Confederation of Indian Industry

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Global Alliance for Improved Nutrition

FACE
CII-Jubilant Bhartia Food and Agriculture Centre of Excellence

*QA/QC Manual for*

# Fortified Refined Bleached Deodorised Edible oil

# Content

# Content

# List of Abbreviations

| | |
|---|---|
| BP | British Pharmacopoeia |
| CECOEDECON | Centre for Community Economics and Development Consultants Society |
| COA | Certificate of Analysis |
| EP | European Pharmacopoeia |
| FCC | Food Chemicals Codex |
| FIFO | First In First Out |
| FSMS | Food Safety Management System |
| FSSAI | Food Safety and Standards Authority of India |
| GAIN | Global Alliance for Improved Nutrition |
| GHP | Good Hygiene Practice |
| HACCP | Hazard Analysis Critical Control Point |
| HDPE | High Density Polyethylene |
| IU | International Units |
| MT | Metric Tons |
| MTD | Metric Tons per Day |
| PET | Polyethylene Terephthalate |
| PVC | Polyvinyl chloride |
| QA | Quality Assurance |
| QC | Quality Control |
| RBD | Refined Bleached Deodorised |
| RPM | Rotations Per Minute |
| SS | Stainless Steel |
| SOP | Standard Operating Procedure |
| TBHQ | Tertiary Butyl Hydroxyl Quinone |
| USP | United States Pharmacopeia |
| VAD | Vitamin A Deficiency |
| WHO | World Health Organisation |

# Glossary

| | |
|---|---|
| Antioxidant | A substance that inhibits the process of oxidation, and counteracts degradation of stored fats and oils thereby increases their shelf life. |
| Adsorbent | A substance that causes adhesion of specific molecules of a solution and creates a film of the molecules on the surface of the solution. |
| Bleaching | The removal of colour producing pigments from fats and oils, during the Refining procedure, usually through the use of an adsorbent. |
| Cholesterol | A compound found in most body tissues which is an important constituent of cell membranes, but can cause blockage of blood vessels if present in high concentrations. |
| Critical Control Point(CCP) | The point in operation where failure of a standard operation procedure (SOP) could cause harm to customers and/or to the business, or even loss of the business itself. |
| Crude Oil | Unrefined oil which contains impurities that make it unfit for consumption. |
| Degumming | The treatment of additives that are added to crude oil to remove impurities with the use of dilute acids or soda. |
| Deodorization | Usage of steam to remove unwanted odours from degummed oil. |
| Expelling/Extraction | Mechanical separation of oil from oil seeds. |
| Food Quality | Both the external (shape, size, color, texture, etc.) and internal (chemical and microbiological) characteristics of a food product that make it fit or unfit for consumption. |
| Fortificant | The nutrient that is added to a food. In the context of this manual it is the addition of Vitamins and Minerals as per GAIN directive. |

| | |
|---|---|
| HACCP | A management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. |
| Hazard | A risk factor present/incorporated in food in any specific part of the supply chain, which can cause deleterious health effects. |
| Oxidation | Incorporation of oxygen in the fatty acid chains in the oil structure, which usually makes it unstable and causes spoilage. |
| Quality Assurance | The process of planning, documenting and agreeing on a set of guidelines those are necessary to prevent contaminants from entering into the food product right from the procurement of raw materials to the distribution of the finished goods. |
| Quality Control | All activities that are designed to determine the level of quality of the delivered food product. It involves verification and comparison of the output to desired quality levels. |
| Rancidity | The presence of an off flavour or odour in an Oil due to oxidation. |
| Recommended Dietary Allowance (RDA) | The level of intake of an essential nutrient that is adequate to meet the known need of the nutrient for healthy humans. |
| Standard Operating Procedure(SOP) | A written procedure prescribed for repetitive use as a practice, in accordance with agreed upon specifications aimed at obtaining a desired outcome. |
| World Health Organisation (WHO) | A specialized agency of the United Nations (UN) that is involved in harmonizing health related policies globally. |

# Introduction 1

# Introduction

The main objective of this manual is to enable the processors of edible oil fortification to address the dual challenges of Fortification; which on one end is mandatory to ensure the decrease in the Vitamin A and D deficiencies across the country, and on the other end has to be done under supervision in the right quantities to ensure that there are no deficiencies in the process of fortification which could lead to hypervitaminosis (overdose of the Vitamins) through fortified RBD (Refined Bleached Deodorized) or under delivery of vitamins as per ADI (Accepted Daily Intake) which could result through process variations, as across the Industry there could be variation in the processing Technology, the raw material quality variation and the Skill level of the shop floor personnel responsible for Edible Oil fortification . Therefore it is vital to establish a HACCP Plan to ensure Control and Assurance of Quality at every step of processing that the Oil seeds are subjected to, so that the final Edible Oil that reaches the Consumers helps to combat Vitamin A and D deficiencies.

The manual provides comprehensive, yet lucid guidelines for both the plant operatives and the Quality professionals to establish and maintain Quality Programs which encompasses, the Quality Control protocol from Raw material receipt to Finished Product delivery, the Quality Assurance Systems to ensure right processes, SOP's, Work Instructions , Formats and Templates are in place to have a consistent operation leading to consistent quality of fortified RBD oil and those critical GMP( Good Manufacturing Practices), GHP ( Good Hygienic Practices), HACCP ( Hazard Analysis and Critical Control Points), PRP's and OPRP's ( Pre-requisite and Operational Pre-requisite programs) as part of HACCP plan that needs to be maintained and monitored on a routine basis.

## BACKGROUND

Fats and Oils are a wide group of nutritionally essential components of a human diet, which are sources of energy along with Carbohydrates & Proteins. Each gram of fat is a concentrated source of 9Kcals of energy, and a diet with the adequate amount of fat prevents usage by the body of proteins as energy sources, so that they could be effectively used for body building. Fats and Oils are also sources of essential fatty acids, which are the precursors for hormones that are regulators of various physiological functions. They support growth and development of the body by acting as carriers to absorb Vitamins like A, D, E and K. Fats also help to improve the flavour and texture of food and provide a feeling of satiety when consumed as a part of any meal.

The major components of Fats and Oils are Triglycerides, which are composed of one glycerol molecule and three fatty acids. The predominant fatty acids consist of saturated and unsaturated carbon chains. The physical and chemical characteristics of any fat or oil are greatly influenced by the kinds, positions and proportions of fatty acids in the triglyceride structure. Fatty acids are usually classified into the following depending upon their degree of saturation:

1. **Saturated Fatty Acids**: These are fatty acids that contain only single carbon-to-carbon bonds. They have high melting points but should not be consumed in large amounts as they potentially increase the Low Density Lipoproteins (Risk factors for cardiovascular complications). They are found primarily in products derived from animal sources.

2. **Unsaturated Fatty Acids**: These consist of at least one double carbon-to-carbon bond in their structure and have relatively lower melting points. They increase the High Density Lipoproteins and decrease the Low Density Lipoproteins. They are called Monounsaturated Fatty Acids (MUFA) or Polyunsaturated Fatty Acids (PUFA), depending upon the number of double bonds in their structure. They are derived commonly from various plant sources.

Vegetable oils are the main sources of Essential Fatty Acids (EFA) in the body. They are essential because they cannot be synthesized by the body and have to be supplied through the diet. EFAs support the cardiovascular, immune, reproductive and nervous systems. Deficiency of EFAs in the body can lead to serious physiological conditions like strokes, obesity, asthma and depression, to name a few.

## Recommended Fat Intake

The Recommended Dietary Allowance(RDA) for total fat in India is a minimum of 15% of the Total Energy Intake, which rises to 20% for women of reproductive age and for adults with a BMI of <18.5 and a maximum of 30-35% of Total Energy Intake. Intake of Saturated fat should be less than 10% of Total Energy (1).

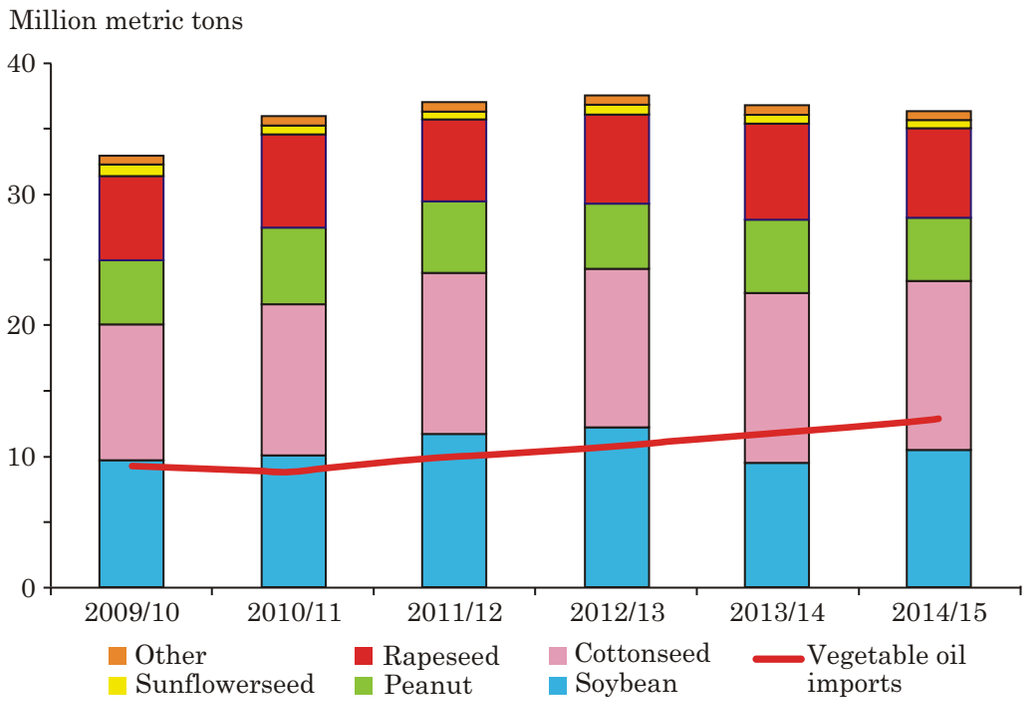
On the basis of these recommendations, the following three parameters are used to classify any oil as healthy/unhealthy:

* Ratio of Saturation to Unsaturation.
* Ratio of Essential Fatty Acids.
* Presence of antioxidants in the oil naturally that prevent the oil from becoming rancid (Developing an off flavour/odour).

## Edible Oil Industry in India

Oilseeds and Edible Oils are two of the most sensitive essential commodities. India is one of the largest producers and importers of oilseeds in the world. (2)

### India production of oil crops, and imports of vegetable oil




Source: *USDA, Economic Research Service, based on USDA, Foreign Agricultural Service,* Oilseeds: *World Markets and Trade Report, February 2015.*

Though the production of edible oil in India has increased over the last decade (3), so has the consumption, thus leading to a proportionate rise in the requirement of import of edible oil. Palm oil, Soyabean oil and Mustard oil are the three most consumed edible oils in India. The preferences vary with geographical variations in the country and the tastes of the consumers. India is fortunate as it has a wide range of oil seeds that are cultivated across different agro-climatic zones. Groundnut, Mustard, Sesame, Safflower, Linseed and Castor are the traditionally cultivated oil seeds. Soybean and Sunflower have recently gained importance. Coconut is the most important amongst the plantation crops. Rice bran and cottonseed oils have recently gained attention amongst the non-conventional oil sources.

The shelf life and nutritional value of various oils used for cooking is a debatable topic as it is determined by various factors like temperature of cooking, packaging procedures, storage temperature, humidity, altitude, etc. There are few oils that can be stored for longer periods than others. It is essential to know the why, what and how of cooking oils to make the right choice.

**How to choose oils for cooking:**

Every oil has a smoking point. It is the temperature at which the nutritional content of oil begins to rapidly degrade. Every time oil is reused, its smoking point gets lower. This is the main reason it is considered a bad idea to eat at places that reuse oil for cooking of food. The best options of oil to be used for cooking are the ones with higher smoking points, as they tend to have longer shelf lives.

## PROCESSING OF EDIBLE OIL

Edible Fats and Oils are derived from plant sources namely oil seeds, and animal sources. While vegetable oils were previously obtained by the cold or hot extraction/expression of the oil seeds, these methods have been largely replaced by solvent extraction which provides a better yield of oil. In this method, the oil is extracted from the oil seed with the use of a light petroleum fraction of Hexane, which is later separated and reused. As hexane is highly volatile, it does not remain in the oil once it is processed. Fats from animals are usually heat rendered with the use of dry heat or steam, to separate them from the protein and other naturally occurring substances in the animal tissues.

Once crude oil is extracted, it is subjected to a Refining process, which includes a series of sub-processes in which physical and chemical protocols are combined to remove undesirable compounds such as phosphatides, free fatty acids, pigments, odours and flavours, waxes, heavy metals and pesticides, without significant loss of the major glyceride components.

*Oil Refining Equipment*

Refining of Crude Oil consists of:

i. Degumming/Conditioning – to remove phosphatides,

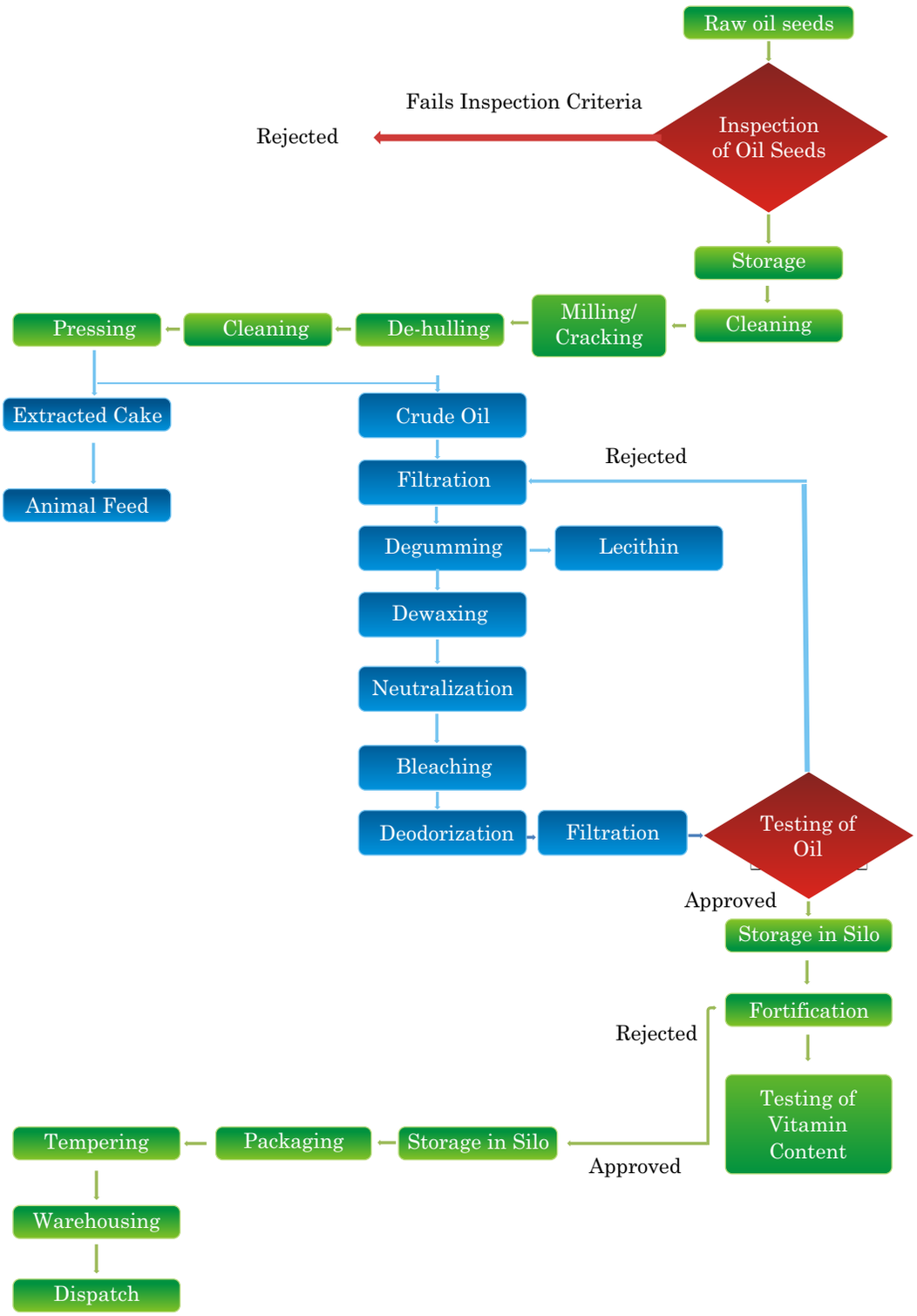
ii. Dewaxing/Winterization – To remove wax residues and saturated glycerides and improve oil clarity by Chilling and Distillation,

iii. Neutralization/De-acidification – to remove free fatty acids by Lye treatment or Distillation,

iv. Bleaching – to remove pigments by adsorption and

v. Deodorization – to remove unwanted odours.

## Process Flow Diagram



## FORTIFICATION OF EDIBLE OIL

As seen in the table above, oils once refined, tend to have a higher smoking point, thus have a longer shelf life. This is the prime reason why refining of oil is an essential processing step after crude oil is extracted from oil seeds to be made edible. Fortification of oil with these becomes necessary to ensure that the oil meets the nutritional requirement of the consumer.

## WHY FORTIFY WITH VITAMIN A AND D?

**Vitamin A** deficiency poses a major threat to the health status and sometimes to the very survival of mothers and young children. Its deficiency not only causes blindness but diminishes a child's capability to fight infections, especially diarrhoea and measles. Subclinical Vitamin A deficiency is very common all over India and accounts for one in every five deaths in the country (4).

**Vitamin D** is an important micronutrient necessary for maintaining Calcium balance and safeguarding the skeletal integrity of an individual. Its deficiency has a deteriorating effect on the normal growth and development of a person in the early stages of life and leads to a diminished bone mass during the later stages, making the person more prone to the susceptibility of fractures and osteoporosis.

Vitamin D deficiency can be because of one or more of multiple causes like:

* Changes in dietary habits and modern food fads leading to low Calcium and Vitamin D intake.
* High fibre diet consisting of phosphates and phytates which deplete Vitamin D stores in the body and increase the Calcium requirement.
* Genetic factors.
* Increase in the number of hours spent indoors which leads to reduced sun exposure.
* Increase in pollution leading to hampered synthesis of Vitamin D by the action of the ultraviolet rays of the sun.
* Repeated pregnancies in Vitamin D deficient individuals leading to increased complications.

Many studies reveal the widespread prevalence of Vitamin A and D deficiencies in both rural and urban India, in both sexes, while the prevalence is higher in pregnant women, older adults and children (5, 6, 7, 8, 9). Although there is awareness about the deficiencies in some populations, there is still a lack in its prevention as sultry hot or humid fluctuating climates in some areas make sun exposure a difficult task.

Food fortification, hence, is a good option to solve the issue of Vitamin A and D deficiencies and if combined with the implementation of right policies and dietary guidelines for supplementation, can go a long way in safely combatting the issue.

It is well recognised according to a report of the WHO, that improvement in the Vitamin A status in the young child population leads to a 23 percent reduction in all-cause child mortality; leading to prevention of 1.3-2.5 million deaths annually among children under 5 years of age and in pregnant women(10,11).

Fortification of staple foods has for long been regarded as a panacea for nutrient deficiencies in general populations. Vanaspati was initially fortified with Vitamin A and D as dairy products were not economically feasible for all populations. However, with refined oil replacing vanaspati as a usual cooking medium, a change in the fortification strategy became mandatory.

Fortification of edible oil is a strategy that is economical as well as feasible to tackle the deficiencies of Vitamin A and D for the following reasons:

* Vegetable oils have a penetration into Indian households of almost 99 percentage, with oil being consumed in each household.
* Cooking oil is a suitable medium for fortification due to its widespread use and fat soluble nature of these vitamins.
* Consumption of vegetable oil, following an increase in the consumer demand, has risen from 11.1kg/annum to 13.3kg/annum (3) and is set to rise up to 17.55 million tonnes in the coming year.
* Vitamin A and D fortification is relevant if the amount of oil consumed is greater than 5g/day (1.8kg/year) (12).
* Scientific data shows that the addition of Vitamin A and D to all cooking oil sold for human consumption is an inexpensive and well-established method for eliminating Vitamin A and D deficiency as a societal problem. Rickets was eliminated in many European countries and in North America by double-fortifying margarine with Vitamin A and D (13, 14, 15, 16).
* The Cost of fortification of oil with Vitamin A and D is minimal.
* It would provide essential amounts of Vitamin A and D to the populations that cannot afford the required amounts of dairy products to meet their requirement.

Fortification of oil is usually carried out in either of the following two ways:

1. Batch method: In this process, the oil and the premix are mixed together batch wise.
2. Continuous mixing: In this method the oil and premix are mixed together by continuous flow of ingredients.

# Vitamin D Potential in India?

- Is there deficiency in sunny India?

**INDIA**

**Latitude of 22 ° 00' N**

**Longitude of 77 ° 00' W**

**More than 80 % of adult Indians not getting enough Vitamin D**

## FACTS

**VITAMIN A**

* The vitamin A that comes from animal sources is fat-soluble, and in the form of retinoic acid, retinal and retinol.

* The vitamin A in fruits and vegetables is in the form of "provitamin A" - vitamin A precursors also known as carotenoids, which must be converted by the human body into usable retinoids.

* Plant derived Vitamin – A are water-soluble and do not accumulate in the body, so toxicity is rare, whereas animal-derived vitamin A can build up in the body and become toxic, if too much is consumed.

**VITAMIN D**

* "Vitamin D" is produced by the skin in response to exposure to ultraviolet radiation from natural sunlight.

* A person would have to drink ten tall glasses of vitamin D fortified milk each day just to get minimum levels of vitamin D into their diet.

* It is nearly impossible to get adequate amounts of vitamin D from the diet. Sunlight exposure is the only reliable way to generate vitamin D in your own body.

* People with dark skin pigmentation may need 20 - 30 times as much exposure to sunlight as fair-skinned people to generate the same amount of vitamin D. That's why prostate cancer is epidemic among black men - it's a simple, but widespread, sunlight deficiency.

* Sufficient levels of vitamin D are crucial for calcium absorption in the intestines. Without sufficient vitamin D, the body cannot absorb calcium, rendering calcium supplements useless.

# About GAIN 2

# About GAIN

The Global Alliance for Improved Nutrition (GAIN) is an international organization that was launched at the UN in 2002 to tackle the human suffering caused by malnutrition.

Driven by a vision of a world without malnutrition, GAIN was created in 2002 at a special session of the U.N. General Assembly on children.

GAIN supports public-private partnerships to increase access to the missing nutrients in diets necessary for people, communities and economies to be stronger and healthier.

With a reach of over 750 million people in more than 30 countries, GAIN's goal is to improve the lives of one billion people by 2015 within the most vulnerable populations around the world through access to sustainable nutrition solutions.

A cornerstone of GAIN's approach to address malnutrition is large-scale food fortification, the addition of essential nutrients (such as vitamin A, iron, iodine and folic acid) to staple foods and condiments such as salt.

A broad range of interventions are required to tackle malnutrition. Food fortification is a key intervention as it is affordable, is population-based, and complements other nutrition strategies - such as supplementation and diversifying diets. For over 50 years, food fortification has been an important public health tool leading to the virtual eradication of conditions including pellagra, goitre, and beriberi in the developed world. Leading economists repeatedly rank food fortification as among the best development returns on investment.

Many developing countries have now introduced food fortification. GAIN is working to strengthen and build sustainability into these programs to reach at- risk populations.

Since its inception in 2002, GAIN has built and supported large-scale food fortification programs in over 25 countries, fortifying staple foods and condiments such as wheat and maize flour, salt, vegetable oil, rice, as well as soy and fish sauces. These programs today are reaching over 700 million individuals.

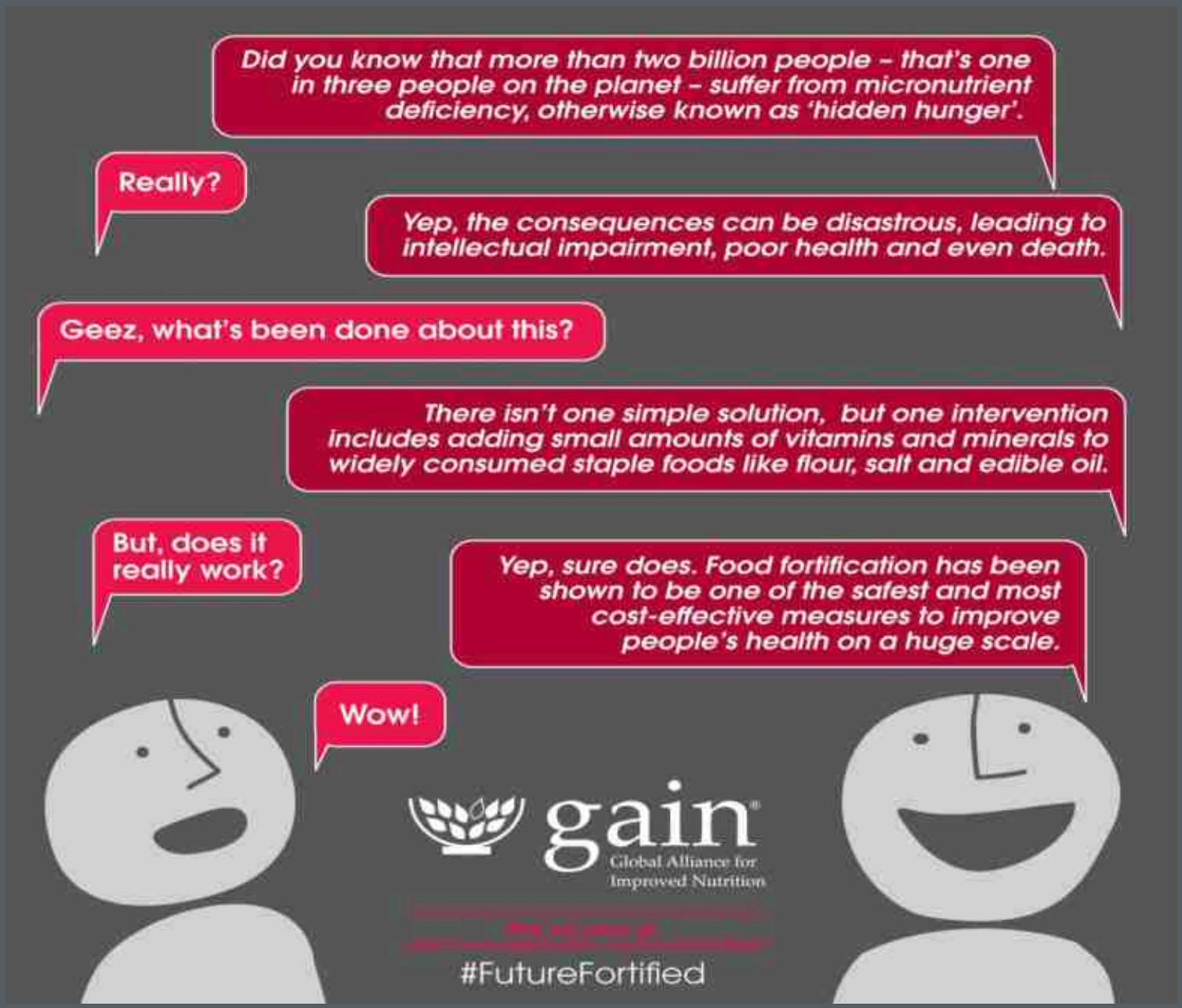
GAIN's approach to food fortification is to work through partnerships including NGOs, governments, academia, and private companies to deliver sustainable food fortification programs.

GAIN further in India has been involved in building capacity and capability in the food fortification of key commodities such as milk, edible oil and wheat flour, with strategic partnership with industries volunteering for this noble cause and also in close proximity with the government in identifying key geographies and key vehicles for fortification.

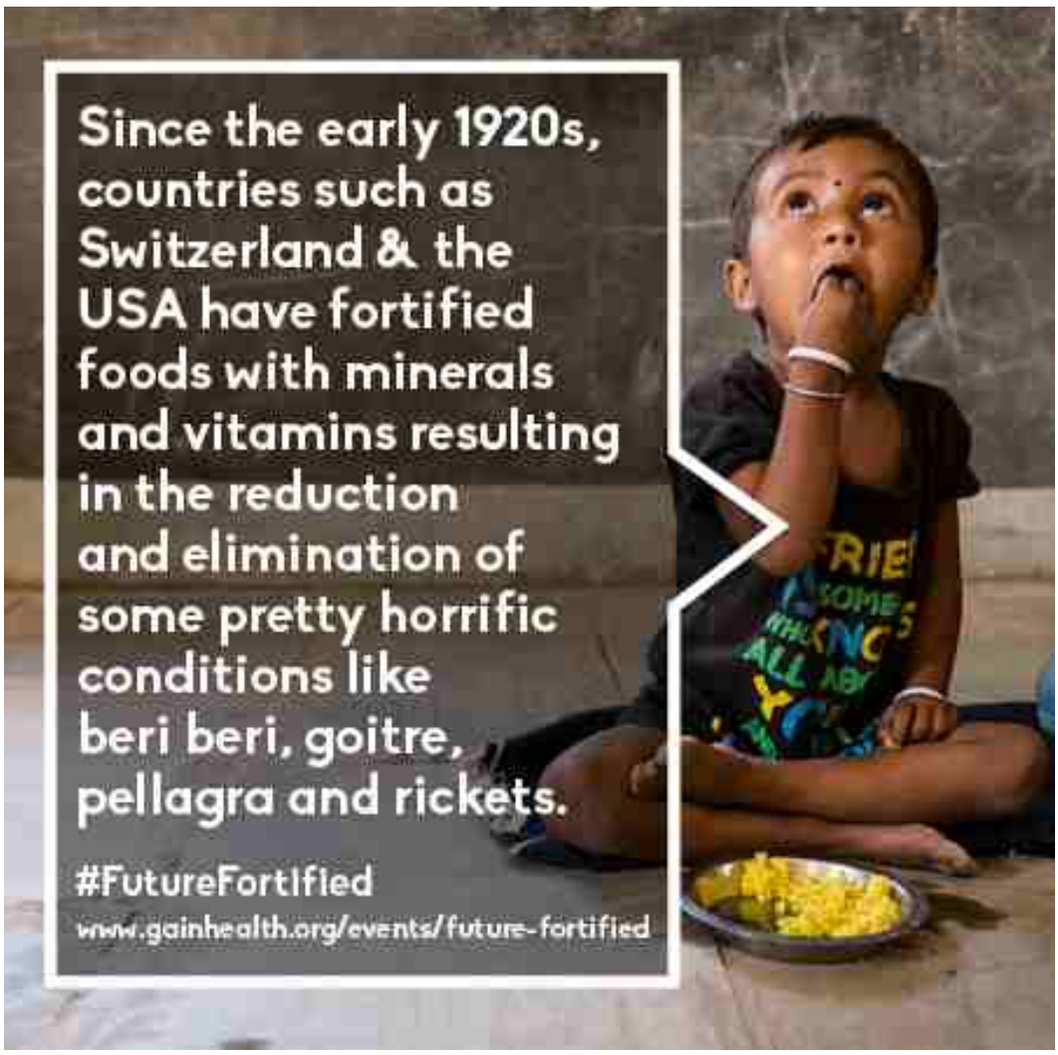
In 2013, GAIN partnered with CECOEDECON to carry out a Soya bean oil fortification project in the state of Madhya Pradesh and supported constant advocacy and social marketing to create a demand for fortified soya bean oil up to 2 years, thus leading to the continued fortification of soya bean oil in the state post the completion of the project.

## FACTS


Hidden hunger represents one of the most common health problems worldwide, with vitamin and mineral deficiencies alone accounting for about 10% of the global health burden
(Source Micronutrient Initiative)
#FutureFortified
www.gainhealth.org/events/future-fortified


Did you know that more than two billion people – that's one in three people on the planet – suffer from micronutrient deficiency, otherwise known as 'hidden hunger'.
Really?
Yep, the consequences can be disastrous, leading to intellectual impairment, poor health and even death.
Geez, what's been done about this?
There isn't one simple solution, but one intervention includes adding small amounts of vitamins and minerals to widely consumed staple foods like flour, salt and edible oil.
But, does it really work?
Yep, sure does. Food fortification has been shown to be one of the safest and most cost-effective measures to improve people's health on a huge scale.
Wow!
gain
Global Alliance for Improved Nutrition
#FutureFortified

## FACTS


Since the early 1920s, countries such as Switzerland & the USA have fortified foods with minerals and vitamins resulting in the reduction and elimination of some pretty horrific conditions like beri beri, goitre, pellagra and rickets.
#FutureFortified
www.gainhealth.org/events/future-fortified


# Food Safety Plan for Fortified Edible Oil Production Based on Risk Assessment

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## Premix

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# Food Safety Plan for Fortified Edible Oil Production Based On Risk Assessment

## ESTABLISHING THE HACCP PLAN

### 1. Preliminary steps to enable Hazard Analysis

#### I. Food Safety Team

* The HACCP team should have a combination of multi-disciplinary knowledge and expertise in developing and implementing HACCP systems. It should include individuals from areas such as engineering, production, sanitation, quality assurance, and food microbiology.
* Appropriate product and process specific knowledge experts must be on the team or must be brought in as subject matter experts externally.
* They work on various parameters such as:
    - **Collection of data** including historical data, causes of food borne diseases, epidemiologic, clinical, normative and lawful data and technological data.
    - **Planning of the activities** such as Time tables and duration of team work sessions, Programs of the implementation of successive HACCP stages.
* The names of each HACCP team member, their HACCP training and their role on the HACCP team shall be documented.
* Highly effective HACCP teams have well defined role clarity and ensure appropriate representation on the team.
* Records shall be maintained that demonstrate that the food safety team has the required knowledge and experience.

#### II. Product Characteristics

* To start a hazard analysis, a full description of the product should be drawn up by the HACCP team.
* The organization shall identify statutory and regulatory food safety requirements related to the above.
* The descriptions shall be kept up-to-date.

**Collection of data on Raw Material**

The following data about Raw Material should be collected and recorded:

* Biological characteristics, which involve microbiological limits for spoilage microorganisms; Chemical characteristics, which involve fortification level, heavy metals i.e. sulfate and physical characteristics include size & foreign material etc.
* Origin of procurement / flexibility in sourcing.
* Cost.
* Treatment, preparation and handling before use.
* Presentation: volume, type of packaging and delivery methods.
* Formulation of ingredients including additives and formulation aids (% of each raw material used).
* Method of production.
* Storage conditions and shelf life.
* Food safety acceptance criteria or specifications of purchased materials & ingredients.

**Collection of data on the Finished Product**

The following data about the Finished Product should be collected and recorded:

* General characteristics: denomination, composition, volume, structure.
* Physical-chemical characteristics: pH, Aw, redox potential (Eh) relevant for food safety, modified atmosphere.
* Packing details.
* Labelling details (This information will help the HACCP team to identify 'real' hazards associated with the process).
* Conditions of storage and lifespan.
* Instruction for handling, preparation, and usage should be described and documented.
* Distribution network conditions.

The organization shall identify statutory and regulatory food safety requirements related to the above and the descriptions should be kept up-to-date.

### III. Intended Use

The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the hazard analysis.

The following should be identified and described up to date:

* Lifespan (e.g. “use by date” or “best before date”)
* Methods of preparation
* Instructions of use
* Foreseeable deviations
* Storage
* Intended target groups of consumers
* The vulnerable groups
* Examination of the adequacy between product and its instructions of use.

### IV. Flow diagrams

Flow diagrams shall be prepared for the products or process categories covered by the food safety management system. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards.

### Steps in the Construction of a Flow Diagram:

* Identification of elementary operations/steps includes cleaning, cooking, extraction, bleaching, deodorization etc.
* Evaluation of introduction of food safety hazard in a flow diagram should be provided.
* Collection of additional information on each elementary operation/steps include:
    - Nature, function,
    - Process, Method, parameters,
    - Entry points of raw material and ingredients,
    - Inputs (raw materials and packaging),
    - Buildings, equipment layout and characteristics, environment,
    - Flow of products (including potential cross-contamination),

- Sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps),
- Technical parameters of operations (in particular time and temperature, including delays),
- GHP (cleaning, disinfection, maintenance),
- Any work and recycling work,
- Removal points of end products, intermediate products, by products and waste.

The following requirements are prerequisites and can be integrated in the HACCP system:

* Cleaning and disinfection procedures,
* Hygienic environment of the establishment,
* Personnel routes and hygiene practices,
* Product storage and distribution conditions.

**On-site confirmation of flow**: After the flow diagram has been drawn up, the multidisciplinary team should confirm it on site during operating hours. Any observed deviation must result in an amendment of the original flow diagram to make it accurate. Records of verified flow diagrams should be maintained.

## 2. Hazard analysis

The Food safety team is required to conduct a hazard analysis to determine the hazards, its control and preventive measures. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed.

### I. Hazard identification and determination of acceptable levels:

Hazard analysis is done to identify and record all expected food safety hazards in relation to the type of product, type of process and actual processing facilities.

The identification is based on:

* Sufficient knowledge and experience of a food safety team.
* The preliminary information like Food safety, Product Characteristics, (raw material, ingredients end products), intended use, flow diagrams, description of process steps and control measures.
* External information including to the extent possible and other historical data.

* Information obtained from the food chain on food safety hazards that may be related to the safety of the end products, intermediate products and the food at consumption.

The HACCP team should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption. The HACCP team should next conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction and combination of control measures to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

* The likely occurrence of hazards in relation to product and process and severity of their adverse health effects.
* The qualitative and/or quantitative evaluation of the presence of hazards based on preliminary information, experience, external information and relevant information from the food chain.
* The presence of possible allergens like soy residues/peanut residues post refining should have proper management such as:
    - Identification of all allergens present in the product, either by design or by potential manufacturing cross contact identified.
    - Declaration of allergens on labels of product or accompanying documentation intended for further processing.
    - Methods used to prevent allergens cross contact by cleaning, line changeover practices and product sequencing.
    - Procedure for allergens identification, declaration and prevention of cross contamination.
* Survival or multiplication of micro-organisms of concern.
* Production or persistence in foods of toxins, chemicals or physical agents.

Introduction of food safety hazards at every step of processing should be identified. The possibilities of introduction of food safety hazard at every steps of chain must be indicated and if the hazard is identified then the consideration is given to:

* The steps preceding and following the specified operation and links in the food chain.
* The process, equipment, utilities/services and surroundings.
* The determination of acceptable level of the food safety hazard in the end product and the methodology of determining them.

* Statutory and regulatory requirement, Customer food safety requirement, Intended use by the customer and other relevant data.
* Records of the process.

**II. Preventive measures**

* After identifying all the significant biological, chemical and physical hazards for each processing step and each ingredient, all the preventive measure shall be identified to prevent hazards from compromising the safety of the finished product.
* Some of the measures which can be used to prevent **chemical hazards** are:
  - Use of only approved chemicals.
  - Having detailed product specifications for chemicals entering the plant.
  - Maintenance of letters of guarantee from suppliers.
  - Inspection of trucks used to ship finished product.
  - Proper labelling and storage of all chemicals.
  - Proper training of employees who handle chemicals.
* Measures that can be taken to prevent **physical hazards** include:
  - Making sure the plant specifications for building design and operation are accurate and updated regularly.
  - Making sure the letters of guarantee for ingredients and product supplies are accurate and updated regularly.
  - Performing random visual examinations of incoming product and materials.
  - Use of magnets and metal detectors to help find metal fragments.
  - Keeping equipment well maintained.
  - Training of employees to identify potentil problems.
* Some of the measures to control **biological hazards** include:
  - Following Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP).
  - Proper maintenance and operation of equipment used to perform tasks.
  - Rinsing of food contact surfaces on equipment with disinfectant and water.

## III. Identification of critical control points (CCPS)

For each hazard that is to be controlled by the HACCP plan, CCP(S) shall be identified for their control measures.

* **Selection and assessment of control measures**
  - Once the hazard assessment is done the control measures shall be selected in order to prevent, eliminate or reduce the food safety hazards to defined acceptable levels.
  - The control measures are reviewed against the identified food safety hazards.
  - The control measures are managed either by operational PRP(s) or the HACCP plan.

* **The selection and categorization based on the following:**
  - Effect on identified food safety hazards relative to the strictness applied.
  - Place within the system relative to other control measures.
  - Feasibility for monitoring.
  - Likelihood of failure in the functioning of a control measure or significant processing variability.
  - The severity of the consequence(s) in the case of failure in its functioning.
  - The control measure is established and applied to eliminate or significantly reduce the level of hazard(s).
  - Synergistic effects.

Control measures shall be implemented either in accordance with HACCP plan or with operational prerequisite programmed (PRPs).

**Determination of critical limits for critical control points**

- Critical limits must be specified and validated for each CCP.
- Critical limits shall be set up to ensure that food safety hazard in the end product is not exceeded and maintained to the acceptable level.
- Critical limits based on subjective data (such as visual inspection of product, process, handling, etc.) shall be supported by instructions or specifications and or education and training.
- Critical limits shall be measurable.
- All critical limits, and the associated permissible tolerances, must be documented in the HACCP Plan Worksheet, and included as specifications in operating procedures and work instructions.

**System for the monitoring of critical control points**

Monitoring is a planned sequence of observations or measurements taken to assess whether the CCP is under control. The established monitoring activity supervisor must be able to provide a written documentation for the same.

* The system shall include all scheduled measurements or observations relative to the critical limit(s).
* The monitoring system shall consist of relevant procedures, instructions and records that cover the following:
    - Observations or measurements can be made continuously that can provide information in time for corrective action.
    - Monitoring devices used.
    - Calibration is done at specified interval, prior to use.
    - Monitoring frequency based on the nature of the product, and the limitations of the devices/tools.
    - Monitoring and checking should be done at regular interval of time.
    - Data derived from monitoring must be evaluated by a designated person with knowledge and authority.
    - Records are generated as part of the CCP monitoring activity and written at the time the measurements are taken.
    - All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

**Corrective actions when monitoring results exceed critical limits**

* If monitoring indicates that critical limits are not being met, thus demonstrating that the process is out of control, corrective action must be taken immediately.
* The corrective action must be based on the assessment of hazards, risk and severity, and on the final use of the product.
* The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented.
* A designated person shall be assigned all the responsibilities and authorities.

* Documented procedures and record of measures taken shall indicate all relevant information (for example: date, time, type of action and subsequent verification check) and shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated.

## 3. Verification planning

**Purpose**

* To check the effectiveness of an implementing and updating process.
* To provide a level of confidence that the food safety plan is based on scientific principles and is adequate to control the hazards associated with the product and process.

**Procedure**

* **Verification of prerequisite control measures**
  - General Prerequisite Programme is verified as specified in verification planning by food safety team.
  - OPRPs are verified in accordance with OPRP plan or by the HACCP plan.

* **Verification of hazard analysis**

  It is based on the following categories as follows:

  - The preliminary information and data collected.
  - Experience.
  - External information including, to the extent possible, epidemiological and other historical data and from the food chain.

  The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data. The determination shall be recorded.

* **Verification of HACCP plan**

  The HACCP plan and its components are verified and updated and records are maintained.

* **Verification of CCP Monitoring**

  Head of quality control verifies the performance of CCP operation with respect to its effectiveness against the identified food safety hazard and submits the report on prescribed format which is reviewed by Food Safety Team Leader.

* **Critical control limits**

  - This review is to ensure that the records are complete and to verify that the documented values are within the critical limits. This review is done at intervals specified in food safety Plan.
  - Based on subjective data (such as visual inspection of product, process, handling, etc.) shall be supported by instructions or specifications and/or education and training.

* **Conducting test/analysis:** This is to verify that the results of test or analysis corroborate the purpose or intent of the CCP, s wherever applicable. This verification is done at intervals specified in food safety Plan for each product and records maintained.

* **Taking of corrective action:** This review is to ensure that the cause of nonconformity is identified, that's the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented.

* **Calibration of process and testing equipment:** This review is to ensure that the records are complete and to verify that the activities have been done in accordance with laid down procedure. This review is done within the reasonable time after the records are made.

  - The outputs obtain after the verification planning shall be implemented in an organization.
  - Verification results shall be recorded and shall be communicated to the food safety team to enable the analysis of the results of the verification activities.
  - If system verification is based on testing of end product samples, and where such test samples show nonconformity with the acceptable level of the food safety hazard, the affected lots of product shall be handled as potentially unsafe.

* **Documentation and record keeping.**

Both documentation and record keeping are the essential parts of the HACCP process. They demonstrate that the correct procedures have been followed from the start to the end of the process, offering product traceability. It provides a record of compliance with the critical limits set, and can be used to identify problem areas. Simple narratives should be used to summarize and explain the decision making process at each step.

**Documentation involves**: Hazard analysis, CCP determination and Critical limit determination.

**Record involves**: CCP monitoring activities, Deviations and associated corrective actions, Verification procedures performed and Modifications to the HACCP plan.

According to the above steps for Risk Assessment and Control, following is a list of Critical Control Points to be carefully supervised and kept in control during Oil Processing:

| STEP | ACTIVITY | QA/QC CRITICAL POINT |
|---|---|---|
| **Seed Harvest and Procurement** | Liaison with farmers, harvesting. | * Specifications of oilseed required<br>* Time of Harvest<br>* Training of workers to separate seeds and avoid contamination with soil<br>* Use of sacks<br>* Rejection of damaged/mouldy oil seeds |
| **Cleaning and Conditioning** | Removal of Physical waste. | * Correct Sampling methods for Inspection of Seeds<br>* Training of staff in Inspection Procedures |
| **Extraction** | Pressing of Oil seeds Mechanically/ With use of Solvent to Extract Oil. | * Checking of Incoming Seeds<br>* Handling of Equipment |
| **Refining** | Degumming, Neutralization, Bleaching and Deodorization of Crude Extracted Oil. | * Volume and Concentrations of Chemicals Used<br>* Training of Personnel to Operate Equipment<br>* Control of Time and Temperature.<br>* Record Maintenance of Batches |
| **Fortification** | Addition of Pre-Blended Vitamin Premix. | * Concentration of Vitamins in the Premix and Pre-blend<br>* Training of staff for Blending Procedures |
| **Packaging** | Filling into Containers and Sealing. | * Specifications for Product Quality<br>* Specifications for Labels<br>* Inspection and Recording Procedures |
| **Storage** | Storage of Oil before Dispatch. | * Control of Store room Temperature<br>* Implementing Cleaning Schedules<br>* Stock Rotation Procedure Supervision<br>* Recording Procedures |

| STEP | ACTIVITY | QA/QC CRITICAL POINT |
|---|---|---|
| **Transport** | Transport of Oil for Distribution. | * Correct Handling to minimise losses |
| **Distribution** | Dispatch of products in required amounts to consumers and retailers. | * Establishing Inspection procedures for receipt of correct specified product.<br>* Establishing Recording procedures |
| **Retail** | Selling of Individual Packs | * Checking for Physical Appearance of Container/Package<br>* Checking for Vital stats like Shelf-life and Date of Manufacture |
| **Consumers** | Consumption of Oil at home level. | * Cooking the oil to optimum temperatures<br>* Preventing Re-use of Oil |

## NON-CONFORMITIES IN OIL PRODUCTS

In the context of ISO 22000, Non-conforming products are products that are potentially unsafe, because they were produced or manufactured during a period where critical limits were violated/ exceeded or when an organization has lost control of a pre-requisite program (PRP) or an Operational pre-requisite program (OPRP).

A non-conforming food product is one that has one or more than one of the following criteria holding good for it:

* The product does not conform to the mentioned Net Quantity/Weight
* The product is contaminated with physical, chemical or biological contaminants
* The product has different organoleptic properties from what is specified.

Identification and separation of all edible oil products that do not meet the requirements of safety, quality or regulations is necessary to prevent their accidental usage, which might lead to customer illness/injury and can cause derogatory effects on the business. The most efficient way to evidently identify them is with the use of identification marks/stickers.

## PROCEDURE FOR VALIDATION & VERIFICATION OF THE HACCP / FSMS PLAN

Prior to implementation of control measures to be included in operational PRP(s) and the HACCP plan and after any change, the organization should validate that:

* the selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated, and
* the control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels.

If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed.

Modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end product characteristics, methods of distribution and/or intended use of the end product.

## FOR MONITORING AND MEASURING

To ensure the performance of the monitoring and measuring procedures, the company shall provide evidence that the specified monitoring and measuring methods are adequately execute. To ensure valid result, the measuring methods and equipment should be:

* Calibrated or verified at specified intervals, or prior to use and the calibration should be done against the standards.
* Adjusted and readjusted whenever requires.
* Identified to enable the calibration status to be determined.
* Secured from adjustments that would invalidate the measurement results.
* Safeguarded from damage and deterioration.

Records of the results of calibration and verification should be maintained.

In addition, the organization should assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is nonconforming, the organization should take action appropriate for the equipment and any product affected. Records of such assessment and resulting actions should be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application should be confirmed. This should be undertaken prior to initial use and should be reconfirmed as necessary.

## EVALUATION OF INDIVIDUAL VERIFICATION RESULTS

The food safety team should systematically evaluate the individual results of planned verification. If verification does not demonstrate conformity with the planned arrangements, the organization should take action to achieve the required conformity. Such action should include, but is not limited to, review of:

* existing procedures and communication channels.
* the results of the hazard analysis the established operational PRP(s) and HACCP plan.
* the PRP(s)
* effectiveness of human resource management.
* training activities.

## ANALYSIS OF RESULTS OF VERIFICATION ACTIVITIES

The food safety team should analyse the results of verification activities, including the results of the internal audits and external audits. The analysis should be carried out in order to:

* confirm that the overall performance of the system meets the planned arrangements and the food safety management system requirements established by the organization.
* identify the need for updating or improving the food safety management system.
* identify trends which indicate a higher incidence of potentially unsafe products.
* establish information for planning of the internal audit programme concerning the status and importance of areas to be audited and,
* provide evidence that any corrections and corrective actions that have been taken are effective.

The results of the analysis and the resulting activities should be recorded and reported, in an appropriate manner, to top management as input to the management review. It should also be used as an input for updating the food safety management system.

# TRACEABILITY SYSTEM

## What is Traceability?

Traceability means the ability to track any food, feed, food-producing animal or substance that will be used as an ingredient at any stage of production, processing or distribution with the help of records. Bar codes, batch number and date of manufacture are some of the tools used for this purpose. It helps in tracking the path of a product or ingredient from the initial supplier through all processing and distribution stages, right to the end consumer.

Requirements: Every individual package of any kind of food product must possess a Barcode, Date of manufacture and Batch number on its label which is a unique code for identification.

**Batch coding**

* It should be identified and applied to both supplier and product.
* Each and every sealable unit in the product batch should be coded.
* Internal documentation should accompany the product batch code.
* The traceability codes of ingredients & primary packaging used for a product batch should be recorded and associated with the batch code.

**Identification the lots throughout the process** is accomplished by labeling the products in order to prevent the various problems that may arise if the ingredients or product are not physically labelled, in such cases the documentation are necessary for identification.

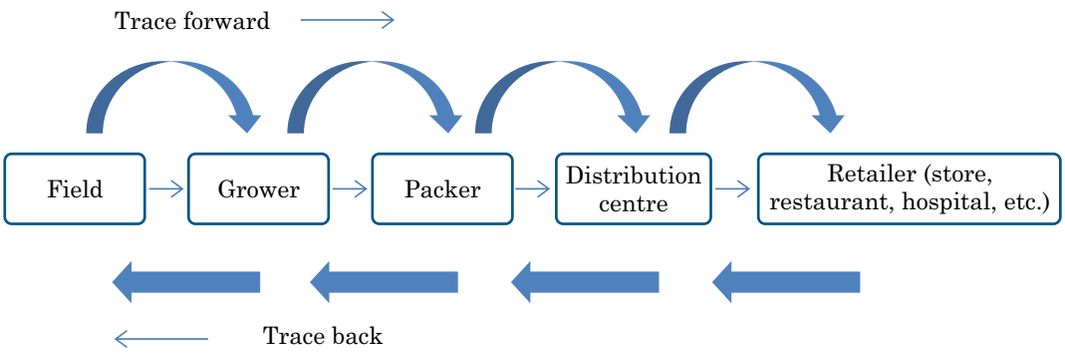
## Types of Traceability System

* **Forward Traceability System**

  In this, each process is deeply analysed using the traceability dimensions. Starting from the field to the Retailer, the Process is analysed with the quality validity and the accuracy of the measurements.

* **Back Traceability System**

  Such traceability starts from the retailer and ends at the field by deeply analysing each process in backward direction.




**The Traceability system is composed of:**

1. Supplier Traceability- of suppliers & their products.
2. Processing Traceability-of foodstuffs through the supply chain.
3. Customer Traceability- of foodstuffs to the immediate customer.

**Procedure for Traceability System**

The organization should establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.

* The Traceability System should be implemented in an organization that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.
* The traceability system should be able to identify incoming material from the immediate suppliers and the initial distribution route of the end product.
* Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal.

  For Example - Every individual package of any kind of food product must possess a barcode on its label which is a unique code for identification and immediate withdrawal of a product or a particular batch of a product, in case of detection of any unacceptable characteristics in the quality of the product can be carried out.
* Records should be in accordance with-statutory and regulatory requirements and customer requirements and may be based on the end product lot identification.

**Product Recall**

According to FAO, food recall is the action to remove food from the market at any stage of the food chain, including that possessed by consumers. There shall be a procedure used to identify and recover potentially adulterated, misbranded and/or hazardous foods in order to prevent potential food safety problems or economic fraud.

The product is recalled from the market due to several reasons which are listed below:

* Presence of allergens in food product without declaring on label
* Bacterial Contamination
* Chemical Contamination
* Communicable Diseases
* Undeclared Ingredients
* Foreign Objects
* Packaging Defects
* Misbranding
* Illnesses identified by the State Health Dept.
* Supplier's notification
* Real or fraudulent consumer claims.

**The major objective of a food recall** is to protect public health by ensuring that:

* There is rapid removal of unsafe food from all possible stages of the supply chain,
* The concerned consumers and customers are informed, and
* The food under recall has been retrieved, destroyed or reprocessed.

## RECALL PROCEDURE

i. A designated person within the organization shall be responsible for delivering safe food in market.

ii. The person must follow the Food Recall procedures when he considers or has reasons to believe that a food which he has processed, manufactured or distributed is not in compliance with the food the rules or regulations, he should immediately initiate procedures to withdraw the food from the market and consumers indicating reasons for its withdrawal and inform the competent authorities thereof.

iii. The person should immediately inform the competent authorities and co-operate with them, if he considers or has reasons to believe that a food which he has placed on the market may be unsafe for the consumers.

iv. He should inform the competent authorities of the action taken to prevent risks to the consumer.

**A Mock Recall i**s a stimulated recall exercise and tests the recall program & procedures to determine if implicated lot(s) are quickly identified and controlled and reconciled against:

- Quantities produced
- Quantities in inventory
- Quantities in distribution

A Mock Recall identifies potential problems and allows personnel to become familiar with recall procedures and provides opportunity for correcting deficiencies in recall procedures.

## PREMIX

A Premix is a clear liquid that has an oily consistency. It is either odourless or has a faint odour and is pale yellow or orange in colour. The premix used for edible RBD oil Fortification is an emulsion of Retinol palmitate/acetate and Vitamin D. It should be incorporated at the rate of 20g/MT.

### Composition of Premix/100 grams

| | |
|---|---|
| **Vitamin A** | Retinol Palmitate - 125 million IU |
| **Vitamin D** | Vitamin D2 Oil – 10 million IU |
| **Antioxidant** | Alpha Tocopherol Acetate |
| **Carrier** | Sunflower Oil |

*The specifications of the premix ingredients must comply with the standards of USP, BP, EP or FCC.*

**Procurement and Inspection**

The premix must be checked for the following when it is received at the oil plant:

* The Quantity and Ingredient specification must be checked against the Purchase order document by the receiving staff.
* Only Hermetically sealed containers must be accepted at the mill.
* The bottles must be examined for COA and must only be accepted if there is no physical damage or leakage as Vitamin A (Retinyl esters) is sensitive to light and can get deteriorated because of the leakage or light exposure.

* It must be used for fortification with the First In First Out principle.
* All records of receipt, storage and dispatch of the Premix must be maintained up-to date and must be available at all times to the concerned person.

**Handling**

* The concerned staff must handle the premix bottles carefully when carried for usage. Any direct physical contact must be avoided.
* In case of physical contact with the premix, medical help should be seeked immediately.
* The bottles should be maintained at 23-32 degree C.
* A pre-blend of the concentrated premix is made as per the regulations before it is added to the oil, depending upon the quantity of oil that is to be fortified.
* Any spillage or wastage of the premix must be avoided. The bottles must be tightly closed and stored in case of an excessive amount remaining.
* The Quality Assurance and Control representative (of the plant or a third party) must ensure that all the above rules are followed and that no waste materials enter the oil along with the premix.

**Storage**

* Premix bottles must be stored in dark bottles in the absence of excessive light or oxygen, as Vitamins are sensitive to light and exposure can lead to deterioration in their concentration.
* The bottles must be stored away from other chemicals or potential contaminants in a cool and clean place.
* The shelf life of the Premix must be considered while deciding on how much stock to maintain. The premix bottles must always be used in the FIFO method.
* Proper records of the receipt, storage and supply of the premix must be maintained in order to ensure unobstructed availability of the premix.
* Time-to-time checking of the stock must be done to ensure that there's no damage or contamination in the premix bottles.

**Issue**

* When the Premix is issued for usage for Oil Fortification, careful handling of the bottle must be ensured.
* FIFO method should be adopted for issue of premix.
* The premix bottle must only be opened at the time of usage and should be closed immediately once used, and kept away from exposure to sunlight or oxygen.
* Proper records of the issue time and date and the staff in charge must be maintained.

## FACTS

**Why Oil (as a fortified product) is better than other Vitamin A/D Rich Foods**

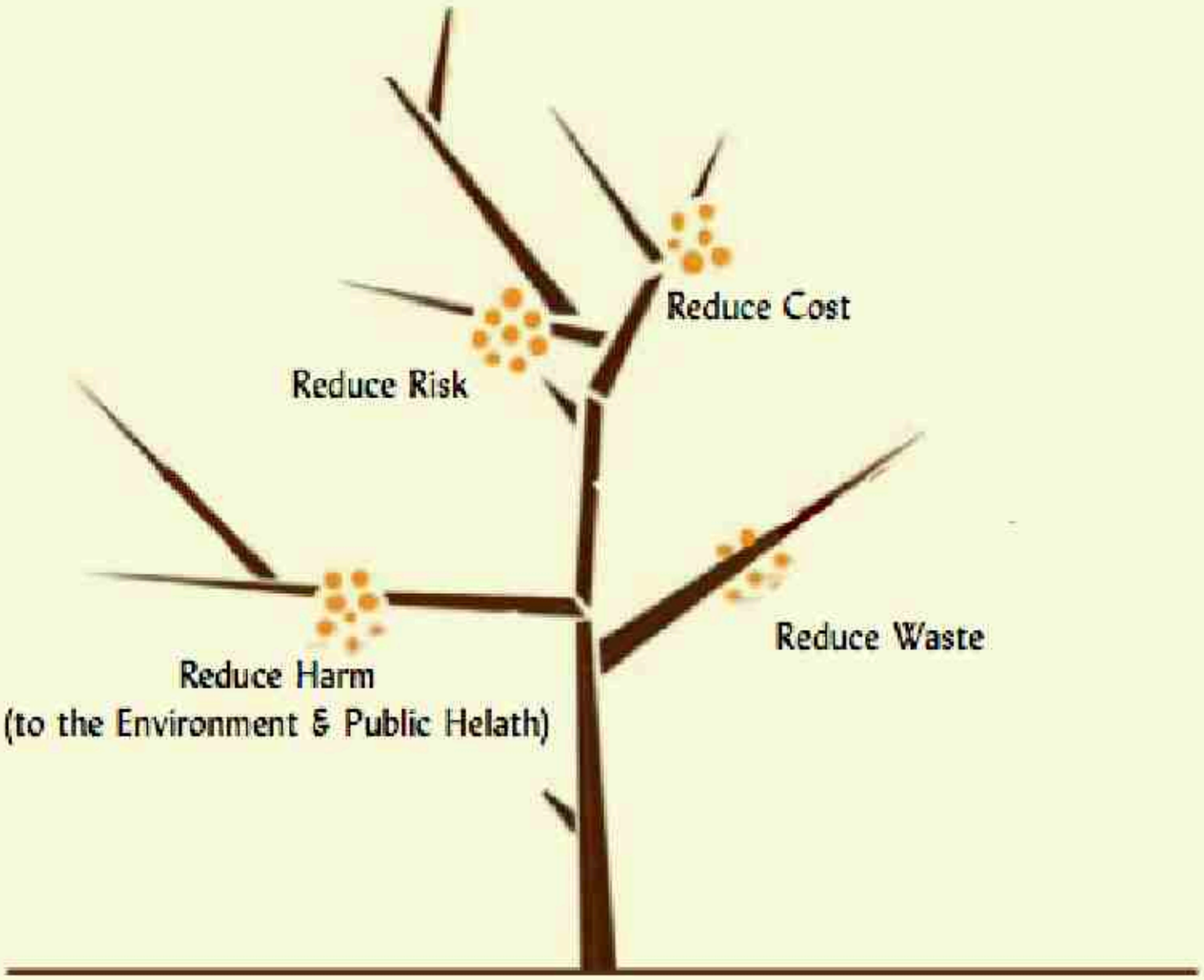
* Vitamin A can be present in foods in the form of Retinol/Retinyl Esters(More easily absorbed by the body) or ß- Carotene (Comparatively less easily absorbed).

* It is always better to have foods that contain more bioavailable forms of Vitamin A. While carrots, sweet potatoes, Green Leafy Vegetables are the plant sources with the highest amounts of vitamin A in them, they contain it mostly in the form of ß-Carotene, while fortified oil contains it in the form retinyl palmitate (A Retinyl ester) that is more easily absorbed by the body.

* Oil has better penetration into households than any other Vitamin Rich foods.

* Fortified Oil is more economical when compared to other sources of Vitamin A and D.

* As Vitamin A and D are both Fat Soluble Vitamins, Oil is a perfect medium for fortification with both, as they are better when mixed in a fat medium.




# Prerequisite Programmes (PRPs) for Fortified Refined Bleached Deodorized Oil

5

# Procedure for Prerequisite Programmes (PRPs)

The organization shall establish, implement and maintain PRP(s) to assist in controlling:

* The contamination of the product from physical, chemical and biological hazards.
* Introduction of the hazards to the product through the work environment.
* The PRP(s) shall be approved by food safety team.
* The Verification of PRP(s) needs to be planned.

## List of PRP's

A. Locations and Surroundings of the Plant

B. Infrastructure and Layout of the Plant

C. Supply of Air, Water and Other Facilities

D. Wastage and Drainage Disposal

E. Suitability of Equipment

F. Evaluation, Selection and Re-Evaluation of Supplier

G. Receipt and Storage of Material

H. Warehousing, Dispatch and Transportation

I. Cleaning and Maintenance

J. Pest Control System

K. Personnel Hygiene

**Key Elements that can be considered during the implementation of the above PRP'S are listed below in each PRP and these are as per the schedule 4 part 2 requirements of FSSA (Food Safety and Standards Act) 2006 and Rules and Regulation 2011 which are applicable to all Food Business Operators.**

*Clean and smooth roads with no pot holes*

*Clean surroundings with no standing water or accumulated garbage*

*Well maintained vegetation- cut short to avoid giving shelter to any pests*

## A. LOCATIONS AND SURROUNDINGS OF THE PLANT

* An edible oil plant should be located in a sanitary place and away from environmentally polluted areas and industrial activities which discharge heavy polutants into the air (like smoke) and water resources.
* It should not prone to flood and infestation of pest.
* The plant premises should be free from standing water, scattered garbage and scrap to maintain the plant surroundings pest free and hygienic.
* The residential facility should be away from food processing area.
* Vegetation should not grow anywhere in the plant premises and the surrounding areas. This may attract insects and provide home for pests.
* Any pest sighting in the surrounding areas like insects, rats, snakes, animals, birds etc. should be immediately reported to the factory manager and take all possible preventive steps for pest control.
* The higher authorities should be informed if there are any damaged roads or path ways within the plant premises so that they can be repaired soon and the environment is free from dust.

## B. INFRASTRUCTURE AND LAYOUT OF THE PLANT

*Smooth flooring with no cracks or holes is easy to clean*

* The walls and floors of the raw material storage area, production and packaging section and the warehouse should be well maintained without any cracks or holes to prevent rodents like rats, cockroaches, etc. from hiding and to prevent dirt from accumulating.
* Production lines and product flow should be designed to have a 'linear flow' from raw materials to finished product.
* The flooring, walls and working surfaces should be of permanent nature and made of non-absorbent, non-toxic materials like tiles, R.C.C, Kota stones, Marble, Eucrite, concrete with Poly urethane (PU) layer, etc. in all the food handling areas.
* Free space should be left in between and around the machines especially in the packaging section to allow easy movement and cleaning.
* There should be a slope of min 8 degree in the flooring towards the drain to ensure no water logging.
* It is preferable that the walls and floor should be of light color so that any pests or dirt can be easily seen and cleaned and should be repainted if paint is peeling off.
* Air curtains or strip curtains should be placed on the doors/ entrances to prevent entry of pests and dust/ dirt from outside.
* The lights on the walls and ceilings should be covered with shatter-proof plastic/ fibre covering to prevent broken glass pieces from falling into the processing area.
* The windows, doors, openings should be screened for ventilation with wire mesh, strip curtains, air curtains, grills as suitable, to prevent the entry of dust, cockroaches, rats, lizards, birds and stray animals like dogs.

* All the doors and windows should be covered with wire mesh to prevent entry of insects and birds.

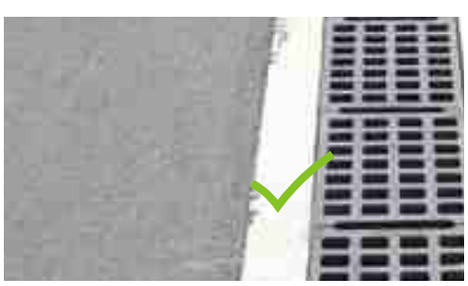
*Use strip curtains in processing and packaging areas*

*Cover all the drain holes in the premises with grill*

* The activities should be compartmentalized during processing of food. The separate dedicated areas should be assigned for each activity like storage, processing, packaging, warehousing etc. to avoid any cross contamination.

**Keep no open drain holes or drains inside the plant**

**Install covered drainage system inside the premises**



* Warehouses should have proper ventilation and illumination. Must have adequate lights and windows/ exhausts for the same.
* A good drainage system in the food plant with sloped floors, adequate number of drains and drain holes should be there and covering of all the drains and drain holes to avoid clogging of drains and entry of pests.

## C. SUPPLY OF AIR, WATER & OTHER FACILITIES

### Water Supply

* The continuous supply of safe potable water for food processing, cleaning of equipment and hand washing purpose should maintain.
* A regular supply of water for toilets, cleaning of floors and for fire-fighting purposes should be provided.
* Water storage tanks should be cleaned periodically.

*RO system for potable water*

* Records should be maintained in a register.

### Gas/ Air Supply for Food Processing

* The air supply to the processing area should be free from odor, dirt, dust, moisture and grease.
* Appropriate pre-treatment should be provided such as passing the air through Silica traps for absorbing moisture and providing grease trap.
* Nitrogen flushing, Carbon dioxide or Oxygen shall be used and have 99.90% purity. Certificate is must for the same from the suppliers before placing the order with them.
* Ambient air sample should be checked frequently to ensure the quality of air like by the test of microbial load.
* Additionally (raw and finished goods) air should be passed through 0.3 or 0.1 micron HEPA filters(High Efficiency particulate Air filter system) or any other appropriate filter for limiting the entry of microbes.
* Vacuum cleaners can also be used for removal of dust from the equipment and other surfaces.

## Other facilities

### Personnel Facilities

* Facilities like clean toilets, separate toilets and changing rooms for male and female workers and other facilities for working personnel must be provided to ensure personnel hygiene.
* There should have sufficient number of wash basins with regular supply of potable water for washing of hands by the food handlers along with soap and facility to dry hands like disposable paper rolls or hand dryers.
* Sufficient number of toilets should be established separately for males and females at some distance from the food handling areas and they should be clean.


*Separate toilets for men and women workers that are clean*


* All the workers should use the refreshment rooms/canteens for eating and resting purposes and should not eat within the food handling areas.
* A separate changing room should be provided for male and female workers to change into clean uniforms before entering the food handling area.
* Workers should be provided with uniforms and disposable hand gloves, hair nets, shoe covers/ clean footwear that have to be worn only inside the food handling premises.

* Display boards should be on the walls of the processing areas with instructions, especially for hygiene practices, to be followed by the workers in local language for easy understanding.

**Ventilation and Lighting facilities**

* The exhaust fans, chimneys, windows installed in the plant should be regularly dusted and cleaned on daily basis.
* All the exhaust openings and windows should be covered with wire mesh to avoid the entry of birds, insects and other pests.
* Lighting fixtures should, where appropriate, be protected to ensure that food is not contaminated by breakages.
* Any broken lights and exhausts should get repaired as soon as possible.

**Toilet Facilities**

* After immediate use of the toilet facility, the washing of hands with soap and facility to dry hands like disposable paper rolls or hand dryers should be provided.
* Sufficient number of toilets separately for males and females at some distance from the food handling areas should be established.
* A separate changing room should be provided to male and female workers to change into clean uniforms before entering the food handling area.
* Uniforms and disposable hand gloves, hair nets, shoe covers/ clean footwear should be worn only inside the food handling premises not in toilets.

## D. WASTAGE AND DRAINAGE DISPOSAL

* The drainage system must be functional at all times to avoid any water logging in the manufacturing plant.
* The waste generated like stones, extraneous matter, spilled oil etc. should be stored away from the raw material, storage or food processing areas and covered in containers.

*Covered drains inside the premises to avoid any water logging*

* The waste generated shall not be disposed into the open areas, outside the factory, on roads or into the drains in order to avoid environmental contamination and the waste disposal should be carried out in eco-friendly manner at designated sites.

* A refuse bin of adequate size should be place in all the manufacturing sections of the plant for efficient collection of waste. Number of bins should be based on the average amount of waste generated in that particular area.

* The dry and wet wastes should be collected separately and segregate the biodegradable, non-biodegradable and recyclable wastes.

*Separate and labelled containers for different types of wastes*

* The waste generated should not be accumulated in the food processing or packaging areas and collection of the waste should be done in covered containers and store them away from the food handling areas.

* The collected waste should be disposed off at regular intervals so that it does not generate bad odour in the area or lead to microbial growth.

* All the drain openings should be screened with metal grills or mesh to avoid garbage from entering the drains leading to blockage and also to prevent entry of insects and rodents.

* Waste bins should be cleaned and dried periodically.

* Records shall be maintained.

## E. SUITABILITY OF EQUIPMENT

* They should be made up of stainless steel materials or a corrosion free material which don't act as a toxic material to food and using of chipped enamelled containers should be restricted.

* The machines, equipment, tools, and containers used in the food manufacture should be cleaned after every day's operations so that no remains of food are left sticking on the equipment surfaces.

* They should be covered either with a proper fitting cover/lid to protect the oil completely from dust, dirt and flies and other insects.

* The machines should be installed in the plant such that there is sufficient free space to allow easy cleaning of the machines and the surrounding area.

* The machinery should be laid in such a manner in the plant that the flow of food material is unidirectional from procurement to processing to packaging to warehousing and then dispatch. This will help avoid cross-contamination of foods at different stages of processing.
* The vessels/ containers used for storage of wastes and by-products should be labelled for easy identification.
* The wastes and by products generated during processing should be kept away from the food items and store the cleaning agents and packaging material in separate areas.
* The equipment used in the food plant should be free from dust and dirt by regular cleaning.
* Labelling and colour coding should be done on each containers and equipment that may help to avoid any confusion.
* The equipment and containers should be periodically check to avoid any damage (corroded, rusted, broken), metal particles chipping off that might be entered into the product stream.
* The machines should be checked regularly for:
    - All steam supply valves and steam traps for leakage.
    - Weighing equipment and temperature gauges.
    - All oil pumps for leakage.

## F. EVALUATION, SELECTION & RE-EVALUATION OF SUPPLIER.

The Organization has established an effective and efficient process to identify and periodically evaluate the performance of their suppliers of raw material, ingredients, packaging material and other chemicals.

Selection of a supplier can be done based on the following parameters:

* He should make a product that conforms to the quality standards of the organization.
* He supplier must be able to coordinate and work with the organization.
* He must be a certified supplier and should possess a valid license.
* He should be capable of conducting a Quality Improvement Plan whenever required by the organization.
* Have a reputation of fulfilling commitment for timely delivery of product to an organization.
    - The suppliers are selected on the basis of above criteria and an approved list of such suppliers is maintained.
    - The performance of all approved suppliers of products and services are reviewed in regular interval of period on the basis of timeliness of supply, quality and quantity.
    - The result of the review shall be communicated to the respective supplier. Where specific supplier performance is poor, his name is deleted from the approved list and the party is informed.

## G. RECEIPT & STORAGE OF RAW MATERIAL

**Receipt of raw material**

* Designated personnel must check the incoming vehicles that bring the raw material for cleanliness and hygiene i.e. the trucks are clean, with no pests or dirt, with no strong odor other than that of the raw material, and covered with tarpaulin when received.
* He should check the raw material for any visual infestation or microbial growth. If present, then reject the raw material immediately.
* He should always do random sampling of the raw material and test the sample as per the internal specification before accepting the raw material.
* He must maintain a record of all the raw materials received, along with the details of the supplier, transport vehicles, date and time of receipt and the test results obtained from the laboratory.

## Storage of Raw Material

*Raw Material storage in Silos*

* The storage area should always be cleaned and dried and that there are no pests in the area.
* For perishable commodities, like fruits, vegetables, meat products, milk etc., the cold storage area should be used.
* The separates areas for storage of raw material, processed foods, packaging materials and wastes should be used.
* The containers and areas used for each of them should be labelled for easy identification.
* The containers being used in the plant for storage of raw materials should not toxic like gunny bags, cartons, containers of stainless steel etc.
* The raw materials should be stored at least 2 feet away from the walls and 4" above the ground on pallets to allow easy cleaning.
* It should follow FIFO (First In, First Out) stock rotation system i.e. the material that is received first shall be sent out first.

**Use pallets to store raw material above the ground**

## Food processing Controls and Food Packaging

* A record should be maintained of all time and temperature treatments and train the workers every few months to follow the same.
* The packaging material should be of food grade with no strong odor of chemicals or colors.

* The packaging material should not be stored directly on the floors. Racks or pallets should be used to keep the material atleast 4" above the ground.

* Visually inspection should be done for each packaging material/ containers before using them for any visible infestation, dead insects; cockroaches etc. on the surface and reject the infested packaging material as it will contaminate the food.


* Inert gases like Nitrogen should be used to provide extra protection to the food from oxidation or microbial growth.

* Every package must have complete labelling along with nutritional labelling as per provisions of Food Safety and Standards Act, 2006.

* Every package of Food must have the batch no. and a unique bar code for tracing back the item in case there is a customer complaint in future.

**Product Information and Consumer Awareness**

* Every package must have a label before the dispatch .

* All information on the label must be according to the regulations made under Food Safety and Standards Act and Rules, 2011.

* Date of manufacturing, MRP, Best before date, Batch number and Net weight should be mentioned on the package to ensure traceability of the product.

* Nutritional information should be provided in grams or % by weight and per serving size in decreasing order of amount of the nutrient present.

* There should be complete information on the label to inform the consumer about how to handle, store, and prepare/ process the food products safely and correctly.

* The information should be provided on any possible allergens present in the food.
* The labels should be verified periodically and changed as per the prevailing regulations.

**Traceability of products**

* Every individual package of any kind of food product must possess a barcode, date of manufacture and batch number on its label which is a unique code for identification.

* Immediately withdraw the product or a particular batch of a product, in case of detection of any unacceptable characteristics in the quality of the product should be reported.

## H. Food Distribution- Warehousing, Dispatch and Transportation

* The warehouses should be cleaned with no pest infestation.
* The adequate lights and ventilation should be provided in the ware house.
* The finished goods should not be stored directly on the floor. They should be stored at least 18" away from the walls and 4" above the ground on pallets.
* The dispatch of finished goods must follow FIFO (First In First Out) system.
* The vehicles used for transportation and distribution before loading should be checked for cleanliness and any visual pest infestation, dirt or rusting.
* The vehicles should be covered after loading with tarpaulin sheets to protect them from any dust, dirt, birds, insects or rains during the transportation and distribution.
* The containers should not be used for transporting food items for any other purpose. If they are used, then they should be cleaned before loading the food packages.
* Registered transport vehicle should be used which have approved state/ national permit (as needed). The documents of the vehicle as well as the driver should be checked before dispatch.

*Cover the road vehicles with tarpaulin sheet to protect against rain and birds, insects.*

## Food Testing Facilities

* The in-house laboratory should have all the equipment and chemicals need for testing of raw materials, in-process foods and finished products.

* The laboratory staff must be competent and trained to understand and assess the quality control parameters during food sample testing.
* If an organization does not have the facility to test a parameter then samples should be sent to an NABL accredited laboratory outside.
* The finished goods should also send for testing to an NABL accredited laboratory periodically.
* A separate space should be maintained for keeping the retention samples in the manufacturing plant.
* Signed test records conducted in the laboratory should be maintained.

# I. CLEANING AND MAINTENANCE

* The cleaning program shall be established and validated to ensure that all the parts of the facility and equipment are cleaned.

  An organization must follow a schedule of cleaning the premises which shall include:

* Place to be cleaned
* When to do the cleaning?
* Who will do the cleaning?
* How the cleaning should be done?
* The inspection should be done before post –clean /pre-start up.
* Cleaning of Equipment should be set in either way to facilitate cleaning in place (CIP) or cleaning out of place (COP).
* The machines should be lubricated periodically to ensure smooth running and food grade lubricants should be used for this purpose.
* The working station, floor or equipment should be cleaned immediately in case of spillage or food left over.
* Cleaning chemicals shall be handled and used carefully as per the instructions given on the MSDS (Material Safety Data Sheet) and shall be stored separately away from food materials.
* The preventative maintenance of machinery, building and facilities should be checked regularly to prevent breakdowns.
* The responsibilities shall be assigned to a designated person for the specific task.
* At the end of day's operations all the equipment should be cleaned and dried.

* Ceilings, walls, floors, doors and windows, wire mesh and grills should be cleaned periodically to remove any accumulated dust, dirt, spider webs etc.
* A monitoring and verification set up should be used in order to ensure the effectiveness of a cleaning program.
* The record of all the cleaning activities in the plant should be maintained.

## J. PEST CONTROL PROGRAM

* A mechanism for ascertaining the pest activity in the manufacturing premises needs to be implemented. Records for pest sighting need to be maintained.
* A licensed agency should be used to implement a pest control program. The pesticides meant to be used are approved pesticides and a list of such pesticides shall be maintained.
* Material safety data sheet (MSDS) for each pesticide should be maintained and readily available for reference in the event of anybody affected by it.
* A schedule of pest control should be prepared keeping in mind possibilities of contamination with the product. This schedule shall be affected by incidence of pest in different seasons. It should ensure that the pest control operator follows the schedule.
* Pesticides should be stored in the Organization premises in such a way that the chances of contamination are precluded.
* Trapped pests should be disposed off expeditiously in a suitable manner outside the Organization premises.
* The 4-Ds approach should be utilized to effectively control pest.

**1D – Deny Entry**

* All holes, cracks on ceilings, walls and floors should be sealed.
* Double doors / air curtains / strip curtains at entrances should be used.
* The windows drain holes and any other openings with wire mesh and metal grills should be covered.
* The entry of animals, birds, and pets should be controlled.

**2D – Deny Shelter**

* Clean all places where pest may live.
* False sealing in storage and processing areas should be avoided.
* Any cracks and holes on walls, floors, ceilings, corners, doors and windows should be repaired.

* Any unwanted articles like damaged tyres; scrap etc. should be thrown away.
* Potential pest breeding sites should be eliminated.
* Water should not be accumulated in the open area within the factory.

*Do not allow water to accumulate anywhere to avoid breeding of pests*

* The wire mesh on windows and exhausts should be regularly clean to remove the accumulated food dust.

**3D – Deny Food**

* Eliminate food sources to pests.
* All food materials shall be stored in sealed / covered containers.
* Floor shall be free from any food wastes.
* Storage, processing and packaging of the food should be done only in dedicated areas.
* The floors and equipment must be dried immediately after cleaning.

**4D – Eradication of Pests**

* Pest infested places; clothing and equipment should be cleaned and disinfected.
* Insectocutors should be used to get rid of any pests within the factory.
* The insectocutors shall be placed 4.5 to 6 m away from food handling area.
* Insectocutors should clean every week.
* All foods should be covered during spraying of pesticides.
* Glue pads or traps should be used for rodents like rats.

* Contaminated food should not use.
* A record of pesticide/insecticide sprayed in the premises should be maintained.

## K. PERSONNEL HYGIENE

**Health status**

* Organization should conduct regular medical check-ups for food handlers at least once in a year by a registered doctor to ensure they are not suffering from any infectious or communicable disease.
* If suffering from any disease, the workers must inform the supervisor and should not be allowed inside the food handling premises.
* The workers should not allow with open cuts or wounds to handle food or equipment as he/she may contaminate the food and /or spread the infection among other workers.
* In case of epidemic in the area/ city, organization must get the food handlers vaccinated.
* Records of these health check-ups should be maintained.
* First aid must be available for workers in case of emergency.
* Records for all first aid medicines and their consumption should be maintained.
* Records should be checked periodically.



**Personal Cleanliness: Open cut should be well covered and bandaged as shown, preferably with a brightly coloured bandage for easy identification , preferably with a metal detector to get identified in metal detectors.**

**Personal cleanliness and behaviour**

* The workers should be motivated for hand washing with soap and water every time after using toilet as well as after touching foreign objects like phones, money, etc. or scratching of body parts, coughing and sneezing. Hand sanitizers should be provided especially in the packaging area.
* An organization must ask the workers to trim their nails and not to wear any nail paints as it may contaminate the wheat flour.
* The workers should not wear any Jewellery or other accessories like bangles, watches etc. during handling of oil at any stage. In case of religious issues like wedding rings etc., hand-gloves must be used. Lost items must be reported.

* The workers should wear gloves, face masks, hair net, uniforms at all times during the operation to avoid contamination and training should be given on how to dispose these masks, gloves, and hair nets. They should throw these after use in the designated bins and not in the open.

* They should not consume alcohol, tobacco or smoke cigarette within the processing area as it may contaminate the whole processing.

* They should not eat food within the premises. They should use the designated canteen area or refreshment rooms for having lunch and tea.

* They should not spit on the walls of the building.


**Visitors**

* There could be external personnel like customers, suppliers, government officials, senior personnel from the organization, students etc. who can visit the manufacturing area. The following practices need to be followed by the visitors to avoid any cross contamination.

* The visitor details like name, contact address, purpose of visit, time and date of visit along with the visitor's signature should be pen down before allow him/ her inside the plant premises.

* Generally visitors should be discouraged to go inside the food handling areas but if he/she goes then food organization shall ensure that visitors wear protective clothing, footwear and adhere to the other personal provisions envisaged in this section.

* The visitor should be provided with face mask, hair net, hand gloves, shoe cover before entering the manufacturing premises.

* The visitor shall not be allowed to physically touch the food being processed.

* A declaration shall be taken from the visitor and verification should be done to check whether the visitors are suffering from any infectious disease or not, or have any cuts / wound or not.

* The visitor should be accompanied at all points.

# How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

**Duration of the handwash (steps 2-7):** 15-20 seconds

**Duration of the entire procedure:** 40-60 seconds

0

Wet hands with water;

1

Apply enough soap to cover all hand surfaces;

2

Rub hands palm to palm;

3

Right palm over left dorsum with interlaced fingers and vice versa;

4

Palm to palm with fingers interlaced;

5

Backs of fingers to opposing palms with fingers interlocked;

6

Rotational rubbing of left thumb clasped in right palm and vice versa;

7

Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;

8

Rinse hands with water;

9

Dry hands thoroughly with a single use towel;

10

Use towel to turn off faucet;

11

Your hands are now safe.

World Health Organization | Patient Safety | SAVE LIVES Clean Your Hands

## FACTS

**HAND WASHING AND HAND HYGIENE**

* 80% of communicable diseases are transferred by touch.

* The most critical times for hand washing are before preparing food and after going to the bathroom.

* The recommended washing time is 15 seconds. The ideal washing time is 30 seconds.

* Most bacteria on our hands is on the fingertips and under the nails.

* Damp hands are 1,000x more likely to spread bacteria than dry hands.


# Production & Process Technology of Fortified Refined Bleached Deodorized Oil

6

# Production & Process Technology of Fortified Refined Bleached Deodorized Oil

## PRODUCTION & PROCESS TECHNOLOGY OF FORTIFIED RBD OIL

Fortification of oil is today a fairly common process across some parts of the world, as oil is one of the most commonly utilized commodities. Fortifying staples like oil is economical and ensures distribution to a larger population. Oil is an ideal medium for fortification with Vitamins as they are fat soluble and it stabilizes them and inhibits their loss.

Oil fortification consists of a series of steps and there are well established procedures to be followed to ensure safe and adequate fortification. The Vitamins A and D must be added to oil at a temperature of about 45-50 degree C.

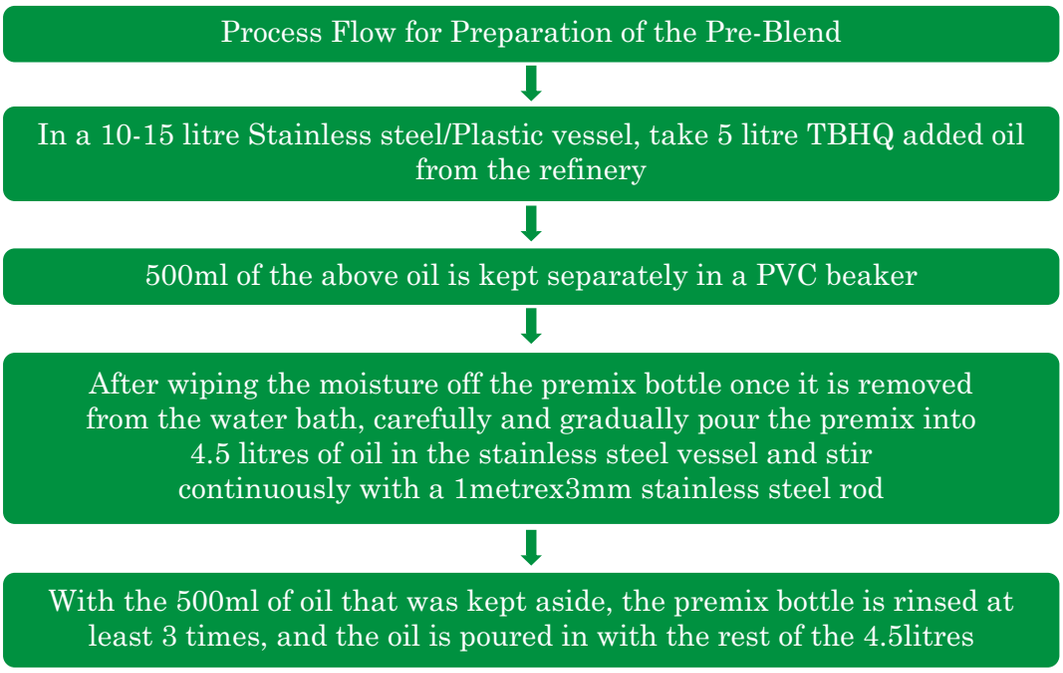
Fortification is only safe when the fortificants are blended and added in the right quantities. The process of fortification involves the mixing of both the vitamins in the right quantities and uniformly blending them in measured quantities of the refined oil.

Vitamin concentration stability is directly proportional to the exposure of the premix to sunlight and oxygen, as these are the two factors that reduce the stability of the vitamin, thus reducing the concentration of the vitamin in the premix. It is excessively sensitive to light and must hence be stored and handled only in opaque bottles to ensure that there is no or minimum exposure to light. Vitamin A in the premix is usually highly concentrated and must be diluted to the regulated quantities to ensure that there is no risk of overdose of the Vitamin, which in long term can be toxic.

**Pre-Blending of the Vitamin Premix**

The main aim of this process is to ensure uniform and adequate mixing of the Vitamin premix into the oil. As shown in the premix content above, Vitamin A and D are present in the quantities of 125 million IU and 10 million IU per 100 grams, to ensure uniform provision of 25 IU of Vitamin A and 2 IU of Vitamin D per gram of fortified oil in 5 MT of RBD oil.

## Process Flow for Preparation of the Pre-Blend




**Mixing of the Pre-blend with the Oil**

The above prepared pre-blend can be mixed with the oil in two ways:

i. In Churns

ii. In Tanks

**Mixing In Churns**

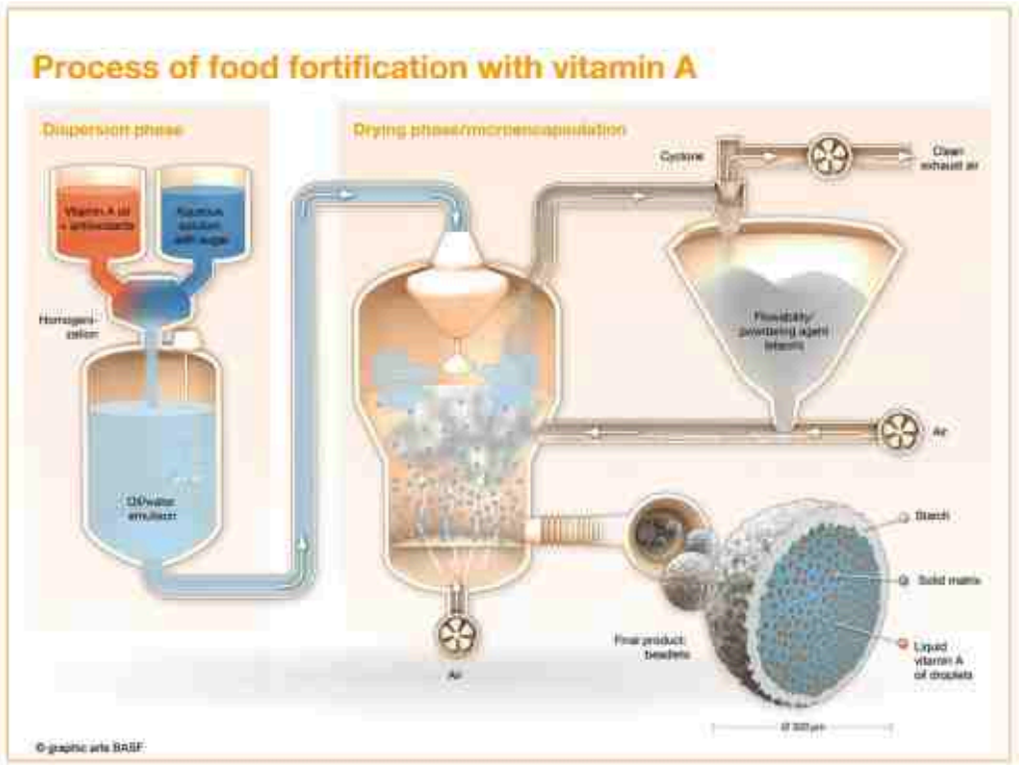
* These are cylinder shaped vessels of a 5MT usual capacity. They are equipped with a stirring system that rotates at 72-90 rpm.
* A charge of 5 MT of oil which has been added with TBHQ is taken from the refinery and is maintained at 32-35°C.
* When the level of the oil in the churn has reached to about half, the stirrer is initiated to rotate and the pre-blend is fully added; and the pre-blend container is rinsed with refined oil and the contents are mixed in the churn. This is continued and samples are obtained from the churn at 30, 60 and 90 minute intervals and tested for the Vitamin A content by Carr-Price test. (Refer Section VIII.) A positive result on the test indicates homogenous mixing of the Vitamin in the oil.
* The time taken for this process to complete is recorded.

*Mixing of Pre-Blend with Oil in Churns*

**Mixing in Tanks**

Sometimes, few oil plants do not immediately pack the refined oil. They have provisions of storage tanks intermediary to the refining and the packaging sections. In order to fortify oil in these tanks, they should be provided with an oil re-circulating system so the pre-blend can be mixed with the oil before it is packed. The following are the steps in this process:

* 5 MT of TBHQ added oil is taken and is maintained at 30-35°C.
* The oil re-circulation system is started and the pre-blend is gradually added.
* The pre-blend container is rinsed with refined oil and the contents are mixed in the tank. This is continued and samples are obtained from the tank at 30, 60 and 90 minute intervals and tested for the Vitamin A content by Carr-Price test. (Refer Section VIII.) A positive result on the test indicates homogenous mixing of the Vitamin in the oil.
* The Time taken for this process to complete is recorded and subsequently determined for every charge of 5 MT of oil.




| S.no | Process | Recommended Temperature (degree Celsius) | Recommended Retaining Time (Minutes) |
|---|---|---|---|
| 1. | Preparation of Pre-Blend - Preheating of Premix | 45 | 45 |
| 2. | Mixing of oil with Pre-Blend | 32-35 | 30, 60 ,90 |
| 3. | Degumming | 70-85 | 30-45 |
| 4. | Bleaching | 110 | 30 |
| 5. | Filtration | 110 | 30 |
| 6. | Deodorization | 250 | 60 |

## FACTS

**TRANS FAT**

* Trans fat is found in shortenings, margarine, snacks such as crackers, candies, and cookies, fried foods, pastries and other foods prepared with partially hydrogenated vegetable oils.

* Trans fat labeling on food packages has been mandatory since 2006.

* If a serving has less than o.5 grams of trans-fat, the label may state ZERO.

* Trans-fat is an artificial creation, but there are some trace amounts of trans-fat found naturally in meat and dairy products, called vaccenic acid.

* Consumption of food containing trans-fat has unequivocally been shown to increase the risk of heart disease by raising levels of LDL (bad cholesterol), and lowering levels of HDL (good cholesterol).


# Quality Control and Analysis of Fortified Refined Bleached Deodorized Oil

7

# Quality Control and Analysis of Fortified Refined Bleached Deodorized Oil

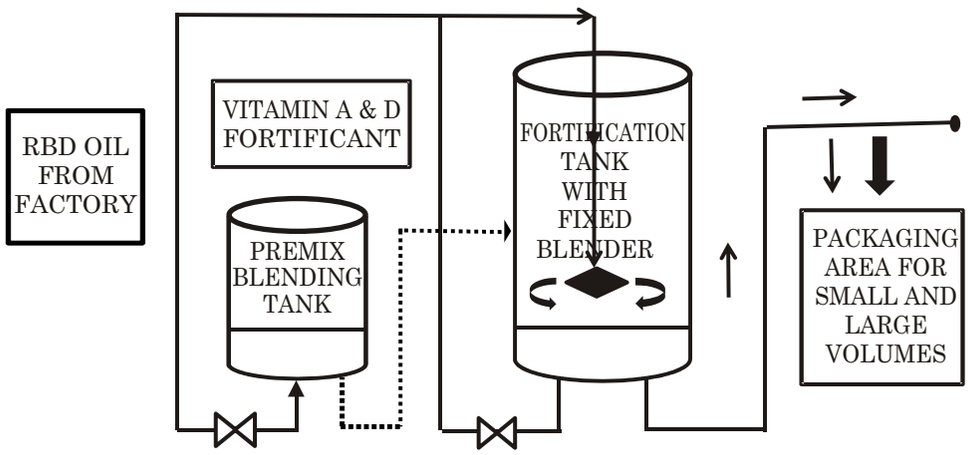
## QUALITY CONTROL AND ANALYSIS OF FORTIFIED RBD OIL

As mentioned above, the Fortification of Oil with Vitamin A and D is a very sensitive process which involves the addition of Vitamin A and D as a pre-blend with oil. There are multiple critical points to be considered in order to ensure safe and uniform fortification of the RBD oil and the Oil processors play a vital role in ensuring that the oil contains both Vitamin A and D in the specified regulated quantities. Quality Assurance and Quality Control in the various steps of the Edible Oil supply chain are of key importance to ensure that safe unadulterated oil is provided to the consumers without being subjected to any fraudulent practices. This requires the committed support of the Management System at the Oil mill. The following factors must be kept in mind during the various steps of Oil Processing:

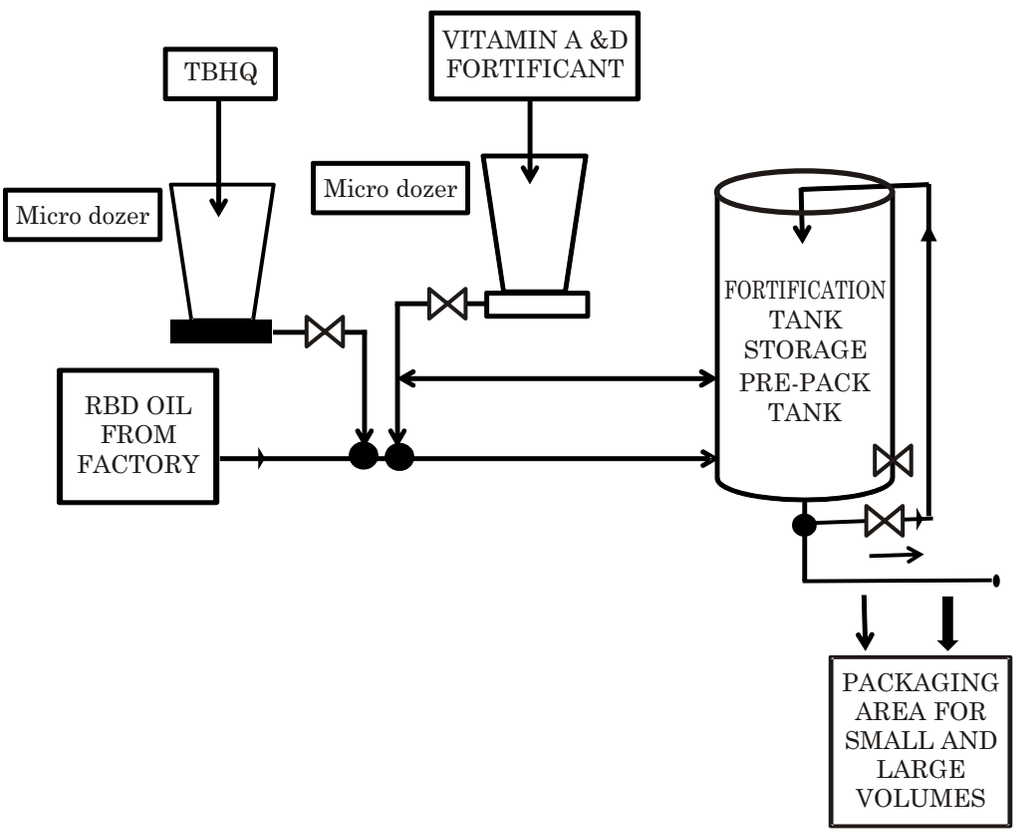
* Oil fortification is not a mandatory aspect and hence many oil refineries are not aware of the point of the fortification process. It should be defined to the refineries on a factory-to-factory basis.
* Each critical control point in the processing of oil should be assigned to individual staffs that are well trained in the control of quality aspects. They should be monitored from time to time and should be checked for updated regulatory information as they are the ones responsible for the specific corrective actions pertaining to their critical control points.
* The Premix Receiving department should maintain a log of the incoming stock and is responsible for the cross-checking of the premix specifications with the regulated requirement.
* The Production staff and the QC staff (In-house or third party) are responsible for the usage of the Premix in the specified safe quantities.
* The Certificate of Analysis (COA) must be obtained from the supplier of the Premix to ensure the right content of Vitamins and acceptable organoleptic properties in the Premix.
* Since Vitamin A is sensitive to light and oxygen, care should be taken that the Premix is exposed to the minimum possible light and oxygen, and is always stored in opaque bottles in cool, dry places. The Premix

must be assessed from time to time to check for its Vitamin content and organoleptic properties and should only be used if it meets the specified requirements.

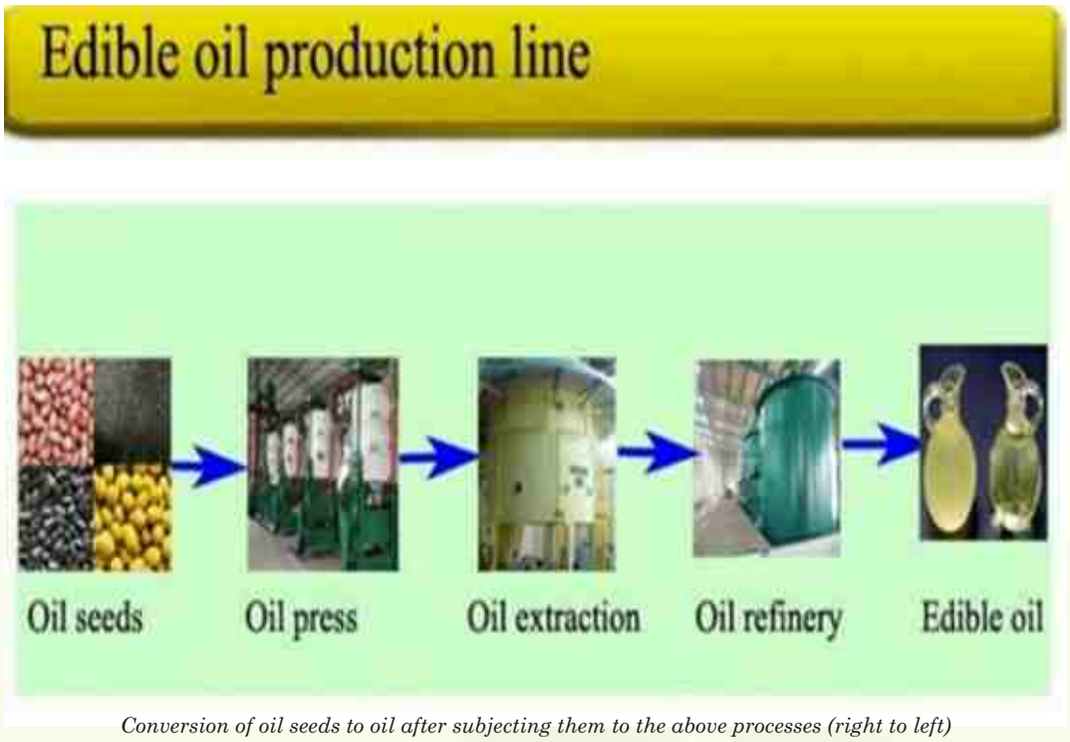
* The addition of the premix, as indicated in the figures below, must only be done post the Deodorization process, either by Batch mixing or by Continuous mixing. Addition of the Vitamin premix prior to complete refinement of the oil will lead to evident deterioration in the vitamin content when the oil is subjected to refinement post fortification.




CONTINUOUS MIXING PROCESS



* The pre-blend is prepared separately and then added to the main oil tank and agitated for uniform mixing.
* The pre-blend must be prepared for use per day and not made and kept in advance.
* The equipment must be adjusted and monitored to deliver the premix without any leakage or delay.
* The premix quality must be checked for a final time before the pre-blend is added to the tank to ensure that there is no deterioration in the quality that might lead to under- or over-fortification.
* The time for mixing for each blender type must be determined and care should be taken to keep the mixing time in control. The samples can be checked at frequent intervals to ensure that there is uniform mixing of the pre-blend (Refer Section IX). Samples must always be carried or stored in opaque bottles and in cool, dry and dark places.
* The oil, once fortified, must be packed immediately as the Vitamins are sensitive to light and oxygen. Packaging of the oil must be done in an opaque container to prevent loss of vitamins during handling and transportation.
* FIFO policy must be followed for packaging and issue of the fortified oil.
* Fortified Oil should contain a label which should specify:
    - Product brand
    - Batch number
    - Address of responsible entity
    - Date of production
    - Shelf-life
    - Declared Levels of Vitamin A and D
* Various SOPs are employed for periodic assessment of the Quality of the Fortified Oil (Refer Section VIII).
* The following are the methods of Quality Control of Fortified RBD Oil:
    - Proper records must be maintained for the Quality Assurance procedures during the procurement and production of the oil.
    - Records must be maintained to check for the Quality Assurance during the procurement, handling, storage and issue of the premix.
    - Records must be maintained for the Quality Assurance practices during the Fortification process.




*Conversion of oil seeds to oil after subjecting them to the above processes (right to left)*

## FACTS

**SOYBEAN OIL**

* Soybean oil is one of the chief poly-unsaturated cooking oils in current usage.

* It is one of the cooking oils with high smoke points; 495 °F, similar to peanut oil, the property which can be employed in setting oil temperature while deep frying food items.

* Soybean oil has a very good lipid profile. It has saturated, monounsaturated and polyunsaturated (SFA: MUFA: PUFA= 16: 24: 58) fats in healthy proportions.

* It is one of the stable cooking oils; having a long shelf life.

* It contains Linoleic acid (omega-6) is the major poly-unsaturated fatty acid found in it. Additionally it is low in saturated fats, and free from cholesterol;

* Soybean, being a vegetable oil, is a good source of plant sterols, especially ß-sitosterol.

* The oil has vitamin K in high concentrations.

# STANDARD OPERATING PROCEDURE FOR TESTING OF FORTIFIED RBD OIL

A Standard Operating Procedure is a written procedure prescribed for repetitive use as a practice, in accordance with agreed upon specifications aimed at obtaining a desired outcome. The following is the SOP for testing of Vitamin A content in Fortified RBD oil:

## RAPID CARR-PRICE METHOD FOR QUALITATIVE TEST OF VITAMIN A CONTENT IN FORTIFIED RBD OIL (ALSO KNOWN AS THE RING TEST)

The Carr-Price Method has been the classical method for Qualitative Analysis of Vitamin A.

**Aim and Scope**

To determine the content of Vitamin A in Refined Bleached Deodorized Edible Oil.

**Principle**

When Fortified RBD Oil is added to a solution of Chloroform saturated with Antimony Trichloride (Carr-Price Reagent), the Vitamin A in the oil reacts with it to yield a transient blue coloured complex. The intensity of the colour is directly proportional to the Vitamin A concentration in the oil, but the reaction does not differentiate between retinyl esters and retinol isomers.

**Reagent Preparation**

The Carr-Price Reagent (Antimony Trichloride Reagent in Chloroform) is prepared by dissolving 105-115g of Antimony in 500ml of Chloroform. The solution is then filtered and kept well covered in a dark bottle.

**Procedure**

- 10ml of Carr-Price reagent is taken in a test-tube.
- 15ml of Fortified RBD oil is slowly added to it.

- The tube if kept straight hinders the formation of a ring at the interface and is hence slightly tilted at an angle of 45 degrees to ensure occurrence of the green-blue coloured ring at the interface.
- The occurrence of the green-blue ring at the interface indicates the presence of Vitamin A in the Oil sample.

**Precautions**

- Proper safety masks and goggles must be worn while testing.
- The Antimony Trichloride reagent must not be inhaled and must be handled carefully.

*Fortified RBD Sample*

*Antimony Trichloride Reagent*

*Pouring Oil Sample into a Test Tube*

*Pipetting Antimony Trichloride Reagent*

*Pouring 10ml of Reagent into a Nessler's Tube*

*Adding 15ml of Oil Sample into the Reagent*

*Formation of Blue-Green ring at the Interface*

*Blue Colouration*

*(For SOP Templates for record of Quality control of Fortificants and Premix, Refer Appendix 2)*

### SAMPLING PLAN LOG SHEET

| Description of Sample | Frequency of Sampling | Number of Test Samples | Quantity of each Sample (gm) | Sampling by |
|---|---|---|---|---|
| * Sampling of Edible Oil for Ring Test | Batch wise | | Not less than 50ml | Mill's Quality Staff |
| Sampling of Edible Oil for Regular (Primary) Sample | Once in a day | | Not less than 50ml per day | Mill's Quality Staff |
| **Sampling of Edible Oil from Storage - from randomly collected bottle | Twice a month | Two from each industry/ month Random selection | Each part should not less than 0.5ltr | External Representative |
| Sampling of Edible Oil from Market | During monthly visit | Ten samples at random from the market per month | Each part should not less than 0.5ltr | External Representative |

** Ring test is conducted once every 3 hours and a record of it is maintained – responsibility of the Quality Staff of the producer.*

*** Collect one sample once in 15 days, for verification by quantitative estimation – responsibility of the project unit.*

## SAMPLING PROTOCOLS AND PROCEDURES FOR FORTIFIED RBD OIL

The process of sampling ensures Quality Control as it consists of representative samples from each batch of oil that is refined and fortified in the mill.

* Samples must always be collected from the packaging area (post refinement and fortification).
* The Samples, Sampling Containers and the Instruments used should be kept clean and free from possible contaminants.
* 0.5L retailer bottles must be utilized for the collection of sample and all sample information must be mentioned on the bottle (Name of mill, Date, Time, Batch number, Quantity, Signature of QA/QC personnel).
* The Sampling should be done for batches with the FIFO method.
* The Samples must be kept in opaque bottles, away from sunlight and possible contamination.
* Each sample bottle should contain an air space of about 5-10% of the total space of the bottle.

* Samples must only be handled by authorized personnel and should not be placed in any of the processing sections.
* Once the sample is tested, if positive, the remaining sample is added to the final production line, and if negative, should be resent to the fortification section.
* The first batch of the day should only be tested after two hours of continued production, to ensure that the fotificant mixes uniformly in the oil. If more than one batch is fortified and packaged in a day, each batch must undergo the ring test.

## REGULATORY REQUIREMENTS

Various Orders and Regulatory Acts were repealed with the declaration and advent of the Food Safety and Standards Act (FSSA) of 2006. With the exit of the Prevention of Food Adulteration Act of 1954, The Essential Commodities Act of 1954, Solvent Extracted Oil, De-oiled meal and Edible Meal (Control) Order of 1967, Vegetable Oil Product Order of 1998 and the Edible Oil Packaging (Regulation) order of 1998, the Control orders of all of these acts were overtaken by the FSSA. Some of the vital reasons for the time-to-time institution of these acts were:

* To regulate and govern the Manufacture, Quality, Distribution and Movement of extracted oils.
* To ensure that oil does not reach the consumers before refinement and before it conforms to the quality standards set for it.
* To ensure that the solvent used for extraction (Hexane) conforms to the regulated specifications, to prevent any potential cross contamination.
* To ensure that the Specific Labelling Requirements were met for all oil products like Vanaspati, Shortenings, Refined and Blended Edible oils, Fat spreads, Margarine.
* To ensure that Good Manufacturing and Hygiene practices were employed during the manufacture or processing of all oil products.

With the advent of the FSSA in 2006, all of these acts were repealed and the control was taken over by the FSSA to ensure safe and good quality oil products reach the consumer.

## AGMARK

The FSSA declared that all vegetable oils should only be sold in the market if they are certified with AGMARK, which certifies Refined and Blended vegetable oils when they adhere to the Blended Edible Vegetable Oils Grading and Marking Rules of 1991.


*AGMARK CERTIFICATION LOGO*

The following are the regulatory aspects for the grant of Certificate of Authorization: *("Certificate of authorisation" means a certificate issued under the General Grading and Marking Rules, 1988)*

* An authorised packer shall take all precautions to avoid contamination of edible vegetable oils with lead or zinc during processing, storage and packing.
* If an authorised packer handles more than one type of vegetable oils in the same premises, adequate precautions shall be taken by him to avoid the mixing of different oils.
* An authorised packer shall make such arrangements for testing vegetable oils as may be prescribed from time to time by the Agricultural Marketing Adviser. He shall also maintain proper records of the analysis of samples.
* All instructions regarding method of sampling and analysis, sealing and marking of containers and the maintenance of records etc. which may be issued from time to time by the Agricultural Marketing Adviser, shall be strictly observed.
* Each container of approved packing material shall be filled with oil from one storage tank or tank wagon only.

## Vegetable oils Packing and Marking Provisions:

**Packing provisions:**

* Vegetable Oils shall be packed either in new, sound, clean and rust free tins or in clean bottles., mild steel drums, railway tank wagons or in approved clean and new thermo plastic containers/ flexible packs like pouches, cans, bottle jars etc.
* The plastic containers shall be manufactured out of food grade plastic materials permitted under Prevention of Food Adulteration rules, 1955.
* The Vegetable Oils shall be packed in the standard size namely, 100gms, 200gms, 5OOgms, 1Kg, 5Kgs and thereafter in multiples of 5 Kgs net weight. The edible vegetable oils may also be packed in corresponding volumetric packing expressed in millilitres or litres along with their weights in gems/krs as the case may be.
* The containers of oils shall be free from any contaminants and shall not be composed of whether wholly or in part, any poisonous or deleterious substance which renders the contents injurious to health.
* The container of oils shall be free from insect infestation, fungus contamination or any obnoxious and undesirable smell.
* The packing shall be done in the manner prescribed for different types of packing,

**Marking provisions:**

* The grade designation mark shall be securely affixed to each container in a manner approved by the Agricultural Marketing Adviser. In addition to the grade designation mark, the following particulars shall also be clearly and indelibly marked on each container:
    - Name of packer
    - Place of packing (business address)
    - Tank filling number
    - Date of packing in plain letters (the date of packing shall be the date of completion of analysis of the sample.)
    - Net weight /volume (wherever applicable)
* Sale Price of the Retail package
* An authorised packer may after obtaining the prior approval of the Agricultural Marketing Adviser or an officer authorised in this behalf, mark his private trade mark on a container in a prescribed manner; provided that the private trade mark does not represent quality or

grade of the Vegetable Oil different from that indicated by the grade designation mark affixed on the container in accordance with these rules.

* The conditions set out in Schedule III shall be the conditions of every Certificate of Authorisation issued for the purpose of these rules.

*(For details regarding the regulations for individual vegetable oils,* refer http://agmarknet.nic.in/vogmrule.htm#main )

## THE LEGAL METROLOGY ACT AND LEGAL METROLOGY PACKAGED COMMODITIES ACT (2009 & 2011)

The various parameters and their specified declarations are listed in the table below. If the following rules are not conformed to, the Manufacturer/Packer/Importer can be fined with up to Rs. 25000/- and for any second offence can be fined up to Rs. 50000/- subsequently followed by a fine of Rs.100000/- or Imprisonment if breaching of the rules is continued.

| | |
|---|---|
| **Registration of Manufacturer/Packer/Importer** | Every individual or firm that pre-packs or imports edible oil for sale/distribution should make an application to the Controller or Director with a fee of Rs.500/- for getting his name and complete address registered *(Refer Rule 27 of the Rules of the Act).* |
| **Quantity Specifications** | No Regulatory Restrictions on Packages of weight/Volume below 50g/50ml. Above which only net quantities of 100g/ml, 175g/ml, 200g/ml, 250g/ml, 300g/ml, 750g/ml, 1kg/ml, 2kg/ml, 3kg/ml, 5kg/ml and then multiples of 5kg/ml are permitted. |
| **Retail Package Details** | Name and Address of manufacturer/packer, Name of brand, Name of Product, Net Quantity, Maximum Retail Sale Price, Date of manufacture, Batch Number should be mentioned. |
| **Area Surrounding the Net Quantity on the Package** | Area surrounding net quantity must be empty for: twice the height of the number on the sides and at least the height of the number on the top and bottom. |
| **Size, Letters and Appearance Area** | The display should be on the main display panel and must be evident and legible. |

*Table Cont.*

| | |
|---|---|
| **Wrapper/External Cover** | Unless the external wrapper of a package is transparent enough to read the specifications if they are on the inner package, the external cover must contain the specifications as mentioned for the retail package above. |
| **Language** | The package must contain the information declared either in English or Hindi (Devnagari). Other languages can be used in addition to Hindi/English. |
| **Exemption for Retail Package** | Packages above 25kg or 25 litres and packages meant for Industrial Users. |
| **Wholesale Package** | Name and Address of manufacturer/packer/ importer, Number of Retail Packages inside, Identification for the commodity inside the package. |
| **Exemption for Packages** | Package containing Fast food items from a Restaurant/Hotel, When Net Weight of the commodity inside is less than 10g/ml, Agricultural package weighing over 50kg, |
| **Advertisement** | Any advertisement publicizing the Retail price of the Commodity should also declare the Net Quantity of the commodity. |

## FOOD SAFETY MANAGEMENT ELEMENTS

**LIST**

A. Documentation requirements

B. Management Responsibilities

   i. Food Safety Policy and Objectives

   ii. Responsibilities and Authority

   iii. Food Safety Team Leader

   iv. Communication

   v. Management Reviews

C. Internal Audit

D. Customer Complaints

E. Corrective Actions

F. Improvement

# A. DOCUMENTATION REQUIREMENTS

## PROCEDURE FOR CONTROL OF DOCUMENTS

### 1. Purpose

To ensure controlled and consistent preparation, dissemination and retrieval of documents relating to the Organization's Food Safety Management System (FSMS).

### 2. Kinds of documents

**Food Safety Management System manual** - This manual is the primary document which defines the authority's definition on requirements of FSMS to be implemented by an organization.

**Standard operating Procedures (SOP)** - It is a procedure specific to policies and standards needed in the operation.

**Forms and Formats**- They are a kind of documents needed to record the implementation of a standard operating procedure.

**Work Instructions (WI)** – It is a step by step process in which the instructions for performing any procedure are directed.

**Specifications Manual**- It specifies the conditions of a system such as temperature, humidity, hygiene etc. and standards for individual food commodity like finish products i.e. oil, raw materials, ingredients etc.

**Testing Manual** – A manual which contains testing method or procedure to perform the test such as free fatty acid & Vitamin A detection in fortified oil.

**Note: A unified numbering system is followed for the entire documented FSMS.**

### Document Preparation and Identification

Documents except the System Manual, originate from their respective functional heads. The documents are prepared on a prescribed format by those who perform the activities. Thus, the ownership of the document rests with the concerned functional heads.

The key elements of any document are

* Document name
* Document number
* Revision number

* Organization name and location
* Prepared by
* Approved by
* Last Updating date

**Identification of change**

In the event of a change in a page of any Management system document and formats, only issue status and date of that page will change. Version number of management system manual will be changed when entire manual is reviewed and revised.

**Approval of document**

**Approval**-The documents are reviewed for their accuracy as well as for adequacy and approved before they are issued by the food safety team leader to the controlled copy holders and other users in the organisation.

**Control of documents**

* The responsibility/ ownership of various kinds of documents can be described in a master list.
* The overall responsibility of document management can be by the document manager.

**Dissemination / distribution of documents**

Document with current data shall be distributed to different department of an organization either manually or automatically.

**Retention of obsolete documents**

The obsolete documents are promptly removed from the place of use at the time of issue of amended or new version of documents. The holders of the original documents are requested to return obsolete documents. A copy of all obsolete documents can be controlled for knowledge preservation and/or legal purposes. Rests of the copies are suitably disposed off.

**Review of documents**

Mechanization should be designed to review the documents and ensure its continued applicability. All the documents are reviewed in case of changes and updation.

**Master lists of documents**

**Master list of Management System document**- It indicates the current

status of the documents which is prepared and maintained. This list is amended when a system document is amended, revised or corrected.

**Master list of documents of external origin**- It includes Legal documents, applicable Association level, National, Regional, International Standards can also be maintained.

## PROCEDURE FOR CONTROL OF RECORDS

### 1. Purpose

* To provide evidence of conformity to requirements.
* Evidence of the effective operation of the food safety management system.
* Ensure proper identification, up gradation, storage, protection, retrieval, retention time and disposition of records.

### 2. Procedure

Records shall be maintained to demonstrate effective operation of the activities. All records /formats are identified and a master list of records is prepared.

While master list of all records/formats is maintained by FSTL, concerned records are maintained in the sections.

### Storage

Records are stored in appropriate locations. They are segregated and placed on identified places. Electronic copies of records, if maintained are backed up regularly.

While current records remain in the section, old records are centrally maintained with due identification for easy retrieval when needed.

### Protection

The records are preserved in such a way that they are readily accessible and do not get damaged. They are protected from insect pest damage, dampness and seepage. Record room is inspected to check that they are not damaged.

### Retrieval

Records are identified, indexed and stored in such a way that they are easily retrieved when needed.

**Retention Time**

The retention time for each kind of record is specified in the master index. The retention period is governed by:

* Statutory and regulatory requirement,
* Requirements of contract if any,
* Shelf life of products plus one-two month.

**Disposition**

After the retention period, the records are disposed of. The manner of disposition depends on the sensitivity of the data and information contained in it.

## B. MANAGEMENT RESPONSIBILITIES

**Management commitment**

The organization should

* Establishing a Food safety policy and ensuring that the key objectives shall be established in line with the business continuity of the organization.
* Communicating to the organization the importance of meeting the standard requirements, customer requirements for food safety as well as statutory and regulatory requirements.
* Ensuring the availability of appropriate resources.
* Conducting planned management reviews.

**Food Safety Policy**

**The Food Safety Policy Should be**

* Appropriate to the role of the organization in the food chain
* Complying with all applicable statutory and legal regulatory requirements and with mutually agreed food safety requirements of the customer
* Reviewing the food safety policy periodically for its suitability
* Communicated, implemented and maintained at all levels of organization.
* Is used to define measurable objectives

**Responsibility and Authority**

Responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the food safety.

All personnel shall have responsibility to report problems to identified person(s). Designated personnel shall have defined responsibility and authority to initiate and record actions.

**Food Safety Team Leader**

Responsibilities include

* Managing the food safety team and organize its work.
* Ensure relevant training and education of the food safety team members.
* Ensures that the food safety management system shall be established, implemented, maintained and updated.
* Report to the organization's top management on the effectiveness and suitability of the food safety management system.

## PROCEDURE FOR COMMUNICATION

**1. Process for Internal Communication**

The different channels of internal communication are team briefing and meetings such as steering committee meetings, food safety team meetings and their minutes, in-office circulars communicating and retrieving documents such as food safety manual, food safety procedures and work instructions.

The organization shall ensure that food safety team is informed in a timely manner of changes, including but not limited to the following:

* Production premises, location of equipment, surrounding environment.
* Raw materials, ingredients, packaging and their storage system.
* Cleaning, sanitation and equipment maintenance.
* Personnel qualifications, knowledge regarding food safety hazards and control measures.
* Customer complaints and feedbacks.
* Finished product and new product.
* Relevant enquiries from external interested parties.

**2. Process for External Communication**

To ensure that sufficient information on issues concerning food safety is available throughout the food chain, the organization should establish, implement and maintain effective arrangements for communicating with:

* Supplier and contractors for certification, standards, quality and cost, availability etc. of raw material and other food items.
* Customers/Consumers in reference to product information, enquires and customer feedback including customer complaints.
* Statutory and regulatory authorities ,
* Any other organization that have an impact on, or will be affected by, the effectiveness or updating of the food safety management system.

Designated personnel shall have defined responsibility and authority to communicate externally any information concerning food safety. Information obtained through external communication shall be included as input to system updating and management review.

Records of the communications are maintained by the concerned personnel and information is used in updating the system and also discussed as input in management review.

## PROCEDURE FOR MANAGEMENT REVIEW

Management reviews are periodically conducted to ensure continuing suitability, adequacy, effectiveness and opportunities for improvement and the need for changes in food safety system

This review includes assessing opportunities for improvement and the need for changes to the food safety management system, including the policy and objectives.

**Review Input**-The inputs to management review include information on:

* Follow up actions from the previous management reviews
* Analysis of results of verification activities like internal and external audits.
* Process performance like of the cleaning process, oil refining process, packaging process and product conformity based on testing of refined oil.
* Changing circumstances that can affect food safety like changes in the product recipe and process conditions.
* Reviewing results of system- updating activities on every management review meeting which includes Food safety policy and objectives, Legal and Regulatory requirements on compliances.

* Review of customer feedback including complaints.
* Status of corrective actions: - actions implemented through the period, and the status of pending actions.
* Review of non-confirming product and out of specification product.
* Emergency situations, accidents and withdrawals including product recall, if any.

The data shall be presented in a manner that enables top management to relate the information to stated objectives of the food safety management system

**Review Output** The output from the management review include decisions and actions related to:

* Improvement of final product in terms of content, packaging and Quality.
* Revision of the organization's food safety policy and related objectives.
* Recommendations for improvement: - The Management Representative presents the data and demonstrates the progress toward achieving continual improvement goals, and reviews current and completed improvement projects.
* Assurance of food safety.
* Review of resource management.
* Records of management reviews are maintained and follow up actions planned.

## C. INTERNAL AUDITING

### 1. Purpose of an Internal Audit

* Continual Improvement &Updating the Food safety management safety.
* Emphasis on defect prevention.
* Reduction of variation &waste in supply chain.

### 2. Selection of an Internal Auditor can be based on the following

* Experience
* Brief understanding
* Education
* Communication skills
* Trained

## 3. Procedure

### Planning the audit

* An audit program of food safety procedure system shall be planned, taking into consideration the status and importance of the processes and the area to be audited, as well as the results of previous audits. The plan must make efficient use of time and should be flexible.
* An audit team should be independent of the audit area.
* Audit schedule drawn from audit program indicate the auditor(s) responsibilities for performing audit, audit dates and audit departments for each audit. The concerned head of department shall be notified of the exact date of the audit.

### Scheduling of Internal Auditing

Scheduling of internal auditing is one of the most important aspects of auditing. Company shall establish this schedule prior to auditing in order to get all the information related to the date, duration and the month of auditing. Moreover the name of the auditor and process shall be mentioned in the format.

### Conducting the audits

* The auditors are selected to audit functions other than their own work to ensure objectivity and impartiality of the audit process. The auditor will go through audit procedures in areas identified for audit and gathers evidence.
* The auditor will evaluate food safety management system and establish the conformity or nonconformity of the processes in operation.
* During audit the factory visit should be maintained in a suitable condition for food production.

### Reporting the audit

* The purpose is to review audit findings in a collection manner to avoid making wrong audit conclusions.
* Report (Non conformity report) should be written on the prescribed format by the auditor indicating corrective action proposal by the auditee and NCR shall be submitted to the auditee.
    - The auditor will do a closing meeting to share the internal audit NC's (non conformity).
    - Internal audit reporting may also indicate areas for improvement as well as area of outstanding performance.

### Do's & Don'ts of an Auditor

| DO'S | DON'TS |
|---|---|
| Punctual | Late |
| Calm and friendly | Too friendly |
| Focused | Influenced by anyone |
| Trustworthy | Give false data |
| Knowledgeable and confident | Pessimistic or doubtful |
| Unbiased | biased |
| Good listener | ignorant |

## D. CUSTOMER COMPLAINTS

### 1. Purpose

To ensure proper handling of product complaints and to minimize their recurrence.

### 2. Procedure

* When a customer complaint is received, it receives the highest priority and authority.
* The complaint is registered and complaint history sheet is opened with all available details.
* Complainant is acknowledged after the receipt.
* Investigation starts with:
  - Analysis of complaint sample from the complainant or bought from the market from the same batch as complainant sample.
  - Visiting the complainant by a technical person for discussion to acknowledge more information.
  - Referring/ forward the complaint to production and quality control and when the results of investigation come out they are discussed and investigated to find the root cause of the problem.
  - After the complaints results of investigation come out they are discussed and necessary Correction and corrective actions are taken to prevent recurrence of such complaints.
  - The complainant is informed of the action taken on his/her complaint and appropriate replacement/compensation provided.
  - The complaint history sheet is completed and complaint is closed.

### 3. Procedure of Corrective actions

The organization shall establish and maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process or system back into control after nonconformity is encountered. These actions include:

* Reviewing nonconformities including customer complaints.
* Reviewing trends in monitoring results that may indicate development towards loss of control.
* Determining the cause(s) of nonconformities.
* Evaluating the need for action to ensure that nonconformities do not recur.
* Determining and implementing the actions needed.
* Recording the results of corrective actions taken.
* Reviewing corrective actions taken to ensure that they are effective.

Records of corrective will be maintained

## E. CORRECTIVE ACTIONS

### 1. Correction

Identification and separation of all edible oil products that do not meet the requirements of safety, quality or regulations is necessary to prevent their accidental usage, which might lead to customer illness/injury and can cause derogatory effects on the business.

The most efficient way to evidently identify them is with the use of identification marks/stickers and controlled with regard to their use and release.

A documented procedure shall be established and maintained defining

a) the identification and assessment of affected end products based on the cause of non-conformity , consequences in terms of food safety and proper handling of potentially unsafe product.

b) a review of the corrections shall be carried out .

All corrections shall be approved by the responsible person(s), and shall be recorded together with information on the nature of the nonconformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots.

**2. Corrective actions**

Data derived from the monitoring of operational PRPs and CCPS shall be evaluated by designated person(s) with sufficient knowledge and authority to initiate corrective actions.

Corrective actions shall be initiated when critical limits are exceeded or when there is a lack of conformity with operational PRP(s).

The organization shall establish and maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process or system back into control after nonconformity is encountered. These actions include

* reviewing nonconformities (including customer complaints),
* reviewing trends in monitoring results that may indicate development towards loss of control,
* determining the cause(s) of nonconformities,
* evaluating the need for action to ensure that nonconformities do not recur,
* determining and implementing the actions needed,
* recording the results of corrective actions taken, and
* reviewing corrective actions taken to ensure that they are effective.

Corrective actions shall be recorded

**3. Handling of potentially unsafe products**

The organization shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that

a) the food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels,

b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain, or

c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

All lots of product that may have been affected by a nonconforming situation shall be held under control of the organization until they have been evaluated.

If products that have left the control of the organization are subsequently determined organization shall notify relevant interested parties and initiate a withdrawal to be unsafe.

The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.

**Evaluation for release**

Each lot of product affected by the nonconformity shall only be released as safe when any of the following conditions apply:

* evidence other than the monitoring system demonstrates that the control measures have been effective;
* evidence shows that the combined effect of the control measures for that particular product complies with the performance intended (i.e. identified acceptable levels as identified)
* the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned.

**Disposition of nonconforming products**

Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities:

* reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels
* destruction and/or disposal as waste.

**Withdrawals**

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe

* top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal, and
* the organization shall establish and maintain a documented procedure for
    - notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
    - handling of withdrawn products as well as affected lots of the products still in-stock, and
    - the sequence of actions to be taken.

Withdrawn products shall he secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they-become safe.

The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review.

The organization shall verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques ( e.g. mock withdrawal or practice withdrawal)

## F. IMPROVEMENT

**1. Continual improvement**

The organization shall continually improve the effectiveness of the safety management system through the active use of communication, internal audit, analysis of results of verification activities, validation results of the control measures, corrective actions, management reviews and food safety management system updation.

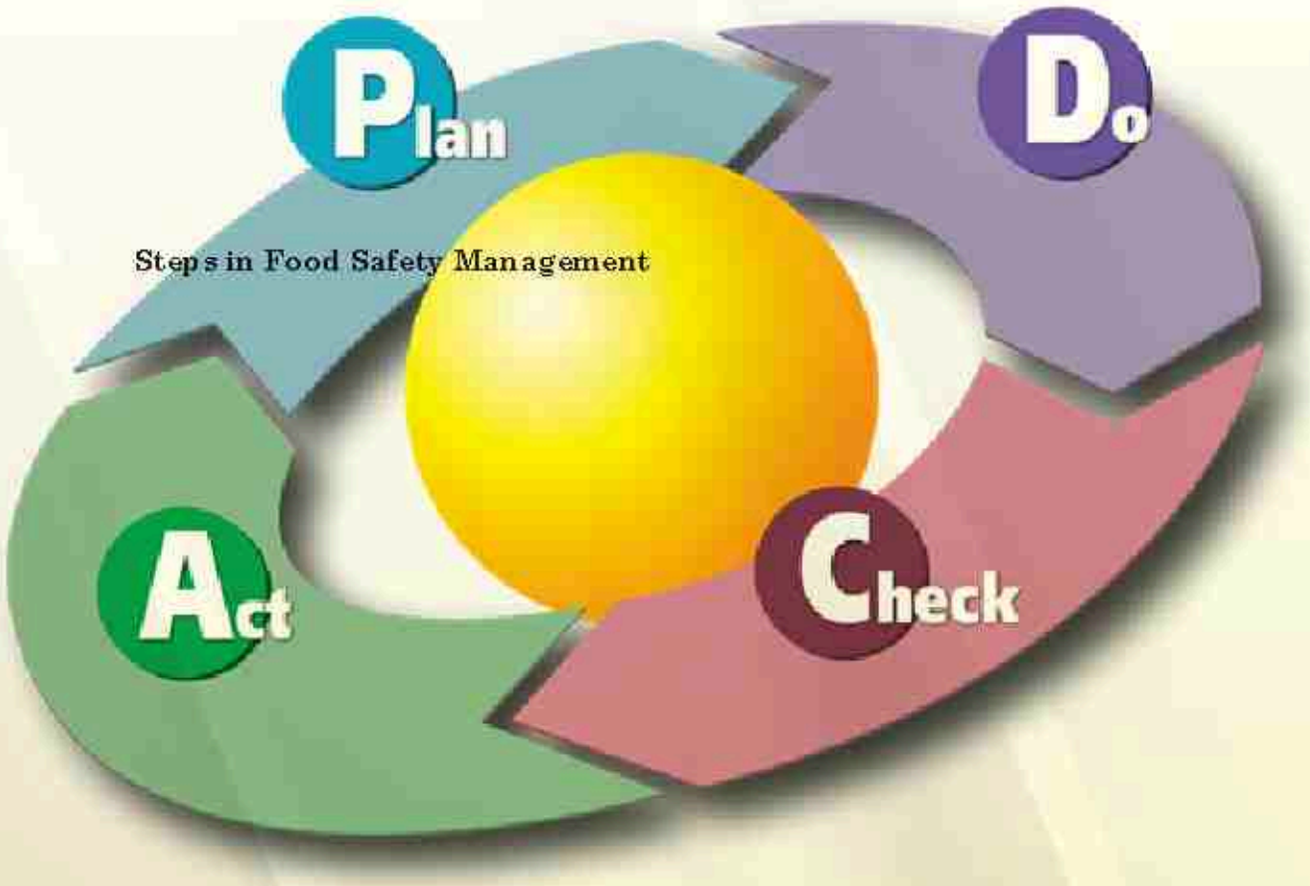
**2, Updating the food safety management system.**

The organization should periodically evaluate (typically once in a year) the need of reviewing the hazard analysis, the established OPRPs and the HACCP plan.

The evaluation and updating activities should be based on the following:

* Input from communication, external as well as internal.
* Input from other information concerning the suitability, adequacy and effectiveness of the food safety management system.
* Output from the analysis of results of verification activities.
* Output from management review.

Records to be maintained for System updating activities and reported as necessary.




Steps in Food Safety Management

## FACTS

**Evolution of Food Safety and Quality Systems**

* The Food Safety and Quality Systems include:
  - Good practices and GlobalGap/EurepGap
  - Quality management system - ISO 9000 standards and HACCP principles
  - Farm - to - fork strategy
* The technical limitations in implementation of these systems is a challenge in meeting food safety requirements
* The larger number of stakeholders in the food system is also a challenge to the management of farm -to folk approach.

# Appendix 1

## A. Saturated Fatty Acids and their Sources

| Common Name of Acid | Number of Carbon Atoms | Melting Point °C | Typical Fat source |
|---|---|---|---|
| **Butyric Acid** | 4 | -7.9 | Butterfat |
| **Caproic Acid** | 6 | -3.4 | Butterfat |
| **Caprylic Acid** | 8 | 16.7 | Coconut Oil |
| **Capric Acid** | 10 | 31.6 | Coconut Oil |
| **Lauric Acid** | 12 | 44.2 | Coconut Oil |
| **Myristic Acid** | 14 | 54.4 | Butterfat, Coconut Oil |
| **Palmitic Acid** | 16 | 62.9 | Most Fats and Oils |
| **Margaric Acid** | 17 | 60 | Animal Fats |
| **Stearic Acid** | 18 | 69.6 | Most Fats and Oils |
| **Arachidic Acid** | 20 | 75.4 | Groundnut Oil |
| **Behenic Acid** | 22 | 80.0 | Groundnut Oil |

## B. Unsaturated Fatty Acids and their Sources

| Common Name of Acid | Number of Carbon Atoms | Melting Point °C | Typical Fat source |
|---|---|---|---|
| **Caproleic Acid** | 10 | - | Butterfat |
| **Lauroleic Acid** | 12 | - | Butterfat |
| **Myristoleic Acid** | 14 | 18.5 | Butterfat |
| **Palmitoleic Acid** | 16 | - | Some Fish Oils |
| **Oleic Acid** | 18 | 16.3 | Most Fats and Oils |
| **Elaidic Acid** | 18 | 43.7 | Partially Hydrogenated Oils |
| **Vaccenic Acid** | 18 | 44 | Butterfat |
| **Linoleic Acid** | 18 | -6.5 | Most Vegetable Oils |
| **Linolen ic Acid** | 18 | -12.8 | Soybean Oil, Canola Oil |
| **Gadoleic Acid** | 20 | - | Some Fish Oils |
| **Arachidonic Acid** | 20 | -49.5 | Lard |
| **Eicosapentanoic Acid** | 20 | - | Some Fish Oils |
| **Erucic Acid** | 22 | 33.4 | Rapeseed Oils |
| **Docosahexanoic Acid** | 22 | - | Some Fish Oils |

## Commonly used Oils and their Smoking Points

| Type of Oil | Smoke Point in Degrees Fahrenheit (For Standard Oils) |
|---|---|
| **Canola oil (refined retail variety)** | 470 |
| **Pomace olive oil** | 460 |
| **Palm oil** | 455 |
| **Coconut oil (refined retail variety)** | 450 |
| **Corn oil (refined retail variety)** | 450 |
| **Peanut oil (refined retail variety)** | 450 |
| **Safflower oil (refined retail variety)** | 450 |
| **Soybean Oil (refined retail variety)** | 450 |
| **Sunflower Oil (refined retail variety)** | 450 |
| **Virgin olive oil** | 420 |
| **Walnut oil (refined retail variety)** | 400 |
| **Extra virgin olive oil** | 375 |
| **Coconut oil (unrefined)** | 350 |
| **Peanut oil (unrefined)** | 320 |
| **Walnut oil (unrefined)** | 320 |
| **Flax seed oil** | 225 |
| **Safflower oil (unrefined)** | 225 |
| **Sunflower Oil (unrefined)** | 225 |

# Appendix 2

### SOP Template 1

Log Sheet for Quality Control of Fortified RBD Edible Oil

| Project Name: | | | | | | | |
|---|---|---|---|---|---|---|---|
| Date | Batch No. | Batch size | Vitamin A+D Quantity (g) | Premix Preparation Time | | Premix Addition Time | Quality Control Review |
| | | | | Start | End | | |
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### SOP Template 2

Log Sheet for Quality Control of Fortificants while Receiving

| Project Name: | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| S. No. | Date of Receipt | Lot No. | Expiration Date | Supplier COA (Received/ Not Received) | Quantity if Retinol palmitate checked on label | Fortificant containers hermetically sealed | | Remark |
| | | | | | | Yes | No | |
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## SOP Template 3

Log Sheet for Quality Control of Premix for Storage Department

| Project Name: | | | | | | | |
|---|---|---|---|---|---|---|---|
| Date of Receipt | Received | | | | Issued | In Stock (C) (C) = (A)-(B) | Receipting person Name & Signature |
| | Suppliers COA | Cans (A) | Lot ID (Can No.) | Expiration Date | Lot ID (Can No.) (B) | | |
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| Premix(Vitamin A+D) amount on premix container in (m IU/100gm) | | | | Sample Premix(Vitamin A+D) compound tested in laboratory in (m IU/100gm) | | | |
| | | | | | | | |
| Date: | | | | Name and Signature | | | |

## SOP Template 4

Log Sheet for Quality Control of Premix for Storage Department

| Project Name: | | | | | | | |
|---|---|---|---|---|---|---|---|
| Date of Receipt | Received | | | | Issued | In Stock (C) (C) = (A)-(B) | Receipting person Name & Signature |
| | Suppliers COA | Cans (A) | Lot ID (Can No.) | Expiration Date | Lot ID (Can No.) (B) | | |
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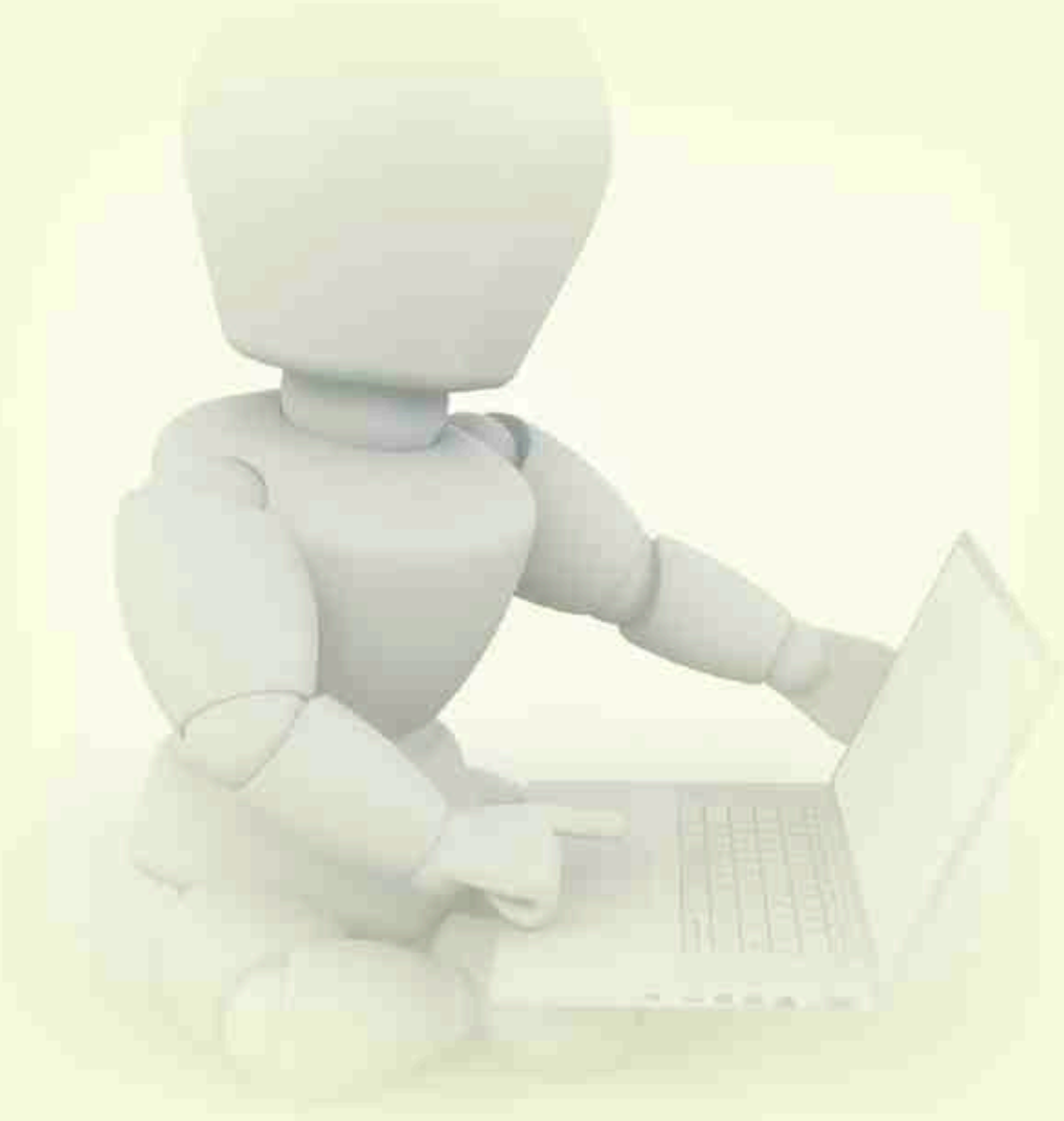
| Premix (Vitamin A+D) amount on premix containerin (m IU/100gm) | | | | Sample Premix(Vitamin A+D) compound tested in laboratory in (m IU/100gm) | | | |
| | | | | | | | |
| Date: | | | | Name and Signature | | | |



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# Notes

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