

HACCP GUIDE FOR SPICES & SEASONINGS



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April 2015

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I. INTRODUCTION AND HISTORY

HACCP is the acronym for Hazard Analysis Critical Control Point. HACCP is the internationally recognized and recommended approach to ensure food safety. It is an analytical tool that enables management to introduce and maintain a cost-effective, ongoing food safety program. HACCP involves the systematic assessment of the steps involved in a food manufacturing operation and the identification of those steps that are critical to the safety of the product. The analysis allows management to concentrate resources into those manufacturing steps that critically affect product safety. A hazard analysis will produce a list of Critical Control Points (CCPs), together with control parameters, monitoring procedures and corrective actions for each CCP. For continuing safety and effectiveness of the plan, records must be kept of each analysis and the efficacy of the study must be verified on a regular basis and when aspects of the operation change.

HACCP is applicable to the identification of all microbiological, chemical, physical and other hazards affecting product safety. It may be applied equally to new or existing products. It requires the full commitment of management to provide the resources necessary for successful analysis and implementation. Much of the effectiveness of HACCP is achieved through the use of multidisciplinary team of experts. The team should have members from relevant areas, e.g. microbiology, chemistry, production, storage, quality assurance, food technology, purchasing and food engineering, so that every aspect of food manufacturing can be considered.

The HACCP system applied to food safety was developed in the 1960s jointly by Pillsbury, the U.S. Army Labs at Natick, and NASA in their development of foods for the American Space Program. It was necessary to design food production processes to ensure the elimination of pathogens and toxins from the foods. As this could not be achieved by finished product testing alone, the HACCP concept was initiated.

In 1971, Pillsbury presented HACCP at the first American National Conference for Food Protection and since then the concept has been evolving in the food industry. The U.S. Food and Drug Administration (FDA) built HACCP into their Low Acid Canned Foods Regulations and the U.S. Department of Agriculture (USDA) has applied HACCP to meat and poultry inspection. The World Health Organization and International Commission on Microbiological Specifications for Foods have encouraged the use of HACCP.

II. FSMA AND PREVENTIVE CONTROLS INTRODUCTION

In 2011, President Obama signed the Food Safety Modernization Act (FSMA) into law. FSMA represents a paradigm shift in food safety by changing from being reactive to a focus on prevention. The introduction of preventive controls regulations presented a new way to look at the existing HACCP structure and language surrounding the controls implemented to prevent hazards from occurring.

III. HACCP PRINCIPLES

HACCP is a system that identifies specific hazard(s), i.e. any biological, chemical, physical or other hazards that can adversely affects the safety of the food, and specifies measures for their control. ASTA recommends that the team conducting the HACCP study first consider what they

all understand as an adverse health affect, so that each team member is working to the same objective.

The system consists of the following basic seven principles (National Advisory Committee on Microbiological Criteria for Foods, 1997):

PRINCIPLE 1: Conduct a hazard analysis

Step 1: Identify the potential hazards to human health that may be introduced into the food product. FSMA lists all microbiological, chemical, and physical hazards as potential hazards. In addition FSMA specifically mentions:

- Pesticides
- Allergenic materials
- Radiological hazards
- Unapproved and undeclared food colors and additives
- Drug residues
- Products of decomposition
- Parasites

ASTA recommends that all of these potential hazards are mentioned in the HACCP study with an explanation as to why some of these hazards are not applicable to the product or process being evaluated.

Step 2: Identify preventive measures that could be used to control the food safety hazard.

PRINCIPLE 2: Identify Critical Control Points

A Critical Control Point (CCP) is a step in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

PRINCIPLE 3: Establish Critical Limits for each CCP

Critical limits are the boundaries of safety for preventive measures put in place at CCPs. A critical limit will usually be a reading or observation such as temperature, time, or pH. A critical limit can be an upper limit where a set amount or level cannot be exceeded. A critical limit can also be a lower limit where a minimum amount is required for safety.

PRINCIPLE 4: Establish Monitoring Procedures

Monitoring procedures are routine tasks, either by an employee or by mechanical means that measure the process at a given CCP and create a record for future use. Continuous monitoring is preferred when it is possible. It is important that the person responsible for the CCP monitoring is given a specific documented CCP training.

PRINCIPLE 5: Establish Corrective Actions

Establish corrective actions to be taken when monitoring shows that there is a deviation from a critical limit. Listed below are some questions that might help when developing corrective actions:

- How will people be informed when the deviation occurs?
- Who will be responsible for controlling the product that may have been affected by the deviation?
- How will we decide what caused the deviation?
- Who will be involved in deciding how to get the process back in control?
- Who in the company needs to sign off on any modifications to plan?
- Who will be responsible for keeping the records of things done in response to a deviation from a critical limit?

PRINCIPLE 6: Establish Record-keeping Procedures

Record-keeping is an essential feature of a HACCP plan. Use simple understandable forms. Make sure employees know exactly what is expected if they are responsible for making a record entry. Make sure the records are signed and dated at the time a specific event occurs.

PRINCIPLE 7: Establish Verification Procedures

Verification procedures are needed to make sure the plan is working correctly. There are three types of verification:

- **Validation:** the initial phase in which the plan is tested and reviewed.
- **Ongoing verification:** that ensures that the HACCP plan is working effectively on a day-to-day basis. Typically verification includes review of all documentation that verifies that the CCP was under control, management review and sign off. CCPs should be verified as active before product is released from the control of the company.
- **Reassessment:** an overall review of the plan that must be performed at least annually, or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.

IV. SCOPE AND PURPOSE

HACCP is a powerful system, which can be applied to a wide range of both simple and complex operations. It is used to ensure food safety at all stages of the food chain. For manufacturers to implement HACCP, they must investigate not only their own product and production methods but also apply HACCP to their raw material supplies, final product storage, and consider distribution and retail operations up to and including the point of consumption.

The HACCP system may be applied equally to new or existing products. It should be used when introducing new products or new production methods or when making modifications to parts of a process. It may also be used to ensure the effectiveness of production support operations such as cleaning systems.

The purpose of this document is to outline HACCP principles to the spice industry and to develop two generic models for spice industry use: 1) a processed spice, 2) a formulated seasoning.

V. BENEFITS

- The benefits from the use of HACCP are many. Key benefits are:
- HACCP is a systematic approach covering all aspects of the food safety chain from raw materials, their growth, harvesting, storage, transportation and purchase. The approach examines potential food safety risk from raw materials, through all processes and storage to final product use.
- Use of HACCP will move a company from a retrospective end product testing approach towards a preventive Quality Assurance approach.
- HACCP provides a cost-effective control of food-borne hazards.
- A correctly applied HACCP study should identify all currently conceivable hazards, including those which can realistically be predicted to occur.
- Use of a preventive approach leads to reduced product losses.
- Use of HACCP focuses on technical resources at critical parts of the process.
- HACCP is complementary to all other quality management systems.
- U.S. regulatory and international authorities approve HACCP as an effective means for controlling food-borne diseases.

VI. HACCP PREVENTIVE CONTROLS PROGRAMS

A. Introduction

Initially known as Good Manufacturing or Agricultural Practices, also known as prerequisite programs, the name of programs is better described as preventive controls, as this term encompasses all programs that are preventive in nature.

HACCP is not a stand-alone program but is part of a larger control system. Preventive controls programs are defined as a range of programs/procedures used to support the HACCP program. Preventive controls programs are essential to the overall management of food safety issues and provide the basic environmental and operating conditions for a manufacturing facility. Many of these programs in the U.S. are based on Good Manufacturing Practices as listed in the Code of Federal Regulations, 21 CFR 110, or practices specified in other federal, state, and local regulations and guidelines. Many preventive controls programs are already in place in food manufacturing plants. If already in place, they should be reviewed and revised as necessary.

Preventive controls programs should be developed, implemented, and documented **before** putting a HACCP plan in place.

Documentation is very important for all programs. A well-written program clearly lists what procedures should be performed, at what frequency, who has responsibility, and what actions should be taken if the procedures are not performed according to the written protocol or if there are any problems occurring with the program. It is this detailed documentation that will help when there is the need for review or updating of the program, perhaps due to new raw materials or new scientific information.

The success of both preventive controls and HACCP programs require continuing training of employees. Without complete understanding, the programs are not likely to succeed. Also, each operating procedure related to a program should include procedures for routine verification by someone other than the person assigned to complete the task.

B. Preventive Controls Programs

Preventive controls have previously been referred to as pre-requisite program, or good manufacturing practices. This new wording is simply to reflect that these types of systems are preventive by their nature and thus have been named accordingly.

As some hazards difficult to recondition/eliminate, it is essential to prevent them in the first place. For example, contaminants such as heavy metals, mycotoxins or pesticide residues are best mitigated through the use of suitable controls in the growing and drying area. The International Organization for Spice Trade Associations (IOSTA) Good Agricultural Practices Guide covers these points and is available from the ASTA Web site.

ASTA is providing two examples of prerequisite programs that can be used as the basis for companies to develop or enhance existing program. ASTA does not endorse one over the other, but merely provides both to allow companies to determine how best to meet their individual needs.

Annex 1: PAS 220 European standard reference

Annex 2: GFSI-Compliant Prerequisite Program/Preventive Controls Matrix (developed by the Global Food Safety Initiative)

VII. GUIDE FOR HACCP PLAN IMPLEMENTATION

Preliminary steps for HACCP plan implementation include:

1. Assembly of the HACCP Team

Selection of correct team members is essential. Various areas of expertise are required and one member of the team should have HACCP training. The HACCP-trained member does not need to be a member of your company. Other members of the team should at least be trained in the principles of HACCP. Other areas of expertise required are:

- In-depth product knowledge
- Knowledge of processing and equipment
- Knowledge of different types of hazards

An example of a HACCP team:

- HACCP trained employee or outside consultant
- Product development employee or outside consultant
- A QA/QC employee who understands the microbiological hazards, the Quality Management System (if applicable) and the details of any prerequisite programs.
- A maintenance technician and/or engineer who knows the equipment and how it functions.
- A sanitation employee who cleans equipment
- A production worker who operates the equipment/process being evaluated
- A receiving employee who inspects incoming materials
- A management/supervisory employee
- A member from a department who has exposure to customer complaints
- A member from the purchasing department

2. *Description of the food and its method of production and distribution*

- What is the product name?
- How is the product to be used?
- What type of packaging is used?
- What is the product shelf-life?
- Who is the intended consumer? (Will it go to susceptible groups?)
- Are there regulatory requirements?
- What are the labeling instructions?
- Is special distribution control needed?

3. *Development and verification a process step diagram(s)*

- What specific process or production line will be studied?
- At what points does the process begin and end?
- What are all the steps in the process that could have a hazard risk?
- What are all the inputs and outputs from the process?
- What are the technically unique characteristics of the process or line?
- Which types of hazards are included?
- A plan/layout of the facility will aid in looking for potential cross contamination routes (vectors of cross-contamination)

VIII. HACCP PLAN DOCUMENTATION

HACCP plan documentation should include:

- Prerequisite programs

- Product description
- Process flow diagram
- Hazard analysis
- Critical Control Point (CCP) Documentation
- HACCP Plan Review

Prerequisite programs should be defined for an effective HACCP Plan. The following are given as a guide that can be applied by each company according to their own risk analysis:

- Cleaning and sanitizing
- Pest control
- Maintenance programs
- Personal hygiene
- Training
- Purchasing
- Transportation
- Processes to prevent cross-contamination
- Allergen management
- Environmental monitoring
- Traceability
- Chemical storage
- Sharp object controls

Product description should include:

- Process/product name, type, and general description
- List of ingredients/recipe
- Origin
- Physical or chemical properties that impact food safety (e.g. pH, water activity)
- Intended use of the product by the customer, defining the consumer target groups that also include the suitability for vulnerable groups (e.g. infants, allergy sufferers)
- Packaging
- Special distribution and storage control
- Shelf-life

Process step diagram should include: (see example on page 18)

- Structural/Location Plan of the premises and equipment layout
- All processing equipment and steps that affect product characteristics
- Details of all transfer and storage systems
- Outsourced processes and subcontracted work
- Potential for process delay
- Rework and recycling
- Low/high-care/high-risk area segregation
- Finished products, intermediate/semi-processed product, by-products and waste
- When the study is completed all CCPs should be clearly labeled and numbered

Hazard Analysis should include:

- Identification of all potential hazards that are expected to occur at each step in relation to the product, process and facilities
- HACCP Team will determine which hazards can be prevented, eliminated or reduced to acceptable levels
- This information will typically come from the severity/likelihood matrix detailed later. Where the control is achieved through prerequisite programs, this shall be stated and validated
- In addition a formalized review using the decision tree diagram will help determine if a process step in a CCP.

CCP Documentation should include:

- CCP number and description of the step in the process
- Hazard that is being controlled
- Control mechanism
- Critical limits for control of the hazard
- Monitoring (method, frequency)
- Corrective action plan(s)
- Record and its location
- Minimum CCP verification activity

HACCP Plan Review should include:

HACCP team shall review the HACCP plan and prerequisite programs at least annually and prior to any changes as:

- Change in raw materials or the supplier of raw materials
- Change in ingredients/recipe
- Change in processing conditions, process flow or equipment
- Change in packaging, storage and distribution conditions
- Change in consumer use
- Emergence of a new risk (e.g. adulteration of an ingredient)

IX. HAZARD TYPES

There are three primary types of hazards to consider when conducting a hazard analysis, and numerous potential hazards within each group. They include, but are not limited to, the following:

Chemical Hazards such as:

- Pesticide residues, fertilizers, antibiotics, other field chemicals
- Heavy metals such as lead, mercury and cadmium

- Cleaning chemicals
- Mycotoxins – aflatoxin, ochratoxin A
- Facility pest control chemicals
- Food additives, such as preservatives and unapproved or undeclared food colors
- Lab chemicals (especially if the lab is within the production building)
- Allergenic materials (the eight major food allergens in the U.S.)

Physical Hazards such as:

- Glass, hard plastics and ceramics
- Metal
- Stones and dirt
- Wood
- String/fibers/soft plastics
- Paint
- Pests and their droppings

Biological Hazards such as:

- *E. coli* and *Salmonella*
- Other bacteria may also be relevant, such as
- *Bacillus Cereus*, *Clostridium perfringens*, *Staphylococcus aureus*
- *Listeria* may need consideration dependent upon the product's intended use

When undertaking a risk assessment for potential physical, chemical or microbiological contaminants, consideration should be given to the potential vectors that can transfer a hazard from one location to another. At a minimum the following vectors should be considered: operatives, maintenance technicians, visitors, contractors, air flow, water flow, mobile equipment, tools, cleaning practices, sampling techniques, pest control technician, recycled packaging and other materials, waste disposal, reworked material, non conforming products. There may be other vectors applicable to your operation. Vectors of cross-contamination are of even more importance when a microbiological treatment has been performed on the material.

The referenced hazards should be considered the minimum for consideration and the HACCP team should evaluate any other potential hazards appropriate to the product or the process. It is recommended that all the above hazards are listed within the study and if they are not considered applicable to the product or process, that the study gives justification for that decision. Following is additional information for each of the three types of hazards.

A. Chemical Hazards

A wide variety of chemicals are used in food production and processing. Some chemicals, such as pesticides used in growing spices, cannot be removed by a subsequent process, thus their control needs to be prior to the intake of the facility. This would normally be through controls in GAP or through product testing/rejection upon arrival.

Some chemical hazards occur in foods due to poor growing, drying or handling conditions or natural conditions that cannot be controlled. Some toxins originating from microorganisms,

molds or bacteria are often considered 'naturally occurring'. The types of chemical hazards found within spices and seasonings which fit into this category, are naturally occurring mycotoxins such as aflatoxin and ochratoxin. Again, once present within the spice they cannot be removed and thus their control must be through prevention by an appropriate testing regime. Low levels of mycotoxins, when found, are most commonly present in capsicums, turmeric, ginger, nutmeg and black pepper.

Heavy metals such as lead, mercury, and cadmium may also be present in spices, normally at low levels, due the natural presence of these chemicals within the growing environment. They may also be present due to environmental contamination within the growing region.

There are also chemicals in processing facilities and manufacturing plants that should be rigorously controlled. These include such items as sanitizers, lubricants, pest control chemicals, cleaning chemicals, laboratory chemicals, and water treatment additives, all of which have the potential to be carried over into the product.

Chemicals added in the manufacturing process for a specific process, such as preservatives, flavor enhancers, meat tenderizers, colors and antioxidants also have the potential to cause harm. While most of these chemicals do not pose a health hazard when used properly, some are capable of causing serious health problems if used incorrectly.

In addition, chemicals used for things such as fumigation, pest control, and microbiological reduction are all likely to leave residues after use. In general these residues are not considered to pose a health hazard if used correctly but legislation in the U.S. specifically regulates some of these residues.

In the U.S., many chemicals found in food processing, both added and naturally occurring, are regulated by FDA, USDA, or EPA. For example, FDA has numerous lists of food additives in 21 Code of Federal Regulations (CFR). In addition, FDA has a list of substances that are specifically prohibited in foods, 21 CFR 189. In some cases, if the substance is necessary in the production of a food product or cannot be avoided by good manufacturing practices, the FDA has established tolerance limits, such as 20 ppb for aflatoxins.

EPA regulates and determines the tolerances or exemptions from tolerances for pesticide residues on raw agricultural commodities in 40 CFR 180.

Allergens are a major concern today for all food manufacturers. Since very small amounts of an allergen are capable of causing reaction in sensitive individuals, the control of potential allergic ingredients and the possibility of cross-contamination are essential in all manufacturing facilities. It is critical that all routes of cross-contamination must be considered including air-borne contaminants, re-worked products, storage of potential contaminants, etc.

Numerous prerequisite programs are needed to control chemical hazards. Included are suppliers/vendor specifications and certifications, and control programs for facility operations, storage, sanitation and maintenance with a well-designed and integrated pest management program.

In addition, consideration should be given to the potential for cross-contamination in the growing environment. Allergenic materials may be grown next to the spice crop and thus both educational

and preventive measures may need to be taken to ensure that the spice does not pose a health hazard to those susceptible members of the community. Consideration should also be given to this potential for cross-contamination within the storage facilities used before the spice is shipped to the U.S.

B. Physical Hazards

For the spice and seasoning industries, a major objective is to remove physical hazards. This is true for any industry that deals with field or comparable materials. Physical hazards usually result in personal injuries, such as a cut from glass or a case of choking from foreign materials.

The ASTA Cleanliness Specifications list extraneous/foreign matter that is considered to be a physical hazard. The list includes, but is not limited to; stones, dirt, wire, string, stems, sticks, nontoxic foreign seeds, excreta, manure and other animal contamination. For HACCP plans, the hazards should be classified as a health risk, legal requirement, aesthetic or ethical problem.

FDA has revised its Compliance Policy Guide to include Section 555.425, “Foods – Adulteration Involving Hard or Sharp Foreign Objects” (1999). FDA classifies a product that is ready-to-eat as being adulterated if it contains a hard or sharp foreign object greater than 7mm in length and less than 25mm in length. FDA has also noted that if the target consumers for a food material are for infants or the elderly, objects between 2mm and 7mm can be viewed as a hazard in such a situation. It should be noted, however, that glass of any particle size is a hazard.

Physical hazard points of entry into the products are in the field, in-transit, due to equipment failure, and poorly maintained facilities and equipment, badly designed equipment or poor storage facilities. Controlling foreign objects in raw materials can be started by specifications, letters of guarantee and vendor inspection and certifications.

Detailed information on recommended equipment for removing the physical impurities from raw spices can be found in the ASTA publication *Principles of Physical Cleaning of Spices*. The guide provides information by spice on recommended equipment, as well as the general functionality of the equipment.

Contaminants in facilities can be controlled with strict compliance to GMPs and having preventive control programs that include insect and pest control, properly protected light fixtures, sanitation, etc. Adherence to regulatory guidelines regarding proper clothing for employees and the absence of jewelry will prevent many problems. Employee education is necessary to help control these foreign materials.

C. Biological Hazards

One of the greatest risks for illness or injury from food comes from microbiological hazards. The Center for Disease Control accumulates statistics and publishes reports on food-borne illness. Reports on outbreaks of food and water-borne disease come to CDC primarily from state and local health departments and some foreign agencies. The data reported for food-borne disease outbreaks do not include sporadic cases that are far more common than large outbreaks. It is estimated that only a small fraction of disease cases are actually reported to CDC.

This information can assist the HACCP team when considering food-borne illnesses.

For an illness to occur, the pathogen must be present in the food and must grow to high enough numbers to cause an infection or to produce toxin. The food must be capable of supporting growth of the pathogen and must remain in the growth temperature range long enough for the organism to multiply. Some organisms, such as *E. coli* 0157:H7, have a very low infectious dose.

Due to the environment in which they are grown, spices often harbor large numbers of bacteria and fungi, including potential spoilage organisms and occasionally organisms of public health significance. In general, roots, berries, and herbs carry a greater microbial load than bark and seed products. Although a number of microorganisms are killed during the drying of spices and herbs, many bacteria and molds survive.

This reduction is only applicable if the drying is carried out in a hygienic manner, which ensures thorough uniform drying and that the herb or spice is not contaminated during the drying process. Guidance on drying techniques can be obtained from the IOSTA Good Agricultural Practice guide that is available from the ASTA Web site.

If the products are not stored and shipped properly, problems may occur. For example, it is important to minimize contact with water during storage and processing to ensure that microbial growth does not occur. In addition, when spices are incorporated into various food products, such as processed meats or dairy ingredients, the foods are capable of supporting growth of the microorganisms.

The bacterial and fungal species in spices include aerobic spoilage organisms, spore-forming bacteria, high-heat stable toxin-producing bacteria, proteolytic and gas-producing bacteria, and mycotoxin-producing microorganisms. Of all the spices, black pepper typically has the highest aerobic plate count, usually in excess of 10^6 cfu/ g. Paprika, celery seed, coriander, turmeric, thyme, basil and other spices can also have plate counts in the millions per gram. Common microorganisms found in spices are listed below.

1. Bacteria

- *Salmonella*
- *Clostridium perfringens*
- *Bacillus cereus*
- *Escherichia coli*
- *Staphylococcus aureus*
- *Listeria monocytogenes*

Sources of microbial contamination include:

- Growing, drying, and harvesting
- Poor import/export procedures
- Inappropriate processing
- Improper storage and distribution temperatures and handling
- Poor personal hygiene among food handlers and production workers

2. *Indicator Organisms*

Indicator organisms do not usually represent a direct health hazard. In some cases, however, they serve to indicate that the potential is present for a health hazard to exist. Common indicator organisms include:

- Standard Plate Count
- Coliforms
- Fecal Coliforms
- *Enterobacteriaceae* (EB)

X. CONTROL OF MICROORGANISMS IN SPICES

Many methods for controlling microorganisms in spices during growing, planting, harvesting, storage, and export are outlined in the ASTA publication *Clean, Safe Spices*. Controls for microbiological hazards will be implemented through HACCP preventive control programs. The most common controls for the biological hazards include:

- Microbiological specifications for raw material and finished spices and seasonings
- Humidity controls
- Prevention of cross-contamination
- Environmental monitoring program
- Food handling practices
- Equipment sanitation
- Employee hygiene
- Storage/distribution controls
- Packaging integrity and usage controls
- Robust Master Sanitation Program and Schedule
- Sanitary design

Microbial Reduction Processes (MRPs)

A variety of Microbial Reduction Processes (MRPs) are employed within the spice industry to ensure the safety of spices. It is important for companies relying on MRPs to validate each process using representative products to which it will be applied. Validation should focus on the critical control point(s) used to deliver the target log reduction. Following is an overview of the three MRPs widely used in the spice industry.

- **Ethylene oxide/propylene oxide fumigation**

Fumigation is the oldest of the MRP treatments. It is widely used in the U.S., but is banned in the EU and a number of other countries. EPA has set ETO residue limits of 7 ppm on spices and 7 ppm on dried vegetables, as well as ECH tolerances of 940 ppm on spices and 940 ppm on dried vegetables. Ethylene chlorohydrin (ECH) is a potential residue of EtO application in spices. ETO is not permitted to be used on basil.

- **Steam and/or dry heat**

Treatment with high-temperature steam is a safe and efficient process for reducing microbial loads. It is particularly useful for whole spices and is good with some herb products. However, the control of water activity after treatment is essential to prevent spoilage and potential microbial growth.

- **Irradiation**

Irradiation is a simple, safe, and efficient way to reduce microorganisms in almost all spices. Irradiation allows the processing of spices in the final packaging, which eliminates the problem of recontamination during re-packaging. Irradiation, however, adds another risk to the process that is known as a radiological hazard. The HACCP Plan should assess this risk, at whatever point in the process, and determine acceptable residual levels or scientific proof through validation and verification. Control of this hazard should then be determined if a CCP or CP.

XI. POST PROCESS CONTAMINATION

Post process re-contamination can be reduced with GMPs and preventive control programs for sanitation, pest control, storage, packaging, and distribution.

Environmental monitoring is a critical aspect in preventing re-contamination. The FDA has designated a formalized environmental monitoring program for food processing facilities. This program separates the environment into 4 designated zones, all of which must be included with the environmental monitoring program.

XII. GUIDANCE ON CONDUCTING THE HACCP STUDY

When the preliminary steps are complete, the multi-disciplined team has been assembled, the scope of the study has been defined, and the intended use of the product has been confirmed, one of the first steps is to produce a process step diagram.

A process step diagram (PSD) provides an overview of the process, but does not give the detail that is necessary to identify all potential hazards. It shows all process steps and all inputs and outputs from the process, with the detail allowing all potential risks to be considered. For example, in the sample diagram, process step M8 shows use of a pneumatic elevator. The input to be consider for risk is M7, air intake. If the system being evaluated uses a bucket elevator instead of a pneumatic elevator, different potential hazards need to be assessed.

Outputs are also detailed as they too could be potential hazards. Correctly controlling the rejects from the metal detector (M13) ensures that they do not become a potential re-contamination risk. The same may apply to reject or byproducts from other parts of the process. Another potential hazard to consider is the taking of samples as product could be contaminated or the packaging may not be re-sealed correctly.

Many of these risks may be covered by existing preventive controls and GMPs, but at the initial stage all potential risks should be referenced.

A. Producing a Process Step Diagram (PSD)

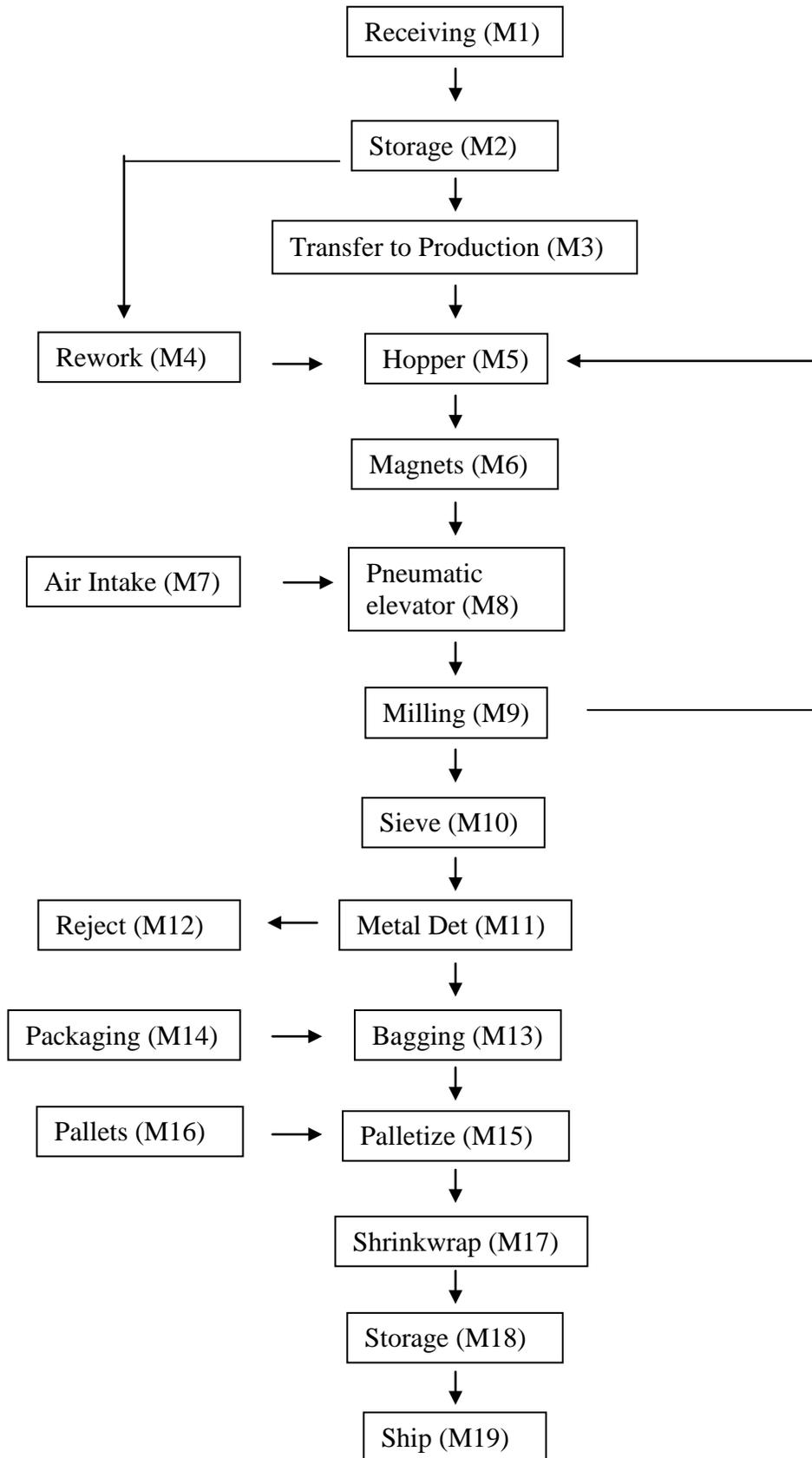
Historically many HACCP studies contained only broad details of the processing within a company. As a result, the details for each process operation were not always recorded and thus it was not easy to verify that all hazards had been considered at each process step.

Within a spice manufacturing operation, there may be many different ways in which products are handled. This could include physical cleaning, milling, blending, packing, microbial reduction, and other processes. It is recommended that each process type have its own PSD to ensure a full risk assessment.

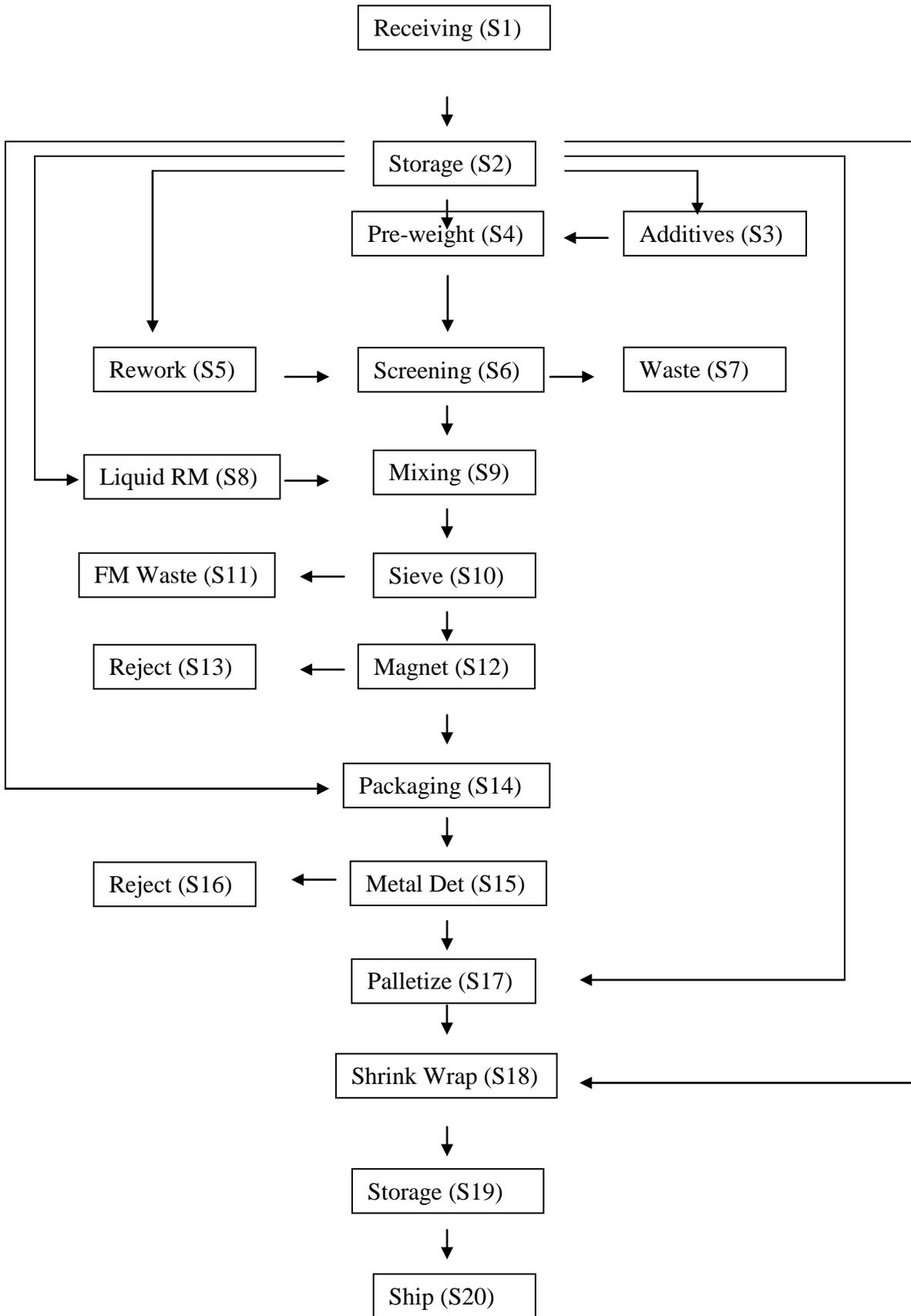
It is important that the HACCP team walk the process to verify that the PSD they are about to work on is true and accurate. Talking to the operators will tell you whether they always follow this procedure or whether they have found an alternative way of doing the task. If so, this needs to be built into the PSD.

Each process step is then given a reference number. In the examples above, M has been used as a prefix to show that it is from the milling operation, and S has been used to show that it is from the seasoning PSD. This technique can be repeated for all applicable processes operated by the company.

SPICE MILLING HACCP PROCESS STEP DIAGRAM



SEASONING HACCP PROCESS STEP DIAGRAM



B. Checklist of Hazards for Consideration

A simple matrix like the one below can help ensure that every potential hazard is considered at each step within the process.

Every box needs to be completed with a checkmark to signify potential risk and an X to indicate that there is no identified risk, ensuring that every aspect is covered.

Having a matrix like this also makes it easy to re-visit the process at some point in the future should the process or other information changes.

Process step	Glass	Hard Plastic	Ceramics	Metal	Stones	Wood	Fibers	Paint	Pests	Pest Excreta	Others
<i>M1</i> Receiving	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓
<i>M2</i> Storage	✓	✗	✗	✓	✗	✓	✗	✗	✓	✗	✓
<i>M3</i> Transfer to production	✗	✗	✗	✗	✓	✓	✓	✗	✓	✓	✓
<i>M4</i> Rework	✗	✓	✗	✓	✗	✓	✓	✗	✗	✓	✗
<i>M5</i> Hopper	✗	✓	✗	✓	✗	✓	✓	✓	✗	✗	✗
<i>M6</i> Magnets	✗	✗	✗	✓	✗	✗	✗	✗	✗	✗	✗
<i>M7</i> Air intake	✗	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗
<i>M8</i> Pneumatic elevator											
<i>M9</i> Milling											
<i>M10</i> Sieve											
<i>M11</i> Metal detector	✗	✗	✗	✓	✗	✗	✗	✗	✗	✗	✗
<i>M12</i> Rejects											
<i>M13</i> Bagging											
<i>M14</i> Packaging											
<i>M15</i> Palletize											
<i>M16</i> Pallets											
<i>M17</i> Shrink wrap											
<i>M18</i> Storage											
<i>M19</i> Shipping											

This matrix could be extended to cover other potential contaminants, as it only covers physical aspects, or separate matrixes can be developed for chemical, microbiological, etc.

C. Severity and Likelihood Evaluation

When considering a hazard and its potential to become a food safety risk, the likelihood of the occurrence of the hazard occurring should be also considered. In addition the severity of the risk

if it occurs also needs to be considered. For example the severity of a small piece of glass being in a product is much higher than the severity associated with a small piece of wood.

It is suggested that a matrix be developed to help guide the team and to make sure they address the highest food safety risks appropriately.

Below is a 3 by 3 matrix that serves the same purpose

Likelihood →		Probability of occurring is low	1	Probability of occurring is medium	2	Probability of occurring is high	3
		Severity ↓					
Would cause permanent health issues	3	CP = 3		CCP = 6		CCP = 9	
Would cause serious, but recoverable, health issues	2	PCP = 2		CP = 4		CCP = 6	
Would cause minor health issues, no need for medical attention	1	PCP = 1		PCP = 2		CP = 3	

In this example, the outcome of the severity / likelihood review will guide the HACCP team to evaluate what sort of control system should be in place.

Low severity/likelihood risks will probably be controlled by a preventive control program (PCP) /GMP.

Medium severity/likelihood risks will probably be controlled by a control program (CP).

High severity/likelihood risks will need to go through the formal assessment, known as the decision tree process, to establish whether they will become a critical control point (CCP), or a CP.

It is recommended that items scoring the highest, located towards the top right hand section of the matrix be given thorough, documented and validated controls, which are checked for completeness on a regular basis. Items with lower scores can have controls that are less frequent.

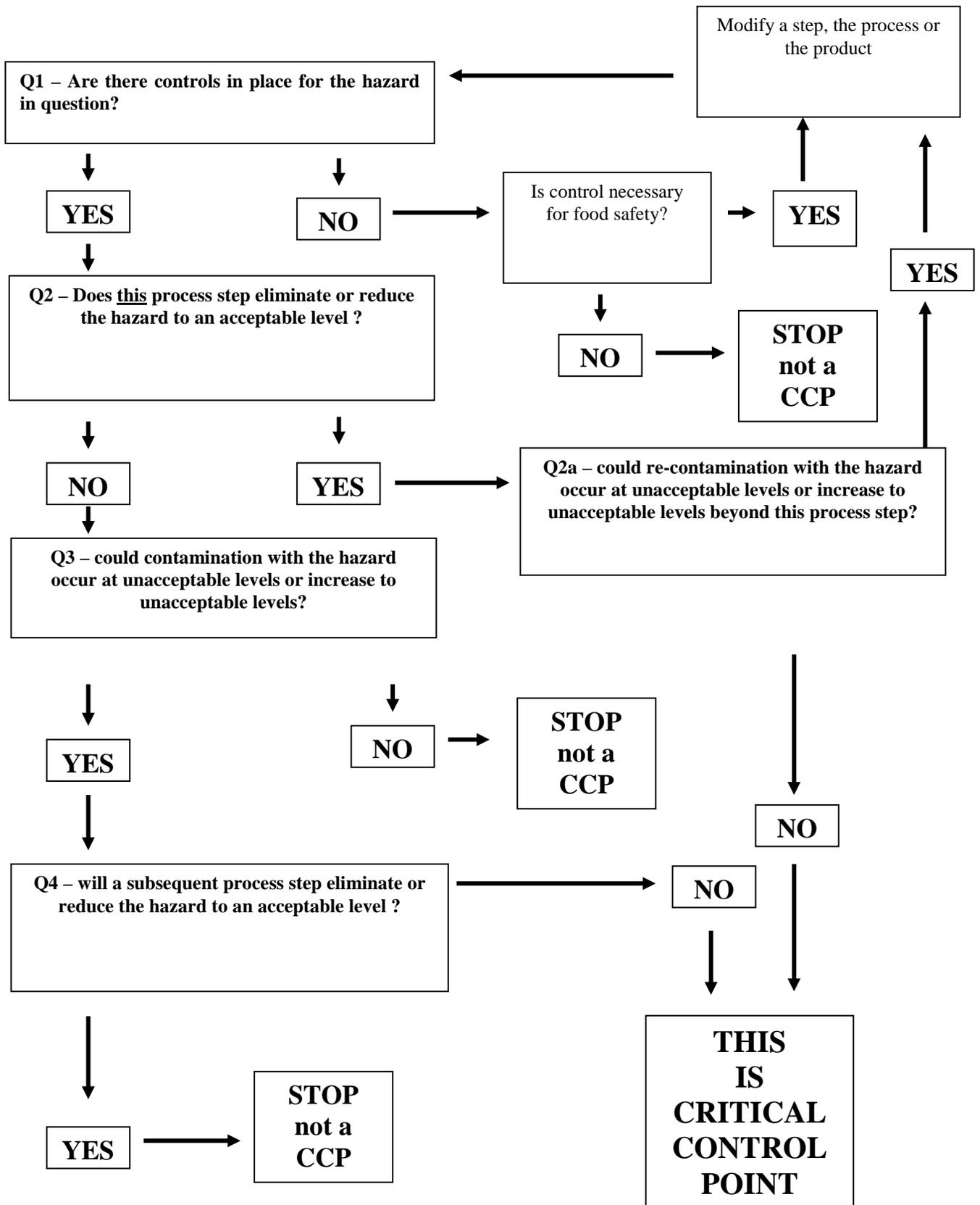
Please refer to Annex 3, Sample Hazard Analysis, as a Hazard Analysis example that uses the above Likelihood/Severity Matrix to help determine and document the control that will be used for the hazard types present in your process steps.

The annex provides good examples to follow as your company develops its own HACCP Plan and hazard analysis.

D. The CODEX Modified CCP Decision Tree

Established in 1963, The CODEX Alimentarius is an international organization, under the umbrella of the World Health Organisation and the Food and Agriculture Organisation on the United Nations. Codex establishes international food standards, guidelines and codes of practice to contribute to the safety, quality and fairness of the international food trade. The adoption of Codex standards are voluntary, however, Codex standards are adopted by many participating countries and serve in many cases as a basis for national legislation.

Codex has established a “decision-tree approach” to HACCP and this information is provided to help companies determine whether a certain step in their process is a control point (CP) or a CCP (critical control point).



Vectors of cross-contamination

When carrying out the study, it is important to ensure that all potential vectors of cross-contamination are considered. A few examples are given below:

- People
- Tools
- Air and water flow
- Equipment
- Recycled packaging
- Pest control contractor
- Waste disposal
- Engineering / electrical contractors
- Process flow
- Storage bins / hoppers
- Product flow
- Laboratory sampling
- Cleaning activity

All of these vectors have the potential to carry contamination from one area within the facility to another and there may be additional factors that are applicable to your operation.

Throughout the preventive control program development, the HACCP study and HACCP implementation, accurate records need to be kept for all aspects of prevention, control and monitoring.

Each system should have its own record-keeping program, which is operational and verified related to the risk. For example, documentation around critical control points would be maintained and verified on a daily basis. Records on storage practices, perhaps a preventive control, might only be monitored and verified on a monthly basis.

Essentially all aspects of the program should have a documented control system.

XIII. HACCP VERIFICATION

Types:

- CCP Verification: Evaluates day to day compliance to the HACCP plan.
- Audit: Evaluates effectiveness of employee training and plan implementation
- Regular 'GMP' audits to verify the effectiveness of the PRP's
- HACCP Plan Verification: Conducted by management or other specifically trained personnel. Ensures all hazards have been identified and every hazard is being controlled.
- Verification examples include but are not limited to:
 - Calibration
 - Accurate measurement of factors such as pH, temperature, flow-rate, etc. Necessary to ensure safe operations
 - Records should include date, time, who performed, calibration method, and data.

- Signature/date of review
- CCP Monitoring Records
 - Include the appropriate information and designed to facilitate review.
 - Ensure monitoring activity is performed as required by the Plan, no monitoring activities are missed.
 - Visually review documentation. Whiteouts, missing information, etc. will prompt corrective action.
 - All results are within critical limits or any deviation is properly identified.
- CCP Corrective Action Records
 - Ensure the report was prepared correctly.
 - Nature and extent of the deviation was recorded.
 - Affected product was identified and isolated.
 - Final disposition of the affected product must be documented.
 - Must identify responsible individuals.

XIV. HACCP VALIDATION

- Conduct an initial HACCP assessment
- Conduct a plan validation for new or significantly changed plans, engineering changes, and impact assessments. In particular this should apply to each CCP where the company should take all reasonable steps to ensure that the control being specified will reduce or eliminate the hazard to an acceptable level. This will often require the company to do challenge testing to assure this compliance.
- Conduct plan validation on a schedule that is no longer than one year or per regulatory requirements
- Conducted by the HACCP Team or external authorities.
- Evaluate if the Plan is (still) effective.
- Review the current System in order to improve Plan.
- Reassessment after any major critical failures.
- Reassessment of the Plan based on HACCP records and information.
- Must record all validation/reassessment activities.
- May require re-training
- Does the scientific data still support the Hazard Analysis?
- Reference Study

It is important that the HACCP system is live, effective and under constant review. Any changes in legislation or scientific data must prompt a meeting of the HACCP team to evaluate this information and the effect it could have on the operational effectiveness of the HACCP.

In addition, internal data such as customer complaints, laboratory analysis, outputs from internal and external audits should all be used to verify the effectiveness of the HACCP system.

XV. HACCP CORRECTIVE ACTION PROGRAM

Corrective actions must be taken when critical limits at a CCP have been compromised. When critical limits are violated, the pre-determined, documented corrective actions should be instituted. These corrective actions should state procedures to restore process control and determine the safe disposition of the affected product.

Corrective action options include:

- Isolating and holding product for safety evaluation
- +Re-processing
- Destroying product

The sooner the deviation is identified, the more easily corrective actions can be taken and the greater the potential for minimizing the amount of non-compliant product.

Effective corrective action plans must:

- Correct and eliminate the cause of the non-compliance to assure that the CCP is brought back under control, and
- Segregate, assess and determine the disposition of the non-compliant product.

Components of Corrective Actions

There are two components of corrective actions:

- To correct and eliminate the cause of the deviation and restore process control, and
- To identify the product that was produced during the process deviation and determine its disposition.

Corrective actions must bring the CCP back under control. A corrective action should take care of the immediate (short-term) problem as well as provide long-term solutions. The objective is to implement a short-term fix so that control can be re-established and the process started again as soon as possible without further process deviation.

When a deviation occurs, identify non-conforming product. There are four steps that may be used for determining product disposition and developing a corrective action plan.

Step 1: Determine if the product presents a safety hazard

- Based on expert evaluation
- Based on physical, chemical or microbiological testing

Step 2: If no hazard exists based on the evaluations in Step 1, the product may be released.

Step 3: If a potential hazard exists (based on the evaluations in Step 1), determine if the product can be:

- Reworked/Reprocessed
- Diverted for a safe use

Step 4: If potentially hazardous product cannot be handled as described in Step 3, the product must be destroyed.

The corrective action report should contain the following:

- Product identification (e.g. product description, amount of product on hold).
- Description of the deviation.
- Corrective action taken, including final disposition of the affected product.
- Name of the individual responsible for taking the corrective action.
- Results of the evaluation when necessary.

XVI. HACCP REVIEW PROCESS

Examples of situations that may prompt a HACCP review include:

- Recall
- Updated risk assessments
- Updated HACCP policy (ies)
- CCP failure – Non-conformance CAPA
- Annual Review (Required per GFSI)
- New process or change in process conditions
- Customer complaints CAPA
- Internal audit CAPA
- Third-party audit CAPA (e.g. GFSI, GMP and/or Regulatory)
- New equipment at any step in the process
- New products
- Specification changes that affect risk assessments
- Emergence of a new risk (e.g. known adulteration of an ingredient)
- New scientific information based on an ingredient
- Customer required microbiological testing
- New spice sources – supplier quality
- Any other GFSI-specific reasons
- Any other federal or regulatory reasons (e.g. FSMA Final Rules)

A HACCP Policy needs to be in effect that clearly states which examples prompt a Team review. At a minimum, there should be an annual review. All reviews should also be documented with a Review Form so that if changes are made, they can be tracked and acted upon in subsequent document/record/form changes. The reviews should also include a signature log of who attended the Review as a record proof of the HACCP Team involvement.

XVII. DEFINITION OF TERMS

Term	Definition
CONTROL MEASURES	Those actions and/or activities that are required to eliminate hazards or reduce their occurrence to an acceptable level.
CORRECTIVE ACTION	The action to be taken when results of monitoring the CCPs indicate a trend towards loss of control.
CRITICAL CONTROL POINT (CCP)	A step which, if controlled, will eliminate or reduce a hazard to an acceptable level.
CRITICAL LIMIT	A maximum and/or minimum value of controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard.
DECISION TREE	A sequence of questions applied to each process step with an identified hazard to identify which process steps are CCPs.
DEVIATION	Failure to meet a critical limit.
DEVIATION REPORT	Record of non-conformance to critical process limits with reference to any product involved in the deviation. May include but is not limited to: date, description of deviation, reason for hold, number of containers held, hold date, product code/identification, product disposition, and responsible individuals.
FACILITY PLAN	A detailed plan of the facility showing all departments, entrances, walls, exits etc. this schematic is often used to show all movement of people, products, equipment etc. giving the ability to look for potential vectors of cross-contamination.
FLOW DIAGRAM	The sequence of operations or equipment that are used to show the flow that the product or process entails.
HACCP COORDINATOR	Individual that is overall responsible for the development, organization, and management of the HACCP Program.
HACCP PLAN	The written document based on seven principles of HACCP which defines the procedures to be followed.
HACCP TEAM	A multidisciplinary group of individuals that undertakes a HACCP study.
HAZARD	A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
HAZARD ANALYSIS	Process of collecting and evaluating information on potential food hazards to decide which are significant and must be addressed in the HACCP plan.
MONITORING	A planned sequence of observations or measurements of a CCP target level and tolerance. These are designed to produce an accurate record and to provide evidence for future use in verification that the CCP is under control.
PREREQUISITE PROGRAMS	Procedures and/or programs that provide the basic environmental and operating conditions necessary for the production of safe, wholesome food.
PROCESS FLOW DIAGRAM	A detailed process flow diagram that shows every activity that is associated with the processing and storage of the product or process in question, including all inputs and outputs from the

	process.
RISK	An estimate of the probability of a hazard occurring. Probability determined by using severity and likelihood of occurrence.
TARGET LEVEL	A predetermined value for the control measure which has been shown to eliminate or control a hazard at a CCP. (see also TOLERANCE)
TOLERANCE	The absolute value for the control measure at a CCP (i.e. the specified degree of latitude); values outside this tolerance indicate a deviation.
VALIDATION	Activities focused on collecting and evaluating scientific and technical information to determine if the overall HACCP plan, when properly implemented, will be effective in controlling hazards.
VECTORS	A item, whether it be people, product, air or water flow, tools and equipment, engineering activity etc. that has the ability to transfer a contaminant from one area to another.
VERIFICATION	Activities, other than monitoring, that determine whether the HACCP plan is working properly, i.e. equipment calibration, records review, micro testing, or application of test pieces.

XVIII. REFERENCES

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3. Codex. *Hazard Analysis and Critical Control Point System and Guidelines for Its Applications*. A'inorm 97/13A. Codex Alimentarius Committee on Food Hygiene, Rome. 1997.
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5. Corlett, D.A., Jr. and Stier, R.F. *Risk Assessment within the HACCP System*. Food Control 2: 71-72, 1991.
6. Council for Agriculture Science and Technology. *Risks Associated with Foodborne Pathogens*. February 1993.
7. Easter, M.C., et al. *The Role of HACCP in the Management of Food Safety and Quality*. J. Soc. Dairy Technol. 47: 42-43, 1994.
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11. International Commission on Microbiological Specification for Foods. *HACCP in Microbiological Safety and Quality*. Blackwell Scientific Publications, Oxford, 1998.

Useful sections are:
 Chapter 10 - raw meat and poultry, pp. 176-193
 Chapter 11 - roast beef, pp. 234-238
 Chapter 11 - canned ham, pp. 238-242
12. International Commission on Microbiological Specification for Foods. *Microorganisms in Foods 4. Application of Hazard Analysis and Critical Control Point (HACCP). Systems to Ensure Microbiological Safety and Quality*. Blackwell Scientific Publications, Boston, 1989.
13. Hefle, S.L. et al. *Allergenic Foods. Critical Reviews in Food Science and Nutrition*, 36(s), S69-S89, 1996.
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15. National Advisory Committee on Microbiological Criteria for Foods. DRAFT document- *FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants*. 1-22, August 1999.
16. National Research Council. *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*. National Academy Press, Washington, D.C., 1985.

Useful section:

Chapter 4-microbiological hazards, pp. 72-103

17. Notermans, S., et al. *The HACCP Concept: Identification of Potentially Hazardous Microorganisms*. Food Microbiol. 11: 203-214, 1994.
18. Pierson, M.D. and Corlett, D.A., Jr. Editors. *HACCP Principles and Applications*. Van Nostrand Reinhold, New York, 1992.
19. Sampson, H.A. *Food Allergy*. J. American Medical Association. 278: 1888-1894, 1997.
20. Stevenson, K.E. and Bernard, D.T. Editors. *HACCP: Establishing Hazard Analysis Critical Control Point Programs., A Workshop Manual*. The Food Processors Institute, Washington, D.C., 1995.

Useful sections:

Chapter 11- forms for hazard analysis, CCPs, critical limits, HACCP master sheet, example HACCP for breaded chicken.

21. Stevenson, K.E. and Bernard, D.T. Editors. *HACCP: A Systematic Approach to Food Safety., 3rd Edition*. The Food Processors Institute, Washington, D.C., 1999.
22. ISO 22000:2005, *Food safety management systems – Requirements for any organization in the food chain*

XIX. SELECTED WEB SITES FOR FOOD SAFETY INFORMATION

A. Federal Government Agencies

FDA Center for Food Safety and Applied Nutrition - <http://vm.cfsan.fda.gov/list.html>

- National Food Safety Initiative
- 1997 Food Code
- The Bad Bug Book
- FDA Defect Action Levels - <http://www.cfsan.fda.gov/~dms/dalbook.html>

USDA Food Safety and Inspection Service - <http://www.fsis.usda.gov/>

- Consumer food safety publications
- FSIS/CDC/FDA Sentinel Site Study (FoodNet) information and data
- Generic HACCP models

USDA/FDA Foodborne Illness Education Information Center - <http://www.nal.usda.gov/fnic/foodborne/foodborn.htm>

- Links to other food safety sites
- Food safety and HACCP Training materials
- Foodsafe- an interactive electronic discussion group intended as a communication tool to link professionals interested in food safety issues.

Centers For Disease Control and Prevention - <http://www.cdc.gov/>

- Morbidity and Mortality Weekly Report- case histories of food and waterborne outbreaks
- Web site provides information on Food Irradiation, Food Safety and Food-Related Diseases

US Environmental Protection Agency - <http://www.epa.gov/>

- Pesticides
- Water quality
- ETO limits

B. Academia

Department of Food Microbiology and Toxicology, University of Wisconsin - Madison

- Food Research Institute

Iowa State University Extension Food Safety Project - <http://www.extension.iastate.edu/foodsafety/>