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Introduction to HACCP

Hazard Analysis Critical Control Point, or HACCP, is a system, which gives us a pro-active common sense approach to the safety management of our food products.

HACCP was originally designed in the early days of the American manned space programme, and was developed by the Pillsbury Company, NASA and the United States Army laboratories, to ensure the Microbiological safety of the astronauts' food.

The HACCP system was launched publicly in 1971, and is designed to identify and control hazards that may occur anywhere in a food processing operation.

The benefits of the HACCP system are as follows:

- A Preventative System
- A Systematic Approach
- Helps demonstrate 'Due Diligence'
- Internationally accepted
- Strengthens Quality Management Systems
- Facilitates regulatory inspection/external audits
- Demonstrates Management commitment

Scope of HACCP Plan

The purpose of this food safety program is to identify and control, prevent and eliminate food safety hazards.

The HACCP Team have identified the Scope of this study as being:

From the intake of product to the arrival of the finished product at the customers, taking into account all possible Microbiological, Chemical or Physical hazards which could occur during this process.

The HACCP Team will ensure that all working practices adhere to all current food safety legislation.

The HACCP team have determined to address the potential of Microbiological, Chemical and Physical contamination through the process of Intake, Handling, Storage, Quality Control and Distribution of product from intake to delivery of the product to the customers.

The HACCP study takes into consideration that the company operates prerequisite programmes, which include:

- Good Manufacturing Practice
- Quality Management Systems
- Preventative Maintenance
- Personnel and Training
- Process Control
- Calibration
- Supplier Quality Assurance

During the formulation of the HACCP study, the team will review the various codes of practice and food regulations and will take the following food safety legislation and Codes of Practice into consideration throughout the study.

This HACCP plan has been prepared in accordance with:
CODEX Alimentarius Guidelines 97/13A for HACCP

European Communities (Hygiene of Foodstuffs) Regulations 2006

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Acar, J., Gokman, V., Taydas, E. E. (1998). 'The effect of processing technology on the patulin content of juice during commercial apple juice concentrate production'. *Zeitschrift fur Lebensmittel-Untersuchung und-Forschung A-Food Research and Technology* **207,**328-331.

Anon (1999). 'Guidance on the control of patulin in directly pressed apple juice.' Published by the UK Ministry of Agriculture, Fisheries and Food, Ergon House, 17, Smith Square, London SW1P 3JR.

Canas, P., Aranda, M. (1996). 'Decontamination and inhibition of patulin-induced cytotoxicity.' *Environmental Toxicology & Water Quality* **11**, 249-253.
Sydenham, E. W., Vismer, H. F., Marasas, W. F. O., Brown, N., Schlechter, M., Vanderwesthuizen, L., Rheeder, J. P. (1995). 'Reduction of patulin in apple juice samples - influence of initial processing.' *Food Control* **6**, 195-200.

HACCP Team

An appropriate HACCP team will be composed of: a HACCP consultant, a mycotoxicologist, a mycologist, a quality assurance manager at the processing plant, a process engineer, representatives of the farmers and the Department of Agriculture, and a scientific secretary. A specialist in the area of fruit juice production and legislative matters will be consulted as and when necessary.

Name	Position	Qualifications / Experiance
	HACCP Team Leader	
	Technical Manager	

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Definitions

Term	Definition
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.
Pre- Requisite Programme (PRP)	Practices and procedures forming the basis of preventable actions: • Receiving, Storage & Transport (e.g. procedure for receipt, approved supplier programme etc.) • Calibration & Maintenance • Cleaning • Pest control • Staff training & Personnel • Product Identification, Traceability & Recall • Premises (buildings & site)
Risk Analysis Table	A tabulated record of all Hazards that affect or have the potential to affect the safety of the products under analysis. The significance of a hazard is rated as low, medium or high and control measures for each hazard are stated.
HACCP Table	Hazards identified in the risk analysis table as being of medium or high significance and their respective control measures are transferred to the HACCP table. The critical limit of these hazards is specified. Details of who will monitor the critical limit to make sure it is not broken are given. Actions to be taken when critical limits are broken are also given. Records of monitoring activities are listed.
Sev	Severity: the consequences of the Hazard occurring H – High – Life Threatening or causing severe illness / injury M- Medium – Moderate illness/injury not life threatening L- Low- Mild illness/injury, not life threatening
Lik	Likelihood: the likelihood of the hazard occurring H- High – Likely to occur often M- Medium – May occur sometimes L – Low – Unlikely to occur
Sig	Significance. The consequences of the hazard occurring when both the severity and likelihood are high, the significance is high.

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Methodology

The flow chart has been designed so that each step has been allocated a number. All steps that are repeated throughout the process have been allocated the same number to save repetition in the risk analysis table.

The method used to establish CCP's within this HACCP plan has been based on the significance of each hazard as determined by the risk analysis table.

Hazards which can be controlled, Prevented or eliminated by the application of Per-Requisite Programme are not included in the HACCP table. Therefore these hazards have been identified in the risk analysis and have not been carried forward to the HACCP table as CCP's.

All other hazards not controlled by PRP and defined as highly significant within the Risk Analysis Table have been carried over to the HACCP table as a CCP. These hazards are all monitored and a record of that activity maintained.

Hazards defined as less than significant within the Risk Analysis Table are not carried over to the HACCP Table and may not be monitored or a record maintained.

TOTAL RISK = LIKELIHOOD x SEVERITY

Likelihood	Severity
1 = Improbable event – once every five years	1 = Negligible – no impact or not detectable
2 = Remote possibility – once every year	2 = Marginal – only internal company target levels affected
3 = Occasional event – once per month	3 = Significant – Impact on critical limits
4 = Probable event – once per week	4 = Major – Impact on customers (may not be the public)
5 = Frequent event – once per day	5 = Critical – public health risk / public product recall

Likelihood	Severity				
	1	**2**	**3**	**4**	**5**
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25

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Product Identification, Intended Use and Process

Apples are a convenience food and can be eaten without further processing, or can be used by the consumer as a cooking ingredient.
Apple juice to be consumed without further heating.
The product is received into the facility in loose format. They are all suitable for all consumer groups.

The products are received into the facility and the goods in checks are carried out. Inspections confirm the following:

- Approved supplier – confirmation
- Variety
- Weight
- Defects
- Quality of packaging

Product Description

Name of Product	Apple juice
Description	13° Brix apple juice with added sugar, preservative (sodium metabisulphite) and water. Filtered through 5 micron filter, pasteurised at 90°C for 2 minutes
Conditions of storage	Bulk tank at reduced temperature until processed. Ambient temperature when processed
Shelf Life	Six month at ambient. Chilled and consumed within4 days once opened
Intended use	Consumed without further heating.
Packaging	Glass bottle or tetrapack - 1 litre
Customer specification	Acid level important to product taste. Within microbiological and mycotoxin guidelines
Target Consumer	Local consumption and export. All age groups

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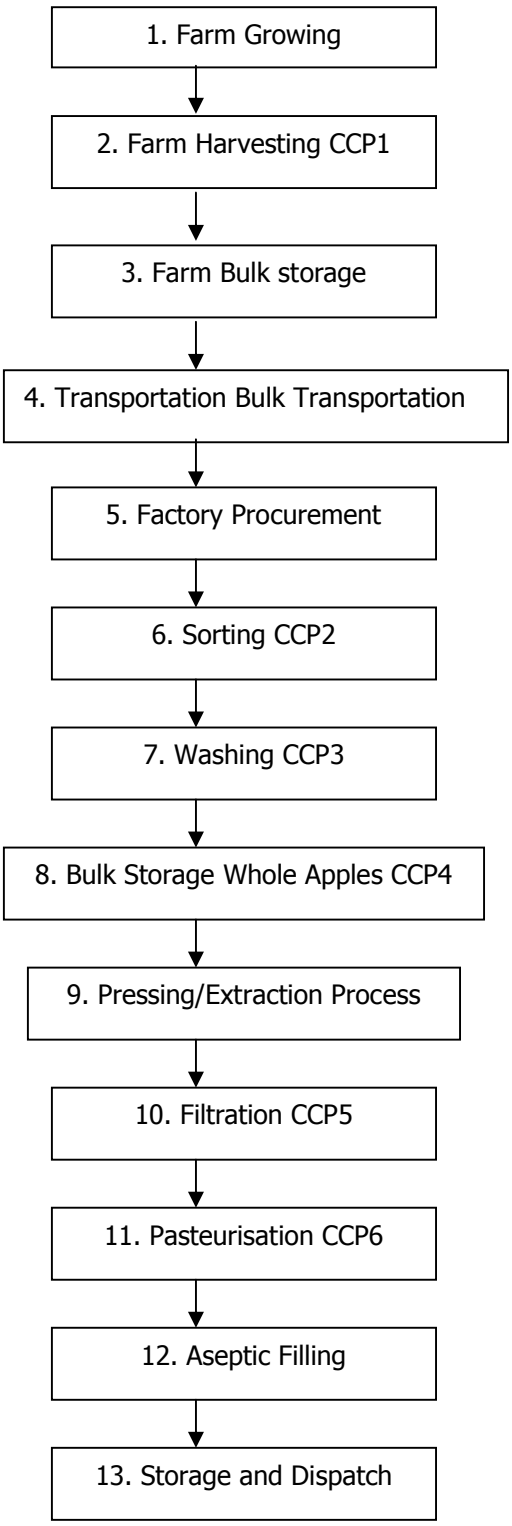
Flow Diagram



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Hazard Analysis

Identification of mycotoxin hazard
Patulin was the only mycotoxin hazard identified in this product. A number of European countries including Switzerland, Belgium, Austria and France have a 50 µg/Litre limit. The lowest limit is 30 µg/kg, in Romania.

Identification of steps in the CFD where mycotoxin contamination is most likely to occur.
Each step in the CFD will be considered in turn.
Patulin contamintion is likely to be produced in the orchard during growing (Step 1) and during bulk storage (Step 3). There is little risk of further contamination during transportation, but damage to apples at this stage can increase the risk of subsequent contamination.
At the factory, patulin contamination is most likely to increase during storage at Step 8.
There is likely to be patulin contamination present in the apples, or the resultant apple juice, at every step in the commodity chain. Hence it is important to both minimise contamination, and reduce levels of contamination to the acceptable level.

Possible Patulin Control Measures
Contamination of the juice can be prevented at steps where rotten or rotting apples can be rejected from the process, either in the orchard when the fruit is harvested, or during sorting in the factory.
Post-harvest patulin contamination can be eliminated, or significantly reduced, by storage at <10°C, and by minimising storage times.
Washing, and in particularly pressure spraying, has been shown to be effective in removing patulin from apples.
Patulin can also be removed from apple juice by filtration, when patulin bound to solid particles of apple flesh are removed.
Inactivation of *Penicillium expansum* spores during pasteurisation at Step 11 will reduce the risk of patulin production in the finished juice.

Development of a HACCP Plan
A spreadsheet summarising the HACCP plan for patulin in apple juice is given in Table. The development of the plan at each step in the CFD is given below.

Step 1: Farm, growing in the orchard - GAP
Growth of the mould *Penicillium expansum*, and subsequent patulin contamination, can occur pre-harvest, where it is associated with damaged and over-ripe fruit. Good Agricultural Practice (GAP) will minimise insect and bird damage.

Step 2: Farm, at harvest - CCP1
The control measure at this step is to efficiently reject rotten and damaged apples during harvesting. Rotten apples are much more likely to contain high levels of patulin than sound looking apples. In one study (Sydenham, E. W., 1995), as much as 70% of patulin present in a batch of over-ripe apples was removed by sorting and removing visually mouldy apples. Application of this control measure at Step 2 is considered a CCP because it will reduce mould contamination to an acceptable level. The effect of this CCP on levels of patulin in the system should not be considered in isolation. The HACCP team will consider the cumulative effects of subsequent CCPs and will judge whether levels of patulin in the final product are likely to exceed acceptable levels. The HACCP team will also consider the fact that removal of mouldy apples at this step will reduce the risk of subsequent patulin production, especially during on-farm storage. There is a subsequent sorting step at Step 6, so it could be argued that sorting is not required here. However, there are strong arguments to support sorting at both steps. Failure to sort at Step 1 will result in greatly increased patulin production at Steps 3, and unnecessary transportation of rotten fruit. There is little doubt that application of this sorting control measure at Step 1 is important for the production of apple juice containing acceptable levels of patulin.
The critical limit for this CCP will relate to the percentage of visibly mouldy apples remaining after sorting, and will be determined by the sorting efficiency which can reasonably be expected at this stage. For this example, the HACCP team considered that 99 per cent of mouldy apples should be removed at this step. The procedure will be monitored by trained supervisors and verified by a grading check on representative samples.

Step 3: Farm, bulk storage - GAP
Application of GAP and GSP is necessary to minimise rotting of fruit and subsequent patulin production during bulk storage. Storage of sound apples is important and the length of storage should be minimised, unless refrigerated storage facilities are used.

Step 4: Transportation - GAP
There is little risk of patulin contamination during short duration journeys, but any physical damage sustained during transportation, including loading and unloading, will predispose the fruit to subsequent mould attack and possible patulin contamination. The correct handling of fruit is therefore required.

Step 5: Factory procurement - GMP
Procurement of batches of low-grade apples, with a high percentage of damaged and rotten fruit, are to be avoided. It could be argued that, with a sorting step to follow, the procurement of low-grade apples would be permissible. However, batches containing >10% rotten fruit, say, will be extremely difficult to sort manually, and the levels of patulin likely to be present will make it difficult to attain an acceptable level of patulin in the finished product.

Step 6: Factory sorting - CCP2
The control measure is sorting to remove visibly mouldy apples. This CCP will reduce the level of mould to an acceptable level, and make a major contribution towards achieving an acceptable level of patulin in the final product. Sorting will both remove mouldy apples missed during sorting at Step 2, and remove apples that have subsequently become mouldy at Steps 3 and 4.
As for Step 1, the critical limit for this CCP will be the acceptable percentage of mouldy apples remaining after the sorting procedure, and monitoring will be by use of a trained supervisor.

Step 7: Factory, washing - CCP3
The control measure is washing the apples using high-pressure water spraying to remove rotten apple flesh, and patulin, from the fruit. Studies (Acar, J., 1998, & Sydenham, E.W., 1995) have shown that washing in this way can remove more than half of the patulin present in the fruit. The critical limits for this CCP will be related to the pressure of the sprays and the duration of the washing step. The water pressure will be monitored using pressure gauges and the washing step will be timed.
Patulin levels will be reduced at this step, but spores will be suspended in the water. This inoculum will increase the risk of mould growth during bulk storage.

Step 8: Bulk storage of whole apples - CCP4
The control measure is to prevent mould growth and patulin production by storing at reduced temperature. If refrigerated storage is not available, then storage time must be minimised. The critical limits are either a storage temperature of <=10°C or a maximum storage time at ambient temperature of 48 hours. These critical limits for temperature are monitored by means of a calibrated thermometer, preferably with a continuous chart read-out, and the storage period is monitored by a timing device.

Step 9: Pressing/extraction process - GMP
Good Manufacturing Practice will ensure that the presses are cleaned regularly to prevent a build-up of mouldy apple waste which could be a source of patulin contamination.

Step 10: Filtration - CCP5
The control measure is the removal of fine, patulin-rich particles held in suspension in the crude juice. Research has shown (Acar, J., 1998) that a significant reduction in levels of patulin can be achieved using filtration. Conventional clarification by means of a rotary vacuum precoat filter resulted in a 39% reduction in levels of patulin, and ultrafiltration resulted in a 25% reduction. Critical limits are set for the size and quantity of particles remaining in the apple juice after filtration. These critical limits are monitored by microscopic examination of samples of apple juice.

Step 11: Pasteurisation - CCP
This step is a CCP for the control of bacterial hazards. However, it can also be considered as a CCP for control of the patulin hazard since pasteurisation will destroy spores of *Penicillium expansum*, and therefore prevent any subsequent mould growth, and patulin production, in submerged culture in the apple juice.
Although patulin levels are unlikely to be reduced significantly during pasteurisation, mould spores will be destroyed and the risk of patulin being produced subsequently in the apple juice will be reduced.

Step 12: Asceptic packaging process - GMP
Following pasteurisation, it is important to prevent the re-introduction of micro-organisms, including mould spores, during packaging. These procedures are covered by GMP.
Packaging is selected which will protect the juice from contamination by micro-organisms, e.g. tetra packs, or glass bottles with air-tight seals for the lid.

Step 13: Storage and dispatch - GMP
No subsequent contamination with patulin is likely.

Process Step	Description of hazard	Control Measures	Control	Critical limits	Monitoring Procedures	Corrective actions	Records
1 Orchard growing	Mould/Pests	Minimise damage caused by birds and insects	GAP				
2 Orchard Harvest	Mould	Remove mouldy and damaged apples Avoid trash and soil contamination	CCP1 GAP	<1% visibly mouldy apples	Visual observation	Discard	Farm records
3 Farm Cooling and bulk storage	Mould	Reduce risk factors Handling and storage at <10°C to minimise mould growth	GAP/ GHP	All staff to be trained	Check training records Automated readout	Discard Adjust temperature Check monit. System Inspect fruit	Farm records
4 Transportation	Mould	Avoid damage and mould contamination	GAP/ GHP				
5 Factory Procurement	Mould	Inspect and reject low-grade apples with >10% mould apples	GMP	<10% damaged fruit	Quality check on representative sample	Reject batch	Factory records
6 Factory Sorting	Mould/Patulin	Remove mouldy apples	CCP2	<1% visibly mouldy apples	Visual observation of samples	Discard or re-sort Adjust inspection procedure	Operator log % reject
7 Factory Washing	Mould/Patulin	Leach patulin from apples. Remove rotten parts of fruit containing patulin with pressure spraying	CCP3	Critical soaking time and pressure of spray system	Time of soaking step; regular check of water spray pressure	Repeat the washing step	Factory records
8 Factory Bulk storage	Mould/Patulin	Temperature control to <10°C in store, and minimise time in store	CCP4	<10°C temperature or <48 hours in store	Thermometer reading Storage time	Check monitoring system Inspect fruit	Factory records
9 Factory Pressing/extract.	Mould/Patulin	Cleaning Batch segregation	GMP GMP				
10 Factory Filtration	Patulin Mould	Remove patulin in particles	CCP5	Size and quality of particles remaining	Laboratory test	Un-block/replace filter Re-filter juice	Factory records

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11 Factory Pasteurisation	Mould	Destroy *Penicillium expansum* spores	CCP6	Correct time/Temp.	Automated readout	Re-pasteurise?	Factory records
12 Factory Aseptic filling			GMP				
13 Factory Storage & dispatch			GMP				

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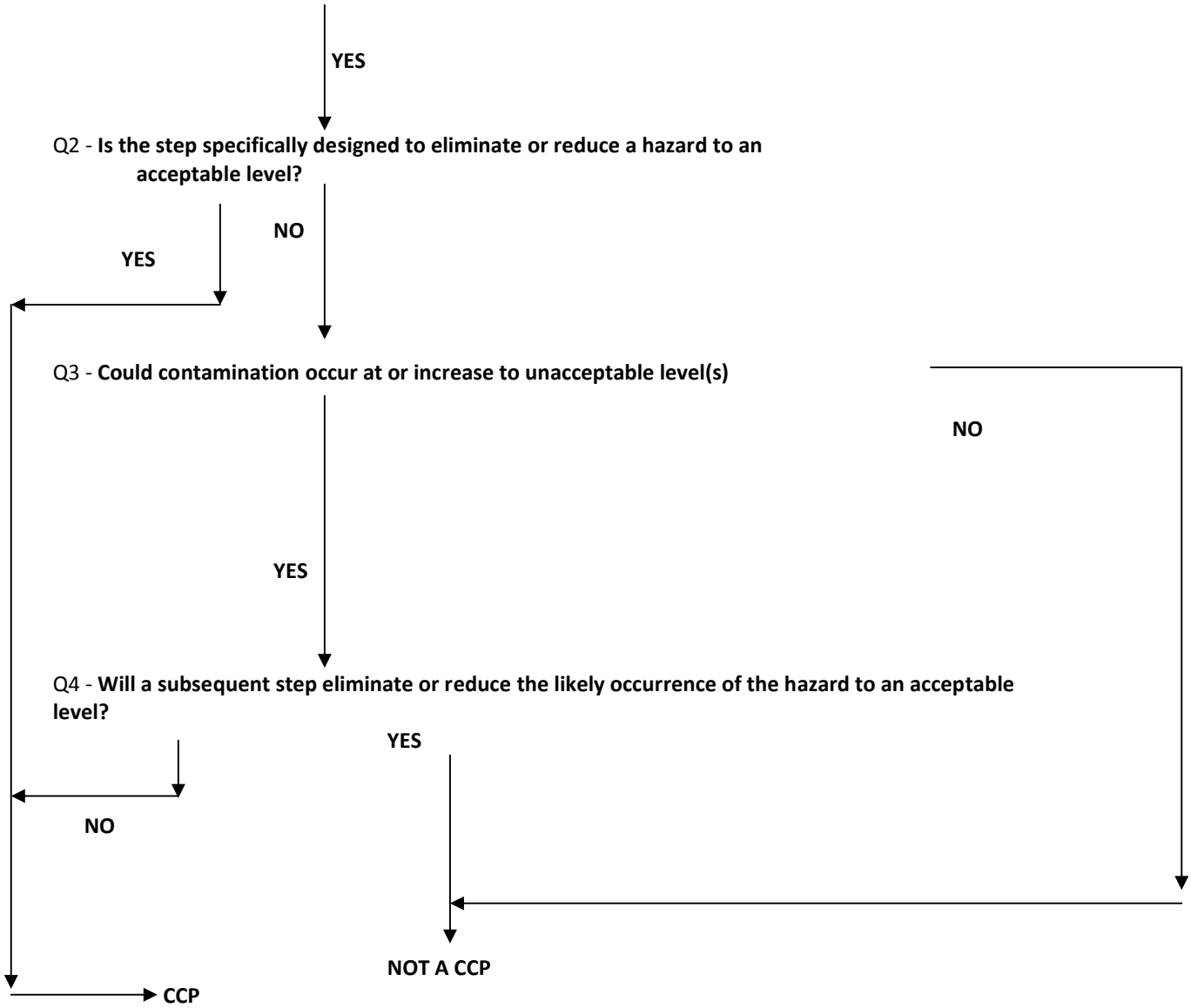
CCP Decision Tree

The CCP decision tree is as follows:



CCP Determination: A CCP is 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. The information collated during the hazard analysis allows for the identification of CCP's. To assist in the decision making process of determining CCP's a CCP decision tree was used.

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Verification procedures

The HACCP plan will be audited quarterly, and amended as necessary.

Documentation and record keeping

The HACCP Plan will be fully documented, and appropriate records kept at each CCP.

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