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CHIFSS
CII-HUL Initiative on Food Safety Sciences

FOOD SAFETY MANAGEMENT SYSTEM (FSMS) GUIDANCE DOCUMENT

FOR MANUFACTURE OF

ICE CREAMS / FROZEN DESSERTS

Prepared by
CII-HUL INITIATIVE ON
FOOD SAFETY SCIENCES (CHIFSS)

CONTENT

Food Safety and Standards Authority of India
Ministry of Health & Family Welfare

Pawan Agarwal, IAS
Additional Secretary &
Chief Executive Officer

FOREWORD

I am delighted to see that on the occasion of inauguration of CII-HUL Initiative on Food Safety Sciences (CHIFSS), a guidance document on Food Safety Management System (FSMS) for Ice creams and Frozen Desserts is being released.

I am equally excited to see that industry, a key stakeholder in food safety, is sharing expertise and contributing to the national food safety agenda.

Food Safety, underpinned by scientific insights, is a progressive approach that prevents foodborne illnesses while ensuring food and nutrition security for the people.

It is our endeavor at FSSAI that food, entering the Indian market, is safe for the consumers and we have taken a number of initiatives in this direction already. In this journey, I am sure if all stakeholders come together, we can achieve a global benchmark in rapidly building a reliable national food safety governance model.

The Guidance document on FSMS for Ice Creams and Frozen Desserts will be a useful document for the Small and Medium Businesses engaged in the manufacturing of Ice Creams and Frozen Desserts in developing their Food Safety Plan.

I sincerely congratulate HUL and CII for this valuable contribution.

(Pawan Agarwal)

FDA Bhawan, Kotla Road, New Delhi - 110 002 | +91 11 23220995 | +91 11 23220996 | ceo@fssai.gov.in | www.fssai.gov.in

ACKNOWLEDGEMENT

Food safety is best achieved when all the stakeholders join hand and contribute in tandem for this noble cause. "Food Safety Management System (FSMS) for Ice Creams/Frozen Desserts" is one such initiative, which we believe will go long way in ensuring the Ice Creams and allied products, produced in India are manufactured with scientifically validated processes that ensures safety for the consumers.

While a large number of people contributed for this document, we would like to extend special thanks to Minakshi Barik, KV Shashi, Nimish Shah and Rajendra Dobriyal from Unilever R&D as well as Meetu Kapur and her team from CII-FACE from Confederation of Indian Industries (CII).

We are also thankful to CEO-FSSAI, Shri Pawan Kumar Agarwal for his constant inspiration and encouragement, especially to contribute to food safety matters.

CHIFSS TEAM

PREFACE

This Food Safety Management System (FSMS) for Ice Creams/Frozen Desserts is prepared with an intent to provide general guidance to manufacturers to ensure that critical food safety related aspects are addressed during the manufacturing process. This document mainly contains pragmatic approaches a business can adopt during manufacture of Ice Creams / Frozen Desserts. However, manufacturers may adopt higher stringency levels, depending on the needs.

It is advised that anyone involved in manufacturing of Ice Creams / Frozen Desserts and allied products is trained appropriately to implement the measures and to demonstrate the behaviors mentioned in the document.

It is to be noted that this guidance document does not intend to replace any legal provisions required by law as applicable from time to time. Further, wherever the provision of this document conflicts with Schedule IV of (regulation 2.1.2) of Food Safety Standards (Licensing and Registration of Food Business Operators) Regulations 2011 or any other regulations, for that matter, the provision given in the regulations shall prevail.

CHIFSS TEAM

ABBREVIATIONS

CCP
Critical Control Point

FSMS
Food Safety Management System

HACCP
Hazard Analysis & Critical Control Point

HTST
High Temperature – Short Time (method of pasteurization)

QA
Quality Assurance

ISO
International Organization for Standardization

GMP
Good Manufacturing Practice

GRR
Goods Received Record

PHE
Plate Heat Exchanger

DEFINITIONS

LOT

Amount of Ice cream/Frozen dessert produced at one time (maximum 24 hours) from one set of materials under the same conditions.

BATCH

An amount of food or materials having the same code.

CLEANING

The removal of soil, food residues, dirt, grease or other objectionable matter.

CONTAMINATION

Unintended ingress of microbial pathogens, chemicals, foreign bodies, spoilage agents, objectionable taints and unwanted matter, into the product and/or process.

CRITICAL CONTROL POINT (CCP)

A step at which control can be applied (and is essential) to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

DESIGN CONTROL POINT (DCP)

A step where the study of a conceptual line design, process design or plans and lay-outs identified the need for control and where there is a need for a food safety hazard to be eliminated or reduced to an acceptable level.

DISINFECTION

Also called sanitation, is the reduction, by means of chemical agents and / or physical methods, of the number of microorganisms to a level that does not compromise food safety or quality.

FROZEN DESSERTS

Frozen Dessert means the product obtained by freezing a pasteurized mix prepared with milk fat and / or edible vegetable oils and fat having a melting point of not more than 37.0 degree C in combination and milk protein alone or in combination / or vegetable protein products singly or in combination with the addition of nutritive sweetening agents e.g. sugar, dextrose, fructose, liquid glucose, dried liquid glucose, maltodextrin, high maltose corn syrup, honey, fruit and fruit products, eggs and egg products coffee, cocoa, chocolate, condiments, spices, ginger, and nuts. The said product may also contain bakery products such as cake or cookies as a separate layer/or coating, it may be frozen hard or frozen to a soft consistency.

HAZARD

The potential to cause harm to people or the environment by a food or its manufacture. Hazards can be biological, chemical & physical.
The potential to cause harm to people or the environment by a food or its manufacture. Hazards can be biological, chemical & physical.

ICE CREAM

Ice Cream, means the product obtained by freezing a pasteurized mix prepared from milk and /or other products derived from milk with or without the addition of nutritive sweetening agents, fruit and fruit products, eggs and egg products, coffee, cocoa, chocolate, condiments, spices, ginger and nuts and it may also contain bakery products such as cake or cookies as a separate layer and/or coating. The said product may be frozen hard or frozen to a soft consistency

MUST

To be implemented immediately, compulsory, mandatory

PRODUCT DESIGN

The integration of raw materials, preservation, processing, packaging labeling and usage to meet manufacturer and customer expectations with respect to safety, quality and shelf-life.

RISK

The likelihood of a hazard resulting in illness or injury.

SHOULD

Strongly advised for current operations and may become mandatory in the future

TRACEABILITY

The degree to which a product or raw material can be traced back to its point of manufacture or supply.

HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP)

A system that identifies evaluates and controls hazards, which are significant for food safety.

1.0 SCOPE

This FSMS guidance document covers the manufacture, storage and distribution of all Ice Creams and frozen desserts including water ice. It deals primarily with food safety and includes guidance on processing, storage, distribution of the same.

2.0 PRE REQUISITE PROGRAMS

Every food-manufacturing unit has to have well implemented pre - requisite programs in place. These need to be appropriated to the organizational needs with regards to the local regulatory requirements

The programs must include:

2.1 FACILITIES, BUILDING DESIGN & LAYOUT

Factory premises, building design, layout, manufacturing and non-manufacturing areas including lighting, heating, ventilation and air conditioning (HVAC) need to be constructed in such a way that it:

- PREVENTS CROSS CONTAMINATION
- ENABLES EFFECTIVE OPERATION, CONTROL, CLEANING, DISINFECTION AND MAINTENANCE
- ENSURES EFFECTIVE CONTROL OF TEMPERATURE, HUMIDITY AND LIGHTING
- PREVENTS PEST ACCESS AND POTENTIAL INFESTATION

2.2 UTILITIES – AIR, WATER, ENERGY

Compressed air used in manufacture for aeration of the product must be clean, dry and free of contaminants. These contaminants can include; dirt, water, oil and micro-organisms. Where air is in direct contact with products or product contact surfaces the quality must meet the criteria of ISO 8573.1.

Where water is used as a product ingredient or for final rinses after cleaning (process water), it must meet potable/drinking water standard. (IS 10500-2012)

Manufacturers must carry out a monitoring program on process water (including microbiological parameters, pesticides and heavy metals) and should be in line with safety limits and legal requirements.

Any buffer and storage tanks must be inspected, cleaned and disinfected regularly.

Steam used directly or indirectly in contact with food must meet drinking water quality requirements.

2.3 PERSONNEL HYGIENE & EMPLOYEE FACILITIES

The facility must provide and meet mandatory hygienic requirements for people, facilities and operations, to protect products from foreign matters and microbiological contamination.

Three levels of risks and associated level of hygiene controls are prescribed:

- GENERAL HYGIENE AREAS
- STANDARD HYGIENE AREAS
- HIGH HYGIENE AREAS

The hygiene control levels assigned to Ice cream/Frozen dessert category manufacturing operations are the following:

- MIX PREPARATION, PROCESSING & AGING AREA: STANDARD HYGIENE LEVEL
- PACKING (PRODUCTION PRODUCT ASSEMBLING): HIGH HYGIENE LEVEL

The hygienic measures applicable to personnel working in production areas must also be applied to contractors / third party workers employed and visitors on technical activities in these areas.

2.4 PREVENTION OF CROSS-CONTAMINATION

The potential sources of contamination at any manufacturing site can be grouped into chemical, physical & microbiological categories. The principle mechanism for contaminant risk management within manufacturing is the use of risk management tools such as HACCP

Manufacturing sites must use risk management tools such as HACCP and must include the prevention of chemical, foreign body like glass and microbiological contamination within the scope of risk management.

2.5 CLEANING & DISINFECTION

Effective cleaning and disinfection is key to ensure high quality & safety standards of the finished products. Validated cleaning and disinfection procedures must be implemented.

Where possible equipment should be cleaned by a Cleaning-in-Place (CIP) system. A CIP system must incorporate the following features:

- EQUIPMENT DESIGNED IN SUCH A WAY AS TO PERMIT EFFECTIVE CLEANING AND DISINFECTION
- CONCENTRATIONS OF CLEANING INGREDIENTS ARE MAINTAINED AT THE CORRECT LEVEL
- TEMPERATURE OF THE CLEANING SOLUTION CIRCULATING IN THE LINE CONTROLLED AND MONITORED AT THE COLDEST POINT

Flow velocity in the lines during pre-rinse and cleaning to provide sufficient mechanical energy for removal of soil should be there. In addition, when chemical disinfection is employed, the contact time and temperature recommended by the law must be met.

Visual inspection of lines (where this is possible) must be carried out prior to production and should include wash tanks, in-line screens and magnets (to prevent cross contamination). Periodic swabs or contact plates should be used to measure actual microbiological levels (monitoring the first product at start-up is an effective measure of cleaning efficiency). Swabbing for microbiological tests should be carried out at a frequency that provides sufficient data for trend analysis.

MANUAL CLEANING

When cleaning in place (CIP) is not feasible, manual cleaning schedules must be prepared, made readily accessible and easy to follow.

DRY CLEANING

For some processes where only dry raw materials are stored or used (for example, dry stores and cone baking areas) dry cleaning methods are preferred over wet cleaning. Vacuum cleaners are suitable for this, if they have an adequate outlet filter to prevent spreading of contamination.

The best approach to prevent the contamination is to maintain the manufacturing area as much dry as possible.

2.6 INTEGRATED PEST MANAGEMENT

All facilities must have a fully documented integrated pest management (IPM) standard operating procedure (SOP).

The IPM SOP must include the following:

- RESPONSIBILITIES FOR BOTH IN-HOUSE PERSONNEL AND THIRD PARTY PEST CONTROL CONTRACTORS
- PREVENTING PEST ACCESS TO THE FACILITY AND PREVENTING PEST CONTROL AGENTS FROM CONTAMINATING PRODUCT, RAW AND PACKAGING MATERIALS AND EQUIPMENT SURFACES
- PREVENTING AND ELIMINATING PEST HARBORAGE WITHIN FACILITIES AND THEIR GROUNDS
- MONITORING POTENTIAL PEST ACCESS AND HARBORAGE
- DETECTION AND MONITORING OF PEST ACTIVITY
    - Specify types of monitoring (mechanical rodent traps, rodent stations, insect light traps, Spider/pest-o-flash, pheromone traps)
    - Monitoring frequencies
    - Monitoring responsibilities

- CORRECTIVE ACTION PROCEDURES FOR
  - Facility maintenance (preventing access)
  - Eliminating actual or potential pest harborage
  - Eradication of pests
  - Responsibilities for corrective action
- VERIFICATION PROCEDURES
- VALIDATION AND PERIODIC REASSESSMENT PROCEDURES
- RECORD KEEPING REQUIREMENTS
- REPORTING REQUIREMENTS

2.7 NON-CONFORMANCE MANAGEMENT

There must be a process used to control non-conforming finished formulation and finished goods, and the mandatory requirements needed to ensure that detection, correction and reporting should be done in an appropriate timeframe.

All corrections shall be approved by the responsible person and should be recorded appropriately, along with its causes

2.8 CORRECTIVE ACTIONS AND RECORDS

- The organization shall ensure that when critical limits for CCP(s) are breached, or there is a loss of control of operations, the products affected are identified and controlled with regard to their use, or release
- Products manufactured under conditions where critical limits have been breached are potentially unsafe products and shall be handled accordingly
- Products manufactured under conditions where operational norms have not been conformed with, shall be evaluated with respect to the cause(s) of the nonconformity and to the consequences thereof in terms of food safety and shall, where necessary, be handled in accordance with handling of potentially unsafe products. The evaluation shall be recorded
- 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.

2.9 TRACEABILITY

Each manufacturing facility has to have 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 shall 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 recall/withdrawal. Records shall be in accordance with statutory and regulatory requirements and customer requirements and may, for example, be based on the end product lot identification. There must be a checklist or audit program in place to cross check the facility, frequently.

2.10 HYGIENIC ENGINEERING & MAINTENANCE

Hygienic design and maintenance is essential for the quality of the products. Furthermore, it is an enabler for optimizing cleaning times and production run length, which in turn can improve costs and sustainability.

There are critical aspects of hygienic design that contributes to safe food manufacturing operations.

- EQUIPMENT DESIGN
- MATERIAL OF CONSTRUCTION
- EQUIPMENT
- PIPING INSTALLATION
- ANCILLARY SUBSTANCES
- MAINTENANCE AND ENGINEERING

3.0 HAZARDS ASSOCIATED WITH ICE CREAM/FROZEN DESSERT MANUFACTURING & HACCP IMPLEMENTATION

Implementing Hazard Analysis and Critical Control Point (HACCP) is crucial for any food manufacturing process. The HACCP plan has to cover the total supply chain, from inbound logistics, through processing, sanitation and maintenance to final use by the consumer. Across the operations, it must be ensured that procedures are available for internal logistics, processing specifications, working instructions, hygiene procedures and preventive maintenance plans. These procedures must cover start-up, shutdown and unexpected stoppages.

Three main types of hazards need to be considered for manufacturing process:

3.1 MICROBIOLOGICAL HAZARDS

The microbiological safety of Ice cream/Frozen dessert is a mandatory consideration. The presence of food-borne pathogens needs to be controlled within specific limits to ensure consumer safety. Also, large numbers of spoilage micro-organisms in raw materials or final products indicate poor process GMP implementation and will result into a poor quality product.

TO ENSURE CONSUMER SAFETY, ICE CREAM/FROZEN DESSERT MUST BE DEVOID OF INFECTIOUS AND TOXIGENIC MICRO-ORGANISMS, AT A LEVEL HARMFUL TO HEALTH AND PROCEDURES MUST BE IN PLACE TO DEMONSTRATE THIS. PATHOGENIC ORGANISMS THAT HAVE BEEN ASSOCIATED WITH ICE CREAM/FROZEN DESSERT AND POST-PASTEURIZATION DOSED INGREDIENTS INCLUDE:

- Listeria monocytogenes
- Salmonella species.
- Escherichia coli (pathogenic strains)
- Staphylococcus aureus (coagulase positive)
- Bacillus cereus

Mould growth needs to be prevented as moulds may produce mycotoxins. Nuts and cereals used in Ice cream/Frozen dessert (post-dosing ingredient and component of cones) are particularly prone to mycotoxins. Allergen protocol **Must** be followed where such ingredients are used.

Risk of Listeria contamination in environment also need to be prevented through proper risk assessment and taking preventive measures. Trend analysis may be the most useful means of exploiting microbiological data. The microbiological counts most frequently used as indicators of Good Manufacturing Practice are the total viable count and the Enterobacteriaceae or coliform count.

3.1.1 MICROBIAL SAMPLING PLAN

Microbial sampling Plan for testing Ice creams and Frozen Desserts should be as per the limits and plan given in relevant table of Appendix-B, of Food Safety and Standards (Food Standards & Food Additives) Regulations 2011.

3.2 CHEMICAL HAZARDS

Chemical hazards are mainly related to:

- CONTAMINATED RAW MATERIALS (E.G. MYCOTOXINS IN NUTS, MILK, FRUITS & PULP, CHEMICAL RESIDUES ETC.)
- INCORRECT USE OF NON-FOOD CHEMICALS (SUCH AS LUBRICANTS OR CLEANING AGENTS)
- TAINTS FROM THE ENVIRONMENT (FOR EXAMPLE AMMONIA, AIRBORNE ODORS OR CHEMICALS)
- MYCOTOXINS FROM FUNGAL GROWTH.

The quality of the incoming raw materials need to be checked in-house for mandatory requirements and can be checked from external lab for presence of any contamination. The supplier assurance of chemical safety can be verified from certificate of analysis of each lot received.

Standard operating procedures need to be in place to avoid contamination where lubricants, cleaning chemicals, coding ink, additives are used in the manufacturing process. Proper cleaning and disinfection of all equipment and environment need to be carried out in such a way that chemical traces must not come in contact with food materials. Proper storage places for all chemicals need to be fixed with proper labelling and usage SOP.

3.3 PHYSICAL HAZARDS

Hazards from foreign bodies such as wood, stones, metal and glass, mainly originate from raw materials and packaging. They can however also be introduced through a poorly designed production process, a poor factory environment or by production and maintenance personnel not following standard operating procedures. Stick products need to be taken care of while production, to avoid ingress of wood splinters from the sticks, into the product.

The risk from contamination from physical hazards must be considered and preventive measures defined to eliminate or reduce the risk to an acceptable level.

3.4 PROCESSING

It is during processing (mix preparation to product assembly and packing) that most of the final product specifications are realized.

Ice cream/frozen dessert manufacturing process may typically involve the following steps.

1. MIX PREPARATION
2. MIX PASTEURIZATION
3. MIX AGING
4. MOLDING/ SHAPING OF THE PRODUCT
5. HARDENING
6. STORAGE

3.4.1 Mix Preparation

Mixing of all ingredients in a high sheer mixer/ homogenizer with proper temperature and time gives a consistent and thorough mixture. There can be different dosing systems for raw materials and manual dosing may also be feasible.

3.4.2 Mix Pasteurization

The mix needs to be pasteurized to eliminate pathogenic bacteria and to ensure quality and shelf life. Different operators, possibly also across different types of formulations, varying pasteurization temperatures may be chosen. However, to ensure safety, pasteurization temperature shall not be below 72oC. It is preferable to employ a high temperature short time (HTST) tube/ plate heat exchanger (PHE) pasteurization. The process can be made more robust by fixing a flow diversion valve (FDV) after the heating cycle. The FDV will ensure the safety of the each batch and material not reaching the desired treatment temperature, is directed back to the pasteurizer. It is mandatory to keep records of each pasteurization cycle and this step is a critical control point (CCP) in the process.

There are restrictions on storage of pasteurized mix:

TABLE 1: STORAGE TIMES FOR PASTEURIZED ICE CREAM MIX

MIX STORAGE TEMPERATURE (°C)	MAXIMUM SAFE STORAGE TIME (HOURS)	MIX STORAGE TEMPERATURE (°C)	MAXIMUM SAFE STORAGE TIME (HOURS)
1	210	2	130
3	108	4	96
5	84	6	72
7	65	8	58
9	50	10	46

Note that temperatures in this table are maximum temperatures - not mean temperatures.

All ice cream mixes, which exceed the maximum recommended storage time should be either discarded or re-pasteurized.

Water Ice Mix Storage

At pH 4.0 or below the growth of bacterial pathogens is unlikely to occur and the main microbiological risk is spoilage by fungi (yeasts and moulds). Water ice may be stored for up to one week provided:

STORAGE TEMPERATURE IS ≤ 5ºC.

MIX IS ≤ pH 4.0.

Initial levels of contamination are minimal (handled hygienically).

Under these conditions the growth of bacterial pathogens will not occur, and significant growth of spoilage organisms, including yeasts and molds, is very unlikely. (Also refer to Appendix -1).

3.4.3 Mix Aging

After pasteurization mix should be cooled down to a specified low temperature, that prevents growth of microorganisms (typically ≤+5ºC), and may need to be aged for a specific period to allow mature the color, flavors and textures. Sampling of the aged mix need to be carried out carefully to prevent environmental contamination.

Colours, flavours and purees introduced into the cooled and pasteurized mix can compromise product safety. This risk can be minimized through a combination of material specification and the procedures for introducing the addition

Mix storage conditions **must** be controlled to prevent contamination and growth of micro-organisms and subsequent contamination of final product. Mix **should** be kept for the shortest practical time at the lowest temperature respecting the correct ageing times required to manufacture good quality Ice cream/Frozen dessert.

3.4.4 Molding /Shaping

Filling, forming, extrusion and assembly operations expose pasteurized Ice cream/Frozen dessert and other raw materials to the factory environment. HACCP will assist in defining cleaning, disinfection and maintenance procedures for all types of lines. These procedures **must** be validated.

For molded stick products procedures **must** be in place for the inspection of the molds to ensure that products will not be contaminated with brine. Checks and cleaning and disinfection procedures are undertaken on a frequent basis and needs to be recorded.

Contact surfaces are a source of contamination due to deterioration of the surface or build-up of product debris. Direct product contact with ambient temperature surfaces **should** be minimized since these will limit run times and require frequent (intermediate) cleaning and disinfection.

Contamination of any ingredients added to the product at the line (nuts, toppings, chocolate, etc.) with either mix or water **should** be minimized. Chocolate or couverture from dipping and enrobing tanks in the production hall **must** not be returned to the bulk storage tanks.

3.4.5 Packaging and Packing

There are 2 types of packing:

PRIMARY PACKAGING

Utmost care needs to be taken while product packs in the primary packing with respect to physical and microbiological hazard. Absence of foreign bodies in the packaging material must be ensured and the packaging material needs to be food grade.

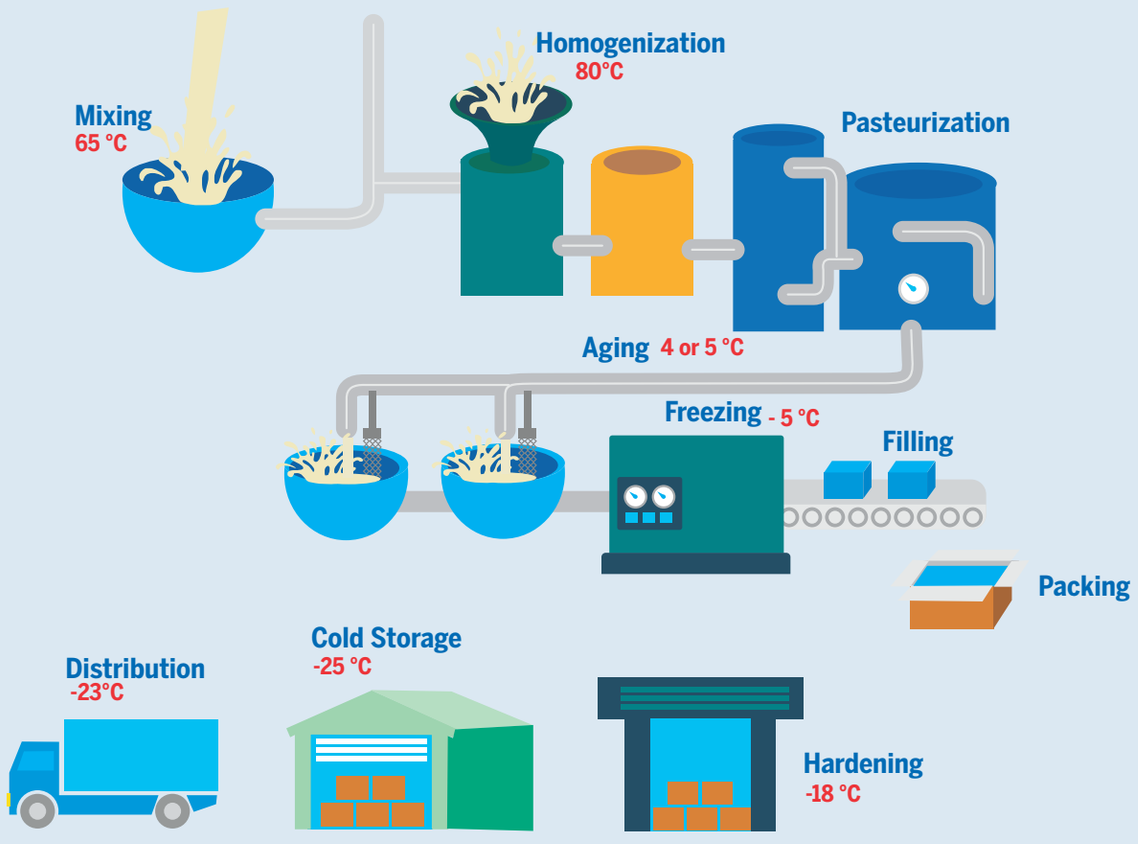
SECONDARY PACKAGING

The packed products can be clubbed together in to a carton of a known size and can be stored. The carton and the primary sleeves must contain all information regarding the manufacture, shelf life details, and costumer care number, ingredient details etc.

3.4.6 Hardening

Hardening systems can be divided into two groups; those that harden wrapped or packaged product and those that harden bulk, unpacked product. Packaged and bulk product must not be run through a hardening tunnel simultaneously since there is a risk of packaging debris contaminating the bulk product. Products that are hardened without primary packing are very vulnerable to contamination from circulating air. Care is required in the construction, maintenance, cleaning and disinfection of hardening tunnels to prevent product contamination. When the tunnel temperature is below (zero) 0o C, bacteria cannot grow. When used for hardening of bulk product the tunnel must be cleaned, disinfected and dried each time the internal temperature goes above freezing. Cleaning and disinfection effectiveness must be validated appropriately, including microbiological sampling.

FIGURE 1: A TYPICAL ICE CREAM/FROZEN DESSERT MANUFACTURING PROCESS



3.4.7 Cold storage of finished goods and consumer safety

Finished product has to meet all requirements of consumer safety, quality and consistency. It also important for the manufacturers to comply with the legal labelling requirements, and in addition it should list the ingredients, highlight and display necessary consumer safety relevant information on the pack.

APPENDIX 1:

MINIMUM PASTEURIZATION REQUIREMENTS OF ICE CREAM/ FROZEN DESSERT MIX

The design of pasteurizers should be followed as required by the regulations applicable from time to time.

HIGH TEMPERATURE SHORT TIME (HTST) PASTEURIZATION

HTST units must be designed and calibrated in such a way that under-pasteurized mix can never cross-contaminate pasteurized mix.

The minimum requirement for HTST pasteurization is 25 seconds at 79.4°C, or equivalent.

Batch pasteurization can be used to safely pasteurize mix but, because it is more susceptible to error than automated HTST systems, increased attention is necessary to correct design and operational and monitoring procedures.

HAZARDS AND RISKS

For pasteurization (and batch pasteurization in particular) the following hazards exist and **must** be evaluated and controlled:

- Survival of micro-organisms due to in-homogeneity of the mix
- Survival of micro-organisms due to under-pasteurization
- Recontamination
- Insufficient cooling

IN-HOMOGENEITY OF MIX

Microbiological survival may occur when microorganisms are protected by material which has not been sufficiently rehydrated

Skimmed milk powder may contain lumpy, burnt and denatured material because of inadequate processing by a supplier whose operation is not fully up to standard. Such material will undoubtedly lead to under-pasteurization because micro-organisms will be protected during the heating process.

Therefore preparation of the mix and pasteurization **should** take place in separate vessels and mix be transferred to the pasteurizer vat through a correctly sized strainer to retain all particles from dry raw materials. A dual system, which can be operated alternately, **should** preferably be installed (as used in mix processing).

Dry powder **must** be prevented from reaching the underside of lids and fittings (for example; shaft passages and vent-holes) because this will not be adequately pasteurized. A Venturi system can be used to dissolve dry raw materials.

UNDER-PASTEURIZATION

PATHOGEN SURVIVAL MAY OCCUR IF THE PRODUCT DOES NOT RECEIVE THE CORRECT TIME/TEMPERATURE TREATMENT

The aim of pasteurization is to obtain at least a 6-log reduction of vegetative micro-organisms. This 6-log reduction **must** be obtained at the coldest spot of the pasteurizer unit. Therefore, it is very important that the pasteurizer vessel is hygienically designed with no dead areas in the vessel or connecting piping and auxiliary equipment.

In case of batch pasteurization, adequate stirring of the formulation **should** be ensured during heating and holding to obtain a homogeneous temperature throughout the pasteurization process. However, stirrers **should** be designed to minimize foam, which can reduce pasteurization efficiency.

It is particularly important to ensure appropriate heating of pasteurizer vessel head spaces. The head space temperature **should** be at least 3°C higher than the mix.

During filling mix **should** not be allowed to splash onto the underside of lids and excessive amounts of foam **should** not be allowed to form.

Temperature of the mix and the head space must be recorded continuously with accurately calibrated devices. All parts of the pasteurizer unit should be easy accessible for cleaning and disinfection.

RECONTAMINATION

THIS CAN OCCUR BY CROSS CONTAMINATION FROM RAW TO PASTEURIZED MIX AND FROM UNHYGIENIC EQUIPMENT, PRACTICES, PEOPLE OR ENVIRONMENT.

All mix (including rework) **must** receive the correct temperature/time treatment. The mix supply line **should** be completely disconnected or sealed from the pasteurizer vessel during pasteurization.
Recontamination from poorly designed equipment **must** be avoided at all times so all equipment **should** be hygienically designed and cleanable.

INSUFFICIENT COOLING

IF THIS OCCURS, IT CAN LEAD TO GROWTH OF MICRO-ORGANISMS

Cooling of pasteurized mix **should** not take place in the pasteurizer vessel because of length of time the product takes to reach a temperature 5°C or less.

Mix cooling **should** be carried out in a Plate Heat Exchanger Cooling unit. Precautions to prevent recontamination of mix due to leakage of the plates (such as pinhole checks and pressure tests) are identical to those specified for HTST installations.

MICROBIOLOGICAL STANDARDS FOR ICE CREAM/FROZEN DESSERT

N	=	The number of samples to be taken per batch
C	=	The number of samples allowable with counts between m and M
m	=	Lower or GMP limit
M	=	Upper limit – no samples may exceed this value
wt	=	Analytical sample size

Confederation of Indian Industry
Third Floor, IGSSS Building, 28, Institutional Area,
Lodhi Road, New Delhi - 110003
Ph: 011-45771000; Fax: 011-45772013; Email: **chifss.face@cii.in**
Website: **www.chifss.in**