HACCP PLAN

Company Name: Gelarto Artisan Ice Cream Boutique

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HACCP plan for: Artisan Ice Cream

People involved in HACCP creation:

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Plan agreed by:

Name: Signed:

Date: Date:

HACCP Manual

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1. Introduction

1.1 HACCP STUDY OF GELARTO OPERATIONS

1.2 INTRODUCTION TO HACCP

HACCP is a tool for identifying what can go wrong to make food unsafe for human consumption and then deciding how it can be prevented. Before HACCP is addressed, a Pre-requisite Programme must be put in place covering the general principles for Food Hygiene as produced by the Codex Alimentarius Commission.

HACCP is a documented and verifiable approach for the identification of hazards, preventative measures and critical control points and the implementation of a monitoring system.

HACCP involves the systematic examination of the many process steps involved in food manufacturing operations and the identification of those steps that are critical to the safety of the product (i.e. Critical Control Points - CCP). Full records must be kept of each study and the study must be verified on a regular basis and updated when changes occur.

HACCP is applicable to the identification of microbiological, chemical, physical and allergen hazards affecting the food safety. HACCP must be applied to a specific process and product combination and should make use of existing information (GMP Guidelines, ISO Procedures etc.).

1.3 PRINCIPLES OF HACCP

The basic principles of HACCP are based on the procedures outlined by the Codex Alimentarius Commission and the National Advisory Committee on Microbiological Criteria for foods.

PRINCIPLE 1 Conduct a hazard analysis. Prepare a flow diagram of the steps in the process. Identify and list the hazards and specify the preventative measures.

PRINCIPLE 2 Identify the CCP in the process

PRINCIPLE 3 Establish critical limits and target values which must be met in order to ensure the CCP is under control.

PRINCIPLE 4 Establish a system to monitor control of the CCP by scheduled testing or observation.

PRINCIPLE 5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is moving out of control.

PRINCIPLE 6 Establish documentation concerning all procedures and records appropriate to these principles and their application.

PRINCIPLE 7 Establish verification procedures which include appropriate supplementary tests together with a review which confirms that HACCP is working effectively.

To help the implementation and use of HACCP the seven principles of HACCP have been broken down to a set of 14 working stages.

1.4 APPLICATION OF HACCP PRINCIPLES/HOW TO IMPLEMENT HACCP

0) Define terms of reference
1) Select the HACCP Team
2) Describe the product and the process
3) Identify intended use
4) Construct a flow diagram
5) On-Site verification of flow diagram
6) List all hazards associated with each step and list all preventative measures associated with each identified CCP.
7) Apply HACCP decision tree to each process step in order to identify CCPs
8) Establish critical limits for preventative measures associated with each CCP
9) Establish a monitoring system for each CCP
10) Establish a corrective action plan
11) Establish record keeping and documentation
12) Verification
13) Review HACCP plan

1.5 GLOSSARY OF TERMS

<u>HACCP</u>

A system which identifies specific hazard(s) and preventative measures for their control.

Preventative measure
Any system in place at a process step that controls the identified hazard(s).

Hazard
The potential to cause harm (to the consumer or the business). Hazards can be biological, chemical or physical.

Flow Diagram
A detailed sequence of steps for the product/process under study.

Step (process step)
A discrete functional stage or unit operation within the process that forms a single operation on the flow diagram.

Critical limit
A value that separates acceptability from unacceptability. It can be regarded as the absolute value for a preventative measure. Values outside of this limit indicate a serious process deviation.

Target value
Criteria which are more stringent than Critical Limits. A predetermined level for a preventative measure which has been shown to eliminate or control a hazard at a CCP.
There should be sufficient differentiation between target value and critical limits to make control possible given the inherent variability of the process.

Critical Control Point (CCP)
A point, step or procedure at which control can be applied and a hazard can be prevented, eliminated or reduced to acceptable levels.

Design Control Points (DCP)
A point, step or procedure, where the study of a conceptual line design, process design or plans and layouts identified the need for control and where there is a need for the hazard to be prevented, eliminated or reduced.

Corrective Action

The actions to be taken when the results of monitoring the CCP indicate a loss of control.

Monitor
To conduct a planned sequence of observations or measurements to assess whether a CCP is under control.

Verification
The procedures, in addition to those used in monitoring, which are used to determine if the HACCP system is working correctly or requires modification.

Validation
Obtaining evidence that the elements of the HACCP Plan are effective.

1.6 TERMS OF REFERENCE

The objectives of the HACCP study in Gelarto products are:

- To identify all biological, chemical, physical and allergen hazards associated with the purchasing, delivering, storing and sale of Gelarto products.

Biological Hazards:

Yeast & Moulds,
Coliforms,
E. coli,
Listeria
Salmonella
Enterobacteriaceae,
Aerobic Mesophile.
Salmonella spp.

Chemical Hazards:

The following chemical hazards are covered by the terms of reference of this study.

Cleaning residues
Printing inks, lacquers from packaging
Chemical contaminants and residues in raw materials.

Physical Hazards:

The following physical hazards are covered by the terms of reference of this study

Metal
Glass
Hair
Wooden splinters

Dust/Dirt particles
Plastic
Insects.

Allergen Hazards:
All common allergens have been considered as part of the HACCP study.

Milk
Egg
Nuts
Soya
Gluten
Crustaceans
Fish
Peanuts
Celery
Mustard
Sesame Seeds
Sulphites
Lupin
Molluscs
and products thereof

1.6 PRE-REQUISITE PROGRAM (PRP)
Pre-requisite programmes are an integral part of HACCP.

For Gelarto the Pre-requisite programmes include:

Supplier list

Pest Control programme – written, implemented and effective pest control programs

Personnel Programme – written, implemented and effective training program for technical training, personal

Complaints Programme – written, implemented and effective complaint management

program

Cleaning & Disinfectant Procedures – written, implemented and effective cleaning and disinfectant programs

Hygiene & Housekeeping Procedures – written implemented and effective hygiene & housekeeping program

Allergen Management – written, implemented and effective allergen management program

Cleaning Chemical Management – written implemented and effective allergen management program

Glass Policy / Breakages Procedure – written implemented and effective allergen management procedure.

General Requirements for Food Manufacture

Toxicological Clearance Programme

As a mandatory procedure, all raw materials, ingredients, processing aids (product contact construction materials, lubricants, cleaning agents etc), processes and primary packaging materials must be cleared for their safety to consumers in accordance with the FE Toxicological Safety Clearance Procedure.

Establishes requirements for a supplier's comprehensive quality system. It identifies elements of a system to be designed, established and maintained for the purpose of ensuring that supplies and services will conform to contract requirements.

1.7 VERIFICATION PROCEDURE

Verification of the HACCP plan ensures that the plan is working successfully. The verification procedure covers three aspects:

- **The Pre-requisite Programmes are assessed to ensure that they will be effective in preventing and controlling those risks of food contamination which it is designed to address.**
  The Programmes are assessed by means of annual audits.

- **The scientific or technical processes to verify that the critical limits are adequate to control the hazards that are likely to occur.**
  e.g. Review of analytical results, customer complaints etc.

- **The HACCP plan as originally applied is appropriate to the process/hazards**.
  This involves review of CCP records and determination that monitoring procedures and corrective actions are being applied.

Review Process

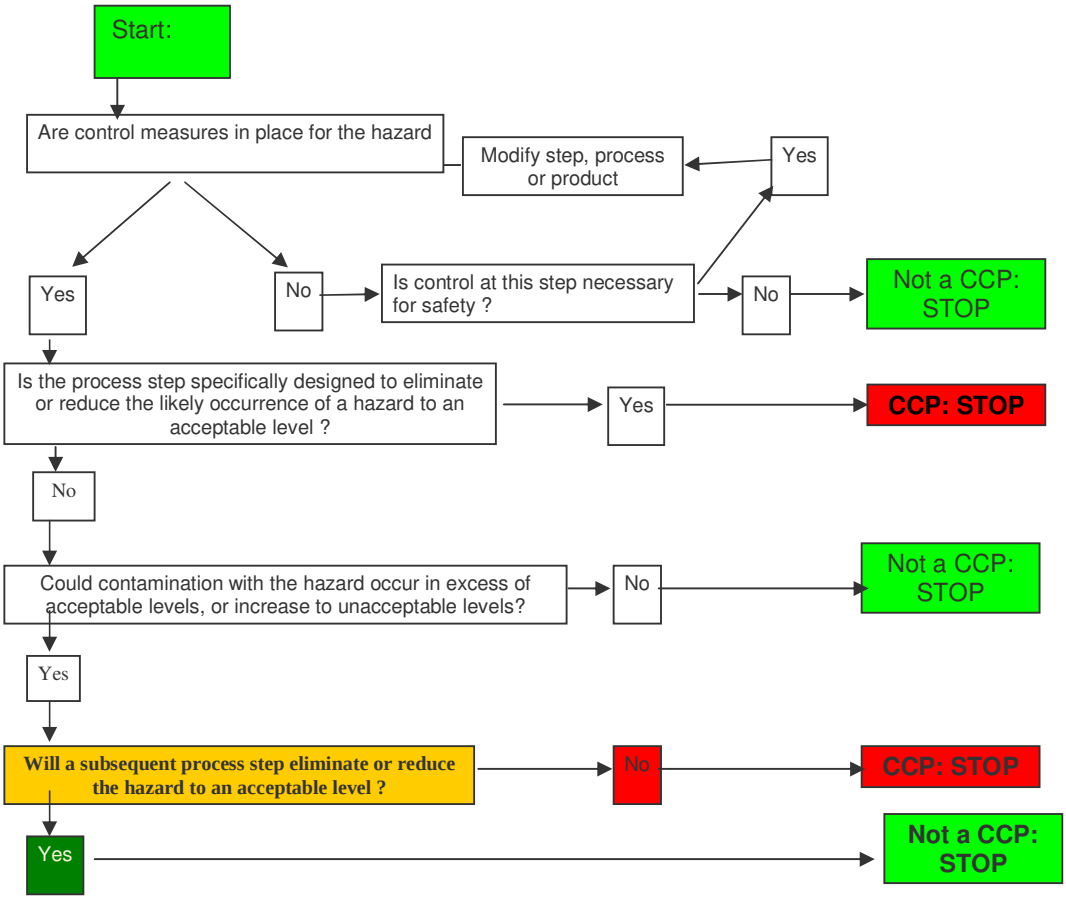
A review of the HACCP plan will also take place with changes that occur such as changes in the process or consumer use and the usage of our ice cream van.

The HACCP review meetings also discuss changes and suggestions arising from the verification process. Review meetings for the HACCP study take place at least once per year.

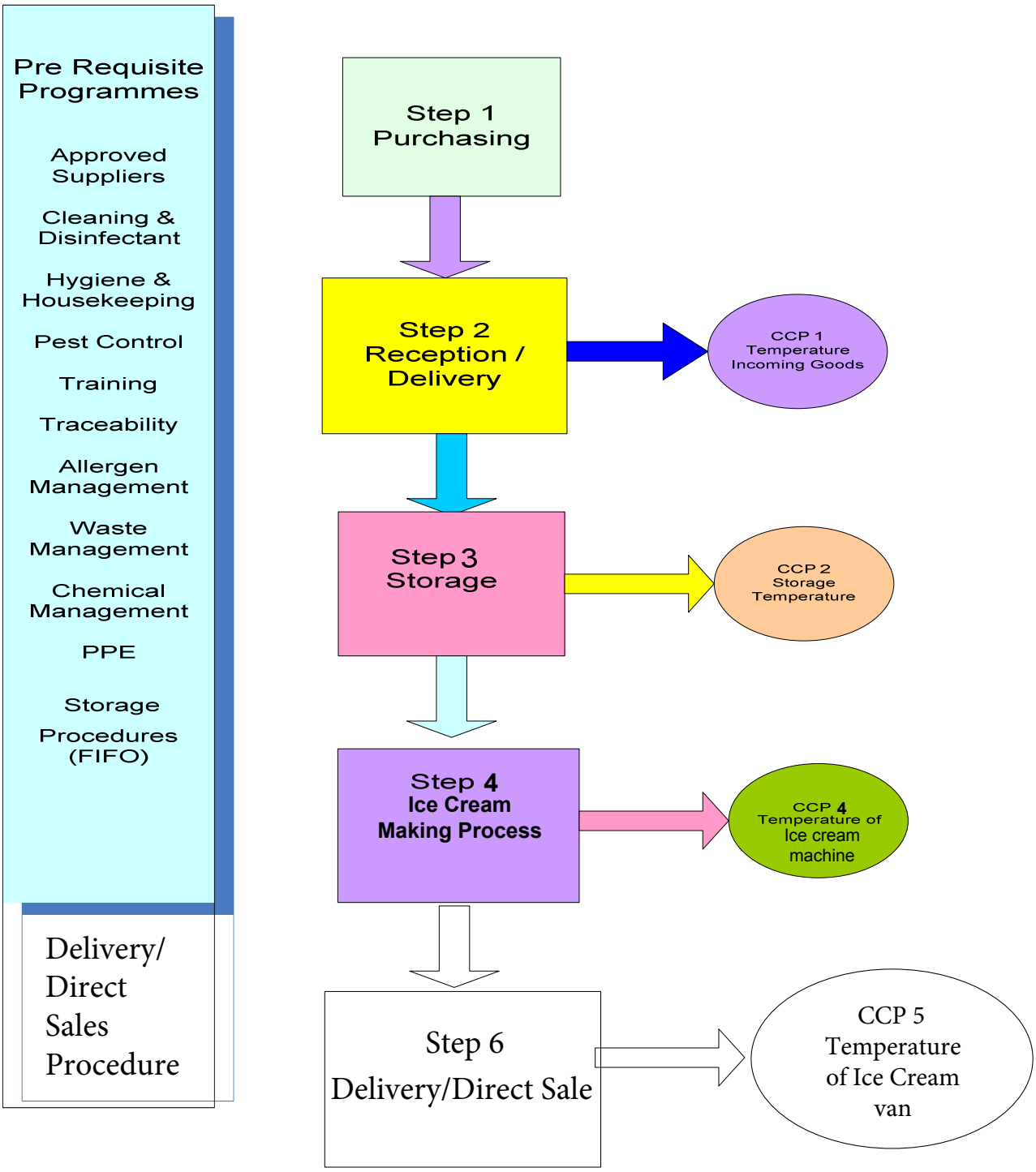
2. Product Description

Product:	Gelarto Artisan Ice Cream
Sales description	Gelarto Artisan premium Ice cream
Product Specification	Product specs including - ingredient list - allergen information - nutritional information
Food Additives	See product specification
Preservatives (minimum concentration)	See product specification
Ingredients / Additives (maximum concentration)	See product specification
Method of Preservation (pH a_w, time, temp, etc)	Frozen product – 18 Degrees Celsius
Storage Conditions	-18 Degrees Celsius
Labelling requirements relating to food safety	Best before date: Ingredients
Product shelf life	3 months
Intended use, abuse potential	Immediate consumption
Target Consumer (High risk population group)	Young Adults 14 – 30 years

3. HACCP Decision Tree



4. Process Flow



5. Process Hazard Analysis

Process Hazard Analysis				
Step 1: Purchasing				
Hazard	**Source**	**Control Measures**	**Comment**	**CCP Y/N**
BIOLOGICAL HAZARDS: Contamination, Growth, Survival				
Micro growth	Ingredients and packaging	Approved Suppliers	PRP	N
CHEMICAL HAZARDS: Contact, Residual Contaminants				
Chemical Contamination of raw materials.	Ingredients, packaging, equipment.	Approved Suppliers	PRP	N
Taints	Ingredients, packaging, equipment.	Approved Suppliers	PRP	N
PHYSICAL HAZARDS: Foreign matter – (Glass, hard plastic, wood, metal etc..)				
Foreign objects	Ingredients and packaging	Approved Suppliers	PRP	N
ALLGENS HAZARDS: Annex 111a of Commission Directive 2007/68/EC				
Milk Egg Nuts Soya Gluten Crustaceans Fish	Ingredients Cross contact	Approved Suppliers	PRP	N

Peanuts Celery Mustard Sesame Seeds Sulphites Lupin Molluscs and products thereof				
Step 2: Reception / Delivery				
Hazard	Source	Control Measure	Comment	CCP Y/N
BIOLOGICAL HAZARDS: Contamination, Growth, Survival				
Microbial	Damage to packaging on all incoming ingredients/ packaging/ raw materials	Correct handling and storage	PRP	N
		Checking condition of delivery before receipt	PRP	N
	Incorrect temperature.	Temperature check of all chilled / Frozen stock at goods receipt.	CCP	Y
Physical Damage	Out of date ingredients Broken containers No longer Hygienic	Check best before dates upon receipt	PRP	N
	Chemical contamination	Visual Inspection	PRP	N
Rodent Damage	Rodent damage to packaging and raw materials	Correct Pest Control procedure	PRP	N
		Checking condition of delivery	PRP	N

		before receipt		
CHEMICAL HAZARDS: Contact, Residual, Contaminants				
Chemical Contamination of raw materials.	Damage to packaging on incoming raw materials.	Correct handling and storage. Checking condition of delivery before receipt	PRP PRP	N N
PHYSICAL HAZARDS: Foreign matter – (Glass, hard plastic, wood, metal etc..)				
Foreign objects / bodies	Damage to packaging on incoming raw materials.	Correct handling and storage. Checking condition of delivery before receipt	PRP PRP	N N
ALLERGEN HAZARDS:				
Milk Egg Nuts Soya Gluten Crustaceans Fish Peanuts Celery Mustard Sesame Seeds Sulphites Lupin Molluscs and products thereof	Damage to packaging on incoming raw materials	Correct handling and storage. Checking condition of delivery before receipt	PRP PRP	N N

Step 3: Storage				
Hazard	**Source**	**Control Measures**	**Comment**	**CCP Y/N**
BIOLOGICAL HAZARDS: Contamination, Growth, Survival				
Microbial	Wrong Temperature	Daily recording of refrigeration / freezer temperatures.	CCP	Y
	Unhygienic storage areas.	Good hygiene and housekeeping.	PRP	N
	Out of date ingredients	All best before dates and batch details recorded. Traceability	PRP	N
	Waste	All waste materials are stored in designated bins and removed daily or as required.	PRP	N
	Employee	Training, Hygiene & Housekeeping, PPE		
CHEMICAL HAZARDS:				
Various Chemicals	Cleaning Agents	Correct procedures for storing and using cleaning chemicals Separate Storage Aera for Chemicals	PRP	N

PHYSICAL HAZARDS: Foreign matter – (Glass, hard plastic, wood, metal etc..)				
Foreign objects	Open / uncovered ingredients. Waste	Correct storage All waste materials are stored in designated bins and removed daily or as required.	PRP PRP	N N
Insects / Rodents	Open / uncovered ingredients.	Correct storage / Pest control procedures.	PRP	N
ALLERGEN HAZARDS:				
Milk Egg Nuts Soya Gluten Crustaceans Fish Peanuts Celery Mustard Sesame Seeds Sulphites Lupin Molluscs and products thereof	Damage to packaging in storage.	Correct handling and storage.	PRP	N

Step 4: Process / Preparation and Pasteurisation				
Hazard	**Source**	**Control Measures**	**Comment**	**CCP Y/N**
BIOLOGICAL HAZARDS: Contamination, Growth, Survival				
Microbial	Employees	Correct PPE, regular hand washing, general hygiene and housekeeping. Training. Appropriate workwear	PRP	N
	Equipment / Utensils	General hygiene and housekeeping, cleaning procedures.	PRP	N
	Machine	Cleaning procedures	PRP	N
	Inadequate pasteurisation	Pasteurisation procedures.	PRP	N
	Out of date ingredients	All Best Before Dates / Batch Details Recorded and checked.	PRP	N
	Waste	All waste materials are stored in designated bins and removed daily or as required.	PRP	N
CHEMICAL HAZARDS: Contact, Residual, Contaminants				
Various Chemicals	Cleaning Chemicals	Cleaning procedures, Food Grade	PRP	N

PHYSICAL HAZARDS: Foreign matter – (Glass, hard plastic, wood, metal etc..)				
Foreign objects / bodies	Jewellery	Correct Housekeeping procedure	PRP	N
	Hair	Hairnet / hats being worn correctly.	PRP	N
	Insects	Pest control	PRP	N
	Waste	All waste materials are stored in designated bins and removed daily or as required.	PRP	N
	Promotional Items	Correct Storage	PRP	N
ALLERGEN HAZARDS: Annex 111a of Commission Directive 2007/68/EC				
Milk Egg Nuts Soya Gluten Crustaceans Fish Peanuts Celery Mustard Sesame Seeds Sulphites Lupin	Utensils	Training	PRP	N
	Cross Contact	Training	PRP	N
	Ice Cream Machine	Cleaning Procedure	PRP	N

Molluscs and products thereof				
Step 5: Sale / Display Cabinet				
Hazard	**Source**	**Control Measures**	**Comment**	**CCP Y/N**
BIOLOGICAL HAZARDS: Contamination, Growth, Survival				
Microbial	Employees	Correct PPE, regular hand washing, general hygiene and housekeeping. Training.	PRP	N
	Equipment / Utensils	General hygiene and housekeeping, cleaning procedures.	PRP	N
	Cabinet temperature	Ingredients stored between -14ºC and -16ºC. Monitor Temperature	CCP	Y
	Out of date ingredients	All Best Before Dates and Batch details are recorded.	PRP	N
CHEMICAL HAZARDS: Contact, Residual, Contaminants				
Various Chemicals	Cleaning Chemicals	Cleaning procedures, Food grade materials in use only.	PRP	N

PHYSICAL HAZARDS: Foreign matter – (Glass, hard plastic, wood, metal etc..)				
Foreign objects / bodies	Jewellery	Correct Housekeeping procedure	PRP	N
	Hair / False nails	Hairnet / hats being worn correctly. Personal Hygiene, Training.	PRP	N
	Insects	Pest control	PRP	N
	Customer / Consumer at Cabinet	Employee Training	PRP	N
ALLERGEN HAZARDS:				
Milk Egg Nuts Soya Gluten Crustaceans Peanuts Celery Mustard Sesame Seeds Sulphites Lupin Molluscs and products thereof	Utensils Cross Contact	Training Allergen warning signs on display Allergen management. Fish	PRP PRP PRP	N N N

6. CCP Identification

Step	CCP	Hazard	Control Measure	Critical Limit	Monitoring Procedure	Corrective Action	Verification	Records
2	CCP 1	Microbiological Growth	Freezing	≤ -18ºC Frozen	Every Delivery	Reject delivery	Yearly Calibration of thermometer	CD001
3	CCP 2	Microbiological Growth	Freezing	≤ -18ºC Frozen	Once daily	Check individual product temp. Dispose of product outside limits	Yearly Calibration of thermometer	CD001
4	CCP 3	Microbiological Growth	Freezing	≤-14ºC	Once daily	Check individual product temp. Dispose of products outside limit	Yearly Calibration of thermometer	CD001
5	CCP 5	Microbiological Growth	Freezing	≤-18ºC	Every Delivery	Check individual product temp. Dispose of products outside limit	Yearly Calibration of thermometer	CD001

7. Cleaning & Disinfectant Procedure

Purpose: To ensure the cabinet is clean, free from debris and all scoops & utensils are sterile in preparation for the following day's sales.

Scope: Cabinets, scoops, utensils and Ice cream machine and freezer van

Procedure: Disinfectant should be left on the surface for a minute and then wiped off.

1. Remove product and place in frozen storage area.
2. Clean cabinet with hot water and a mild detergent.
3. Sterilise scoops and spatulas using Selgiene or similar disinfectant.
4. Rinse scoops well and dry with paper towel before storing. Never clean in dishwasher or leave soaking overnight.
5. Clean glass using paper towel and glass cleaner. Ensure all smears and marks are removed. Never spray glass cleaner directly into cabinet.
6. Clean the sink area using hot water and paper towels. Pour a cup of hot water down the drain.
7. Clean the counter cone holder with a damp cloth and ensure all ice cream spillages are removed.
8. Once a week turn off the cabinet and defrost completely. (This will maintain proper temperature control and ensure that the airflow grills are kept free of ice).
9. Dismantling and washing the removable parts of the Ice cream machine as per the manual provided. All parts should be sterilised with Selgiene or similar disinfectant and washed with hot water and dried.
10. Once a week the freezer vans freezer part should be cleaned and sterilised with a disnfectant.
11. Complete cleaning record.

Records:

Daily Cleaning CD002
Weekly Cleaning CD003
Ice Cream van cleaning sheet CD011

8. Hygiene & Housekeeping Procedure

Purpose: To ensure a high standard of hygiene & housekeeping is maintained in the facility at all times.

Scope: All area of the food business, all employees and food handlers.

Procedure:

1. A clean as you go policy must be in place to ensure there is no build up of dirt, debris and waste throughout the day. Worktops must be cleaned down regularly throughout the day.
2. Waste disposal bins must be emptied at least daily or more frequently if required. Bins should be covered with a lid. Pedal bins should be used where possible. Where pedal bins are not in place, hands must be washed after removing the lid from the bin.
3. Scoops and spatulas should be stored in water with lemon juice / citric acid. The water should be changed every hour (increase frequency to every ½ hour during busy periods.
4. When not in use scoops and other utensils must be stored to prevent them becoming dirty or contaminated.
5. Cleaning cloths and scouring pads should be changed regularly. (Scouring pads should be disposed of at the end of every day).
6. Drying cloths should not be used.
7. All personnel must maintain a high standard of personal hygiene. Regular hand washing with disinfectant soap is preferred to wearing disposable plastic gloves. Where gloves are used hands must be washed before putting on gloves. Gloves must be changed hourly or whenever they become damaged or soiled.
8. Where possible a separate person who is not preparing or serving food should be responsible for handling money. Where not possible hands must be washed after handling money.
9. All food handlers must wear clean protective clothing which must be changed daily.
10. Main washing basin must be disinfected before washing fruits or other food products.
11. Food handler's nails must be kept short, clean and unvarnished.
12. Eating, drinking or smoking must only take place in designated areas, away from food prep or serving areas.
13. Jewellery should not be worn by food handlers with the exception of a plain band wedding ring.
14. Chewing gum is not permitted
15. Non-staff members are not allowed in the storerooms or the ice cream making facility.
16. Food handler's cuts, sores or grazes must be covered with a waterproof dressing.
17. Do not serve Ice cream if you are suffering from diarrhoea, vomiting, jaundice, fever, sore throat with fever, infected skin lesions, discharges from the eyes, ears, nose, mouth or gums.

9. Pest Control Procedure

Purpose: To ensure the risk associated with pest infestation is eliminated or reduced to an acceptable level.

Scope: External and internal areas of the food business.

Procedure:

1. Check your premises regularly for signs of pest, such as small footprints in dust, droppings, holes in walls and doors, nests, gnawed goods or packaging, grease or smear marks, urine stains on packaging, bodies of insects, live insects, webbing, nests, droning or buzzing and maggots. Keep a record of these routine checks.
2. Check deliveries thoroughly for signs of pest. Do not accept a delivery if it shows signs of pests such as gnawed packaging or insects, e.g. beetles
3. Keep external areas tidy and free from weeds. Make sure bins have close-fitting lids and are easy to clean.
4. If you see signs of a pest infestation, call a pest contractor immediately. Write the contact details for your pest contractor on the contacts list in the diary.
5. If you think any equipment, surfaces or utensils have been touched by pests, they should be washed, disinfected and dried to stop harmful bacteria from spreading.
6. If you think food has been touched by pests in any way, throw it away.
7. Make your pest checks more frequent.
8. Improve staff training on recognising signs of pests and encourage them to report problems immediately.
9. If you have persistent problems with pests, consider employing a pest contractor, if you do not have one already.
10. Make sure no food or dirty plates etc. are left out at night – these are a source of food for pests.
11. Make sure that checks for pests are carried out regularly.
12. Put reminders of when to check for pests in your diary.
13. If you have a pest contractor, keep a record of their contact details and visits in your diary, as well as any feedback or action points they recommend. Make a note of when you have carried these out.
14. Never let pest control bait/chemicals, including sprays, come into contact with food, packaging, equipment or surfaces, because they are likely to be poisonous to people.

Records: Pest control Record Sheet CD012

10. Training

Purpose: To ensure all employees are trained to carry out their job.

Scope: All permanent and temporary staff.

Procedure: Training needs must be assessed per job function. All food handlers must received basic food handling training and HACCP training before starting their job. Records must be kept of all training. Training needs must be review annually.

Records: Training Record CD004

11. Goods Receipt, Traceability, Storage & Delivery Procedures

Purpose: To ensure all deliveries are in good condition before receipt. To ensure batch traceability is maintained and products are stored and delivered correctly.

Scope: All deliveries, all batches and all products.

Procedure:

1. Where the contents of the unit is moved to another container the batch details and best before dates must be recorded.

2. All ice cream products must be stored at -18º Celsius. Ice cream products in the dipping cabinet must be stored between -14ºC and -16ºC Temperature records must be maintained.

3. Packaging materials must be stored in a cool dry clean place.

4. Packaging and food materials must **not** be stored on the floor.

5. At all deliveries the temperatures must be recorded and the freezer van should be cleaned after all deliveries.

Records: Weekly Temperature Sheet CD001

Delivery Check Sheet CD006
Ice Cream van cleaning Sheet CD010
Ice Cream van Temperature Sheet CD011
Ice Cream Process Sheet CD013

12. Allergen Management

Purpose: To ensure that those individuals, who know they suffer from a food allergy, will be able to avoid inadvertent exposure to specified allergens in Gelarto products.

Scope: All products, all common allergens.

Procedure:

1. A sign should be on display informing allergen information at all times for customers.

2. Please refer to the product specification when giving a consumer advice on allergens present in the product as an ingredient. Always inform the consumer that due to the nature of the scooping activity we cannot guarantee no cross contact with undeclared allergens has occurred.
3. Do not assume that a product does not contain an allergen – always check the product specification.

13. Cleaning Chemicals Management

Purpose: To prevent contamination of food products with cleaning chemicals.

Scope: All cleaning chemicals.

Procedure:

1. All cleaning chemicals used must be suitable for use in a food business.
2. Cleaning chemical must be stored in a designated area away from food ingredients or products.
3. Cleaning chemical must be clearly labelled. Never transfer the contents to an unmarked container.
4. Material safety data sheets must be kept on file for every chemical used on site. Always consult the material safety data sheet before using a chemical familiarise yourself with what to do in the event of accidental contact with eyes or skin.
5. In the event of accidental spillage consult the material safety data sheet before tackling the spill.

Records: Material Safety Data Sheets.

14. Glass Policy & Glass Breakage Procedure

Purpose: To ensure the use of glass is limited and to ensure that where glass is in use it is controlled.

Scope: All glass used on site, including lights, windows and glass kitchenware.

Procedure:

1. The use of glass on site should be limited as much as possible.
2. Where glass is in use a full inventory of the glass used must be kept.
3. Glass must be regularly inspected to ensure there are no cracks or damage which could result in glass contamination of food products.
4. In the event of a glass breakage the area around the breakage must be cornered off.
5. Any uncovered and/ or open products must be removed from sale.
6. The glass breakage must be cleared and disposed of appropriately.
7. Records of all glass breakages and glass audits must be kept.

Records: Daily Cleaning Check sheet CD002

15. Complaints Management & Incident Procedure

Purpose: To ensure all product complaints and incidents are reported.

Scope: Complaints & incidents relating to Gelarto products.

Procedure:

1. Gather all complaint / incident details i.e. nature of complaint / incident, product name, consumer name and contact details, batch details and best before dates etc.
2. Complete product complaint / incident report form.
3. Product complaint / incident report form to be filed and kept.

Records: Product complaint / incident report form CD005