Adequate supply of potable water for beverages.	
b	Appropriate facilities for safe & clean storage of water.	
c	The water is examined chemically and bacteriologic ally by a NABL Accredited laboratory at a defined frequency and whenever the potential for contamination or an epidemic is identified.	
d	Ice and steam wherever in use during processing is made from potable water.	
7	PEST CONTROL SYSTEM	
a	Treatment with permissible chemical, physical or biological agents within the permissible limits are carried out.	
b	Adequate control measures are in place to prevent insect and rodents from entry into the processing area.	
c	The area has proper mesh and fly catchers at appropriate locations to prevent pest entry.	
8	CONVEYANCE AND TRANSPORTATION AND HANDLING OF FOOD	
a	The vehicle/transportation used to carry cooked/prepared/processed food is clean and not used to carry anything else.	
b	The conveyance and transportation are provided with temperature	

	control system.	
c	Handling of food should be minimal. It should be ensured that utensils, crockery, cutlery and specially hands of the food handlers/seller are clean and sanitized	
9	CLEANING AND MAINTENANCE	
a	Cleaning and sanitation programme is drawn up, observed and the record of the same is properly maintained. The schedule include: • Area needs to be cleaned • Frequency of cleaning • Method of cleaning	
b	Sinks with a draining board, detergent and hot water shall be provided to ensure proper cleaning of utensils, crockery and cutlery there will be a separate place for washing pots and pans.	
10	OPERATIONAL FEATURES	
a	The source and standards of raw material used are of optimum quality and as per Regulation and standards laid down under the Act.	
	Meat, poultry, fish and other non-veg products are only sourced from licenced / authorized vendors.	
	Frozen products to be received at temperature below -18C and fresh / chilled products to be received at temperature below 5C	
b	Test report from own or NABL accredited/ FSSAI notified labs regarding microbiological contaminants in food items are available.	
c	Thawing of frozen meat or poultry are carried out in one of the following ways - At refrigeration temperature for not more than 24 hours - Under running water at room temperature for not more than 90 mins - In a microwave.	
d	Cooling of products for further use are treated as follows: - Temperature brought down from 60C to 21C in 2 hours and to 5 C or below in the next 4 hours.	
11	AUDIT/ DOCUMENTATION AND RECORDS	
a	Records of daily production, raw material utilized and sales are available.	
b	Appropriate records of food processing/ preparation, food quality, laboratory test results, pest control etc. for a period of 1 year or the shelf-life of the product; whichever is more.	
12	PRODUCT INFORMATION AND CONSUMER AWARENESS	
a	All packaged food products carrying label and requisite information as per Regulations are made.	

13	TRAINING	
a	Food handlers and production floor managers/ supervisors underwent appropriate food hygiene training.	

Sample FSMS Plan for Food Service Units

Operational Step	Hazard	Control Measure	Critical Limit	Monitoring Method	Corrective Action	Responsibility	Record
Receiving	Microbial Growth in RTS received	Receive below the danger zone	4 ⁰ C +/- 2 degrees	Incoming Receipt Check	Reject Lot	Purchase Manager	Incoming Material Receipt Log
Storage	Microbial Growth in Food to be consumed raw	Store below the danger zone	Fish 4 ⁰ C +/- 2 degrees for 7 days	Daily Monitoring of Freezer Temperature	Inform Chef, and re adjust freezer temperature	Sanitation Officer	Refrigerator, Freezer Temp Log
Preparation	Microbial Contamination through food contact surface, and handlers	• Restrict ill employees;	Nil	Thrice a day checks	Inform Chef, reject lot if contamination suspected	Sanitation Officer	Food Area Checklist
		• Control bare hand contact	Nil				
		• Separate raw from ready to eat food	Always				
Preparation	Microbial Growth during Process 1 Food preparation	Work at 4 ⁰ C or below	4 ⁰ C +/- 2 or below and within 2 hours	Chef to control Time and temperature	reject lot	Chef	Raw Foods Preparation Log
Cooking	Bacterial, Parasitic, Viral Survival during Cooking	Cook to Product Internal Temperature, Time	Product core temperature 75 ⁰ C +/- 2 degrees for 60 secs	Chef to control Time and temperature	reheat till requirements satisfied	Chef	Cooked Food Preparation Log
Cooling	Microbial Growth during Cooling of foods, Process 3	Quick chilling to below danger zone	Cool food from 75 ⁰ C to 5 ⁰ C within 2 hours	Chef to control Time and temperature	reject lot	Chef	Raw Foods Preparation Log
Reheating	Microbial Growth during Re heating of foods, Process 3	Bring and hold to Safe zone	Reheat to 75 ⁰ C for 60 sec	Chef to control Time and temperature	reject lot	Chef	Cooked Food Preparation Log
Holding	Microbial Growth during Holding of foods, Process 1	Hold below danger zone	5 ⁰ C or below and use within 4 hours	Chef to control Time and temperature	reject lot	Chef	Raw Foods Preparation Log
Holding	Microbial Growth during Holding of foods, Process 2, 3	Hold above danger zone	75 ⁰ C or above and use within 4 hours	Chef to control Time and temperature	reject lot	Chef	Cooked Food Preparation Log

SELF- INSPECTION REPORT FORM

Transporter

Date of Self-Inspection:	
Name of the Establishment:	
Address of premises:	
Tel. No.:	
Fax No.:	
Category of licence (Central/ State)	
License No.:	
E-mail Address:	
Name of the Manager / Authorized Signatory:	
No. of Shifts:	
No. of Employees:	
Kind of business:	
Type of business ownership:	Limited/ Private limited/ Public sector undertaking/ Co-operative/ Partnership/ Proprietorship/other.

Please mark as Status as appropriate

In order

x

not in order

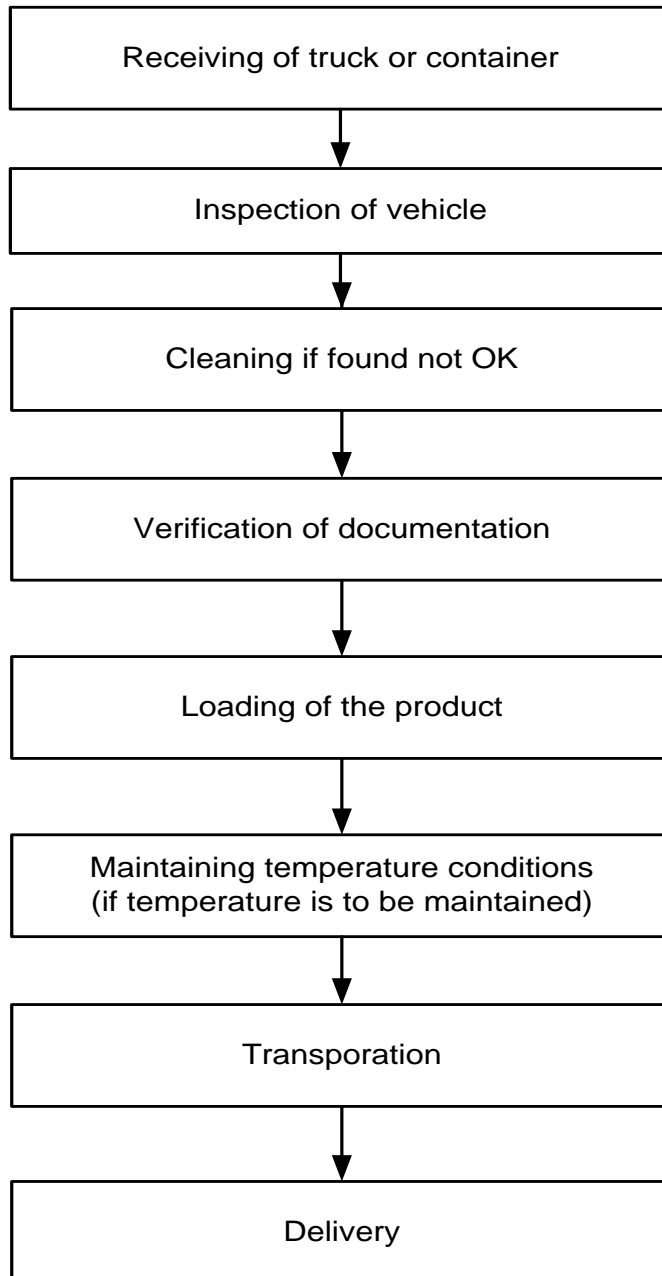
* If Status is marked not in order, please provide target completion date

	Area	Status
1	LAYOUT	
a	The premise to keep transport vans is a sanitary place and free from filthy surroundings	
b	Food transporting vans are built of solid, rust/ corrosion resistant materials and kept in clean and good condition.	
c	Food transporting vans shall be protected from sun, wind and dust and when not in use, are kept in clean place and properly protected.	
2	TRANSPORTATION SYSTEMS	
a	While transporting, appropriate arrangement for storage of food & food ingredients is provided and adequately segregated and labeled.	
b	Systems to adequately maintain time- temperature control at the time of transport, where ever necessary. .	
c	Containers used for transport are made of non toxic, non corrosive, non absorbent material.	
d	Cold Storage facility, wherever necessary/ provided.	
e	Conveyance & transportation of food being done in an appropriate state of cleanliness, particularly if the same vehicle has been used to carry non-food items.	
f	Appropriate arrangement for storing the food during transport to prevent physical damage.	
3	EQUIPMENT AND FIXTURES	
a	Appropriate facilities for the cleaning and disinfecting of equipments and instruments and preferably cleaning in place (CIP) system are adopted; wherever necessary.	
4	PERSONAL HYGIENE	
a	No person suffering from any infection or contagious disease.	
b	Arrangements are made to get the staff medically examined once in six months to ensure that they are free from infectious, contagious and other diseases.	
5	PEST CONTROL SYSTEM	
a	Treatment with permissible chemical, physical or biological agents within the permissible limits are carried out in transport vehicles.	
b	Adequate control measures are in place to prevent infestation from insects and rodents during transport.	
7	CLEANING AND MAINTENANCE	
a	Cleaning and sanitation programme is drawn up, observed and the record of the same	

	is properly maintained.	
8	OPERATIONAL FEATURES	
a	Arrangements for monitoring Temperature & Relative Humidity	
9	AUDIT/ DOCUMENTATION AND RECORDS	
a	A periodic audit of the whole system according to the Standard Operating Procedure conducted regarding Good Manufacturing Practices/Good Hygienic Practices (GMP/ GHP) system.	
b	Appropriate Record of daily food transport, pest control etc. for a period of 1 year or the shelf-life of the product; whichever is more.	
10	PRODUCT INFORMATION AND CONSUMER AWARENESS	
a	All packaged food products carry a label and requisite information as per provisions of Food Safety and Standards Act, 2006 and Regulations so as to ensure that adequate and accessible information is available to each person in the food chain to enable them to handle, store, process, prepare and display the food products safely and correctly and that the lot or batch can be easily traced and recalled if necessary	
11	TRAINING	
a	It is ensured that all workers are aware of their role and responsibility in protecting food from deterioration. The workers have the necessary knowledge and skills which are relevant to transporting/handling of food so as to ensure the food safety and food quality.	

Sample Flowchart for Transportation

Transporation



Sample FSMS Plan for Transporters

Operational Step	Hazard	Control Measure	Critical Limit	Monitoring Method	Corrective Action	Responsibility	Record
Cleaning of vehicles	Physical (dirt, stone particles woodchips in vegetables) Residual Cleaning / pest Control Chemical Growth of Microbiological (high microbiological load of raw materials, presence of pathogenic bacteria)	Establish Vehicle Cleaning and Sanitation SOPs Define levels of cleaning chemicals Establish Pest Control SOPs with approved agents	As per FSSA 2006 and company internal specifications	Verify cleaning and sanitation schedules Through visual inspection	Do not load vehicles unless they are in compliance with specifications	QA	Cleaning and Sanitation logs Pest Control logs
Transportation	Physical (dirt, stone particles woodchips in vegetables) Growth of Microbiological (high microbiological load of raw materials, presence of pathogenic bacteria)	Ensure trucks are covered, and maintained Control temperatures of transportation	Company internal specifications based on product sensitivity	Vehicle Inspection Temperature logs	Product to be discarded or processed to make safe if unsafe conditions occur	QA	Vehicle Inspection Reports Temperature logs in transit