NZ Distillery Design and Setup Guidelines

PART 4 - FOOD SAFETY MANAGEMENT

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APPENDICES

INTRODUCTION

This section of the Start Up Guideline series covers the topic of food safety management for a distillery and explains the process to be followed when registering your business, and the ongoing requirements for maintaining registration.

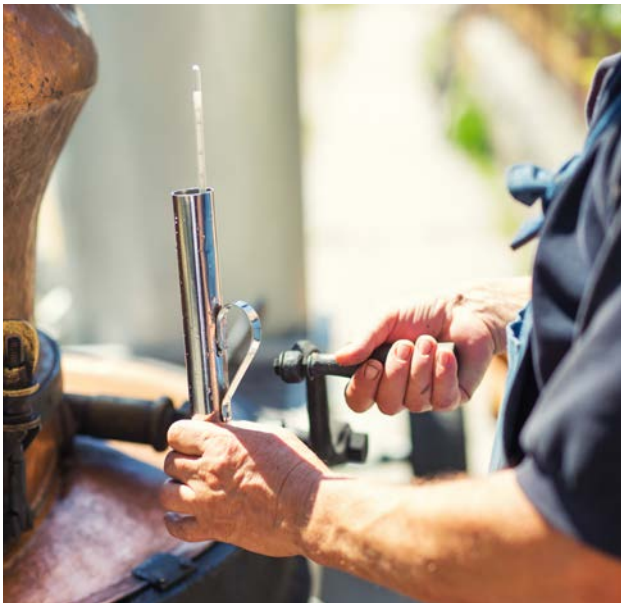
In New Zealand, food safety management is a paramount concern, and the country has established rigorous systems to ensure the highest standards are maintained throughout the food supply chain. The New Zealand Food Safety Authority (NZFSA), now part of the Ministry for Primary Industries (MPI), plays a crucial role in overseeing and regulating the safety of food products. The country adheres to the Hazard Analysis and Critical Control Point (HACCP) principles, a systematic approach that identifies and addresses potential hazards at various stages of food production. Stringent monitoring, inspection, and certification processes are in place to ensure compliance with these standards. Furthermore, collaboration between government agencies, industry stakeholders, and the scientific community enhances the overall effectiveness of the food safety management system. New Zealand's commitment to transparency, education, and continuous improvement underscores its dedication to safeguarding public health through a robust and comprehensive approach to food safety.

1. FOOD SAFETY

1.1 START-UP & ONGOING REQUIREMENTS

START-UP	ONGOING	COMMENT
Arrange NP3 audit. Register as a food business with MPI or your local council	Arrange periodic audits (varies, minimum every 2 years). Renew food business registration every 2 years.	

1.2 FOOD ACT 2014



The Food Act 2014 helps make sure that food sold throughout New Zealand is safe. Distillers are required to comply with the Food Act. The content of this section is taken from MPI's (Ministry for Primary Industries) website.

A central feature of the Act is a sliding scale where businesses that are higher risk, from a food safety point of view, will operate under more stringent food safety requirements and checks than lower-risk food businesses.

The Act has been in force since March 2016 and introduced other changes, including:

- the way food recalls are managed
- changes for food importers
- penalties and enforcement.

The Act has two food safety measures:

- Food control plans (FCPs): Written plans for managing food safety on a day-to-day basis. These are used by higher-risk businesses.
- National programmes: A set of food safety rules for medium and low-risk businesses. If you're under a national programme, you don't need a written plan (or develop written procedures), but must register, meet food safety standards, keep some records, and get checked.

1.3 FOOD REGULATIONS 2015

The Food Regulations 2015 relates to the details required in a Food Plan. The Ministry for Primary Industries (MPI) has a questionnaire on their website to determine the requirements for operating a food manufacturing business.

The questionnaire on the MPI website regarding food safety rules assists in determining which food safety category your activity falls into. The answers to the questionnaire are in *Appendix F*.

1.3.1. National Programme 3

National Programme 3 (NP3) sets the food safety rules for medium-risk businesses. This category applies to brewers and distillers.

To bring your business under NP3 you need to:

- check what you need to do to make safe food
- be prepared to tell an official (a food safety verifier) how you make safe food
- keep some written records to show what you do about important food safety issues.

The Food Act 2014 requires independent verification via a 5-step process:

Step 1. Confirm if NP3 is the relevant National Programme level for your business. NP3 is for medium-risk food businesses including manufacturers of alcoholic and non-alcoholic drinks.

Step 2. Good safety practices must be followed. Written records confirming compliance must be kept.

To bring your business under NP3 you need to:

- check what you need to do to make safe food
- be prepared to tell an official (a food safety verifier) how you make safe food
- keep some written records to show what you do about important food safety issues.

MPI has developed a guideline for following food safety practices and keeping records called My Food Rules that can be used by businesses.

To cover the aspects required by Step 2 of the NP3, some examples of the types of responses required by NP3 are included in Appendix G. Information can also be sourced from the Hazard Analysis and Critical Control Point (HACCP) Plan that is discussed in section 11.5 and is attached in Appendix H. A formal HACCP is not mandatory but is a good way to demonstrate compliance with NP3.

Step 3. Arrange for a verifier to check your business before registering.

Verifiers are professionals who will visit your business to check you are selling safe and suitable food. They could be from your local council or an independent agency. Confirmation of verification must be included in the registration application.

If you are a new business, your verifier must visit within 6 weeks of registering. If you are an existing business, your verifier must visit within 6 months of registering. In some circumstances, new businesses can apply to extend the date when their verification is due.

a. Arrange a verifier. MPI has a verifier map and a register with a list of auditors.

Contact the verifier to check if they can do your verification within your timeframe and ask how much they will charge. It's a good idea to ask for quotes from more than one verifier.

Councils and independent verifiers set their own fees. Prices range from $115 to $210 an hour plus travel fees. The time it takes to verify you will depend on the complexity of your business and how well you are managing food safety.

b. When you have chosen who you want, ask them for a letter to confirm they will verify you. Include the letter with your application to get registered.

Step 4. Register with MPI or your local council.

You must register with your local council or MPI (more so if you're registering several sites) and renew your registration every 2 years.

You must register as a food business with your local council if your business is based in one Council District or is a mobile business or an online business – in which case you must register with the local Council where your business is based (for example, where you live).

If you operate from fixed places (shops or packing houses) in more than one council area, you have a choice. You can either register each place separately with each local council or register them all with MPI.

Registering with a Council:

- get a letter from a verifier or auditor to say that they will verify you (see Step 3)
- contact your local council and ask for a registration form
- complete any other requirements set by the council
- complete a scope of operations form
- return all documents to your local council.

Registering with MPI:

To register your multi-site business with MPI you will need:

- a letter from a verifier or auditor to say that they will verify you (see Step 3)
- a copy of the Companies Act registration certificates for any parts of your business that are limited liability companies
- a completed registration form
- to pay to register your business – the application fee is detailed on the registration form
- a completed scope of operation form specific to your type of business.

Step 5. Arrange a verifier visit to your business.

The verifier will check you are making safe food and keeping records. They will give feedback on areas that need improvement.

TIMEFRAME FOR CHECKS

If you are a new business, your verifier must visit 6 weeks after registration and the maximum extension is another 6 weeks. If you are an existing business, your verifier must visit within 6 months of registering.

FREQUENCY OF VISITS

How often you are checked will depend on how successfully you are managing food safety. This could be as little as once every 2 years if you are managing food safety well.

1.4 HOW TO MAKE FOOD SAFE (STEP 2 OF NP 3)

To meet the requirements of the NP3, different aspects of the business will be looked at during the verification process. In some instances, records will need to be kept. The required records under the NP 3 are listed in Table 11-1. (Source: National Programme 3 Guidance, viewed 3 March 2022)

Table 11-1 Records required for NP 3

NP3 RECORDS	REQUIRED	WHEN SOMETHING GOES WRONG	EXAMPLE PLAN ELEMENTS TO MEET NP3 REQUIREMENTS
Competency and Training	✓		Keep a training record for all staff showing training in each area of the Food Safety Plan (an example is presented in Appendix G)
Sickness	✓		A sickness policy and register are required. An example is presented in Appendix G.
Water Test Results	✓		This requirement is not applicable to operations on Town Supply although filtering is still recommended. If the operation uses its own water supply, regular water testing is required, and the results need to be retained as proof.
Pests		✓	An inspection regime is required with records kept on the areas checked and dates. Records of any pest management actions need to be recorded if pests are found.
Maintenance		✓	Maintenance records kept for any maintenance with food safety implications.
Sourcing, receiving and tracking	✓		An Approved Supplier List is maintained that includes the agreed specification of the materials being supplied. Certificates of acceptance should be retained as part of the batch records especially if there was a recall required.
Thoroughly cooking or pasteurising Food		✓	This requirement is not applicable due to the high alcohol content being biocidal.
Reducing water content		✓	This requirement is not applicable to alcohol as it applies to other food materials where the control of bacteria is undertaken by limiting the available water for them to live e.g. in high sugar products such as jam.
Making food acidic		✓	This requirement is not applicable to alcohol as it applies to other food materials where the control of bacteria is undertaken by creating a low pH that bacteria can't survive in (<pH4.6) e.g. in pickled products such as sauerkraut or gerkins.

NP3 RECORDS	REQUIRED	WHEN SOMETHING GOES WRONG	EXAMPLE PLAN ELEMENTS TO MEET NP3 REQUIREMENTS
Foreign Matter		✓	Maintenance operations are controlled to ensure contaminants and tools etc are cleaned prior to production. Glass materials are minimised and accounted for during each stage of production where they are used. The bottles are rinsed and dried prior to filling and the alcohol is filtered at bottling
Packing and Labelling		✓	NZ Customs and NZFSA have some requirements on some of the information that needs to be shown on a label. Batch information needs to be recorded on the bottle to provide a link to the production information for that batch to allow for a product recall is that ever occurred.
Transportation Food Temperature	✓		This requirement is not applicable to alcohol as it applies to putrescible food materials where the food control deteriorate at ambient temperature. Alcohol does not require temperature control.
Checking the programme is working well		✓	Audits of the food safety programme are required to ensure all of the actions required under the plan are being undertaken consistently and that the controls are effective. The results of the audit need to be recorded.
Recalling food		✓	Batch records are required to ensure all of the materials used to make the batch can be traced back to the raw materials used to make the finished product.

The top 5 requirements checked by a verifier as indicated by the NP 3 Guidance are:

1. Competency and training
2. Cleaning
3. Personal hygiene
4. Sourcing, receiving, and tracing materials
5. Process controls

Under a national programme, written procedures or a documented food control plan are not required for non-high risk food businesses but alcohol production is covered by the highest NP. Record keeping of food safety and suitability management is however required. It is up to the business' discretion if it decides to write its own food safety and suitability rules or to follow the NP3 Guidance. The verification process will determine if the rules in place appropriately manage food safety and suitability. An example of a comprehensive food safety plan is presented in Appendix H.

There are several aspects of food safety and suitability that will be checked during verification and they are indicative of the requirements of the NP3 and the New Zealand

Food Safety Authority (NZSFA).

1. **Setup**

    - Adequate number of trained and competent staff
    - A copy of all documents or records kept for at least 4 years
    - Process in place to determine effectiveness of food safety and suitability rules followed.

2. **Places and equipment**

    - Historical land and building use
    - Land use compatibility with neighbours
    - Safety and suitability of building, fixtures, fittings and equipment
    - Storage of maintenance compounds and chemicals
    - Process in place for maintenance checks and services.

Records of wrong abnormal or unexpected events during maintenance must be kept.

3. **Suitable Water**

    - Suitability of water used
    - Process in place to check and maintain water equipment and facilities.

If self-supplied water is in use, records of water analysis tests must be kept.

4. **Staff**

    - Level of competency and training
    - Allocation of responsibilities and tasks and how they are carried out. Records of these must be kept.
    - Health and hygiene.

5. **Food-handling controls**

    - Food source i.e. supplier
    - Food receipt
    - Food storage
    - Food processing
    - Food display
    - Food packaging
    - Food transportation
    - Food disposal
    - Food recall.

Records of suppliers, type and quantity of and food ingredients received and added into the production process, and customers must be kept.

6. **Health and hygiene requirements**

    - Hand washing area
    - Process if a staff is sick or unwell.

Records of incidents where staff is sick and process followed to ensure food contamination did not occur.

7. **Cleaning, sanitising and maintenance**

    - Cleanliness and waste management
    - Cleaning and sanitising of specific equipment
    - Maintenance.

8. **Miscellaneous**
    - Temperature-measuring devices and calibration
    - Single-use items
    - Animals and pests.

A verified NP3 plan is the minimum requirement. Food Safety Hazards should be actively identified within the business operation and measures for their control put in place and monitored. A Hazard Analysis and Critical Control Point (HACCP) plan is a structured way to do this and may be a useful process to undertake.

1.5 HACCP

An example HACCP plan for a distillery is attached in Appendix G. Implementing HACCP involves applying HACCP principles to the extent possible to all direct processes and inputs within your food operation in line with the 7 overarching principles identified by MPI:

1. Identify hazards — Biological, chemical, and physical hazards that could be reasonably likely to occur in food ingredients should be identified along with available control measures. The MPI hazard database assists with information on reported food safety hazards that can occur in New Zealand food ingredients.

2. Determine critical control points (CCPs) — A CCP is a step at which control can be applied to prevent, eliminate or reduce a food safety hazard to an acceptable level.

3. Establish critical limits for each CCP — A critical limit provides the measure for separating acceptability from unacceptability at a CCP.

4. Establish CCP monitoring requirements — Suitable monitoring activities are necessary to ensure that the CCP is under control.

5. Establish corrective actions — These are the actions to be taken when monitoring shows a CCP is out of control. That is, a critical limit has been exceeded. Actions include: restoring control at the CCP, making decisions on product disposition, and preventing re-occurrence of the CCP failure.

6. Verifying the HACCP system is working as intended — Within-business verification is required to ensure that your HACCP application is complying.

7. Establish record keeping procedures — HACCP documentation must be correctly maintained, including: identification and analysis of hazards, CCP determination, and critical limit determination. Records are also kept for tracking CCP monitoring, corrective actions taken and HACCP system verification.

1.6 FURTHER INFORMATION

Links to useful internet sites relating to this topic are attached as *Appendix A*.

APPENDIX F –
MPI QUESTIONNAIRE RESULTS

MPI QUESTIONNAIRE SUMMARY REVIEW

Q 1. What will you do?
A - Make, cook, pack or sell food or drink to be eaten later.

Food businesses that may fall in this group include dairies, supermarkets, butchers, abattoirs, bakers, fishmongers, factories, your home or an online store, farms, wineries or breweries.

Q 2. What will you do?
A - Sell food to other businesses.
Sell food directly to consumers.

Q 3. Will your product be exported by you or anyone else?
A - Yes.

Q 4. Will you export any of these?
A - No.

Q 5. Will you export any of these?
A - No.

Q 6. Who will make or grow the food or drink you will sell?
A - We will.

Q 7. Which of these will you be?
A - Winery or brewery.

Q 8. What will you sell?
A - Drinks.
Includes vinegar and oils.

Q 9. Which of these will you make, process or bottle?
A - Alcoholic drinks.

For example, wine, beer or spirits.

Q 10. Which of these will you make or bottle?

A - Spirits and liqueurs.

For example, gin, whisky(ey) or brandy.

Q 11. Which of these will you do?

A - None.

Q 12. Will you defrost (thaw) frozen food or drink?

A - No

Q 13. Which of these will you do?

A - Use good bugs to make or preserve food and drink (also known as fermentation).

For example, kimchee, sauerkraut or pickles.

Q 14. Which of these will you do?

A - None.

Q 15. Which of these will you do?

A - None.

Q 16. Will you sell food over the internet?

For example, through your own online portal or you interact with a customer through a third party online market place such as UberEATS, Trade Me or Facebook.

A - Yes

APPENDIX G – NP3 NOTES

MORE DETAIL ON NP3 FOOD SAFETY PLAN

Staff Training and Competency

It is company policy that all personnel, including temporary staff, affecting conformity to product requirements shall be competent on the basis of appropriate education and training, and/or where applicable on the basis of skills and experience, and be adequately supervised. A training programme and adequate supervision is put in place for all new personnel until they have been assessed as competent.

Basic elements of employee training include hygiene requirements and awareness of the relevance and importance of their activities in maintaining quality objectives and contributing to food safety.

New staff receive training pertaining to their job description and also personal hygiene, reporting of illness, cuts and accidents. The key personnel have undertaken an introduction to Food Safety course.

Refresher training is undertaken as appropriate to ensure staff retain a basic knowledge and understanding of basic hygiene and the Food Safety Program. The aim is to provide refresher training every 2 years.

Staff training is recorded in the following training matrix which also can include other staff training.

Table 1 Staff Training Matrix

EMPLOYEE	POSITION	DATE EMPLOYED	FOOD SAFETY TRAINING, 2 YEARLY	HAZARDOUS SUBSTANCES, 2-YEARLY	FORKLIFT, 3-YEARLY
Name	Job	Date	Date	Date	Date
Name	Job	Date	Date	Date	Date
Name	Job	Date	Date	Date	Date
Name	Job	Date	Date	Date	Date

SICKNESS REGISTER

In some instances, staff may be excluded from working with product or moved to a different part of the factory that doesn't involve handling finished product or packaging if there a risk of contamination after coming back to work from an illness or being involved with sick people.

Personal hygiene, behaviours and requirements for manufacturing processes, proportional to the hazard posed to the process area or product, are established and documented based on risk assessment.

If an employee reports an Illness then this must be reported in the following table.

Table 2 Sickness Register

EMPLOYEE	SYMPTOMS	DATE OF SYMPTOMS	DATE NOTIFIED	ACTION TAKEN	FAECAL RESULT (IF ANY)	DATE EXCLUDED FROM WORK	DATE RETURNED TO WORK

PEST MANAGEMENT

Contractors are available to undertake management of traps, undertake spraying and fumigations if required. As a minimum, regular inspections of storage and production areas should be undertaken. A typical management regime would be monthly to 2 monthly residual spraying inside and outside the building boundary, rodent traps inside and outside the building including the boundary fence and insect light traps with sticky boards to catch flying insects.

MAINTENANCE

Preventative Maintenance is carried out in key areas including:

- Buildings
- Air Compressors (if used)
- Production Equipment
- Services.

Table 3 Maintenance

CRITERIA	NCI IMPLEMENTATION
A system of planned maintenance shall be in place including all equipment.	The Plant Maintenance System is managed by Engineering staff or contractors. The Programme operates on all areas covering: • lubrication • Filters (including air filters) • Process Thermometers on equipment

Maintenance programmes shall be systematically applied to minimize the potential for contamination of product by equipment. Priority shall be given for maintenance request where Health and Safety is a risk then food safety is next priority.	The person undertaking the work signs-off that all work materials have been removed and the equipment cleaned. Health and Safety issues are first priority but next in line are food safety risk issues. Maintenance is carried out in such a way that production on adjoining equipment is not at risk of contamination so the equipment or area is taken out of production, segregated and released to the Engineer to complete the work required. Preventative Maintenance (PM) is undertaken as per the PM schedule. Operators are able to undertake more frequent maintenance activities such as lubricating equipment. These activities are listed on maintenance sheets which list the cleaners and lubricants to be used.
A procedure shall be in place to remove any potential contaminant from machinery and equipment after maintenance work.	On the maintenance request form there is a section at the bottom that requires the person undertaking the maintenance to sign-off that all materials have been removed and the machine is clean.
Maintenance personnel shall follow the prescribed procedures including, where appropriate, hygiene measures. Temporary engineering and modifications should be avoided, shall be controlled and shall not become permanent. Effective measures shall be implemented.	Maintenance personnel all adhere to the company hygiene policy and area specific hygiene and dress codes. Temporary repairs are only allowed if product safety is not put at risk and a permanent repair is schedules within a reasonable timescale. After all maintenance work there is a thorough clean up (accounting for machines parts, materials and tools), the equipment or area is cleaned prior to resumption of production and the Maintenance Repair Request form is signed by the person undertaking the work to confirm it is safe to return to production.
	Maintenance personnel are trained in food safety hazards associated with their activities and how to provide hygienic maintenance services. Relevant procedures and records are maintained including: • Engineering Procedures • Preventative Maintenance Schedule • Maintenance Request Form

Lubricant Use

All lubricants used on food packaging manufacturing equipment in locations where there is risk of lubricant contact with food material are food grade.

PHYSICAL CONTAMINATION

Table 1 presents controls to prevent physical contamination. Equipment is generally covered

which minimises contamination. Food safe cleaners should requested from cleaning suppliers. These can be found on https://www.mpi.govt.nz/food-business/maintenance-cleaning-products-animal-product-processing/maintenance-compounds-register-and-list/ .

Table 4 Physical Contamination Controls

CONTAMINATION	CONTROL
Pests	The Pest Control procedures discussed above.
Wood	The hygienic design of the building and pre-cleaning procedures for wooden pallets
Cardboard	Only new cardboard is used for packaging. Other cardboard packaging that comes in with raw materials is removed away from the production equipment.
Glass/Perspex/Ceramics	Perspex or polycarbonate may be used for guarding on machines and there may be some glass skylights and light covers. Ceramics are unlikely to be used in alcohol manufacture, but care is required with glass hydrometers. If there is a breakage of glass or brittle material, there are procedures for reporting it.
Hair	Hair is controlled by the Personnel Hygiene and Facilities policies which require the use of hairnets.
Jewellery & Personal effects	The risk from jewellery and personal effects is controlled by restricting their use near production equipment.
Metal	Cleaning and inspection of equipment is required prior to production. Bottles are washed before use to remove physical contaminants and the supplier has been reviewed against food safety requirements. Monitoring is by verification audits and supervision of production.
Packaging Materials	Packaging materials are controlled through supplier approval, the Management of purchased materials and services Policies and inspections.
Cleaning Equipment and Materials	The risk from cleaning equipment and materials is controlled by visual checks of equipment prior to use. Equipment with damage is replaced and not to be used.
General Physical	The risk from general physical hazards is controlled by covering products and raw materials as appropriate, the hygienic design of equipment & buildings, controlled preventative maintenance and general Good Manufacturing Practices procedures and training. The alcohol is filtered just prior to bottling.

APPENDIX H –
HACCP PLAN

INTRODUCTION

A distillery plant produces alcohol and is therefore part of the food chain. Under the Ministry for Primary Industries (MPI) regulation of food safety alcohol manufacture comes under National Programme 3 which requires a food safety plan to be prepared for this activity. The Food Safety Plan (FSP) is part of the manufacturing process to ensure the safety of the products produced.

BUSINESS DETAILS	
Legal name	
Trading name	
Activity : Alcohol manufacture	
Postal address	
Telephone	
Email	
List below any other premises that are used in connection with the food business (e.g. premises used for storage or preparation of food). These activities and sites will also be covered by this Food Control Plan. If water is used for food purposes, identify the source of the water supply	
Location(s)	
Street address (1) (premises where food business operates)	
Water supply	
Street address (2)	

Activities/water	
Supply source	
Street address (3)	
Activities/water	
Supply source	
Street address (4)	
Activities/water	
Supply source	

Operator: The operator is the owner or other person in control of the food business. If the Food Control Plan applies to more than one food business, the operator is the person responsible for the Food Control Plan*

Name	
Physical address ☐ Business / ☐ Residential	
Telephone	
Email	

*Operator of each food business (if plan applies to more than one food business). Add additional rows as necessary.

Name	
Physical address ☐ Business / ☐ Residential	
Telephone	
Email	

Day-to-day manager [write 'as above' if the day-to-day manager is the operator] The day-to-day manager is the person who has the overall responsibility to make sure that the Food Control Plan is being followed and the appropriate checks and records are completed.
The records and your plan must be kept for at least 4 years. All records must be written in English and be easy to read. All records must include a date and the name of the person who performed the task.

Name and/or Position	
Telephone	

Registration authority (this will be your local council unless your FCP covers premises situated in more than one council jurisdiction or you have a third-party verifier in which case it will be MPI).

Registration authority	MPI or Council [Council name]:
Contact person	
Address	
Email	
Verifier (if not local council)	
Verification agency	
Contact person	
Address	
Telephone	
Email	

Business Layout

You must make sure that the design and physical location of your food business allows you to make safe and suitable food.

You need to draw a map and floor plan that includes:

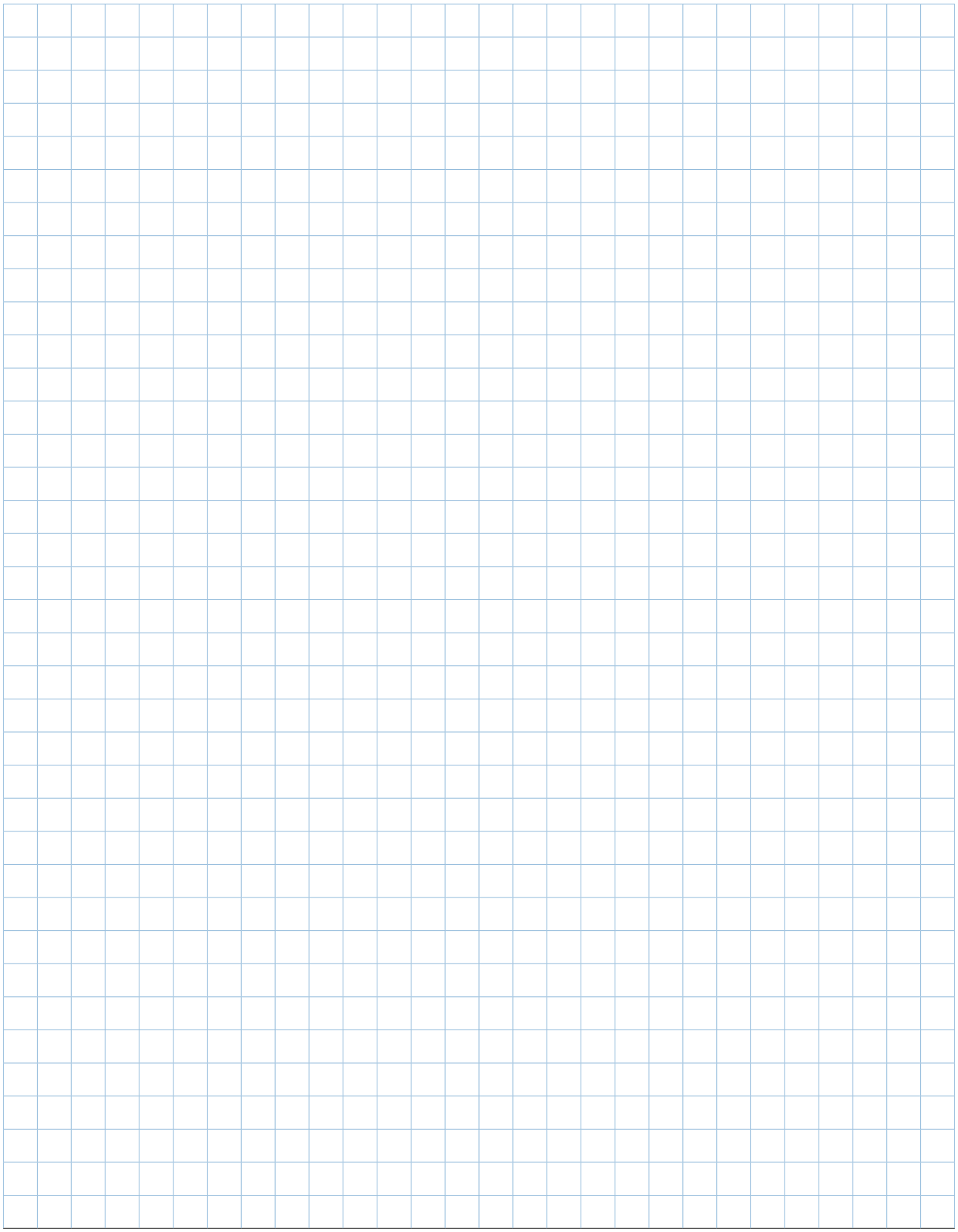
- your building,
- the buildings surrounding it,
- what happens in the different areas on your map, including your food preparation areas (e.g. your mixing and processing areas),
- what happens in your buildings, including non-food activities,
- what happens in the different areas of the building,
- some non-food activities being conducted in the same or neighbouring building/property that might affect food safety may need to be included in your map of your business.

Layout — Inside of your business

*This could be a hand drawn plan or photograph.

Layout — Outside of your business

*This could be a hand drawn plan or photograph.



FOOD SAFETY PLAN

One of the main ways of reducing the risk of food safety hazards is to assess the risks of each part of the process which is undertaken by the assessment of the Hazards Analysis of Critical Control Points (HACCP) in the manufacturing process. The FSP enables your Company to have confidence that its products are produced to the highest safety standard, knowing that it has systematically identified all potential microbiological, chemical & physical hazards associated with their product. Controls have been implemented to ensure hazards are eliminated where possible or reduced to a safe level. Corrective actions are in place to ensure any products with food safety hazards are removed prior to distribution.

The steps required in a HACCP Plan are:

Table 1 – HACCP Plan Steps

HACCP PLAN STEPS
Assemble a HACCP Team – customise to own operation,
Describe the Product and its intended use
Construct Flow Diagrams
Conduct a hazard analysis
Identify Critical Control Points (CCP)
Establish Critical Limits for Critical Control Points
Establish a system for the monitoring of Critical Control Points
Establish corrective actions to be taken when monitoring indicates that a CCP is not under control
Establish verification procedures to confirm the HACCP system is working
Establish documentation concerning all procedures and records appropriate to these principles and their action. - documentation for each batch - certificate of compliance/certification (also raw materials) - tracing system (suppliers) – batch records

HACCP TEAM

The team that has assessed the food safety risks is made up of:

- The owner
- The Distiller/Brewer
- Other staff

The HACCP Team is responsible for:

- Following HACCP procedures and constructing the HACCP Plans
- Validation and verification of the HACCP system
- Review of the effects of any process or product change on the Food Safety Management System
- Updating the HACCP plan

SPECIFICATIONS

Specifications should include sufficient detail for the identification and assessment of food safety hazards as follows:

- Biological, chemical and physical characteristics
- Composition of formulated ingredients including additives and processing aids
- Place of origin
- Method of production
- Packaging and delivery method
- Storage conditions/requirements and shelf life
- Preparation and/or handling before use
- Food Safety acceptance criteria
- Intended use.

Raw Materials, Ingredients and Product Contact Materials

The main materials purchased for manufacturing alcohol from fermentable materials are presented in *Table 2*.

Table 2 Brought in Materials (list as appropriate for your organisation)

MATERIAL	SUPPLIER	HAVE A SPECIFICATION	SUPPLIER ASSURANCE	COMPLETE AND ON FILE
Fermented items				
Barley	Supplier name	Yes	Certificate of compliance	✓
Maize	Supplier name	Yes	Certificate of compliance	✓
Malt	Supplier name	Yes	Certificate of compliance	✓
Sugar	Supplier name	Yes	Certificate of compliance	✓
Molasses	Supplier name	Yes	Certificate of compliance	✓
Fruit	Supplier name	Yes	Certificate of compliance	✓
Vegetables	Supplier name	Yes	Certificate of compliance	✓
Non Fermented items				
Wine	Supplier name	Yes	Certificate of compliance	✓
Alcohol	Supplier name	Yes	Certificate of compliance	✓
Spices and Additives	Supplier name	Yes	Certificate of compliance	✓
Wooden barrels	Supplier name	Yes	Certificate of compliance	✓
Bottles	Supplier name	Yes	Certificate of compliance	✓

Complete specifications for suppliers are maintained on file. Approved suppliers are set-up in a Database with their list of contacts. Suppliers of primary contact materials (bottles or cans) that will contact food are reviewed against international food contact regulations such are those of US FDA, EU and China which all include reference to good manufacturing practice. Secondary contact suppliers such as packaging suppliers are reviewed via a questionnaire.

Table 3 - Materials

CRITERIA	FERMENTABLE MATERIAL	NON FERMENTABLE
Biological, Chemical and physical characteristics	Free of volatile compounds, compliant with pesticide and heavy metal residues, mycotoxin-free	May vary
Formulated ingredients composition	May vary	May vary
Origin	May vary	May vary
Method of production	May vary	May vary
Packaging and delivery methods	May vary	May vary
Storage conditions and shelf life	May vary	May vary
Preparation before use or handling	May vary	May vary
Food safety acceptance criteria	All are prequalified	All are prequalified, no physical contamination

Table 4 - Packaging Materials

CRITERIA	BOTTLES	OUTSIDE PACKAGING
Biological, Chemical and physical characteristics	May vary	May vary
Formulated ingredients composition	May vary	May vary
Origin	May vary	May vary
Method of production	May vary	May vary
Packaging and delivery methods	May vary	May vary
Storage conditions and shelf life	May vary	May vary
Preparation before use or handling	May vary	May vary
Food safety acceptance criteria	All are prequalified	All are prequalified, no physical contamination

Product Intended use

Alcohol is directly consumed Alcohol mixtures are inherently biocidal due to heating processes involved in their manufacture and the properties of alcohol.

Table 5 - Alcohol Description

PRODUCT DESCRIPTION	DETAILS
Product Name	Alcoholic spirit
Describe the product	Gin, Whisky(ey), Vodka Rum, xx%
Customer Usage	Drink
Preservation from chemical composition	Naturally biocidal, kept in sealed bottles
Microcidal treatment	Naturally biocidal
Shelf life	Un opened – many years
Storage Conditions	Ambient °C, Minimal moisture
Customers	Public over 18 years old

PROCESS DESCRIPTION INCLUDING FLOW DIAGRAMS

Section 2 of this guideline discusses the process in detail.

Bought in Materials

All Raw materials (including packaging) only come from suppliers that are on the approved supplier list. All suppliers receive the required specifications and must abide by them. The bottles are compliant with international food contact regulations such as United States Food and Drug Administration (US FDA) and European Union (EU) Regulations. Vendors are reviewed prior to supply.

Receipt of Inwards goods

The Storeperson and/or Stores Team Leader visually checks the inwards goods for any signs that they may not meet the required standard. Inwards goods are either delivered direct to their allocated storage point or are transferred to their storage points as soon as possible.

Process Vessels

Process vessels are cleaned thoroughly prior to making a new batch with food safety cleaners and the vessels are rinsed.

Quarantined Product

All products that are suspected of not meeting customer requirements are quarantined in a “hold” area. A QC Inspector, Manager, Team Leader or Distiller isolates the product. In practice anyone can place suspect product in the “hold” area to be checked. The “Hold” product is tested and material within specification is released following sign-off by an approved person. Hold material may be reworked, downgraded or dumped as determined by the Production Manager or Owner/Operations Manager.

Storage of Finished Goods

Final packed product is stored in a finished goods store awaiting distribution. Prior to being loaded onto a truck, the product receives a final external inspection to identify any damaged outer packaging indicating there may be damaged products. Any pallets/boxes noted with damaged product or the outer packaging is damaged are returned to the Hold area to be re-sorted by production and signed off by an approved person.

Distribution of Final Product

Despatch staff are issued a pick list via the financial production database with details of what product needs to be sent out and where it needs to go. Despatch staff inspect trucks and containers prior to loading finished goods and a check sheet is filled out to record their results. The approved haulage contractor delivers final products to the customers. Products receive external visual inspection by the driver at point of delivery and while unloading. Any product rejected by the customer is either not unloaded from the truck or uplifted as soon as possible then returned to the producer.

GENERAL FOOD SAFETY HAZARDS

Food safety hazards that are reasonably expected to occur in relation to the processes undertaken have been identified. Relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended. The following sections list the potential hazards from alcohol manufacture.

List of General Hazards

Table 6 lists examples of biological, chemical and physical hazards.

Table 6 - Hazard Examples

BIOLOGICAL HAZARDS	CHEMICAL HAZARDS	PHYSICAL HAZARDS
Bacteria (spore-forming) such as	Pesticides	Adhesives
Clostridium botulinum	Prohibited substances	Lead
Clostridium perfringens	Direct Toxic elements and compounds	Tinplate, off-cuts
Bacillus cereus	Indirect Toxic elements and compounds	Glass
Bacteria (non-spore-forming) such as	Lead	Wood
Campylobacter spp.	Zinc	Stones
Pathogenic Escherichia coli (including E. coli 0157)	Cadmium	Metal
Listeria monocytogenes	Mercury	Insulation
Mycobacterium tuberculosis	Arsenic	Bone
Mycobacterium avium subspecies paratuberculosis	Cyanide	Plastic
Shigella (S. dysenteriae)	**Contaminants such as**	Maintenance materials such as nuts, bolts and washers
Shigella (S. dysenteriae)	Lubricants	Feathers
Staphylococcus aureus	Cleaners	Leaves
Streptococcus pyogenes	Sanitizers	Insects
Contamination with Bacteria from pests	Coatings	Raw material powder
Viruses such as	Paints	Personal effects
Hepatitis A and E	Hydraulic fluids	Tools

BIOLOGICAL HAZARDS	CHEMICAL HAZARDS	PHYSICAL HAZARDS
Norwalk virus group	Pest control chemicals	
Rotavirus	Plasticizers	
Corona virus 19	Vinyl chloride	
Protozoa and parasites such as	Printing/coding inks	
Giardia lamblia		
Blood or other body fluids		

Foods That can Cause Allergic Reaction

The following types of foods can cause reactions in susceptible persons and therefore they are not used in the production of alcohol.

Table 7 - Examples of Allergens

Cereals containing gluten	Peanuts	Shellfish	Eggs
Sesame seeds	Nuts	Soya	Mustard
Celery/celeriac	Milk	Fish	Lupin
Sulphur dioxide and sulphites			

SPECIFIC HAZARDS, CRITICAL CONTROL POINTS & MONITORING

Walls and doors are well sealed which restricts insects and other physical contaminants entering the plant. Regular fumigations are undertaken through the whole plant with pyrethrum type insecticides as well as residual sprays around both the inside and outside boundary floor areas. There are brittle materials throughout the plant such as skylights however for much of the process sealed vessels are used.

There are pest traps at all entrances to the building and insect light traps spread around the site especially near doors.

General Chemical Controls

Cleaning Chemicals - There is physical separation between product and cleaning chemicals and there is segregated storage of chemicals.

Allergens – allergens are not used on-site.

Lubricants – This is controlled by the hygienic design of plant/equipment and only food grade lubricants being used on production machinery. This is monitored by hygiene and housekeeping audits, and supervision of production.

Chemicals General – This is controlled by segregated storage of chemicals. Monitoring is by hygiene and housekeeping audits and supervision of production.

General Microbiological Controls

Areas where there is a potential for microbiological contamination to exist are identified by undertaking a risk assessment. The risk assessment also identifies control measures including segregation of areas if required. The food safety team has carried out an assessment to determine sources of potential contamination, the likelihood of contamination of the product and the severity of potential contamination. Based on the results of the assessment, control measures have been implemented in food processing and storage areas. The cooking and distillation process kills microbes however does not kill the toxins generated by them so microbiological control of raw materials needs to be considered.

The control measures include:

- Changing of protective work wear
- Defined traffic patterns
- Equipment segregation
- People segregation
- Dedicated tools and cleaning equipment

General Physical Controls

As the majority of the manufacturing process of alcohol is undertaken in closed vessels there is limited opportunity for physical contaminants to get into the vessels. The final process involves a physical separation of alcohol by vaporisation so carry over is not possible. Certified suppliers of bottles provide a guarantee there are no contaminants in the bottles. (Washing of the bottles is probably still recommended to provide your own assurance).

Wood - Controlled by the hygienic design of building and use of wooden pallets in process or production areas is limited. Monitoring is by hygiene and hou*sekeeping audits and supervision of production.*

Glass/Perspex/Ceramics - Controlled by the Contamination Policy which includes glass and brittle material and breakage procedures/reporting. This is monitored periodically by the critical glass/brittle material register and inspection.

Lighting throughout the building is LED and the light covers are made of aluminium. The roof of the building ranges from 10 – 13.5 m high so there is a very low potential for day to day activities causing damage to the lights.

Hair, Jewellery & Personal effects - Controlled by the Personal Hygiene Policy. Monitoring is by hygiene and housekeeping audits and supervision of production.

Packaging Materials - Controlled through supplier approval, incoming materials procedure and inspections. Monitored by verification audits and supervision of production

Cleaning Equipment and Materials - Controlled by visual checks of equipment prior to use, equipment with damage is replaced and is not to be used. Monitoring is by hygiene and housekeeping audits and supervision of cleaning.

Stationery - Controlled by the restriction of use of stationery materials in the bottling area as per the Contamination Prerequisite programme. Monitoring is by Hygiene and Housekeeping Audits and Supervision of Production.

Prerequisite Programmes

There are a range of key food safety requirements for businesses to consider to ensure safe products are manufactured. Table 8 lists guidance for each parameter.

Table 8 - Prerequisite Programmes

PREREQUISITE PROGRAMME	COVERS	DESCRIPTION
Establishment verification	Environmental Control - potential sources of contamination from the environment Design and construction of buildings, Site location and standards verification audit.	• The establishment shall be designed, constructed and maintained in a manner fit for the nature and purpose of the food packaging manufacturing operations to be carried out, the food safety hazards associated with those operations and the potential sources of contamination. • Buildings shall be of durable construction that presents no food safety hazard to the food packaging. • Consideration shall be given to potential sources of contamination from the local environment. • All areas within the boundaries of the establishment shall be maintained in an appropriate condition to prevent contamination.

PREREQUISITE PROGRAMME	COVERS	DESCRIPTION
Layout & workspace	Layout of premises and workspace, Internal design and layout traffic patterns, Internal structure (ceilings, floors, internal walls, lighting, doors, equipment, temporary structures) Storage prerequisite programme, stock control, chemical storage.	• Internal layouts shall be designed, constructed and maintained to facilitate good hygiene and manufacturing practices. • The movement patterns of materials, products and people and the layout of equipment shall be designed to protect against contamination sources, unintended mixing of materials or products and cross-contamination. • Buildings shall provide sufficient space to allow a logical flow of materials, products and people through the production process. • Temporary structures shall be designed, located and constructed to prevent pest harbourage and contamination.
Utilities	Site services Control of water supply Air quality and ventilation Control of compressed air and gases, Lighting	• The provision and distribution routes for utilities to and around production and storage areas shall be designed to prevent contamination. • The supply of water of a suitable quality shall be sufficient to meet the needs of the food packaging production process and not cause a food safety hazard. • The organization shall establish requirements for air used for direct food packaging contact and shall monitor accordingly. • Suitable and sufficient ventilation (natural or mechanical) shall be provided to remove excess or unwanted steam, dust and odours. • Ventilation systems shall be designed and constructed such that air does not flow from contaminated areas to clean areas. • Compressed air and other gas systems used in food packaging manufacturing shall be constructed and maintained so as to prevent contamination. • The organization shall establish requirements for gases used for direct food packaging contact (including those used for transporting, blowing or drying raw

PREREQUISITE PROGRAMME	COVERS	DESCRIPTION
		• materials, intermediate products, food packaging or equipment) and shall monitor accordingly. • Requirements for filtration, humidity and microbiology shall be assessed. • The lighting provided (natural or artificial) shall allow correct operation of the food packaging production process.
Waste management	Waste management, Waste handling, container management, Waste disposal, Drains and drainage system (n/a no water used in the process).	• Systems shall be in place to identify, collect, remove and dispose of waste in a manner that prevents contamination. • Waste shall be kept away from production and storage areas. Bins and containers for non-production waste shall be appropriately identified, emptied regularly and if necessary, provided with lids. • Drains shall be designed, located and constructed to prevent potential for contamination.
Equipment	Equipment Hygienic Design, Preventative and Corrective Maintenance System.	• Equipment used in production and packaging areas shall be designed to prevent contamination. • All parts of equipment coming into contact with food packaging shall be designed and constructed to facilitate cleaning and maintenance. • Equipment components containing metals of known toxicity (e.g. mercury) shall not be allowed where they could compromise the food safety of the food packaging. • A system of planned maintenance shall be in place including all equipment.
Purchased materials and services	Purchasing, Supplier approval and monitoring, Control of incoming materials.	• Purchasing of materials, services and subcontracted activities that may impact food safety of food packaging shall be controlled such that the suppliers used have the capability to meet the specified requirements. • There shall be a documented procedure for the evaluation, approval and monitoring of suppliers in place to ensure compliance. The method used shall be justified by risk

PREREQUISITE PROGRAMME	COVERS	DESCRIPTION
		assessment and hazard analysis, including the potential food safety hazard to the food packaging. • All incoming raw materials shall be inspected, tested or covered by Certificate of Analysis/Declaration of Conformance to verify conformance to specified requirements prior to acceptance or use. The method of verification shall be documented.
Contamination and cross contamination	Food Packaging Contact Surfaces, Prevention of contamination, Prevention of microbiological contamination, Prevention of physical contamination (pests, wood, cardboard, glass perspex, ceramics, hair, jewellery and personal effects, metal, packaging materials, cleaning equipment and materials, general physical), Prevention of chemical contamination, Food allergen management, Pathogen testing procedure	• Food packaging contact surfaces shall be constructed from materials suitable for the intended use, to prevent contamination. • A hazard analysis shall be carried out. If applicable, measures to prevent microbiological, physical and chemical contamination shall be implemented. • Whenever a contamination incident occurs, the process of cleaning up or the maintenance shall be carried out under the control of a designated person. After cleaning up or maintenance a documented release procedure shall follow. Any contaminated product that cannot be effectively cleaned shall be discarded. • Chemicals, including cleaning materials and lubricants, shall be evaluated and controlled in order to prevent product contamination.
		• Where there is a potential food safety hazard due to migration or other transfer mechanism, controls shall be implemented to prevent or control the hazard. • Where a potential for contamination from food allergens has been identified, controls shall be established, documented and implemented to prevent or control the hazards and to record and label accordingly.
Cleaning and Disinfecting	Cleaning Programmes, Cleaning Agents and Tools, Cleaning Procedures, Monitoring of Cleaning	• Cleaning programmes appropriate for specific areas shall be established to maintain the production equipment & environment in a hygienic condition.

PREREQUISITE PROGRAMME	COVERS	DESCRIPTION
	Effectiveness	• Cleaning programmes shall be monitored, at frequencies specified by the organization, to assess their continuing suitability and effectiveness.
Pest control	Pest control, Pest control programme, Prevention of pest access, Prevention of pest harbourage and infestations, Pest monitoring, Exterior bait station, Interior monitoring, Insect light traps, Bird control, Pesticide management, Pest eradication.	• Appropriate measures shall be implemented to avoid creating an environment conducive to pest activity. • Pest management programmes shall be documented and shall identify target pests and address plans, methods, schedules, control procedures and, where necessary, personnel training requirements. • Pest monitoring programmes shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. • Records of pesticide use shall be maintained to show the type, quantity and concentrations used; where, when and how applied; and the target pest.
Personnel hygiene and employee facilities	Personal Hygiene and Personnel Facilities, Personnel Canteen Facilities, Protective Work Wear, Staff Instruction, Medical Screening, Sickness reporting systems, Visitor/Contractor screening, Personal Cleanliness, Personal Behaviour.	• Requirements for personal hygiene and behaviour proportional to the hazard posed to the food packaging shall be established and documented. • Personnel hygiene facilities shall be available to maintain the degree of personal hygiene required by the organization. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated. • Staff canteens and designated areas for food storage, consumption and smoking shall be situated and appropriately managed to prevent contamination of production areas. • The organization shall ensure that personnel who work in or enter into production or storage areas shall wear work clothing which is fit for purpose, in good condition & which not present any potential for contamination. Work clothing shall be suitably segregated from personal clothing.

PREREQUISITE PROGRAMME	COVERS	DESCRIPTION
		• All injuries, including minor cuts, shall be treated immediately and in an appropriate manner. • A documented procedure shall describe the behaviour required of personnel in production and storage areas.
Rework verification	Rework, Rework Storage Identification and Traceability, Rework Usage	Rework shall be stored, handled and used in such a way that the food safety performance of food packaging, quality, traceability and regulatory compliance are maintained.
Product Withdrawal/ Recall procedures	Product recall procedure, Receipt of external information, Initial procedure, Action plan and investigation, Communication,	Systems shall be in place to ensure that products failing to meet required food safety standards can be identified, located and removed from all necessary points of the supply chain.
	Limiting the damage and restoring customer confidence, Deliberate or malicious contamination, Product recall report, Types of defects which may lead to a product recall (microbiological, chemical and physical), Product recall team contact names / responsibilities.	
Storage and transport	Storage, Warehousing, Stock Control, Chemical Storage, Dispatch and Distribution - Vehicles, Containers	• Raw materials, intermediate products and food packaging shall be stored and handled in such manner to avoid contamination such as dust, condensation, fumes, odours or other sources. • Effective control of warehousing temperature, humidity and other environmental conditions shall be provided where required by food packaging or storage specifications. • Vehicles, conveyances and containers shall be maintained in a state of repair, cleanliness and condition consistent with requirements given in relevant specifications and contracts.

PREREQUISITE PROGRAMME	COVERS	DESCRIPTION
Packaging information verification	Packaging information, Product labelling control Packaging print control	• The organization shall be able to demonstrate compliance with food safety requirements and agreed specifications. • The organization shall provide and update food safety relevant information on product applicability and restrictions of use to its customers.
Food defence system verification	Food defence, Vulnerability assessment, Risk analysis Access controls, Control of visitors & contractors Procedure, Verification of the control of visitors and sub-contractors, Prerequisite security measures (outside measures, storage, transport, mail handling, information, general internal, processing area, chemical/hazardous material control, personnel, incident response)	• Each organization shall assess the risk to products posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures. • The site security assessment shall be kept up to date. Personnel shall be trained in site security measures.

FOOD DEFENCE/FRAUD FSSC REQUIREMENTS

Further to the PRP above food fraud and food defence are not only food safety risks but a business risk as issues with either of these can seriously affect business reputation. Table 9 lists the requirements for food defence and food fraud prevention.

Table 9 - Food Defence and Food Fraud Prevention (FSSC22000)

2.5.3 FOOD DEFENCE	2.5.4. FOOD FRAUD MITIGATION
2.5.3.1 Threat assessment **The organization shall have a documented procedure in place to:** **a)** Conduct a threat assessment to identify and assess potential threats; **b)** Develop and implement mitigation measures for significant threats.	**2.5.4.1 Vulnerability assessment** **The organization shall have a documented procedure in place to:** **a)** Conduct a food fraud vulnerability assessment to identify and assess potential vulnerabilities; **b)** Develop and implement mitigation measures for significant vulnerabilities.
2.5.3.2 Plan **a)** The organization shall have a documented food defence plan specifying the mitigation measures covering the processes and products within the FSMS scope of the organization. **b)** The food defence plan shall be supported by the organization's FSMS. **c)** The plan shall comply with applicable legislation and be kept up to date.	**2.5.4.2 Plan** a) The organization shall have a documented food fraud mitigation plan specifying the mitigation measures covering the processes and products within the FSMS scope of the organization. b) The food fraud mitigation plan shall be supported by the organization's FSMS. c) The plan shall comply with applicable legislation and be kept up to date.

Food Defence Actions

Based on the findings of a risk analysis, the Crisis Management Team identify and implement food defence actions that will lower the various levels of risk.

These actions include ensuring as a minimum:

- Access controls are in place
- Sensitive Processing areas are restricted to authorised employees only
- Raw Materials, Finished Products, Packaging, Equipment and Chemicals are stored in specific storage areas and secured
- Products are delivered to customers on secure vehicles which are sealed with a tamper evident tab.

Access Controls (4.15a ISO/TS 22002-4)

Documented access control requirements need to be established proportional to the hazard posed to the process area, or product, based on risk assessment.

The following standards are applied:

- The access control system operates on the basis that the site is a secure site and it ensures that all visitors and contractors are authorised, supervised and introduced to the company's standards of operation. Access codes/key cards are required for entry into the office.
- Vehicle entry and exit from the facility is restricted and only authorised visitors and sub-contractors are permitted on site. There is 24/7 security camera surveillance on all entrances.
- Visitors are required to complete a visitor questionnaire as part of the food safety programme to if they are going into the production area. The questionnaire provides information on the site codes of practice and rules.
- All visitors and contractors that haven't been inducted are accompanied at all times while in the production areas.
- All personnel are encouraged to challenge unknown or unidentified visitors.

By following this system the company reduces the risk of dangerous behaviour and deliberate contamination of alcohol occurring.

Control of Visitors & Contractors

The company has established, documented and implemented a system for the control of visitors and sub-contractors on site, which is maintained in order to meet the requirements of the Food Safety Quality Management System and ensure the safe production of products.

The visitor and contractor control procedure ensures that all visitors and contractors to the site are authorised and introduced to our standards of operation. By ensuring visitor contractors are informed, the company reduces the risk of dangerous behaviour and product contamination inadvertently occurring.

General Site Visitor/Contractor Rules:

- The Site Hygiene Policy must be adhered to at all times.
- The removal of any company property including equipment, product, or intellectual property from site is strictly forbidden without explicit permission from the General Manager in writing.
- Smoking is not allowed on the site.
- Drugs are not allowed to be brought onto the site or consumed there.
- All visitors are required to complete a health questionnaire prior to being permitted access to the production area. Any issues are referred to the compliance person.
- Contractors must ensure that their activities do not result in contamination of raw materials for alcohol production, and in particular must ensure that all dust, swarf, and waste producing activities are secured and segregated from alcohol production areas.
- No process which produces gas, fumes, or vapour should be undertaken without prior obtaining a work permit from the Engineering Manager.
- Only chemicals on the Company Approved list are allowed to be used on site and then subject to proper precautions and to certain restrictions.
- Chemicals must be approved by the Compliance person before they come onto site and then stored and used in the proper and safe manner.

All visitors and contractors that are not inducted in the company's procedures are accompanied whilst on site by a member of staff who ensures all the visitors and/or contractors comply with company hygiene procedures prior to entering areas of site operation and wear company supplied personal protective equipment. All personnel are responsible for ensuring visitors are made aware of any special restrictions or product safety requirements whilst on site.

Verification of the Control of Visitors and Contractors

Documented hygiene audits including checking the control of visitors and sub-contractors throughout the site need to be undertaken at 3 monthly intervals.

Reference Checks for Personnel (4.15b ISO/TS 22002-4)

Medical assessments are undertaken on all staff which includes drug and alcohol testing.

Control of Confidential Information (4.15c ISO/TS 22002-4)

Confidential information is kept in the office environment and the main computer system which is only accessible to allocated staff. Sensitive documents are disposal of via a locked wheely bin which is processed via a secure contractor.

Security of Storage and Production Areas (4.15d ISO/TS 22002-4)

Vehicle access to the site as a whole is via locked gates that have to be opened from the office or by issued Fobs. Access into the plant is controlled at both entrances from the office. Care needs to be take to prevent tailgating forklifts through despatch roller doors during the day but the forklift staff would notice this and pedestrians would have to have been granted access through the site border to get to that area already. People are working around the storage and production doors when these access points are open.

Transport and Distribution (4.15e ISO/TS 22002-4)

Customer's trucking companies are used for deliveries outside of Auckland and the products can either be loaded on the truck deck or packed in a container. Containers are required for shipping interisland or overseas.

Verification of Food Defence System

The effectiveness of food defence prerequisite programmes is assessed regularly, and procedures modified as necessary taking into account the results of the assessment and the capability of the selected control measures to control the identified food safety hazards. The results of the assessment and subsequent modifications are recorded.

Table 10 - Risk Assessment Summary

CATEGORY	EVENT DESCRIPTION	EXISTING CONTROLS	RISK SCORE
Raw materials faked	**Event** Materials received are not of the same quality or materials have been substituted for lower quality materials **Consequence** The alcohol is not of the typical quality with potential customer loss of confidence or effects to customer's products	Ingredients are not from high risk countries and the suppliers have quality systems in place	250
Supply Chain undertake food fraud or bioterrorism	**Event** Deliberate acts to commit bioterrorism or fraud are taken in parts of the supply chain. **Consequence** If altered or contaminated materials are used to make alcohol (including packaging) they may cause effects to customer's products with potential loss of confidence.	The Company's supply chain is consistent. Supplier questionnaires are used and suppliers have quality systems in place.	250
Company Staff undertake food fraud or bioterrorism	**Event** Deliberate acts to commit bioterrorism or fraud are taken in parts of the supply chain. **Consequence** If altered or contaminated materials are used to make alcohol (including packaging) they may cause effects to customer's products with potential customer loss of confidence.	Regular quality checks are undertaken by both equipment operators and QA staff.	250

CATEGORY	EVENT DESCRIPTION	EXISTING CONTROLS	RISK SCORE
Labels could be used to make fake product	**Event** labelled material could be used to make a bottled product to infiltrate the customer's supply chain to commit either fraud or a deliberate act of bioterrorism. **Consequence** There will be effects to customer's products with potential for effects on consumers. Customers will most likely sue your company and your reputation would be tarnished.	The site's yard is fenced with a security fence and gates with security cameras at multiple points. Labels and bottles are kept within a secure building and waste materials are destroyed.	250
Some external person comes on site and tries fraud or bioterrorism	**Event** Some external person comes on site and tries to take some alcohol to commit fraud or bioterrorism. **Consequence** There will be effects to customer's products with potential for effects on consumers. Customers will most likely sue you and your reputation would be tarnished.	There is a key only entry to the operational areas of the site, only the visitor's carpark is open to the road. The offices are key only entry from the front so official visitors need to be received by staff. There are many cameras around the inside and outside of the plant.	250

PERSONAL HYGIENE

The purpose of this policy is to ensure a good standard of personal hygiene, uniform use and control of hazards to help prevent food safety hazards associated with staff.

The staff hygiene policy covers all aspects of potential contamination associated with staff. Staff and their inadequate handling of containers are a major source of hazards in the food industry. To prevent hazards associated with staff, this policy covers aspects of hand hygiene, uniform use, consumption of foodstuffs, smoking and staff illness.

In some instances, staff may be excluded from working with product or moved to a different part of the factory that doesn't involve handling finished product or packaging if there a risk of contamination after coming back to work from an illness or being involved with sick people.

Personal hygiene, behaviours and requirements for manufacturing processes, proportional to the hazard posed to the process area or product, are established and documented based on risk assessment.

The following standards are applied as part of the Personal Hygiene and Personnel Facilities prerequisite programmes:

- Hygiene Policy
- Hygiene Code of Practice
- Pre employment medical screening
- Staff facilities
- Sickness Reporting
- Protective clothing.

All personnel, visitors and contractors are required to comply with the documented policies and procedures. Employees are briefed as to the requirements on induction and compliance is monitored by supervisory staff. All visitors and contractors are briefed on requirements on arrival on site and are required to sign a declaration stating they understand and will adhere to site requirements. All visitors and contractors are accompanied on site at all times unless they have been inducted.

Staff Training

It is company policy that all personnel, including temporary staff, affecting conformity to product requirements shall be competent on the basis of appropriate education and training, and/or where applicable on the basis of skills and experience, and be adequately supervised. A training programme and adequate supervision is put in place for all new personnel until they have been assessed as competent.

Basic elements of employee training include hygiene requirements and awareness of the relevance and importance of their activities in maintaining quality objectives and contributing to food safety.

New staff receive training pertaining to their job description and also personal hygiene, reporting of illness, cuts and accidents. The key personnel have undertaken an introduction to Food Safety course.

Refresher training is undertaken as appropriate to ensure staff retain a basic knowledge and understanding of basic hygiene and the Food Safety Program. The aim is to provide refresher training every 2 years.

The "Personal Hygiene Policy" & "Staff Illness and Exclusion from Work Policy" is reviewed regularly to ensure staff understand and follow this procedure. The aim is that these should be reviewed after each major update to the policies or at a period of 2 years.

Production Controls to prevent Cross Contamination

If fermentable materials are used in production the cooking processes are separated from the distilling processes. Raw alcohol and finished products are labelled clearly and the type of alcohol being produced is also noted. All of the production vessels are cleaned between different alcohol types e.g. gin and rum or different versions of rum etc. The bill of materials for manufacture of the next order is verified before commencing that batch.

Allergens

Allergenic materials are not kept on site.

Cleaning

All facilities and equipment are designed to exclude any source of excessive or unusual contamination and to be easily cleaned. The company supports and maintains comprehensive cleaning procedures for all areas on site with specific attention to higher risk areas. The following systems are applied as part of the cleaning prerequisite programmes for all areas which can impact food safety:

- For all areas, detailed cleaning instructions are available and cleaning checklists completed.
- All personnel are trained in the specific cleaning requirements & instruction for their areas.
- When an item is cleaned a record of this cleaning is completed and the cleaning is checked and signed off by the Manager.

Each Cleaning Work Instruction has specific details including:

- Protective Equipment to be worn
- Cleaning Equipment to be used
- Chemicals to be Used
- Method of Cleaning
- Any precautionary measures
- Frequency of cleaning

A clean as you go philosophy is used which is briefed to all staff and monitored by the Manager to ensure all personnel keep their areas in a clean and tidy state.

The cleaning of all critical plant and equipment is verified. Manual cleaning and records of the work being done are inspected, checked and signed off by supervisory staff.

Pest Control

It is a prerequisite that the company operates a proactive system for the prevention of contamination of products by pests and ensures there are effective controls and processes in place to minimise pest activity. At the design stage, measures are taken to reduce the risk of contamination by aiming to restrict the access of pests on site. Hygiene, cleaning, incoming materials inspection and monitoring procedures are implemented to manage pest activity.

Raw materials, packaging and finished products are stored to minimise the risk of infestation. Where pests on stored raw materials are considered a risk, appropriate measures are included in the control programme such as residual spraying. All incoming goods are inspected for pest infestation and the building is adequately proofed.

In order to prevent risk of contamination no animals are allowed on site.

The company employs a Pest Control Association registered pest control contractor to implement a pest control programme and maintain the site free from pest contamination.

The pest control programme incorporates:

- Internal crawling insect and rodent traps
- Internal Insect Light Traps
- External rodent traps, both on the building side and boundary

The Manager is responsible for managing Pest Control on site, liaison with the Pest Control Contractor and maintenance of the Pest Control File.

Monitoring is by hygiene and housekeeping audits, and supervision of production.

Maintenance

Regular maintenance of production equipment is performed by the Engineer to ensure all machinery is kept in good working order. Approved food grade lubrication is used in all production machinery/equipment where there may be a chance of oil contamination of the product.

It is a prerequisite that there is a Plant Maintenance System and that Corrective and Preventative Maintenance Prerequisite Programmes operate on all areas which may affect the conformity of product and that:

- Maintenance is carried out in such a way that production on adjoining lines or equipment is not at risk of contamination so the equipment or area is taken out of production, segregated and released to the Engineer to complete the work required.
- Maintenance personnel all adhere to the company hygiene policy and area specific hygiene and dress codes.
- After all maintenance work there is a thorough clean up, accounting for components, materials and tools, the equipment or area is cleaned prior to resumption of production and the HACCP section of the maintenance request form is signed to confirm it is safe to return to production.
- Maintenance personnel are trained in food safety hazards associated with their activities and how to provide hygienic maintenance services.

It is a prerequisite that all of the following areas are covered by the maintenance system:

- Critical Equipment as listed below that monitors hazards at critical control points (critical equipment has a specific documented schedule of regular maintenance, inspection and calibration)
  - Buildings
  - Air Compressors
  - Manufacturing Equipment
  - Packing Equipment
  - Services.

The maintenance programme is managed by the Engineer.

Visual Checks for Contamination

From receipt of inward goods through to final product packaging, visual inspection of products is an important control. Adequate lighting is also an important aspect of visual inspections.

Visual inspections are able to identify hazards such as mould growth, broken/torn packaging and the presence of types of foreign matter as well as quality defects.

Critical times for inspections include:

- Receipt and storage of packaging
- Final end of line inspection
- Inspection of packaging prior to use.

It is important that staff ensure they are vigilant when they undertake a visual inspection, as they are an essential part of the line of defence, in terms of preventing contamination reaching the consumer.

RISK ASSESSMENT METHODOLOGY

The first stage of the risk assessment process is the setting of the criteria (consequence and likelihood) that risk will be measured against.

The second stage of the assessment is to identify events which may affect the objective of producing food safe packaging. This is done by the Food Safety Team reviewing the processes undertaken in detail and identifying plausible scenarios relating to physical, chemical or biological hazards that could eventuate.

A food safety hazard as a biological, chemical or physical agent in food with the potential to cause an adverse health effect. A significant food safety hazard as a food safety hazard identified through the hazard assessment, which needs to be controlled by control measures, which are actions or activities that are essential to prevent a significant food safety hazard or reduce it to an acceptable level and are identified by hazard analysis.

The food safety team will also use the hazard analysis prompts in Table 11 to identify potential food safety hazards:

Table 11 - Food Safety Hazard Analysis Prompts

NO.	PROMPT
1	Are the materials, ingredients or food contact packaging likely to have microbiological hazards present?
2	Are the materials, ingredients or food contact packaging likely to have chemical hazards present?
3	Are the materials, ingredients or food contact packaging likely to have physical hazards present?
4	Are there any characteristics of the food packaging which prevent hazards?
5	Is it possible the product could be subject to recontamination?
6	Is product contamination (consider direct and indirect contamination) with hazardous microbiological organisms from equipment, process environment or personnel likely to occur?
7	Is product contamination (consider direct and indirect contamination) with hazardous chemical substances from equipment, process environment or personnel likely to occur?
8	Is product contamination (consider direct and indirect contamination) with hazardous physical objects from equipment, process environment or personnel likely to occur?
9	Does the layout of the facility provide an adequate separation of materials from finished packaging?

10	Can the facility be cleaned to permit the safe handling of packaging?
11	Can employee health or personal hygiene practices impact the safety of the packaging?
12	What is the likelihood that the food packaging will be improperly stored?

The HACCP team considers the probability of the hazard occurring, the severity of the hazard on the consumer, the vulnerability of the targeted consumer, the survival and multiplication of any biological hazards, the presence of chemicals or foreign bodies, contamination at any stage in the process and possible deliberate contamination or adulteration.

For each event (food safety hazard) the likelihood of the hazard occurring in the end product considering preliminary information such as PRP and other existing controls prior to application of additional control measures is assessed. The severity (consequence) of the significant food safety hazard in relation to its adverse health effect in relation to its intended use is assessed qualitatively, on the basis of expert judgment considering the existing controls. This judgment is scored to give a risk for the current state of the process.

A further evaluation is made of the risk incorporating potential treatments, which may be required if the untreated risk is not acceptable.

Notwithstanding the use of the AS/NZS ISO 31000 definition of risk, given the nature of the objective and the level of this assessment, positive risks (opportunities) are not considered, so the risk criteria do not include positive scales.

Consequence

The consequence scale used is shown in Table 12. This consequence scale is non-linear in line with the criteria used by the company. The consequence criteria have been defined in terms of degree of effect on the user of the packed food as a result of the packaging.

Table 12 - Consequence Descriptions

RANKING	CONSEQUENCE OF EVENT	DESCRIPTION
5	**Nuisance**	Not significant / No one expected to be injured.
10	**Minor**	Can cause short term / minor discomfort
25	**Major**	Can cause longer term illness but resolvable
75	**Serious**	Can lead to extensive illness / severe deterioration of contents.
150	**Critical**	Can cause fatality

Likelihood

The ranking of the likelihood of the event occurring is based on the company's experience with other food safety incidents, as well as the level of confidence in the information on which the decision will be based on. This likelihood scale is non-linear in line with your company's criteria and is set out in Table 13.

Table 13 - Likelihood Descriptions

RANKING	LIKELIHOOD OF EVENT OCCURRING	DESCRIPTION	INDICATIVE PROBABILITY RANGE
10	Rare	**Exceptional circumstances only. Not likely to occur.** A very high level of confidence/information.	5%
25	Possible	**Could occur, but not expected / Have heard of it at other establishments.** There is a moderate level of confidence/information.	30%
50	Likely	**Will probably occur in most circumstances / known to have happened at our business.** There is a low level of confidence/information.	70%
100	Almost Certain	**Expected to occur in most circumstances. Very high probability.** There is a very low level of confidence / information.	95%

Risk Criteria

The following risk ranking, likelihood and consequence scales are used for this study. Risks are described as one of the following: Low (L), Medium (M), High (H) and Extreme (E) as presented in *Tables 14 and 15*.

Table 14 - Risk Ranking Matrix

	Severity of Effect Ranking	CONSEQUENCES				
		Nuisance	Minor	Major	Serious	Critical
Likelihood		5	10	25	100	225
Almost certain	200	M (1,000)	H (2,000)	H (5,000)	E (20,000)	E (45,000)
Likely	100	L (500)	M (1,000)	H (2,500)	E (10,000)	E (22,500)
Possible	50	L (250)	L (500)	M (1,250)	H (5,000)	E (11,250)
Unlikely	25	L (125)	L (250)	M (625)	H (2,500)	E (5,625)
Rare	12.5	L (62.5)	L (125)	L (312.5)	M (1,250)	H (2,812.5)

Table 15 - Risk Response Table

RISK SCORE	DESCRIPTION	EVALUATION	RECOMMENDED ACTION
>5,000	**Extreme**	Evaluate Critical Control point criteria for significant hazard (risk).	• Significant Critical Risk: CCP or Multiple CCPs required; • Select and implement treatment option immediately; • Assign management responsibility for treatment; • Supervision of treatment by senior management. Immediate action to avoid
>1,250 ≤5,000	**High**	Evaluate operational PreRequisite Programme or Critical Control Point criteria for significant hazard (risk).	• Critical Risk Manage using OPRPs or CCPs; • Select and implement treatment option; • Assign management responsibility for treatment; • Oversight of treatment by senior management.
>500 ≤1,250	**Moderate**	Not considered significant but should aim to keep the risks As Low As Reasonably Practicable	• Safety Risk: Manage using PRPs • Ongoing monitoring and review; • Assign management responsibility for monitoring.
≤500	**Low**	Acceptable	• Quality risk: Manage using PRPs • Ongoing monitoring and review.

When determining the final risk, the existing controls already in place are considered. The likelihood of an adverse effect can be considered prior to additional controls being implemented as an Operational Prerequisite Programme or Critical Control Point.

Control Measure Requirements

For each identified significant food safety hazard a Critical Control Point (CCP) or Operational Prerequisite Programme (OPRP) shall be implemented. OPRP and CCP have the following requirements:

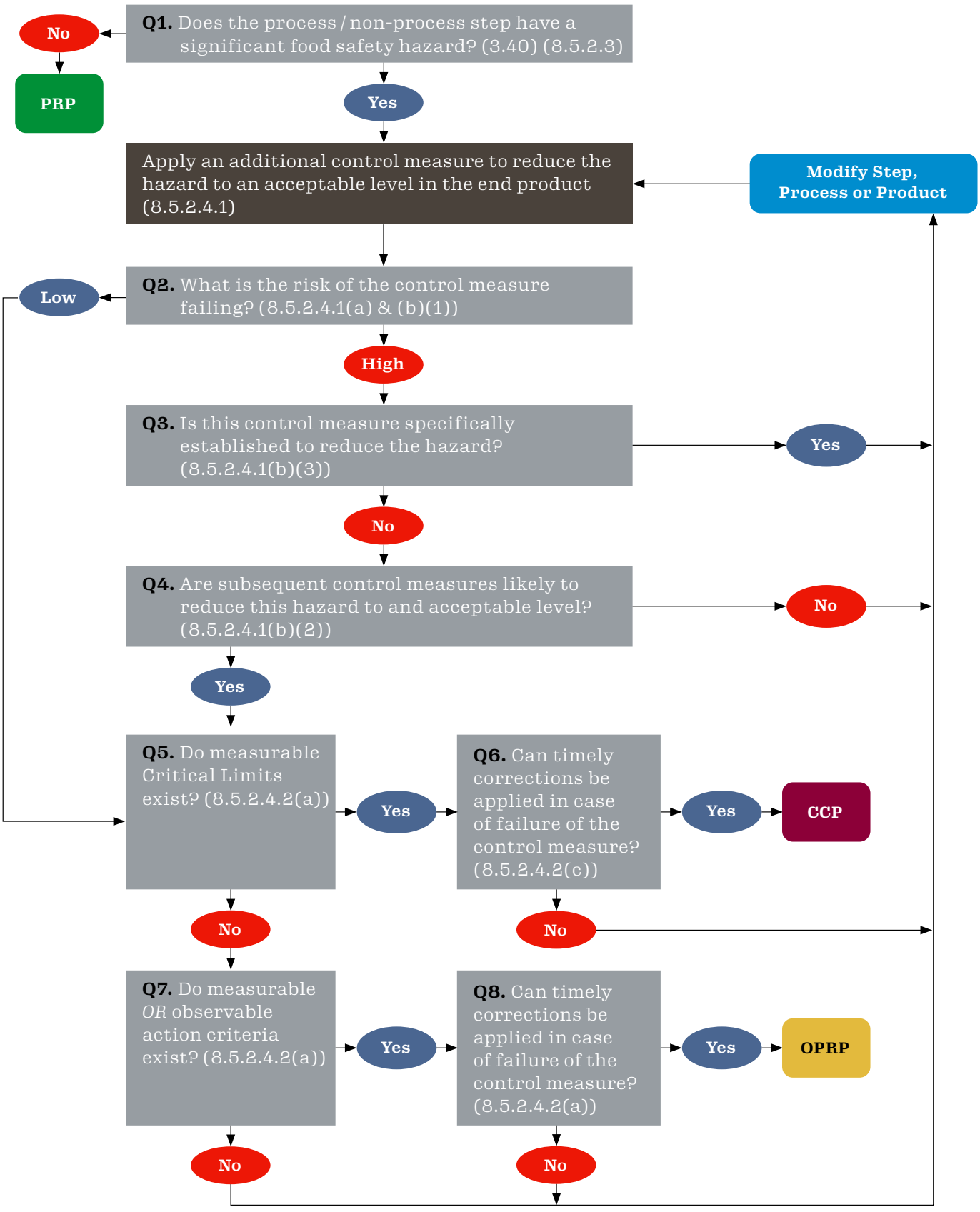
The main information required in the Hazard control plan are:

- The Food Safety Hazard Controlled
- Critical limits or Action Criteria
- Critical limits or Action criteria rationale
- Critical limits or Action criteria (measurable - CCP & OPRP or observable - OPRP only)
- Monitoring Procedures
- Corrections/Actions to be made if the action criteria isn't met.

The monitoring system established for the control measure(s) to detect failure to meet the critical limits or the action criteria is presented in Table 16.

Table 16 - CCP & OPRP Monitoring Requirements

MONITORING SYSTEM	
a)	Measurements/observations
b)	Monitoring methods or devices used
d)	Monitoring frequency
e)	Monitoring results and records of monitoring
f)	Responsibility and authority related to monitoring
g)	Responsibility and authority related to evaluating results


Q1. Does the process / non-process step have a significant food safety hazard? (3.40) (8.5.2.3)
No
PRP
Yes
Apply an additional control measure to reduce the hazard to an acceptable level in the end product (8.5.2.4.1)
Modify Step, Process or Product
Q2. What is the risk of the control measure failing? (8.5.2.4.1(a) & (b)(1))
Low
High
Q3. Is this control measure specifically established to reduce the hazard? (8.5.2.4.1(b)(3))
Yes
No
Q4. Are subsequent control measures likely to reduce this hazard to and acceptable level? (8.5.2.4.1(b)(2))
No
Yes
Q5. Do measurable Critical Limits exist? (8.5.2.4.2(a))
Yes
Q6. Can timely corrections be applied in case of failure of the control measure? (8.5.2.4.2(c))
Yes
CCP
No
No
Q7. Do measurable OR observable action criteria exist? (8.5.2.4.2(a))
Yes
Q8. Can timely corrections be applied in case of failure of the control measure? (8.5.2.4.2(a))
Yes
OPRP
No
No

Hazard Assessment

STEP	HAZARD TYPE [C, M, P]	HAZARD/REASON	PREVENTIVE MEASURE [GMP]	MONITORING PROCEDURE [ANALYSIS]	CRITICAL FACTOR/ LIMIT/CONTROL	CORRECTIVE ACTION	RESPONSIBLE PERSONNEL
Incoming raw materials - CCP1 (Grain and other fermentable materials)	M	E. coli, B. cereus, Cl. perfrigens	Control of storage conditions, Certified suppliers	Visual control for mould presence and microbiological control	103, 104, 103 cfu /g respectively	Rejection of batch Change storage conditions	Quality control manager
	C	Toxic metals presence Methanol content in wine, alcohol, fermented grains	Certified suppliers	Toxicological control with AAS Chemical analysis	As < 1, Pd < 10, Cd < 1, Hg < 1 (mg/kg) Methanol <0.5 g/L	Change supplier Change supplier, Dilution with large quantities of clean material	
Fermentation – CCP and CP							
QUALITY							
CP	M, C	Presence of chlorine in water	Filtration and dechlorination	Analysis of water	NA	Use of filters and demineralization treatment	Quality control manager
CCP	M, C	n-butanol and sec-butanol formation	Avoid bacterial contamination and long interval before distillation	NA	NA	Control of distillation process	Quality control manager

CFU = (bacteria) Colony Forming Units

STEP	HAZARD TYPE (C, M, P)	HAZARD/REASON	PREVENTIVE MEASURE (GMP)	MONITORING PROCEDURE (ANALYSIS)	CRITICAL FACTOR/ LIMIT/CONTROL	CORRECTIVE ACTION	RESPONSIBLE PERSONNEL
CCP	M, C	Acetic acid formation by acetic bacteria	Avoid equipment and pump contamination, use of GMP	Analysis using potentiometer and titration	Maintenance of pH 4.0- 4.5 and acidity 2.5-5.0 g H2SO4/L,	Control of distillation process	Quality control manager
			(hygiene and aseptic procedures)		long interval before distillation		
CCP	C	Excessive formation of ester and aldehyde	Use of proper yeast, avoidance of multiple yeast reuse	NA	NA	Control of distillation process	Quality control manager
CCP	C	Higher alcohol formation	Use of proper yeast, control of fermentation temperature, pH, and excessive oxigenation	NA	Maintenance of pH ≥ 4.0; temperature ≤ 32 °C, long interval before distillation	Rejection of batch	Quality control manager
QUALITY							
CCP	C	Ethyl carbamate precursor formation (citruline and arginine)	Avoidance of excessive nitrogen fertilization, high temperatures, and nitrogen yeast supplementation, use of proper yeast and Good Management Practices	NA	NA	Control of distillation process	Quality control manager

STEP	HAZARD TYPE (C, M, P)	HAZARD/REASON	PREVENTIVE MEASURE (GMP)	MONITORING PROCEDURE (ANALYSIS)	CRITICAL FACTOR/ LIMIT/CONTROL	CORRECTIVE ACTION	RESPONSIBLE PERSONNEL
CCP	C	Methanol formation	Presence of pectin from bagasse – use of sieve with smaller openings, removal of decanted and floating residues from juice	Visual inspection of residues	Visual inspection	Control of distillation process	Quality control manager
Distillation – CCP3 and CP							
QUALITY							
CP	C	Dimethyl sulfide (DMS) formation, affecting sensory quality	Use of copper equipment for distillation	Sensory analysis using GC-MS[2]	Sensory acceptance of: DMS ≤ 2.48 ppm	Storage or aging process	Trained personnel
CCP	C	High copper content in the final product	Control of pot still cleaning	Chemical analysis	Cu ≤ 5 mg/L	Rejection of batch	Quality control manager
SAFETY							
	M	E. coli, B. cereus, Cl. Perfrigens Temperature and distillation time	Control of distillation procedure, frequent cleaning	Microbiological control Time-temperature on-line monitoring	10, 10^4, 10^3 cfu/g respectively 63 – 80°C for 10 – 12 hours	Rejection/ redistillation of specific batch	Production manager

2 GC-MS = Gas chromatography – Mas Spectrometry 3 AA = Atomic Absorption Spectrometry

STEP	HAZARD TYPE (C, M, P)	HAZARD/REASON	PREVENTIVE MEASURE (GMP)	MONITORING PROCEDURE (ANALYSIS)	CRITICAL FACTOR/ LIMIT/CONTROL	CORRECTIVE ACTION	RESPONSIBLE PERSONNEL
CCP	C	"Heads" components in excess (acetaldehyde, esters, and methanol)	Control of "heads" cut volume (about 2 % of pot still volume)	Analysis using GC-FID	Aldehydes ≤ 30 mg/100 mL AA ; ester ≤ 200 mg/100 mL AA; methanol ≤ 20 mg/100 mL AA	Redistillation: cutting more the "heads" fraction	Quality control manager
CCP	C	"Tails" components in excess (acetic acid and furfural)	Control of "tails" cut volume	Analysis using GC-FID	Acetic acid ≤ 150 mg/100 mL AA; furfural + 5HMF ≤ 5 mg/100 mL AA	Redistillation: cutting more the "tails"	Quality control manager
CCP	C	Furfural formation	Control of sugar content in the final wine (at the end of fermentation), control of presence of yeast residues	Analysis using HPLC	Furfural + 5HMF ≤ 5 mg/100 mL AA	Redistillation: cutting more the "tails"	Trained personnel
CCP	C	Acrolein formation (from pot still or fermentation)	Avoidance of high temperature during distillation, control of "heads" cut volume (about 2 % of pot still volume)	Analysis using HPLC	Acrolein ≤ 5 mg/100 mL AA	Redistillation	Quality control manager
CCP	C	Presence of heavy metals	Use of stainless steel tanks	Analysis of metals using AAS	NA	Rejection of batch	

4 HPLC = High Pressure Liquid Chromatography

STEP	HAZARD TYPE (C, M, P)	HAZARD/REASON	PREVENTIVE MEASURE (GMP)	MONITORING PROCEDURE (ANALYSIS)	CRITICAL FACTOR/ LIMIT/CONTROL	CORRECTIVE ACTION	RESPONSIBLE PERSONNEL
CCP	C	Ethyl carbamate formation	Control of distillation process, temperature, in case of slow distillation, use reflux system in the pot still. Assess Urea concentration and use proper yeast cultures.	Analysis using GC-MS	Ethyl Carbamate ≤ 0.15 ppm Wine distillate 0.4 ppm, fruit brandies 60 ppm, rum 70 ppm, sherry <1%	Rejection of batch or dilution with large quantities of clean spirit	Quality control manager
Storage of distillate – CCP4	C	Content of total anethol in cis-anetol		HPLC[4] analysis		Recall of specific distillate batch	Quality control manager
Addition of deionized water – CCP5	C	Water quality Electric conductivity	Frequent control on the system in use GMP Use of deionizer	Chemical and toxicological analysis with AAS Continuous recording of deionizer	Within specifications prescribed in Directive 80/778/EC <20 ms/cm	Pause of water flow and analysis of one or more samples Automatic discontinuation of the deionizer	Quality control manager
Aging process – CCP6 and CP							
QUALITY							
CP	M	Microbiological contamination caused by used wooden barrels	Cleaning wooden barrels before use	Microbiological analysis	Absence of yeast, mold, and bacteria	Wooden barrel rewashing	Trained personnel

4 HPLC = High Pressure Liquid Chromatography

STEP	HAZARD TYPE (C, M, P)	HAZARD/REASON	PREVENTIVE MEASURE (GMP)	MONITORING PROCEDURE (ANALYSIS)	CRITICAL FACTOR/ LIMIT/CONTROL	CORRECTIVE ACTION	RESPONSIBLE PERSONNEL
CP	C	Acetic acid excessive formation	Use of well-preserved wooden barrels, avoidance of long aging period	Analysis of cachaça using GC-FID	Acetic acid ≤ 150 mg/100 mL AA	Rejection of batch	Quality control manager
CP	C	Reduction of ethanol content	Control of temperature and humidity of warehouse	Ethanol measurement	Minimum of 38 % ABV	Rejection of batch	Trained personnel
SAFETY							
CCP	C	Adverse chemical compounds from wooden barrels	Use of proper wood species	Chemical analysis	Certified and proper wooden barrels	Rejection of barrel	Quality control manager
CCP	C	HPA and furfural formation due to intensive toasting process	Control of toasting intensity and temperature during cooperage, wash wooden barrel before reusing it	Chemical analysis	Carbonization of wood	Rejection of batch	Trained personnel
Filtration and standardization - CP							
QUALITY							
CP	C	Turbidity caused by excessive quantity of minerals in water	Use of specific water filters for mineral removal	Chemical analysis	Visual turbidity	Filtration using a specific filter for mineral removal, cold filtration	Trained personnel

STEP	HAZARD TYPE (C, M, P)	HAZARD/REASON	PREVENTIVE MEASURE (GMP)	MONITORING PROCEDURE (ANALYSIS)	CRITICAL FACTOR/ LIMIT/CONTROL	CORRECTIVE ACTION	RESPONSIBLE PERSONNEL
SAFETY							
CP	C	Water contamination with heavy metals	Use of specific water filters for heavy metal removal	Chemical analysis using ionic chroma-tography	Pb ≤ 200 µg/L and As ≤ 100 µg/L	Filtration using a specific filter for heavy metal removal	Quality control manager
Bottling - CP and CCP7 & 8							
QUALITY							
CCP7	P	Bottles improper for foods and drinks, bottles condition	Supplier certificate	On-line visual control empty and full bottle	Absence of undesirable foreign materials & particles, rifts in the lute, cracks or scratches	Rejection of faulty bottles	Trained personnel
CCP8	P	Defects, incorrect labelling	GMP, Testing of the machinery	On-line visual control	Absence of defects & correct labelling	Rejection of faulty bottles and standardization of the equipment	Trained personnel

CFU = (bacteria) Colony Forming Units

STEP	HAZARD TYPE (C, M, P)	HAZARD/REASON	PREVENTIVE MEASURE (GMP)	MONITORING PROCEDURE (ANALYSIS)	CRITICAL FACTOR/ LIMIT/CONTROL	CORRECTIVE ACTION	RESPONSIBLE PERSONNEL
CP	C	Presence of detergent residues	Control of washing system and water flushing	Avoidance of detergent residues by rinsing several times	No detergent residues	Rinsing several times	Trained personnel
SAFETY							
CP	P	Physical contamination (glass, machine parts, insects)	Use of visual control and GMP in bottling area	Visual control	No physical contaminants inside the bottle	Rejection of contaminated bottle	Trained personnel
Storage – CCP9							
	C	Alteration of organoleptic properties	Proper storage conditions	Organoleptic analysis	Set by each plant	Rejection of faulty batch, Moderate storage conditions	Trained personnel

ESTABLISHING VERIFICATION PROCEDURES

The HACCP team establish verification procedures to confirm that the HACCP plan including controls managed by pre-requisite programs are effective including:

- internal audits
- review of records where acceptable limits have been exceeded
- review of complaints
- review of product incidents.

Hazard Analysis input information is reviewed and updated as necessary. The management review of both the quality and food safety system is undertaken quarterly.

This review is documented, and the minutes distributed effectively through the company including any changes to information. The HACCP Team Representative is responsible for distributing t he minutes and preparing new information for the team to review. All Team members are required to proactively seek any new relevant information so that it can be brought to the attention of the team. Significant changes that could potentially affect PRP(s) and/or the HACCP Plan lead to a full review of the HACCP system.

The following areas are verified by 3 monthly HACCP verification audit and review of Key Performance indicators:

- PRP(s) are implemented and effective
- Hazard Control Plan is implemented and effective
- PRP(s) Infrastructure and Maintenance are implemented
- Hazards are within identified acceptable levels
- Input to the hazard analysis is updated
- All other procedures required for the effective operation of the Food Safety Management system are implemented and effective.

The Food Safety Lead is responsible for establishing an audit schedule, allocating audit responsibility and ensuring that results of verification audits are recorded and communicated to the HACCP team

Documentation

Documentation must be kept to confirm that the HACCP system is effective. Records can be also used to show compliance to the system.

Documentation for each batch of final product is also recommended. This will enable tracing of source of failure in the even where a critical limit is reached. Records to be kept can include certification from suppliers.

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