HACCP AWARENESS COURSE

HACCP

Level 1

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FOOD SAFETY //
QUALITY CONSULTANCY

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Introduction and History of HACCP

Chapter 1

What is HACCP?

Primarily **HACCP** is the acronym for **H**azard **A**nalysis and **C**ritical **C**ontrol **P**oint. HACCP is a pro-active system to ensure food safety. HACCP is internationally accepted by competent authorities as the most effective means to control foodborne diseases and injury. Since the focus on Quality is not part of the scope, HACCP cannot be considered a tool to control quality, the aim is the consumer health.

HACCP is a systematic approach to assess and identify food safety Hazards and Risks that could reasonably take place and determining the necessary controls to eliminate or reduce them to a minimum.

Historically, Pillsbury Company (1950-1960) in the United States in conjunction with the Army and the National Aeronautical and Space Administration (NASA) invented the base of HACCP to develop food for astronauts. Before HACCP was invented, the only means of making sure food was safe was by testing, a practice that was impractical to do in outer space. Since the 1950's, HACCP has been recognized by several regulations in the US and made mandatory in livestock production.

In 2004 the EU issued the Regulation EC852/2004 in which reference was made to the Guidelines for HACCP implementation by the CODEX (FAO/WHO), making it a legal requirement to all EU member states.

HACCP Definitions

Control Measure:
An action taken to prevent, eliminate or reduce to an acceptable level, a food safety hazard.

Corrective Action:
The action taken when a Critical Limit has been exceeded at a Critical Control Point.

Critical Control Point:
A process step at which control can be applied and is essential to prevent, eliminate or reduce to an acceptable level, a food safety hazard.

Critical Limit:
The value which separates safe products from potentially unsafe products

Flow Diagram:
An illustration of the sequence of steps used in the production of food.

Flow Diagram Verification:
This is the check done to make sure that the Flow diagram is accurate and complete.

HACCP
Is a system that identifies, evaluates and controls hazards related to food safety.

HACCP Plan
Is a document that is written in accordance to the seven principles to ensure control of food safety hazards.

HACCP Team
Is a multidisciplinary group of people that are suitably knowledgeable of the industry and practices, assigned to develop and maintain a HACCP system.

Hazard
A physical, chemical or biological agent that has the potential to cause injury.

Hazard Analysis
This is the process that collects information and evaluates if any potential hazards are present during every process identified in the Flow Diagram.

Monitoring
This is a routine activity held at every CCP, carried out at a pre-determined frequency to measure if a CCP is under control.

Process Step
This is the title given to a stage or operation in the food manufacturing chain.

Risk
This is the likelihood of a hazard occurring.

Verification
The practice to obtain evidence that there is compliance with the HACCP plan.

Chapter 2

The 7 principles of HACCP

The HACCP systematic approach, according to the Codex Alimentarius, is based on seven principle. The Codex Alimentarius was built by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) in a joint effort to promote food safety (1963). Any standard issued by Codex Alimentarius is effective globally.

The seven Principles of HACCP	
1	Conduct a **hazard** analysis
2	Identify **critical** control points
3	Establish critical **limits**
4	Establish **monitoring**
5	Establish **corrective** action
6	Establish **verification**
7	Establish **record** keeping

Chapter 3

The Pre-Requisite Programmes (PRP's)

Prerequisites are basic food safety requirements that must be in place before you even start to design the HACCP plan. Having these set of practices implemented in your system, will help the HACCP team have better focus. The PRP's can be divided into three categories, **Premises**, **Personnel** and **Raw Materials**.

Premises

1. It shall be well designed and constructed.
2. Equipment shall be well designed and built for the purpose to facilitate good hygiene.
3. Building and equipment maintenance will be planned to keep such items in good condition and working order.
4. Instrument Calibration to assure reliable readings and measurements.
5. Waste Management will help the premises to avoid accumulation.
6. Planned Cleaning and Disinfection to keep the place effectively clean at all times.
7. Pest Control Programme is needed to prevent pests from entering the premises.

Personnel

1. Personal Hygiene and Food Safety Training. (Food Handling License)
2. Medical Screening for new employees.

Raw Materials/Finished Product

1. A Supplier Approval Program will aid standardising recipes and have a consistently safe product.
2. Stores Management will help you consume the raw materials in an effective manner.
3. Traceability & Recall Management are legal requirements according to Regulation EC 178/2002.

Documents and records for each of these PRP is necessary as evidence of the effectiveness.

Chapter 4

The 12 steps to HACCP

Once the PRP's are in place, it is now time to start planning the HACCP study. We have seen in Chapter 2 that there are seven principles to HACCP, however to facilitate implementation there are five preparatory steps that need to be implemented first.

Preparatory

1. Assemble a **HACCP team**
2. **Describe** the Product
3. Identify **intended use** of the product
4. Construct a process **flow diagram**
5. **Verify** the process flow diagram

Principles

6. Conduct a **hazard analysis** – P1
7. Identify **critical** control points – P2
8. Establish critical **limits** – P3
9. Establish **monitoring** – P4
10. Establish **corrective** action – P5
11. Establish **verification** – P6
12. Establish **record** keeping – P7

Step 1 – Assemble a HACCP Team

A HACCP team must be multidisciplinary; meaning that it consists of people with different perspectives and disciplines. An example of a multidisciplinary team would consist of

- Quality Assurance Manager (commonly the HACCP team leader)
- Maintenance Manager
- Purchasing & Stores Manager
- Production Manager
- Operations Manager

- Production Supervisors
- Microbiologist

The scope is to assemble a team that has enough technical knowledge about the product and the process to ensure a thorough evaluation. One of the members has to be recognised as the team leader. Not all the team members need to be employees of the firm, external talent can be sourced. For maximum effectiveness, the HACCP team is ideally trained in the subject. As a minimum, the HACCP team leader must have an in-depth knowledge of the subject. The team will be responsible for the development, implementation, management and maintenance of the HACCP plan.

Step 2 – Describe the Product

The process of describing the product will help the team define it and the process by which it is manufactured. A typical description would be:

1. Identify the general category e.g. bakery, confectionary, ice cream, beverages, meats etc.
2. Identify the processing e.g. baking, frying, freezing, pasteurisation, milling, freeze-drying etc.
3. Identify the typical attributes of the finished product e.g. pH (Acid – Alkaline), Moisture & Water Activity (a_w), Salinity etc.

The process is key to identifying the risk for the food category; e.g., raw meat and cured meat (ready to eat) are both meat but experience a very different treatment and therefore will be channelled to a separate HACCP plan.

The technical information identified in point 3 will be helpful to point out which products are more prone to microbiological growth. Low pH, low a_w and high salinity all ward off microbiological growth and therefore foods with such attributes will be of a lesser risk.

Step 3 – Identify Intended Use of the Product

It must be noted that not all food produced is suitable and intended for the general public and therefore the intended consumer must be identified in the HACCP plan.

Firstly, the processing level: Some food types are Ready to Eat (RTE) and other food require further cooking/processing. RTE's will not be processed any further, but consumed as is; therefore, every potential risk must be evaluated and controlled.

Secondly, some foods are marketed for specific segments of the population e.g. children, babies, elderly, allergy sufferers which are more susceptible to injury. Such risks are to be taken into considerations during the risk assessment.

Step 4 – Construct a Flow Diagram

The process flow diagram illustrates how a series of processes interact with one another to produce the finished food. It is usually in designed in a linear format commencing with the first identifiable process e.g. receiving of Raw Materials to Distribution. A HACCP flow diagram should avoid including peripheral activities that make part of the prerequisites e.g. Pest Control, Cleaning etc. but focus on the direct processes involved to manufacture the product.

Diagram 2 is an example of a flow diagram*. (Some of the process may or may not apply to every food preparation).*

Step 5 – Verify the Flow Diagram

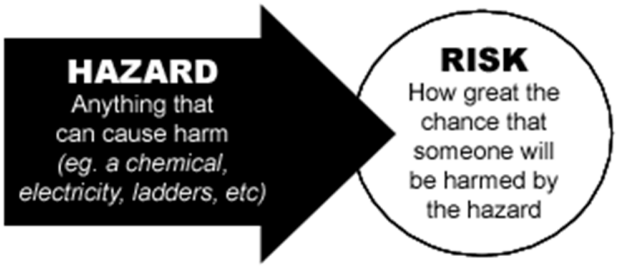
It's a common mistake to assume that once the process flow diagram was designed and discussed in an office, the task is complete, however, it is often the case that parts of the process are overlook because these are taken for granted. To counteract this oversight, the flow diagram will be verified. Verification is done by taking a copy of the flow diagram into the facility and follow the actual flow of processes by physically walking it together with the HACCP team. Every step must be illustrated on the flow diagram to ensure that no potential hazards are missed.

The verification process has to take into consideration variations in the process e.g. production shifts, and adjacent product manufacturing (seasonal items). Therefore, it is ideal if the verification is done during the busiest time to witness any deviations to the process.

Step 6 – Conduct a Hazard Analysis (**Principle 1**)

In this step, the HACCP team will identify potential Food Safety Hazards (FSH). FSH's will cause illness and injury and are categorised under **Physical**, **Chemical**, **Biological** and **Radiological**. During such analysis, it is easy to become overly cautious and begin to consider unlikely scenarios as a potential FSH e.g. an airplane crashing on the factory. Identified hazards must be vetted through a lens of "what could reasonable and likely happen".

It is best to first define a Hazards and a Risk. The illustration on the right shows the difference.



The Hazard Analysis (HA) is composed of two parts; Raw Material Evaluation and Process (step) Evaluation. An accurate HA is crucial for the effectiveness of the HACCP program. If the HA fails to identify a potential risk, the food may become contaminated and unsafe for consumption hurting many people.

Hazards may be present in food, intended or unintended e.g.

1. **Intended**: An olive stone is physical hazard that is there by nature,

2. **Unintended**:

    a. Pathogenic bacterium like Salmonella in ready to eat food due to cross-contamination from raw chicken breast.

    b. Pieces of bone in boneless chicken due to mechanical failure.

Biological Hazards

Biological hazards are living microorganisms or their by-products that will render the food they inhabit unfit for consumption. Microorganisms can be filed into four categories determined by the conditions by which these are found/end up in the food, the acronym **PIGS** is very helpful to aid memory:

Presence – Already in the food during purchasing.

Introduction – Introduced by a process failure, mishandling, mechanical contamination or pest activity.

Growth – Multiplication due to mishandling of temperature.

Survival – During cooking or pasteurisation, pathogens will be eliminated or reduced to a controlled level, however if the process fails these might survive and grow.

When microorganisms are transported by vectors (insects, birds, rodent, humans), it is good to clarify that the vector is not the true hazard, but the actual microorganism carried around is the hazard.

Common sources of biological hazards are mainly unprocessed raw materials, contaminated water, faecal matter and other vectors.

Viruses	Bacteria	Parasites	Mould	Prions
Hepatitis A	Salmonella	Taenia solium (Tapeworm)	Ochratoxin producers	vCJD causing (mad cow disease)
Norovirus	E.Coli	Giardia lamblia	Aflatoxin producers	
Rotavirus	Staphylococcus aureus	Entamoeba histolytica		
	Bacillus cereus	Diatoms		
	Campylobacter	Dinoflagellates		

Chemical Hazards:
Chemical hazards come from various sources, some are naturally occurring such as heavy metals (Lead, Mercury, Cadmium etc.), toxins that are by-products of moulds (Mycotoxins), diatoms (Domaic Acid) and Algae. Some chemicals such as preservatives, allergens and vitamins are added intentionally in food. In inappropriate levels, preservatives and vitamins are toxic and carcinogenic. Allergens will cause an allergic reaction only in allergic individuals. Other chemicals are carryovers or caused by contaminations. Examples of chemicals are maintenance lubricants, cleaning detergents, pesticides, metal leakage (Copper, Tin, and Aluminium).

Physical Hazards:
Physical hazards are foreign objects that end up in food and can cause injury if consumed.

Physical Hazard	Effect
Broken Glass Shards and brittle plastic	Cuts in mouth, oesophagus, stomach and intestines
Metal – Needles, Pins, Staples, Fish hooks, nails, wires, blades	Cuts in mouth, oesophagus, stomach and intestines. Can be stuck in the throat and food passage. May cause choking.
Wood – Toothpicks, Matches, Splinters	Can be stuck in the throat and choke the consumer.
Stones, Olive bone, Date bone	Can break teeth
Bone Fragments	Cuts in mouth, oesophagus, stomach and intestines. Can be stuck in the throat and food passage. May cause choking.
Shells – Broken, Mussels, Snail Shell	Cuts in mouth, oesophagus, stomach and intestines. Can be stuck in the throat and food passage. May cause choking.

Radiological Hazards:
In some cases, food is threated by a weak radioactive source to sterilize it before shipping for a better shelf life. Consequently, a background level of radioactivity might be present in the food. Such practices are greatly discouraged and it is uncommon to find irradiated products manufactured within the EU.

Some food stuff is expected to have normally present hazards due to their nature, e.g. bones in chicken and pits in dates, however if the product is marketed as boneless or pitted respectively, then bones and pits will be considered as a hazard because the consumer will expect the product to be free from these hazards.

Natural products in their raw form, namely agricultural products, tend to contain more physical hazards than processed ingredients do.

Each process on the flow diagram must be evaluated for hazards that are reasonable likely to occur. Once risks are identified, these must be assessed for their likelihood to occur and the severity of the consequence should these occur and be consumed.

For each identified hazard, a control measure must be implemented to eliminate or reduce it to an acceptable level.

"More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specific control measure." Codex Alimentarius (2009)

Step 7 – Determine Critical Control Points (CCP's) (**Principle 2**)

Now that the hazards and their respective control measures are identified, the next step is to determine which of the control measure/s is/are critical control point/s. The most popular method of determining a CCP is by making use of a decision tree as shown in diagram 2.

It is not recommended to use HACCP templates that belong to other facilities, as every plan is unique according to the facility's integrity, practices and culture.

Examples of CCP's are: cooking/baking, cooling/chilling, sifting, filtration, sanitisation, metal detection etc.

It is good to note that it is not obligatory by the principles of the Codex Alimentarius to have a CCP however, in some countries HACCP plans are regulated by law and certain processes are by default a CCP. The absence of a CCP in a plan does not imply that if is free of hazards but merely one that does not specifically fall under the exact definition of the requirements.

Step 8 – Establish Critical Limits (**Principle 3**)

Critical limits must be defined and validated for each CCP. The limits must be measurable and based on science to be able to eliminate a hazard or reduce it to an acceptable level. A critical limit is the maximum or minimum value at which a process must be operating to be effective. It is important to note that the critical limit is a measure of the process step and not a measure of the effectiveness i.e. when a cooking process will identified as a CCP, the core temperature and time are the critical limits however testing for the presence of pathogens is not.

Other commonly used criteria are:

- Temperature & time for Cooling/Chilling
- % Free water (A_w) in the end product
- Concentration of Sanitiser e.g. available Chlorine
- Sensitivity of a Metal Detector or X-Ray

Step 9 – Establish a System to Monitor a CCP (**Principle 4**)

Once CCP's are identified, these must be monitored and made sure that these do not go beyond the set critical limits. The following elements must be predetermined and clearly defined for each in the HACCP plan for each CCP:

- Person responsible (and his/her substitute in case of absence)
- Monitoring Method (Work Instruction)
- Frequency of Checks

It is good practice that the person in charge of monitoring the CCP has a job that closely relates to the task of monitoring the CCP e.g., the person responsible to pack food will also be responsible for the metal detector checks. Training to the owner of the CCP and his/her substitute is necessary and their know-how should be periodically tested.

The monitoring method must be clearly explained in a written procedure (Work Instruction). The procedure must define what, why and how (including instruments needed) the CCP will be monitored. It must also refer to the critical limits.

The frequency of monitoring is specific to every CCP and the surrounding scenario. It is common practice that a start-up check and end of production are done to ascertain that the process was in control during the entire process. However, in certain cases, checks are performed more often at predetermined intervals (e.g. every hour) to minimize the amount of product to be quarantined *(refer to step 10)* in the event critical limits are not met and control was lost temporarily.

All checks associated with a CCP must be recorded on a controlled document, dated and signed by the person responsible for the checks. An employee in charge of Food Safety will be verified these records. *(Refer to step 11)*

Step 10 – Establish the Corrective Action to be taken when monitoring indicates that a particular CCP is out of control (**Principle 5**)

Corrective actions must be in place for every CCP identified to deal with deviations when these occur. An effective corrective action will put back the process within the critical limits once executed.

The following steps are good actions to take in case of an out of control situation:

1. Put on hold (quarantine) all the product from the last good check. Putting a product on hold means not releasing the product to the consumer or distribution.

2. Decide what the production line should do; either stop the processing line or allow the line to continue, putting the entire product on hold. Product that is on hold must be easily distinguishable from good product.

3. Find the root cause of the problem and eliminate it, to bring the process back in control.

4. Once the root cause of the problem is dealt with and control of the CCP is restored, it is now time to decide whether to rework or reject and dispose of the quarantined product. In some cases, a quarantined product may be safe to rework, in other cases due to irreversible contamination, this must be rejected and disposed of safely.

5. The incident will be documented and kept on file.

Step 11 – Establish procedures for verification to confirm that the HACCP system is working effectively (**Principle 6**)

HACCP is a proactive system that anticipates issues before these happen and as such, processes that are considered critical to food safety will be **verified** that these are done correctly and **validated** for effectiveness.

Verification

A typical example of verification is the review of monitoring records to assure that these are filled at the correct frequency and that the critical limits were met at all times. From a higher perspective, checking the calibration of an instrument that is used for monitoring is also considered verification. For every verification activity, records must be maintained.

It is important that a different person does the verification, other than the person doing the monitoring otherwise, the exercise will be biased and ineffective.

During verification, the verifier either finds the records in place and puts a signature on the document as evidence or finds something is not right. Either the monitoring is not being done on time or at the right frequency or a critical limit has not been met and the corrective action plan was not followed. In such cases, the corrective action must be implemented immediately to control the situation. This sheds light on the importance of verification to be effected before the product is released from the factory to the market. If the product has already left the facility, a withdrawal or recall will be necessary.

When such instances of loss of control are experienced, the root cause why the monitoring process was not executed efficiently must be identified. A corrective action and preventive action will have to be implemented to avoid reoccurrence. Such incidents will be recorded and kept on file.

Validation

Whilst there are various methods of validation, for the purpose of this course, we shall consider prospective validation as our method of choice. Validation is a documented exercise whereby a system is scrutinised to confirm that it does what it was planned to do. This makes it a very important part of HACCP as it proves its effectiveness. Validation will be performed upon implementation of a new HACCP plan. Upon a successful validation, a revalidation will be only necessary annually during the HACCP review meeting unless an incident takes place in the meantime. An example of an incident that merits revalidation is a customer complaint or a recall/withdrawal.

Methods of validation may be microbiological testing of finished products and surface (including hands), review of trends in documented incident reports, customer complaints and corrective actions.

During the annual HACCP review meeting, the records generated by the validation exercises will be discussed and where possible and necessary improvements will be implemented.

The following scenarios depict where a HACCP review meeting will be necessary to revalidate the plan:

- Transfer of production from one area to another. (both within the facility or out-sourced)
- Changes to the product, the plant, the manufacturing process, the machinery, the cleaning process, or other changes that could affect product safety.
- A consecutive series of batches that fail to meet the expected standard.
- Drastic changes in production volumes, both increase and a decrease will require a review due to stock management and other factors that may affect semi-processed materials.

Step 12 – Establish documentation concerning all procedures and records appropriate to these principles and their application (**Principle 7**)

Documentation is the means by which proof is provided that the HACCP plan has been implemented. Documentation has to be controlled, in the sense that changes to any document must not be done by whoever decides to make a change but, a change has to be discussed with the HACCP team. A typical document will have the following features:

- Document name/title
- Document number
- Date of Issue
- Version Number
- Saved File location

- Person/s approving the document

When a document will be used, it will become a record and therefore, it needs to be dated and signed. It is practical to keep in mind that records are a legal requirement and need to be legible.

Conclusions and Benefits

HACCP has many benefits, which may include the following:

- HACCP is a systematic approach that follows the manufacturing process from start to end to assure food safety.
- Using HACCP will shift the company approach from a passive one to being proactive by perceiving hazards and risks before incidents take place.
- It provides a cost effective method to control foodborne hazards.
- It reduces product loss and therefore increase efficiency.
- Being an internationally recognised system, it will facilitate international trade.
- It integrates well with other Quality Management Systems.
- HACCP is a legal requirement and therefore, ensures legal compliance.

Diagram 1 – Example of a HACCP Flow Diagram

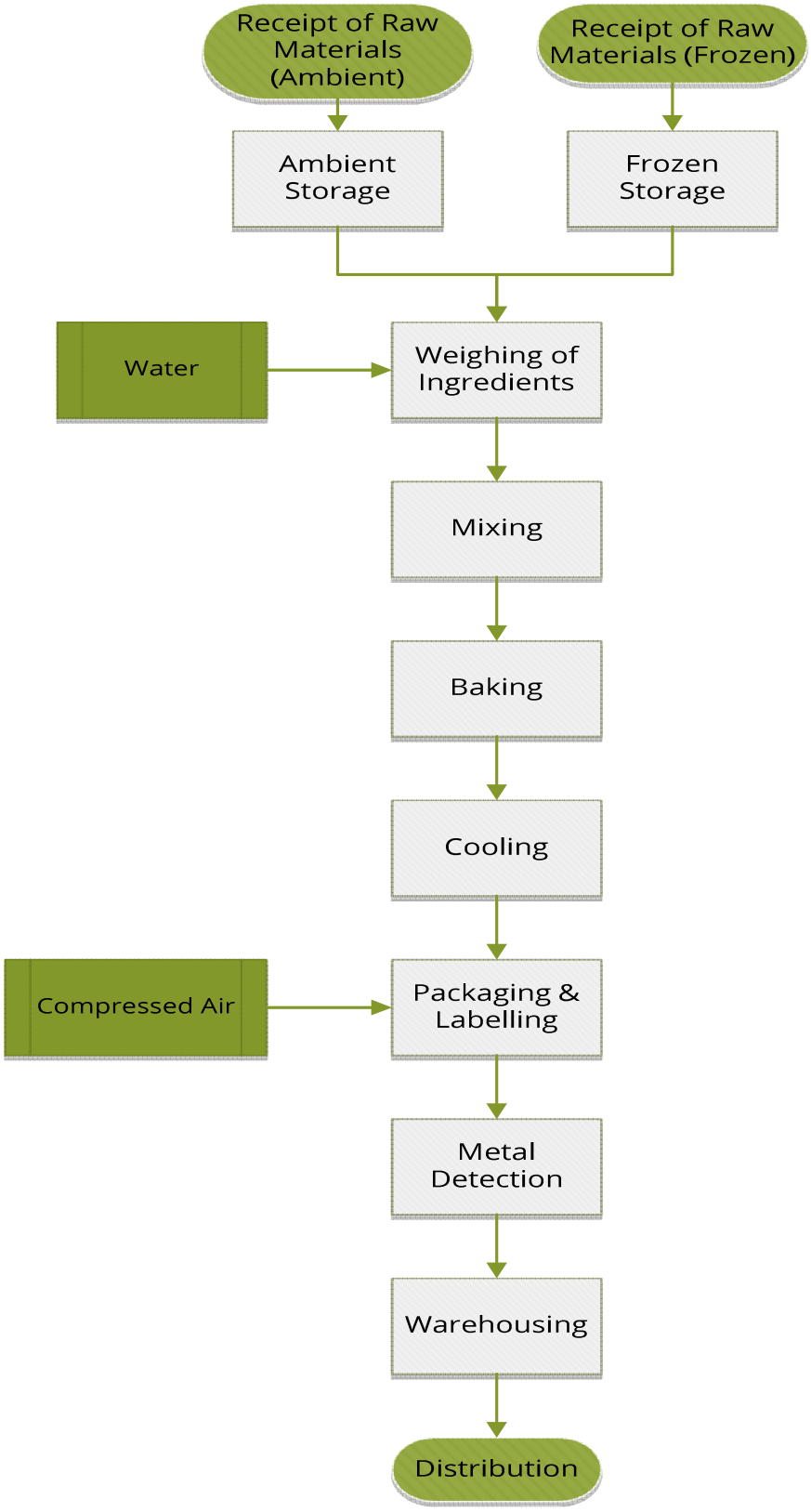


Diagram 2 – 4 Question Decision Tree