

FoSTaC Food Safety Training for Retail and Distribution with Special focus on Health Supplements and Nutraceuticals

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- Module 1: Good Practices for Wholesalers and Distributors
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Section A: Course Objectives

Section B: Introduction to Health Supplements and Nutraceuticals

- Difference in Life Expectancy Men & Women
- Life Expectancy vs Health
- Understanding the food category
- Product categories
- Identifying key words Health Supplements & Nutraceuticals
- Examples of dosage forms
- Examples of Health Supplements & Nutraceuticals
- Marketing distinction by food category system
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 - FSMP
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- Salient Features
- FSSA: Section 3 (n): Definitions
 - Food business
 - Food business operators
- Licensing Regulations
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- Batch/Date
- Declaration regarding consumer information
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- Advisories/Warnings

Section E: Composition of Health Supplements and Nutraceuticals

- Safety of ingredients and substances used
- Schedules permitting use of ingredients
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Section F: Introduction to Food Safety

- Definition Food safety
- Definition FSMS
- What is FSMS program
- FSSAI Schedule 4 overview
- Food safety hazard (Physical, chemical, biological)
- Food spoilage

Section G: FSSAI's Schedule 4 – Part2 (Good Practices)- Retail & Distribution with special focus on Health Supplements and Nutraceuticals

Module 1- Good Practices for Wholesalers & Distributors

- Location & surroundings
- Layout & design of food premises / retail shops
- Equipment & containers
- Facilities
- Operations & Controls
- Management & Supervision
- Audit, documentation & records
- Sanitation & Maintenance of Establishment Premises
- Personal Hygiene
- Training

Module 2- Good Practices for Transporters

- Operations & Control
- Management & Supervision
- Audit, documentation & records
- Sanitation & maintenance of transportation vehicle

Section G: FSSAI's Schedule 4 – Part2 (Good Practices)- Retail & Distribution with special focus on Health Supplements and Nutraceuticals

Module 3- Good Practices for Sellers (Pharmacists, Retailers & E-commerce)

- Location & surroundings
- Layout & design of food premises / retail shops
- Equipment & containers
- Facilities
- Operations & Controls
- Management & Supervision
- Food testing facilities
- Audit, documentation & records
- Sanitation & Maintenance of Establishment Premises
- Personal Hygiene
- Product Information & Consumer Awareness
- Training

Section H: Planning Food Safety Management Systems

FSMS program

- Defining the process steps
- Flow diagram
- Developing FSMS plan
- HACCP
 - Sources of hazard
 - History & Definition
 - FSMS Principles
 - Hazard analysis & Risk assessment
 - What is CPP, Determining CCP
 - Establishing critical limit
 - Establish a Monitoring system
 - Establish corrective action
 - Establish verification system
 - Establish documentation system

Section A

Objectives

FoSTaC Training for Retail & Distribution – With Special focus on Health Supplements & Nutraceuticals



Objectives

- This training is intended for Pharmacists/ Retailers/ Distributors/ Transporters and Wholesalers engaged in sale and distribution of Health Supplements & Nutraceuticals.
- It aims to sensitize and propagate the information on this category of foods.
- General Requirements on Hygienic and Sanitary Practices, as per “Part II of Schedule 4” of Food Safety and Standards (Licensing & Registration of Food Businesses) Regulations, 2011 under Food Safety & Standard Act, 2006
 - (<http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html>)
 - (<http://www.fssai.gov.in/home/fss-legislation/food-safety-and-standards-act.html>)

Section B

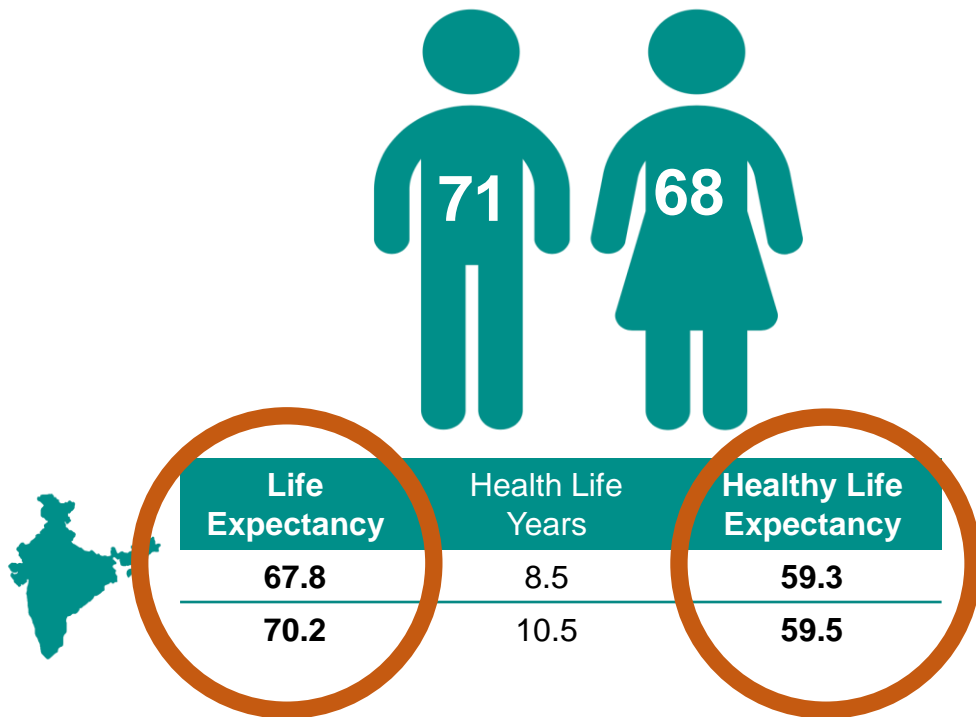
Advance Level Introduction to Health supplements and Nutraceuticals



Difference in Life Expectancy

Men & Women

- Life Expectancy is increasing worldwide.
- Still a difference in life expectancy for man and woman of 5 years.
- Despite increasing life expectancy, health did not improve.



- Increasing years does not increase healthy years
- We need to strengthen our personal capacity & take preventive measures.

“Safe, wholesome and hygienic food will create ‘Swastha Bharat’.”
Hon’ble Prime Minister of India

WHO assessed the role of Nutrition*

- **More than 40% of nutrition related diseases take place before the age of 70.**
- **Approximately one third of cancers can be prevented.**
- **Up to 80% of heart disease, stroke and diabetes type 2 deaths are preventable.**

Source: www.who.int/gho/ncd/en/index.html



Balanced diet & Diet diversity is important for Healthy Lifestyle



Health Supplements and Nutraceuticals are meant to supplement the diet



Understanding the food category

Health Supplements & Nutraceuticals

- Regulated under FSSAI
- Inform consumers correctly; as given on the label
- Meet their needs and expectation about the product;
- Importance of supplementing the diet;
- Understand Nutrition labelling

Product categories

Health Supplements

Nutraceuticals

Food for Special Dietary Use

Food for Special Medical Purpose

Prebiotics

Probiotics

Identifying key words


Health Supplements & Nutraceuticals

- Labeled “**HEALTH SUPPLEMENT**” OR “**NUTRACEUTICAL**”
- Supplement the diet
- To be taken in small measured quantities
- Not represented for use as conventional food
- Above age of 5 years



Identifying key words

Health Supplements & Nutraceuticals

- It is presented in dosage forms (to be administered) in small unit doses such as capsules, tablets, powder, liquids etc.; and
- It shall not include any sterile preparations (injectable, eye drops) 
- Does not claim to cure or mitigate any specific diseases



Health Supplements & Nutraceuticals

Examples of dosage forms



Tablet



Soft Gelatin Capsule



Hard Gelatin Capsule

Liquid



Effervescent tablets



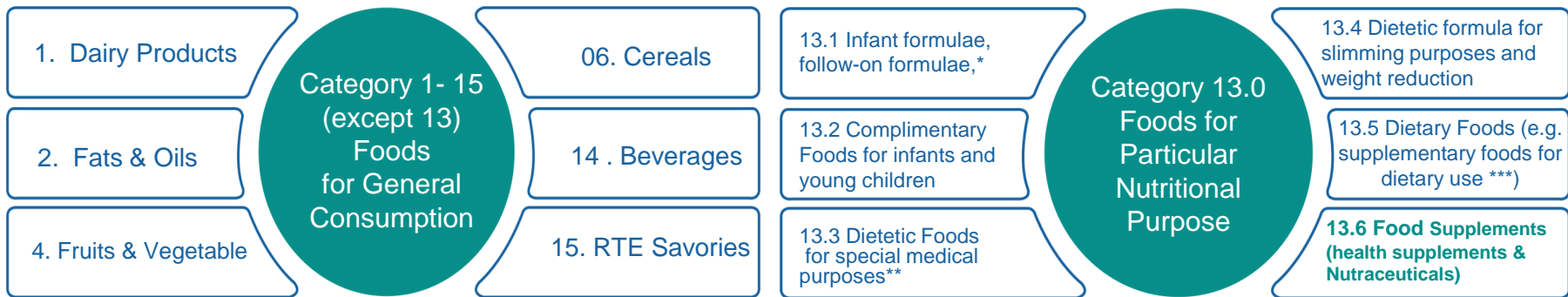
Powder



Examples of Health Supplements & Nutraceuticals



Marketing distinction by food category system



- Conventional Foods

- Special dietary/medical needs

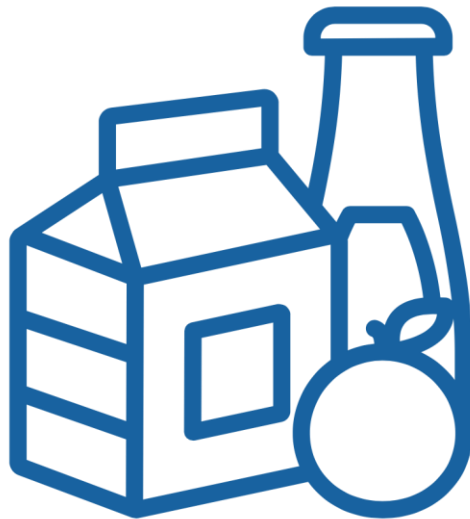
* and formulae for special purposes for infants

** (excluding products of food category 13.1)

*** excluding products of food categories 13.1-13.4 and 13.6

CONVENTIONAL FOOD

THE \neq



Foods represented as conventional foods



Foods represented as conventional foods



FOOD FORTIFICATION

THE \neq



Supplementation

- Supplementing the normal diet;
- Through concentrated sources of nutrients (i.e. mineral and vitamins) or other substances
- Marketed as capsules, tablets, powders, solutions etc.;
- Designed to be taken in measured small-unit quantities; and
- Are not to be sold in nor represented as conventional foods; and are
- Not drugs or medicines

“Fortification”

- deliberately increasing the content of essential micronutrients i.e. addition of vitamins or minerals in a food to:
 - improve the nutritional quality of food and
 - provide public health benefit with minimal risk to health
- Food fortification is usually done in **staple foods** so that it will be regularly consumed by the people.

Fortification of foods

Example

- Milk with Vitamin A & D
- Salt with Iron & Iodine
- Wheat Flour with Iron, Folic Acid, Vitamin B12
- Edible oil with Vitamin A & D
- Rice with Iron, Folic Acid, Vitamin B12



MEDICINAL PRODUCTS

THE \neq



Health Supplements & Nutraceuticals

- Regulated under the Food Safety and Standards 2006
- not intended to diagnose, treat, mitigate or prevent any disease
- Are not to be marketed or presented or claimed to have such properties;
- Even though they share forms such as tablets, capsules, pills, powders, liquids etc.
- They are distinguished with declaration “
NOT FOR MEDICINAL PURPOSE”

Medicinal products

- Regulated under the Drug & Cosmetic Act 1940
- Are intended to diagnose, treat, mitigate or prevent any disease
- Includes all medicines for internal or external use of human beings or animals
- Share some forms such as tablets , capsules, pills, powders, liquids,...

Routes of administration

Health Supplement & Nutraceuticals vs Drugs

Drugs

- Taken by mouth (orally)
- Given by injection intravenously, intramuscularly or subcutaneously
- Sublingual administration
- Ocular/otic route
- Sprayed into the nose/skin
- Topical administration

Health Supplement & Nutraceuticals

- Taken by mouth (orally) only

FOOD FOR SPECIAL DIETARY USE (FSDU)

THE \neq



FSDU

- Specially processed or formulated to satisfy a dietary requirements owing to certain physiological or specific health conditions like
 - Low weight, obesity, diabetes, high blood pressure
 - Pregnant and lactating women
 - Geriatric population, hypoallergenic
- Can be used in formats for oral feeding through enteral tubes but not for parenteral use
- shall not include the normal food which is merely enriched or modified with nutrients and meant for mass consumption, intended for improvement of general health for day to day use
- do not claim to be targeted to consumers with specific disease conditions
- not include the article of food intended to replace complete diet covered under food for special medical purpose.



FOOD FOR SPECIAL MEDICAL PURPOSE (FSMP)

THE



FSMP

- Shall include food specially prepared for weight reduction and intended as total replacement of normal diet
- Classified in 3 categories:
 - nutritionally complete food with a standard nutrient formulation
 - nutritionally complete food with a nutrient-adopted formulation specific for a disease, disorder or medical condition'
 - nutritionally incomplete food with a standard formulation or a nutrient-adopted formulation specific for a disease, disorder or medical condition'
- Shall be used only under medical advice and exclusive or partial feeding of persons with limited or impaired capacity to digest, absorb, metabolize or excrete ordinary food stuff
- **Recommended to be used under medical advise only**
- **No FBO shall advertise the FSMP for general public**

FSMP

Examples



PREBIOTICS & PROBIOTICS





- **PREBIOTICS**

Foods with live micro-organisms beneficial to human health, which when ingested in adequate amount ($\geq 10^8$ CFU/g).

- Lower viable number may be specified with proven studies on health benefits with those numbers subject to the prior approval of the Food Authority.

- **PROBIOTICS**

The prebiotic component, not an organism, to which the claim of being made, shall be characterized for a given product by providing the source, origin, purity, chemical composition and structure, vehicle, concentration and amount in which it is to be delivered to the host.

- The labelling, presentation and advertising shall not claim that the prebiotic has the property of preventing, treating or curing a human disease, or refer to such properties.

Section C

Regulations for Health supplements and Nutraceuticals



Salient Features

Definitions, General Requirements,
Claim requirements

Categories namely

- Health Supplements
- Nutraceuticals
- Food for Special Dietary Use (FSDU)
- Food for Special Medical Purpose (FSMP)
- Foods with added Probiotic ingredients
- Foods with added Prebiotic ingredients
- Specialty foods containing plant or botanical ingredients with safe history of usage and
- Novel foods – Need prior approval as per FSS (Approval of non specified Food and Food Ingredients) Regulations, 2017

Food Business and Food Business Operator (FBO)

FSSAI: Section 3 (n): Definitions

“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 and Food Business Operator (FBO)

FSSAI: Section 3 (o): Definitions

“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;

FSSAI: Section 31: Licensing and registration of food business.

(1) No person shall commence or carry on any food business except under a license.

Licensing Regulations

- Food Safety Compliance System (FoSCoS) is an online application to apply for License/Registration Certificate.

<https://foscoss.fssai.gov.in/>

- Can be registered under Category 13: Foodstuffs intended for particular nutritional uses.
- They can apply for Central License for sale/distribution of these products.

FSSAI: Section 27. Liability of the Manufacturers, Packers, Wholesalers, Distributors and Sellers

- (1) The manufacturer or packer of an article of food shall be liable for such article of food if it does not meet the requirements of this Act and the rules and regulations made thereunder.
- (2) The wholesaler or distributor shall be liable under this Act for any article of food which is—
 - (a) supplied after the date of its expiry; or
 - (b) stored or supplied in violation of the safety instructions of the manufacturer; or

FSSAI: Section 27. Liability of the Manufacturers, Packers, Wholesalers, Distributors and Sellers

- (c) unsafe or misbranded; or
- (d) unidentifiable of manufacturer from whom the article of food have been received; or
- (e) stored or handled or kept in violation of the provisions of this Act, the rules and regulations made thereunder; or received by him with knowledge of being unsafe.

FSSAI: Section 27. Liability of the Manufacturers, Packers, Wholesalers, Distributors and Sellers

- (3) The seller shall be liable under this Act for any article of food which is
- (a) sold after the date of its expiry; or
 - (b) handled or kept in unhygienic conditions; or
 - (c) misbranded; or
 - (d) unidentifiable of the manufacturer or the distributors from whom such articles of food were received; or
 - (e) received by him with knowledge of being unsafe.

ACTIVITY- 1

1. Health supplements and nutraceuticals are regulated under FSSAI.
True/False
2. How health supplements and nutraceuticals are distinguished from drugs
 - a. not intended to diagnose, treat, mitigate or prevent any disease
 - b. They are distinguished with declaration “NOT FOR MEDICINAL PURPOSE”
 - c. Both
 - d. None
3. Which category of food must be labelled with advisory “**Recommended to be used under medical advise only**”
 - a. FSDU
 - b. FSMP
 - c. Vitamins
 - d. Probiotics
4. Are health supplements and drugs same?
Yes/No
5. Health Supplements and Nutraceuticals are meant to supplement the diet.
True/False



Section D

Labelling

Labelling information

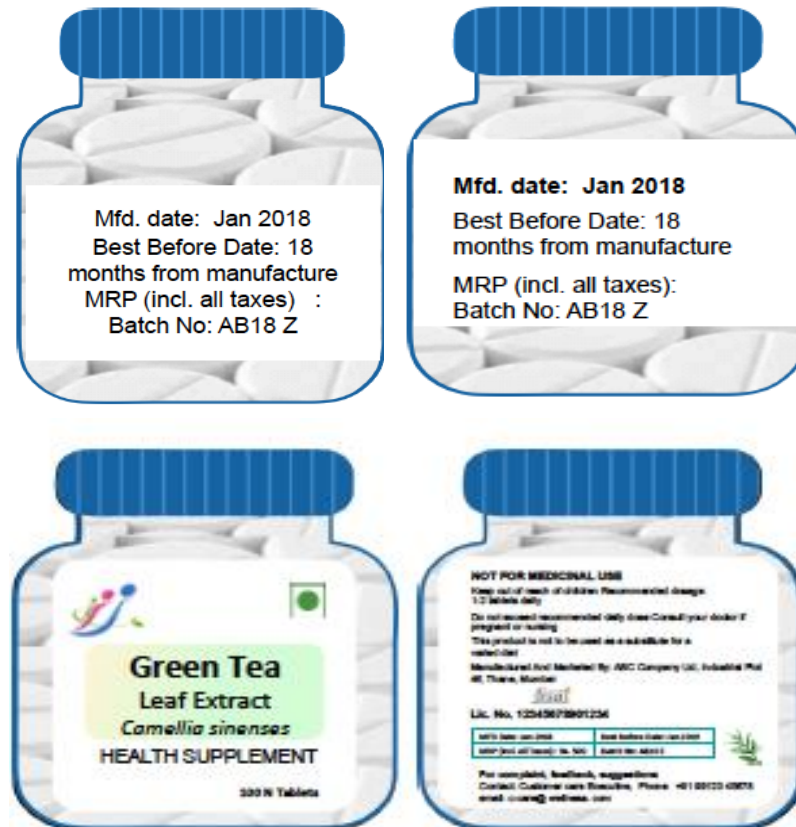


1. Code/Batch Number

by which the food can be traced in
manufacture and identified in distribution.

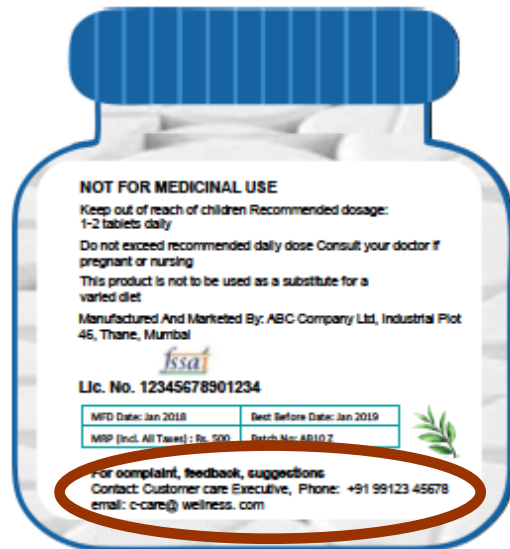
2. Date Marking

Check if product has Best Before date/ Use
By date/ Expiry date



3. Consumer care details

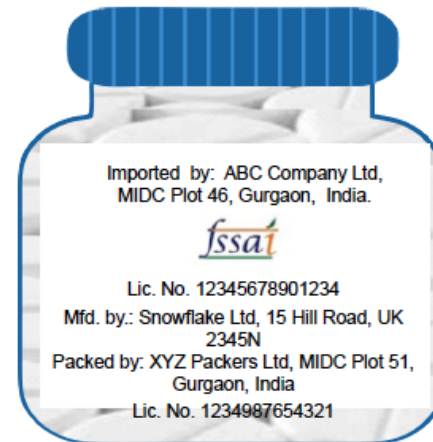
4. Check for conditions of storage



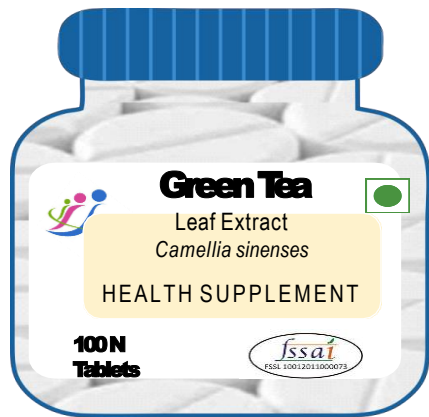
For complaint, feedback, suggestions
Contact: Customer care Executive, Phone: +91 99123 45678
email: c-care@wellness.com

Licensed and identifiable Manufacturer, or Distributor

- 1 FSSAI Logo and License number
- 2 Name and Address Manufacturer, Importer



How to identify fake/genuine supplement



Check for FSSAI Logo & FSS License number



Check the Seal



Declarations regarding
consumer information:



Name of the category

Look for the term “**HEALTH SUPPLEMENT**” or “**NUTRACEUTICAL**”



What you should know

Nutrition Labelling

Serving size, Recommended usage, Percent RDA

Nutrients or substances with nutritional or physiological effect

Ingredients declaration

Presence of Allergens

Advisories

Not for medicinal use, pregnant/nursing women etc.

Phenylketonurics

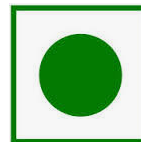
Recommended not to exceed usage

RDA

Recommended daily allowance

Veg / Non-veg Logo

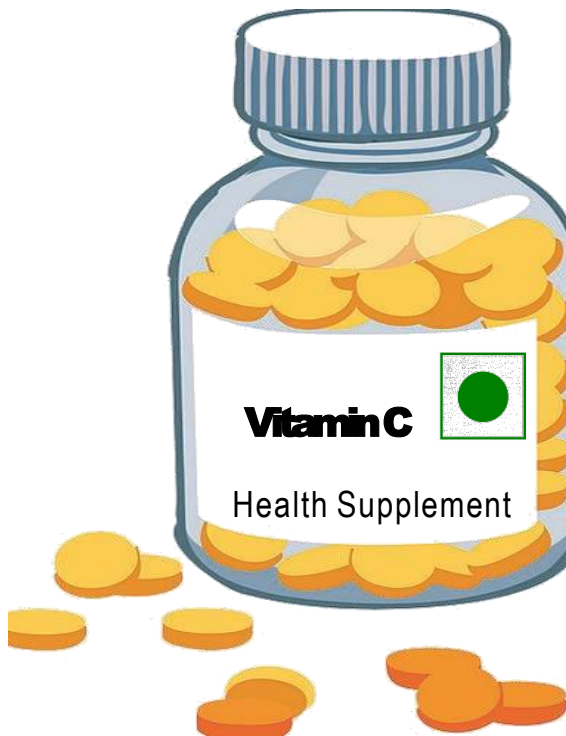
Look for “VEG” or “NON-VEG” Logo



VEG



NON-
VEG



Understanding Recommended Use



Recommended Use” & “Serving Size”

- Read the serving size on label
- Recommended Use declared on the label
- Do not advise more than the recommended use
- If you miss one, don't take two to make up for it

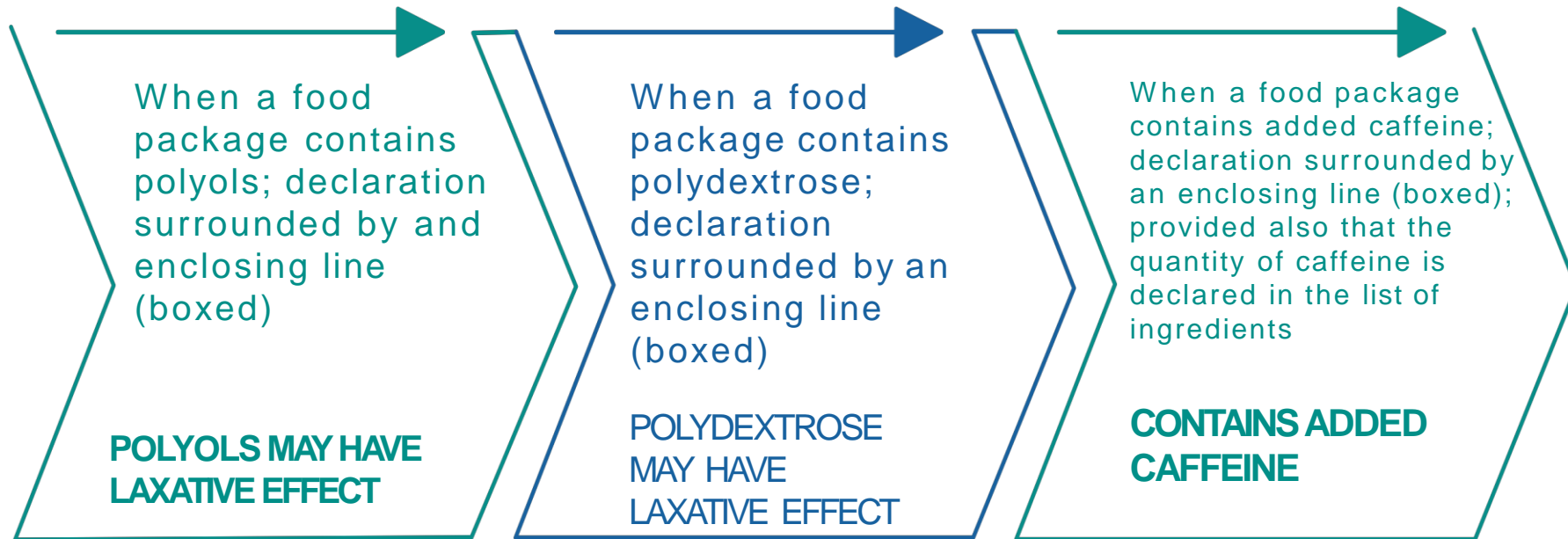
- Serving size gives the amount in one serve: 1 Tablet (500mg)
- Recommended Use: gives the number of serves(dose) and frequency per day.



Advisories

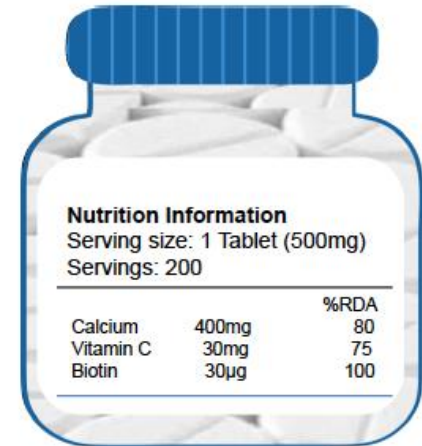
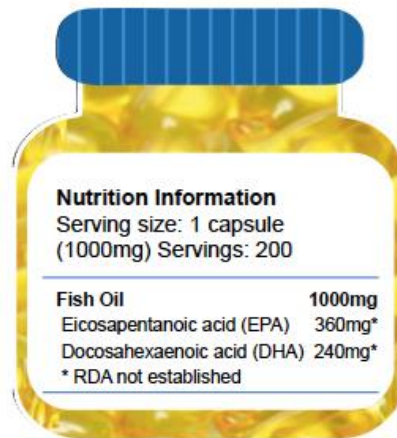


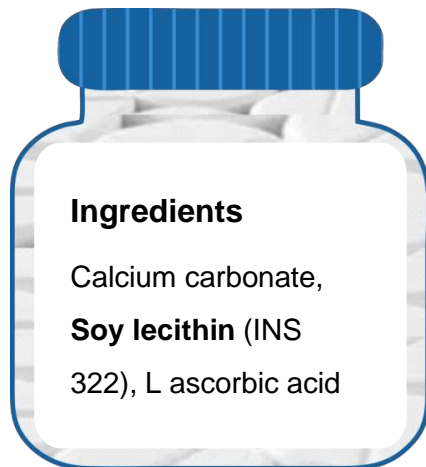
Warning



Nutrients or substances with nutritional or physiological effects are given in Nutrition Information Panel

- Quantity (Amount) of Nutrients
- Percent of the Recommended Daily Allowance (RDA)





Food allergies can be serious

Always ask the customer for
any food allergy

Read all ingredients on the
Labels

Do inform the customer about
allergens (if any) in the
product

Declaring allergens is good practice

Ingredients causing allergies or intolerances

- Cereals containing Gluten ; i.e, wheat, rye, barley, oats, spelt or their hybrid strains and their products
- Crustacean and their products
- Milk and egg products
- Egg and egg products
- Fish and fish products
- Peanuts, tree nuts and their products
- Soybeans and their products
- Sulphite in concentration of maximum 10mg / kg

Ingredients:

Calcium carbonate, **soy lecithin**
(INS 322), L ascorbic acid

Ingredient in bold

Ingredients:

Calcium carbonate, soy lecithin
(INS 322), L ascorbic acid

Ingredient underlined

Ingredients:

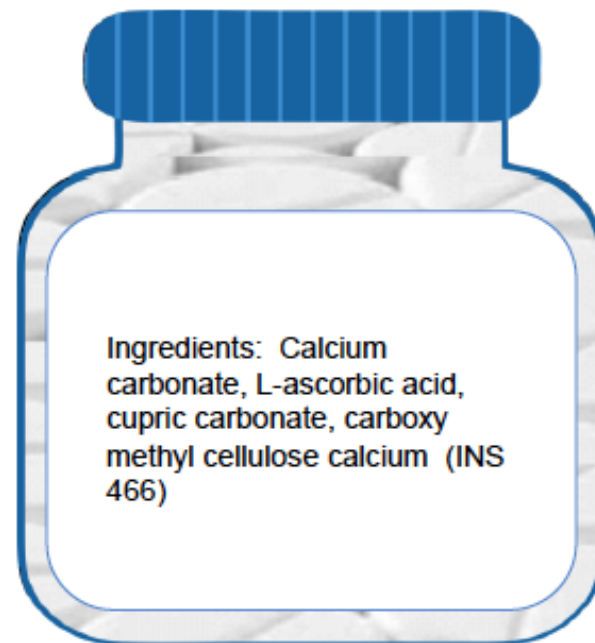
Calcium carbonate, soy lecithin
(INS 322), L ascorbic acid
Contains soy derivatives



Section E

Composition

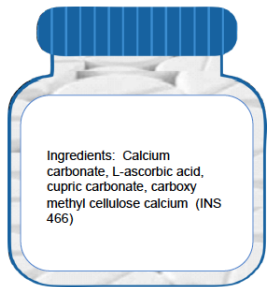
Composition



Safety of ingredients and substances used

- Only ingredients permitted by FSSAI can be used
- Approval is based on safety assessment for the purpose of use
- Food Additives, excipients are permitted by FSSAI under applicable conditions of use
- Appropriate advisories and warnings are provided on the label

Schedules permitting use of ingredients



Schedules permitting use of Additives

Ingredients	Schedule	Health Supplements	Nutraceuticals
Vitamins and minerals and their forms	I		
Amino acids	II		
Plant and botanicals	IV		
Nutraceuticals as ingredients	VI	Enzymes only	
Probiotics	VII		
Prebiotics	VIII		

Category	Schedules					
Health Supplements & Nutraceuticals	V A	V B	V C	V D	V E	V F

Section F

Advance Level Introduction to Food Safety



What is Food safety?
What is FSMS?
Why it is important?

What is Food Safety

Food Safety means assurance that food is acceptable for human consumption according to its intended use.



What is FSMS as per FSSAI

- FSS Act 2006 defines **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 there under, the definition of FSMS shall be read as the above and the requirements for this be taken as that defined under **Schedule IV & Critical Control Point**.



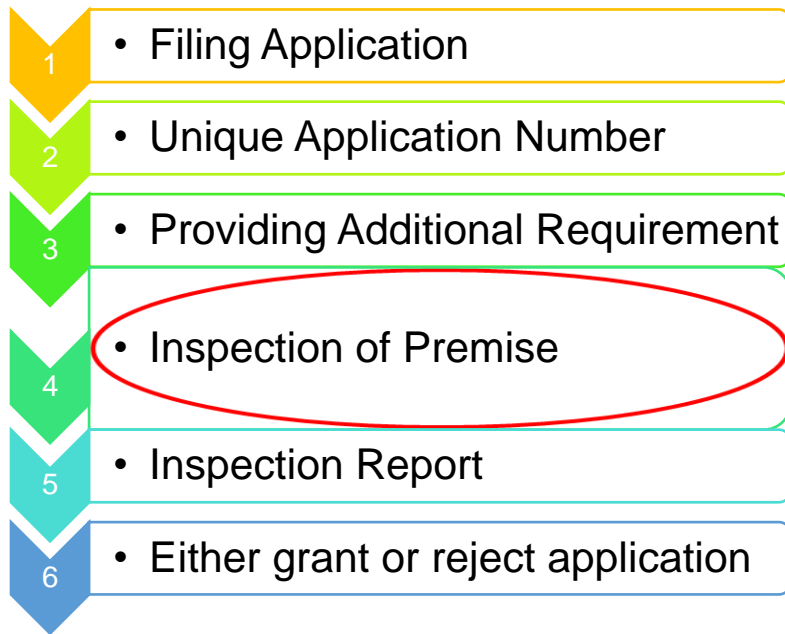
FSMS Program Based on FSSA



Schedule IV

1. **Why?** Section 16 of the FSSA, holds FSSAI responsible for regulating and monitoring the manufacture, processing, distribution, sale and import of food so as to ensure safe and wholesome food.
2. **How?** By introducing basic hygiene and safety requirements in the form of Schedule IV
3. **Where in FSSR?** The Schedule IV has been mandated for compliance by introducing it as a licensing requirement/condition under the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

Where does it impact?



Non-conformance may lead to

1. Under FSS (Licensing and Registration of Food Businesses).
 - a) Notice/ rejection of application during inspection for licensing.
 - b) Notice/cancellation of license during periodic food safety audit by the Licensing Authority.

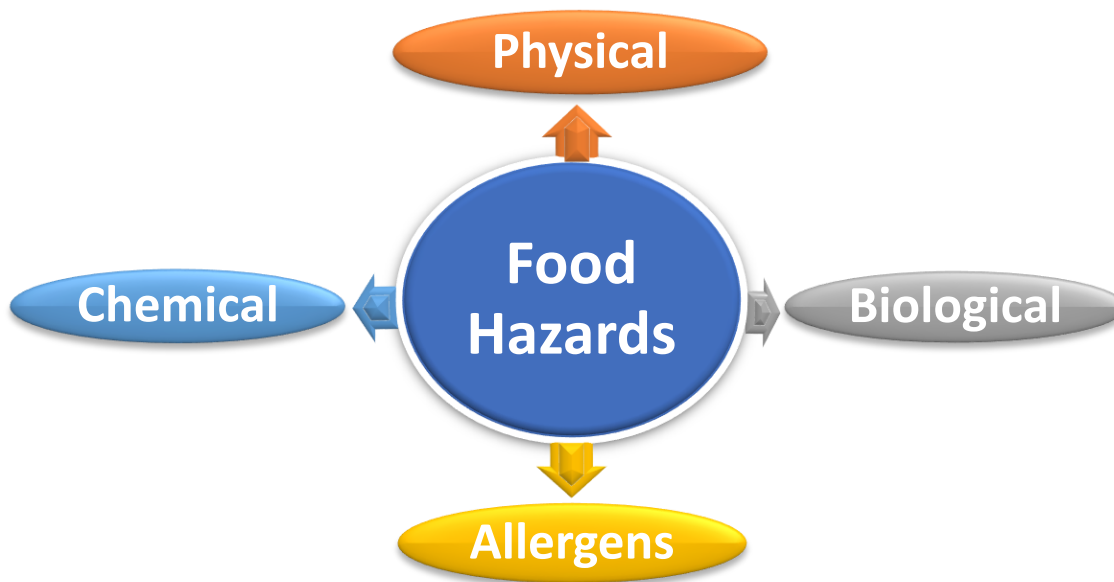
2. Under Section 56 of FSSA.
 - b) Penalty of up to Rs one lakh for unhygienic or unsanitary processing or manufacturing of food under.

What are food safety hazards?
Types...
Source..

What is food spoilage?

Food Safety Hazards

Food Safety Hazard- biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect.



Physical Hazard

Physical Hazards: Any foreign object (inanimate) found in the food or a naturally occurring object (bone in fillet), that poses; a hazard is called a 'Physical Contamination'.

Common Physical Hazards include:

- Glass
- Chipped pieces of cutlery and crockery
- Metal shavings from cans and foils
- Stapler pins
- Blades
- Plastic films used for wrapping or chipped pieces of disposables
- Lint and threads
- Band- aids
- Hair
- Finger nails
- Bones
- Jewellery pieces

Chemical Hazard

Naturally occurring and process induced chemical substances that can cause a food borne illness is called a 'Chemical contaminant or Hazard'.

Process Induced Chemical Contaminants include:

- Toxic metals in the catering set up or supply chain
- Pesticides, Colorants
- Cleansing products and sanitizers
- Equipment lubricants
- Chemical Food Additives, Preservatives
- Packaging materials-migration of residues from packaging material to oil.
- Adulteration with other oils or mineral oil

Natural Chemical Contaminants include:

- Allergens
- Mycotoxins

Biological Hazard

Biological hazards are organisms, or substances produced by organisms, that pose a threat to human health. They are a major concern in food processing because they cause most food borne illness outbreaks.

Major biological hazards include:

- **Bacteria** ex: *Salmonella* spp., *Enterohaemorrhagic Escherichia coli*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Clostridium botulinum*
- **Yeast & Mold** ex: *Candida*, *Aspergillus* sp, *Helicosporium*

Biological Hazard causes

1. **Food Borne Infections** result when a person consumes food containing pathogens; which grow in the human intestine and cause discomfort or disease. Typical symptoms of a 'food borne Infections' do not appear immediately.
2. **Food Borne Intoxications** result when a person consumes food containing toxins in it; that cause discomfort or disease. Typical symptoms of a 'food borne Intoxication' appear quickly.
3. **Food Borne toxin** mediated infections result when a person consumes food containing toxins produced by the pathogens in it; which grow in the human intestine and produce toxins that cause discomfort or disease.



Food Spoilage

Conditions favouring growth of microorganisms

FAT TOM

Conditions	Definition
Food	Food borne Microorganisms draw nutrients from Potentially hazardous foods
Acidity	Food borne Microorganisms grow well between the pH range of most foods
Temperature	Microorganisms grow well between the temperature range of 5°C – 60°C, most commonly known as the 'Danger Zone'
Time	Microorganisms need sufficient time to grow; when exposed to the 'Danger Zone'
Oxygen	Microorganisms require oxygen in free or combined state; to favor their growth
Moisture	Microorganisms require moisture to grow and is measured in the form of 'Water Activity (Aw)'

ACTIVITY- 2

1. Unclean hands is due to
 - a. Improper handling
 - b. Biological Hazard
 - c. Improper processing
 - d. Non-Standard sanitation.
2. Temperatures of are important factor in food (HSN) being safe.
 - a. Transportation
 - b. Processing
 - c. Handling
 - d. All above
3., if not disposed in a scientific manner it can breed pest and micro organisms which is a threat to food safety.
 - a. Physical hazard
 - b. Chemical Hazard
 - c. Waste
 - d. Allergens
4. Food safety is much dependent on the food handler's personal behaviour and health status.
True/False
5. Product storage zones must have humidity to ensure food safety.
 - a. More than 80%
 - b. Less than 65%
 - c. More than 65%
 - d. Less than 80%



Section G

FSSAI's Schedule 4 – Part 2 -
Good Practices- Retail &
Distribution with special focus on
Health Supplements and
Nutraceuticals

Section G- Module 1

Good Practices

for Wholesalers & Distributors

(Health Supplements and Nutraceuticals)

Good Practices for Wholesalers & Distributors

Health Supplements & Nutraceuticals

- Location & surroundings
- Layout & design of food premises / retail shops
- Equipment & containers
- Facilities
- Operations & Controls
- Management & Supervision
- Audit, documentation & records
- Sanitation & Maintenance of Establishment Premises
- Personal Hygiene
- Training

Location and Surroundings



Location should be:-

- Away from pollution
- Protect the premises from environmental contamination
- - Should not have direct access to any residential area

Layout & design

- Enable separate & designated areas for storing of different varieties of products.
- Floors, walls, ceilings, doors should be designed:-
 - minimize accumulation of dirt
 - smooth and easy to clean.
 - not have flaking paint



Equipment & Containers



Strapping



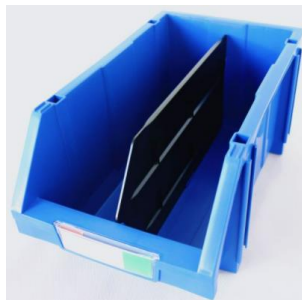
Tape



Material Handling



Stacker



Small container

Equipments like trolleys, racks shall be

- made up of non-corrosive / rust free material
- easy to clean and maintain
- well-maintained & repaired / discarded.
- Dustbins shall be provided with lid and cleaned
- shall be stored at a designated place

Facilities



Water Supply



Drainage & Waste disposal



Personnel facilities and toilets



Ventilation and Lighting

Facilities: Water Supply

- Non-potable water for cleaning
- Potable water for drinking
- Clean and safe water storage
- The water storage tanks shall be cleaned
- Pipeline for non-potable water must be identified/differentiated



Facilities: Drainage and waste disposal

- Waste shall be regularly collected
- Collected waste shall be stored so that it will not contaminate any other material
- Covered containers for waste storage
- Waste shall be handed over to a local waste-collecting body
- Periodic disposal of waste/refuse
- Pedal operated adequate size bins



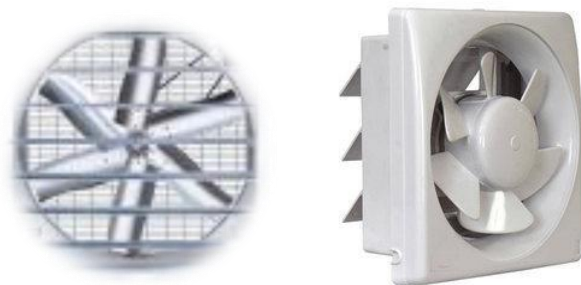
Facilities: Personal facilities and toilets

- Facilities for washing and drying hands
- Supply of hot and cold water
- Separate lavatories for males and females
- Suitably located Changing facilities for personnel
- 'Do and Don'ts, Personal Hygiene, shall be put up



Facilities: Ventilation & Lighting

- Premises must be well ventilated
- Adequate Natural /artificial lighting
- Protected lightings



Operations & controls: Receiving

5 key considerations to assure an effective receiving inspection setup

1. A set of requirements (checklists, approved samples for comparison, examples of common defects...)
2. A way to focus on the most important criteria e.g Seal integrity
3. A procedure to follow, step by step.
4. A way to report findings and help with traceability.
5. A way to drive improvement in the supplier base, when needed.



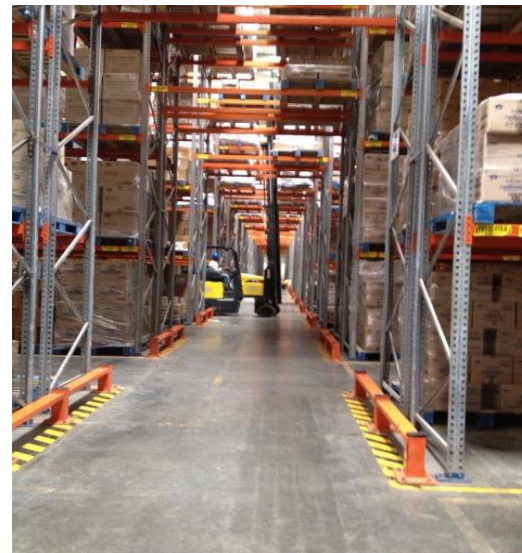
Operations & controls: Receiving

- Procurement from FSSAI/FDA/Ayush-licensed/registered supplier or licensed from other regulatory authorities.
- HSN products receiving must be according to storage capacity of the processing plant.
- HSN products must be confirmed by Certificate Of Analysis for their conformance.
- Check all containers for seal integrity and cleanliness as per inspection checklist at the time of receipt.
- Check packaged RM for 'expiry date'/'best before'/'use by date', packaging integrity and storage conditions.
- Vehicle inspection



Operations and Control: Storage

- Constructed to protect food from any contamination
- FIFO (First In First Out) system
- Storage instructions over food packaging
- Storage of veg. Health supplements and Nutraceuticals above non-veg. HSN products, on separate racks.
- Periodic monitoring of seal integrity



Operations and Control: Warehousing

- Storage at least 18 inch away from walls and off the floor (viz. on pallets, racks, cupboards)
- Clean, dry, ventilated & hygienic condition
- Temperature & humidity control systems using calibrated equipment. Record Keeping
- Designated, Segregated, Enclosed areas (as per Central and State Legislations) for hazardous, toxic and flammable material storage
- HSN products kept under refrigerated / chilled conditions shall be monitored.
- Materials should be stored in clean containers.
- Containers should be free from pest/rodent infestation.



Operations and Control: Distribution

- Material shall be protected from contamination
- Hygienic and sanitary conditions shall be maintained
- Cleaning & disinfection of vehicles shall be carried out between loads
- Temperature controlled vehicles shall be used if required



Operations and Control: Management & Supervision

- Educated, skilled, trained or experienced personnel (engaged in process & quality control operations) to perform assigned functions.
- Managers and supervisors :
 - Must have necessary knowledge and skills to judge potential risks and
 - Take necessary action to rectify deviations.
- Provide trainings & resources to employees to develop food safety culture at work.



Audit, documentation and records

- Periodic review of GMP and GHP
- Records of daily sales and inward/outward stock
- Appropriate records shall be maintained
- Example of common records to be maintained are:-
 - product receiving
 - pest control reports
 - cleaning and housekeeping reports
 - personal hygiene
 - waste disposal
 - daily sales
 - stock registers



Note: Documentation required for traceability/mock recall must be maintained and records must be kept as per manufacturer recommendations.

Sanitation and maintenance of establishment premises

Cleaning and maintenance

- Detailed cleaning and maintenance program
- Cleaning chemicals and tools shall be stored away
- Cleaning chemicals shall be clearly identified
- Cleaning frequency, procedure, equipment, cleaning material and method should be maintained



Sanitation and maintenance of establishment premises

Pest control systems

- Non-attractive environment for the pests
- A pest control program along with maintained date and frequency
- For insects – insect-killer, fly-catcher, fly-killer,
- For rodents – roda-box, rat trap
- HSN products should be stored in pest-proof containers



Personal hygiene: Health status

- Medical examination shall be carried out
- Regular health check-ups of food handlers
- Record for all the check-ups must be kept



Personal hygiene: Personal cleanliness

- Clean clothes / protective clothing,
- Frequent hand washing
- Trimming hair and nails should be practiced



- Avoid smoking, spitting, sniffing,
- do not eat or drink in warehouse area,
- Avoid certain habits viz. scratching nose



Personal hygiene: Visitors

- Visitors should be discouraged
- Proper care shall be taken to ensure food safety and hygiene
- Shall follow all safety and hygiene rules



Training

- Effective and regular training for food handler
- Personal behaviour, personal hygiene, and food safety during handling food, storage, FIFO, etc.



Section G- Module 2

Good Practices for Transporters (Health Supplements and Nutraceuticals)



Good Practices for Transporters

- Operations & Control
- Management & Supervision
- Audit, documentation & records
- Sanitation & maintenance of transportation vehicle

Operations and Control

Transportation tankers or containers used should be:-

- Dedicated
- Identified clearly
- Protected from contamination
- Well maintained hygienic and sanitary
- Cleaning and disinfection of vehicle
- Temperature controlled vehicle



Management and supervision

Documents such as-

- Do's & Don'ts for transportation
- Cleaning of vehicle
- Inspection before use
- Temperature control
- Safe & hygienic manner



Audit, documentation and records

Documentation and Records of-

- Daily vehicle inspection
- Vehicle cleaning
- Vehicle maintenance
- Transportation details



Note: Documentation required for traceability/mock recall must be maintained and records must be kept as per manufacturer/distributor recommendations.

Sanitation and maintenance of transportation vehicle

Cleaning and maintenance

- Vehicles shall be cleaned adequately
- Tarpaulins should be washed properly
- Frequency of cleaning should be maintained



Sanitation and maintenance of transportation vehicle

Pest control systems

- Infestation needs to be monitored
- Fumigation should be practiced



Section G- Module 3

Good Practices for Sellers *(POS- Pharmacists, Retailers & E-commerce)* *(Health Supplements and Nutraceuticals)*



Location and Surroundings

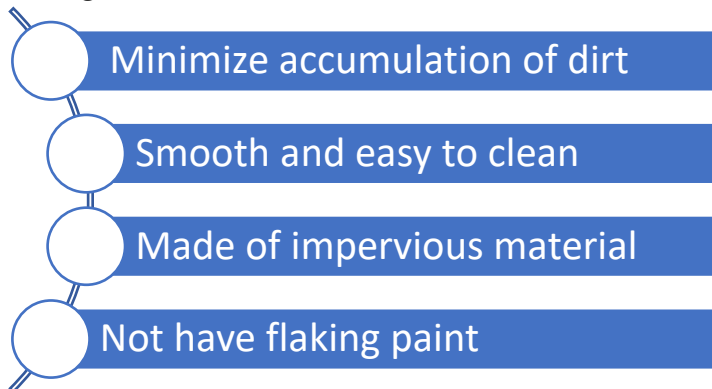


Location shall be:

- ✓ Away from environmentally polluted areas
 - Disagreeable or obnoxious odor,
 - Fumes
 - Excessive Soot
 - Smoke
 - Chemical or biological emissions
- ✓ Should not have direct access to any residential area

Layout & design

- Enable separate & designated areas for storing of different varieties of products.
- Walls of the premises shall be tiled at operational height
- Floors, walls, ceilings, doors should be designed to:-



**Cleanable, durable,
impervious to
moisture**

**Cracks allow bacteria
and molds to
accumulate**



Equipment & Containers



Equipment & Containers shall be-

- made up of non-corrosive / rust free material
- smooth, free from any grooves
- easy to clean and maintain
- non-toxic and non-reactive
- of food grade quality
- shall be stored at a designated place

Facilities

Water
Supply

Drainage &
Waste
disposal

Personnel
facilities and
toilets

Air quality
and
ventilation

Lighting

Power
backup

Water Supply

- Only potable water
- Away from any hazards or contaminants
- Periodic cleaning of storage tanks
- Differentiated non- potable water pipes



Drainage and waste disposal

- Waste shall be regularly collected
- Collected waste shall be stored so that it will not contaminate any other material
- Covered containers for waste storage
- Waste shall be handed over to a local waste-collecting body
- Periodic disposal of waste/refuse
- Pedal operated adequate size bins



Personal facilities and toilets

- Facilities for washing and drying hands
- Supply of hot and cold water
- Separate lavatories for males and females
- Suitably located Changing facilities for personnel
- 'Do and Don'ts, Personal Hygiene, shall be put up



Ventilation & Lighting

✓ Air quality and ventilation:

- No contaminated air shall flow towards the clean area

✓ Lighting :

- Adequate Natural /artificial lighting
- Protected lightings



Operations & controls: Receiving

5 key considerations to assure an effective receiving inspection setup

1. A set of requirements (checklists, approved samples for comparison, examples of common defects...)
2. A way to focus on the most important criteria e.g Seal integrity
3. A procedure to follow, step by step.
4. A way to report findings and help with traceability.
5. A way to drive improvement in the supplier base, when needed.



Operations & controls: Receiving

Supplier Approval & Procurement

- Procurement from internally approved suppliers.
- Procurement from FSSAI/FDA/Ayush-licensed/registered supplier or licensed from other regulatory authorities.
- Evaluation of approved supplier w.r.t quality supplied & other factors
- HSN products receiving shall be according to storage & display capacity of the unit.

Procedures to confirm incoming materials meet specifications through

- Certificate Of Analysis,
- Visual inspection (specially for seal integrity)
- Review of label for allergens etc.

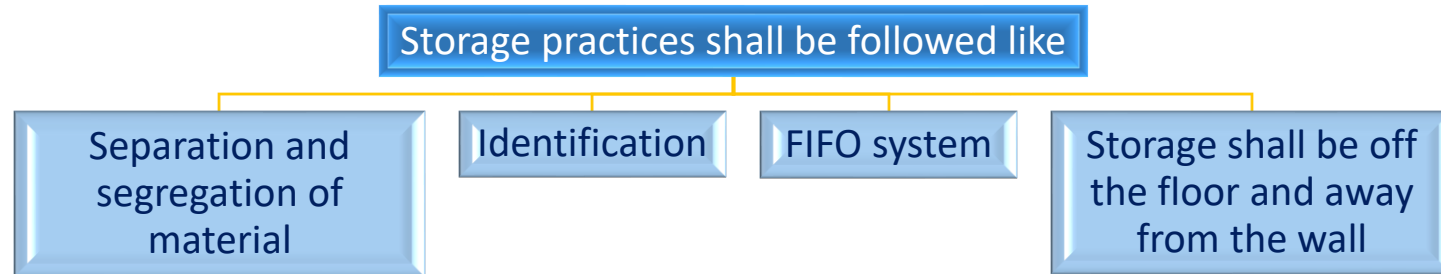


Operations & controls: Receiving

- Check all containers for seal integrity and cleanliness as per inspection checklist at the time of receipt.
- Check products for 'expiry date'/'best before'/'use by date', packaging integrity and storage conditions.
- Vehicle inspection



Operations and Control: Storage/Display



Operations and Control: Storage/Display

- Clean, dry, ventilated & hygienic condition
- All HSN products must be kept as per their temperature & humidity requirement.
- Monitoring of control systems using calibrated equipment.
- Designated, Segregated, Enclosed areas (as per Central and State Legislations) for hazardous, toxic substances and flammable material storage



Operations and Control: Storage/Display

- HSN products under refrigerated / chilled conditions shall be monitored.
- Time & temperature shall be noted
- Care should be taken so that the defrosted / thawed material is not stored back after being kept for long time at ambient temperature.



Operations and Control: Packaging

- All materials must be checked for seal integrity.
- Materials should be stored in clean containers / shelves.
- Containers should be free from pest/rodent infestation
- Packaging material should conform to regulatory standards



Operations and Control: Distribution service (Home delivery)

- Material shall be protected from contamination
- Hygienic and sanitary conditions shall be maintained
- Cleaning & disinfection of vehicles shall be carried out between loads
- Temperature controlled vehicles shall be used if required



Operations and Control: Management & Supervision

- Educated, skilled, trained or experienced personnel (engaged in process & quality control operations) to perform assigned functions.
- Managers and supervisors :
 - Must have necessary knowledge and skills to judge potential risks and
 - Take necessary action to rectify deviations.
- Provide trainings & resources to employees to develop food safety culture at work.
- Employees performing specialized job functions: Government / Recognized industry certified



Food testing facilities

Regular testing in accredited lab

- For complaints retailer / FBO shall arrange for testing
- From external laboratory



Audit, documentation and records

- Periodic review of GMP and GHP
- Records of daily production / sales, raw material
- Appropriate records shall be maintained
- Example of common record maintained are:
 - raw material / product receiving
 - processing
 - laboratory test reports
 - pest control reports
 - cleaning and housekeeping reports
 - personal hygiene
 - waste disposal
 - daily sales
 - stock registers



Note: Documentation required for traceability/mock recall must be maintained and records must be kept as per manufacturer recommendations.

Sanitation and maintenance of establishment premises

Cleaning and maintenance

- Detailed cleaning and maintenance program
- Cleaning chemicals and tools shall be stored away
- Cleaning chemicals shall be clearly identified
- Cleaning frequency, procedure, equipment, cleaning material and method should be maintained



Sanitation and maintenance of establishment premises

Pest control systems

- Non-attractive environment for the pests
- A pest control program along with maintained date and frequency
- For insects – insect-killer, fly-catcher, fly-killer,
- For rodents – roda-box, rat trap
- Foods should be stored in pest-proof containers



Personal hygiene: Health status

- Annually medical examination shall be carried out
- Health check-ups and vaccination for food handlers
- Record for all the check-ups as well for the vaccinations



Personal hygiene: Personal cleanliness

- Clean clothes / protective clothing,
 - Frequent hand washing
 - Trimming hair and nails should be practiced
-
- Avoid smoking, spitting, sniffing,
 - do not eat or drink in processing area,
 - Avoid certain habits viz. scratching nose,
 - Running fingers through hair, scratching body parts, etc



Personal hygiene: Visitors

- Visitors should be discouraged
- Proper care shall be taken to ensure food safety and hygiene
- Shall follow all safety and hygiene



Training

- Effective and regular training for food handler
- Personal behaviour, personal hygiene, and food safety during handling supplements and nutraceuticals, storage, FIFO, etc.



ACTIVITY 3

For Direct Sellers (PoS)

- ❖ It is not necessary to store the product at required temperature.

YES or NO?

- ❖ Equipments shall be _____

- a) Difficult to clean
 - b) Toxic
 - c) Food grade quality
 - d) Reactive

- ❖ Give any two/three example of personal behavior.

- ❖ Pest control programme is not mandatory.

YES or NO?



ACTIVITY 3 contd..

- ❖ Personal cleanliness includes _____
 - a) Hand washing
 - b) Growing Long nails
 - c) Sniffing all time
 - d) Frequent smoking

- ❖ All visitors are allowed without any food safety and hygiene practice.
YES or NO ?

- ❖ Storage racks and referigerators should be cleaned at defined frequency
YES or NO ?

- ❖ Lights should be _____
 - a) Unhygienic
 - b) Covered/Protected



ACTIVITY 3 contd..

❖ Which is the **right picture** amongst the two !!



ACTIVITY 3 contd..

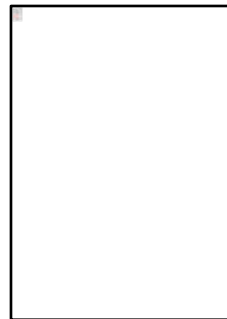
❖ Point out which is the **wrong** picture !!



ACTIVITY 3 contd..

❖ Prepare a checklist for-

- 1) Vehicle inspection Checklist.
- 2) GHP checklist for premises
- 3) Instrument Control Plan (ICP) for instruments used in premises including
- 4) Checklist to ensure right product kept on shelf (Reconciliation and shelf life)



Example_Checklist

Section H

Planning Food Safety

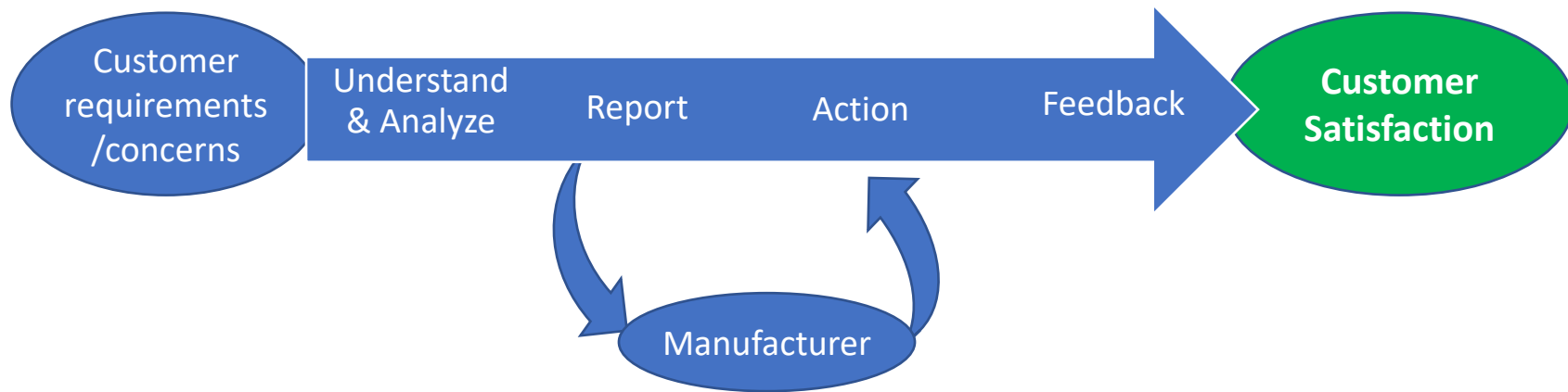
Management Systems for FBOs
engaged in retail and distribution
for health supplements and
nutraceuticals

It is good to understand FSMS for retail and distribution personnel

Why it is good to understand FSMS?

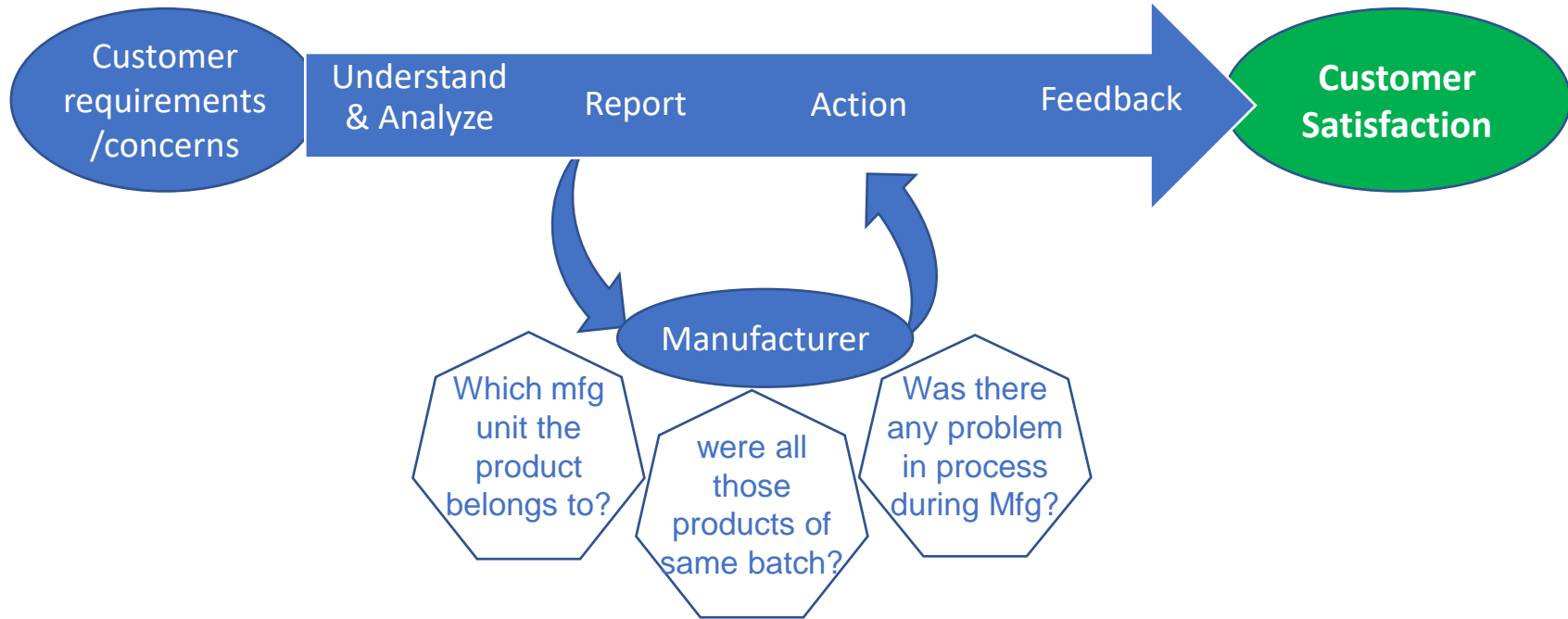
For continual improvement

When it comes to issues of food safety, consumer trust is fragile and in a competitive market it is important to provide products and services that distinguish your business from your competitors



Continual Improvement

In case of consumer complaint, traceability provides a means for the brand owner to determine what went wrong?



FSMS Program

Schedule 4 Compliance

- Schedule 4 checklist compliance
- Based on GMP/GHP

FSMS Plan

- Flow Chart
- Hazard and control
- Critical limit and Monitoring
- Corrective action
- Responsibility and Record

Defining the process steps



Process Information:

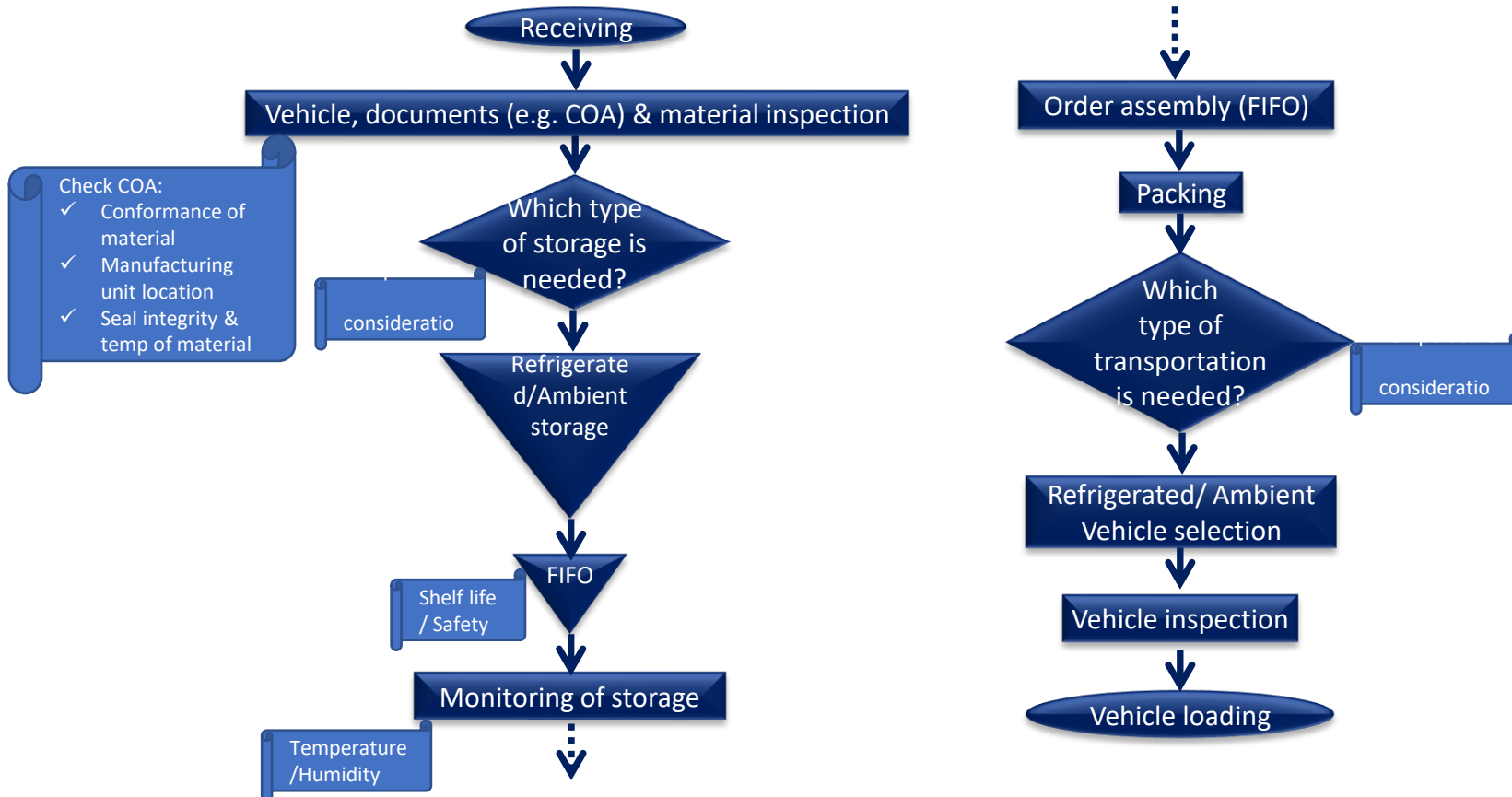
Process Flow Diagrams:

Indicating all ingredients, preparation steps, Serving, Re usage, facilities for cleaning & Disinfection

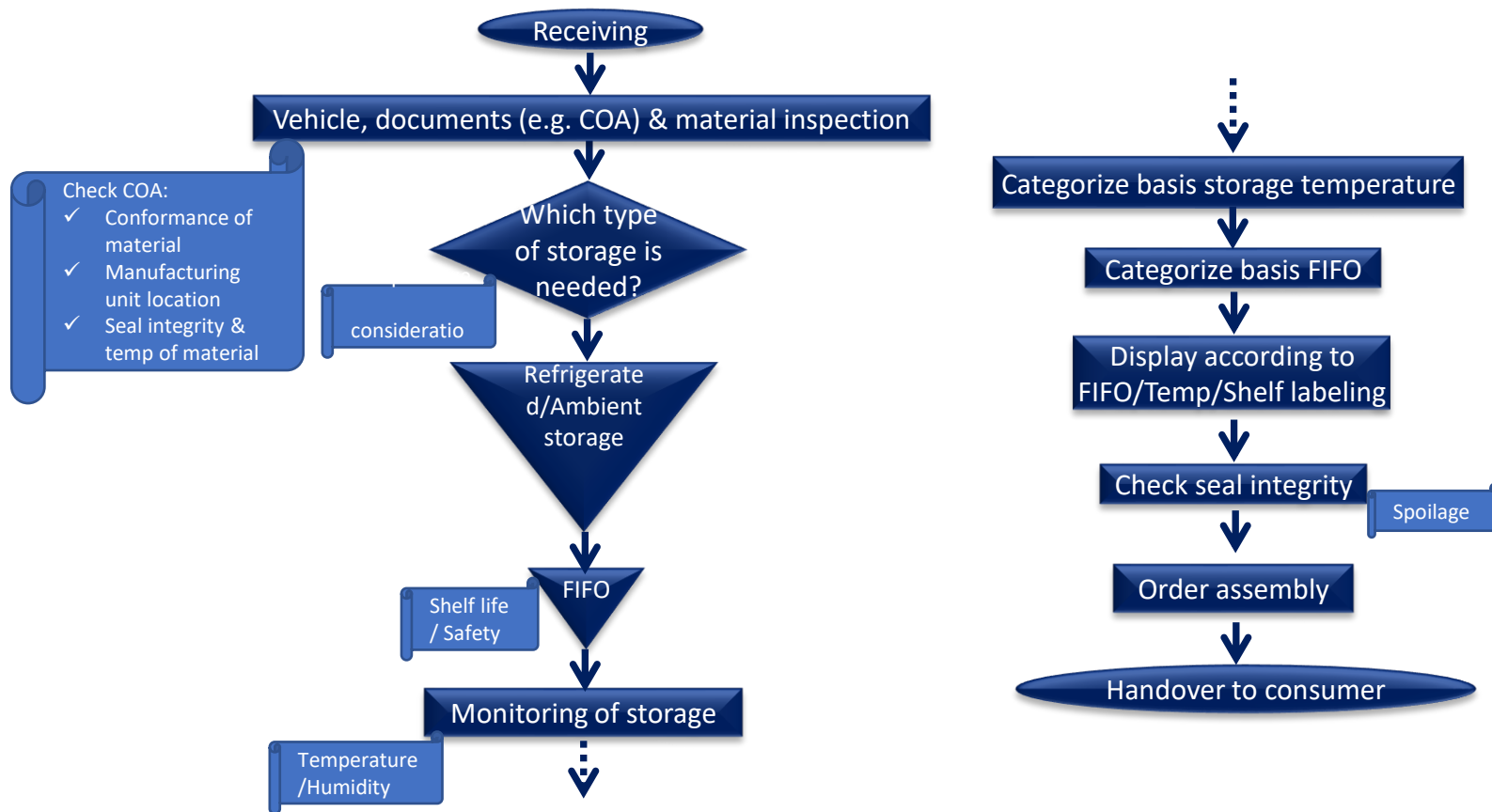
Depicting storage & preparation, serving areas, personal facilities, rodent & pest control devices

Control and periodic verification(at least annual) of the process information.

Process Flow Diagram for Distributors



Process Flow Diagram for Retailers



Developing a HACCP Plan

Hazard

A biological, chemical or physical agent in,
or condition of, food with the potential
to cause an adverse health effect.

Types of Hazards...

1. **Physical:** Foreign material like hair, stone, dirt, metal, wood
2. **Chemical:** Oil, Grease, Pesticides, Toxins
3. **Biological:** Bacteria, Viruses, Moulds, worms, flies

Sources of physical contamination

- People
- Packaging materials
- Machinery/Equipment
- Premises
- Pests
- Environment
- Raw materials

Sources of biological contamination

- Raw food
- People
- Equipment
- Air and dust
- Soil
- Pests
- Water
- Food waste

Sources of chemical contamination

- Pesticides, preservatives, mould inhibitors
- Veterinary drugs
- Cleaning chemicals
- Food additives
- Perfume, scented soap
- Chemical reaction between metal and acidic food
- Machine oils

HACCP Principles

1. Conduct a hazard identification & risk assessment
2. Determine the CCPs
3. Establish critical limits
4. Establish a monitoring system
5. Establish corrective actions
6. Establish verification procedures
7. Establish documentation

Hazard Analysis

The process of collecting and interpreting information on hazards and conditions leading to their presence to decide which are significant for food safety

Risk Assessment

		Probability / Likely hood		
		High (3)	Medium (2)	Low (1)
Severity or Consequence	High (3)			GMP
	Medium (2)		GMP	GMP
	Low (1)	GMP	GMP	GMP

Control Measure

Any activity that can be used to prevent, eliminate or reduce to an acceptable level a food safety hazard.

What is a CCP?

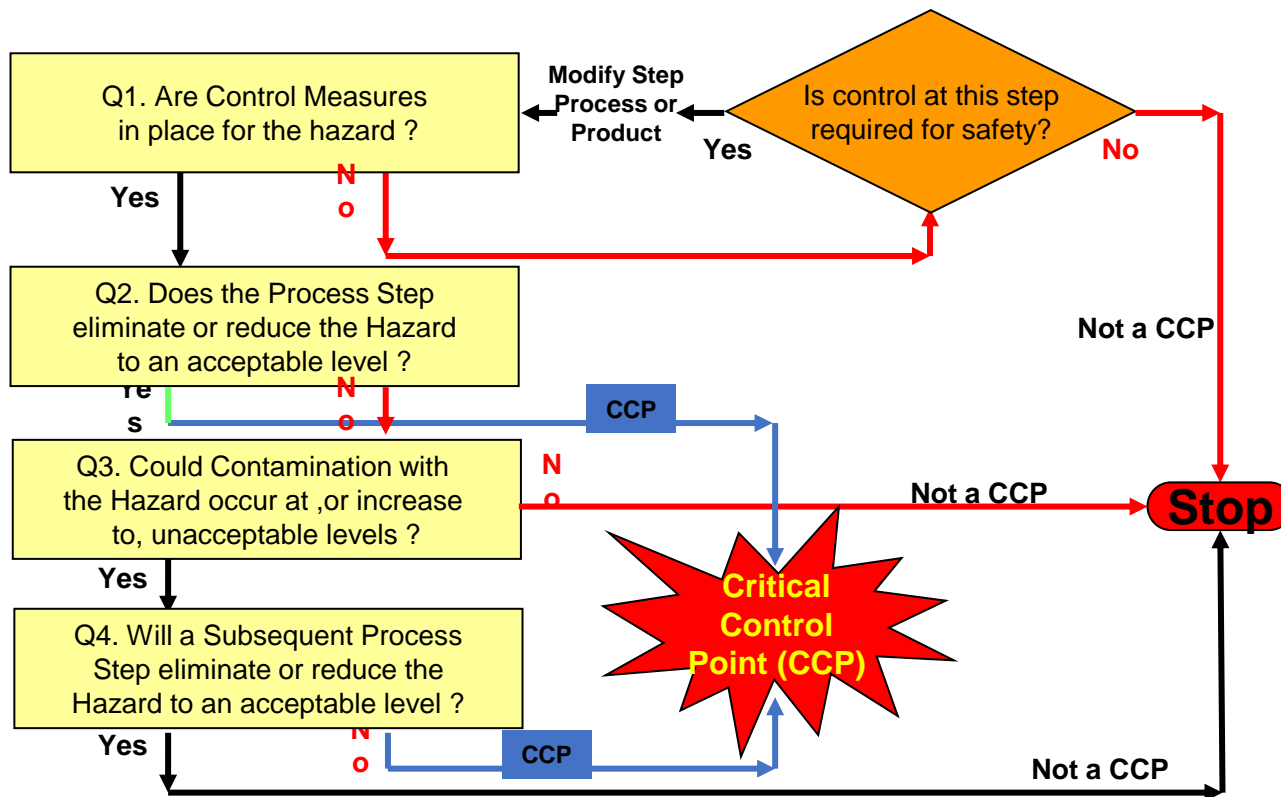
A step

where control can be applied and is essential to

prevent, eliminate or reduce

a food safety hazard to acceptable levels.

Determine the CCPs



Establish Critical Limit(s)

- Establish target levels and tolerance which must be met to ensure each CCP is under control
- Specify the criteria which MUST be met to ensure that each hazard (which makes a Process Step a CCP) is in “control”.
- E.g., Pest infestation, temperature control
- Pest control effectiveness

Establish a monitoring system

- Establish a monitoring system to ensure control of the CCP by scheduled testing or observations.
- Establish target levels and tolerance which must be met to ensure each CCP is under control.
- **Monitoring Procedures:**
 - What?
 - When?
 - Where?
 - How?
 - Who?

Establish Corrective Action

Establish corrective action, when a CCP is moving out of control.

- Adjust the process to bring back under control
- Action plan for nonconforming material

Establish Verification Procedures

Establish Verification Procedures, consisting of:

- Verification of Monitoring
- Verification of Corrective Action

Make practical plans for checking whether the HACCP

Plan is working or not.



Establish Documentation

Establish documentation concerning all
procedures and records

For further elaboration on HACCP, developing hazard control plan would be useful

ACTIVITY 4

- ❖ Which of these is/are HACCP principle/s.
 - a) Conduct a hazard identification & risk assessment
 - b) Determine the CCPs
 - c) Establish critical limits
 - d) Establish a monitoring system
 - e) Establish corrective actions
 - f) Establish verification procedures
 - g) Establish documentation
 - h) All of above
- ❖ Is schedule 4 a part of FSMS program? **Yes, or No?**
- ❖ Should FIFO/FEFO be followed during dispatches of FGs. **Yes, or No?**
- ❖ Is documentation required for all procedures **Yes, or No?**
- ❖ If conformance data in COA of health supplements are out of specifications, should you accept the consignment? **Yes, or No?**



Thankyou for your kind attention



Contact us

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for Health supplements
and Nutraceuticals

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