

HACCP GUIDE FOR SPICES & SEASONINGS



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TABLE OF CONTENTS

INTRODUCTION & HISTORY	1
SCOPE, PURPOSE AND BENEFITS	2
HAACP PREREQUISITE PROGRAMS	3
HACCP PRINCIPLES	8
GUIDE FOR HAACP PLAN IMPLEMENTATION	10
HACCP PLAN DOCUMENTATION	11
HAZARDS	
CHEMICAL	12
PHYSICAL	14
RECOMMENDED CLEANING EQUIPMENT	15
BIOLOGICAL HAZARDS	16
HAZARD ANALYSIS/SPICES AND PROCESSED SEASONINGS	
CHECKLIST OF QUESTIONS	19
PRODUCT DESCRIPTION —	
PROCESSED SPICE: BLACK PEPPER	23
FLOW DIAGRAM	24
WORKSHEETS	25
PRODUCT DESCRIPTION —	
PROCESSED SEASONINGS	29
FLOW DIAGRAM	30
WORKSHEETS	31
LIST OF TYPICAL RECORDS	34
HACCP VERIFICATIONS/VALIDATIONS	35
RECOMMENDED HAACP MANUAL LAYOUT	37
DEFINITION OF TERMS	38
REFERENCES FOR HACCP TEAMS	40
SELECTED WEB SITES FOR FOOD SAFETY INFORMATION	42
ASTA SPICE MICROBIOLOGY	
BACTERIOSTATIC AND SYNERGISTIC PROPERTIES OF SPICES	45
EPIDEMIOLOGY & PATHOGENS	48
MICROBIAL PROFILE OF RAW SPICES	52
ALLERGENS	57
GOVERNMENT REFERENCE PAPERS	
FEDERAL REGISTER — PART II 21 CFR PARTS 123 & 1240	67
NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS	76
PAPERS PRESENTED AT ASTA TECHNICAL FORUM — OCT 2002	
A REGULATORY OVERVIEW — HACCP & FOOD SECURITY	93
FOOD SAFETY ISSUES FOR INDUSTRY	103
MANAGING FOOD ALLERGENS	115
HACCP PREREQUISITE PROGRAMS	124
DEVELOPING A HACCP PLAN	130

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 (with critical limits), 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 microbiological, chemical, and physical 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, quality assurance, food technology, and food engineering.

The HACCP system applied to food safety was developed in the 1960's jointly by Pillsbury, the US 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 Food and Drug Administration built HACCP into their Low Acid Canned Foods Regulations and the Department of Agriculture 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.

SCOPE AND PURPOSE

HACCP is a powerful system, which can be applied to a wide range of 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.

BENEFITS

The benefits from the use of HACCP are many. Key benefits are:

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

HACCP PREREQUISITE PROGRAMS

Introduction

HACCP is not a stand-alone program but is part of a larger control system. Prerequisite programs are defined as a range of programs/procedures used to support the HACCP program. Prerequisite 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 United States 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 prerequisite programs are already in place in food manufacturing plants. If already in place, they should be reviewed and revised as necessary. Prerequisite 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.

The success of both prerequisite 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.

Prerequisite Programs

Following is a list of prerequisite programs that typically apply to manufacturing facilities. The programs will vary by application to different products and processes.

Premises/Facilities

- Building structures and utility systems
- Pest prevention / proofing
- Outside property
- Waste management
- Water quality (Treatment and Testing)
- Air quality (Testing)

The entire building structure and surrounding areas and equipment need to be considered. The goal is to minimize potential contaminants from coming into contact with the food and cross-contamination risks of different food products. For example, the building can pose a safety risk with porous surfaces, poor sanitation and maintenance. Surfaces should be non-porous and easy to clean. Buildings must have tight-fitting windows, screens, and doors. Any openings in the walls, floor, or ceiling where insects, rodents, and birds can enter or hide must be cleaned. Good pest control systems must be in place, both inside and outside of the building. It is important that

HACCP PREREQUISITE PROGRAMS

the areas surrounding the outside of the building be kept clean and free from debris, refuse, and other unrelated material. Store items away from the walls. Having a clean plant or warehouse that is surrounded by debris will cause problems. Ensure that waste is removed from the facility without the risk of it contaminating on route and make sure its storage does not give harborage to pests.

Receiving/Storage/Distribution

- Raw materials
- Receiving/storage/distribution areas
- Letters of guarantee
- Container/truck inspection
- Hold and release
- Label review for instructions, (e.g. "Keep Refrigerated")
- Pallet controls

All raw materials should be purchased from an approved supplier and to up-to-date specifications. All raw materials should be kept separate from finished products. Upon receipt, all raw materials, packaging, and containers/trucks should be inspected prior to acceptance. Various guarantees may be required from suppliers. Proper environmental conditions such as temperature and humidity must be controlled, monitored, and documented to assure raw material safety and wholesomeness.

Raw materials can act as cross-contaminants to other ingredients. This is particularly important for those products that are considered allergens. Products must be carefully segregated. Therefore, storage areas must be properly planned to minimize damage and cross-contaminations issues. It is important that pallets do not become a source of contamination, thus design, condition and use should be specified.

General Quality Systems/GMPs

- Chemical Control Program
- Approved suppliers
- Rework practices
- Macroanalytical testing
- Microbiological testing
- Environmental monitoring for pathogens
- Formula monitoring
- Product sequencing
- Glass and Brittle Plastic policy

Written specifications should be in place for all chemicals, ingredients, and packaging. An approved supplier program is helpful in controlling raw materials while assuring that the suppliers are complying with applicable laws, using GMPs and have food safety programs in place.

HACCP PREREQUISITE PROGRAMS

A control program for use and storage of cleaning and sanitation chemicals, fumigants, and other items used in or around the facility is necessary. Chemicals must be properly labeled and stored in areas separate from food storage areas. The chemical storage area should be accessible to appropriately trained personnel only.

Documented systems and procedures must be in place for macroanalytical and microbiological testing. Laboratories for testing, whether internal or external, should be audited on a regular basis.

Training

The need for HACCP training is paramount. The success of the HACCP program is dependent on nearly everyone in the company. The personnel involved in HACCP must understand their role within the HACCP program. Thus, those involved must understand what HACCP is, they must have the skills necessary to make the HACCP system operate properly and also understand what is expected of them.

Recall/Traceability

- Hold and release
- Recall procedures
- Traceability/coding

Every company must be able to trace all raw materials and finished goods. Proper lot coding of all materials and appropriate records are necessary. Good records may limit the amount of material to be recalled.

It is recommended that trial recalls (or mock recalls) are performed on a regular basis. Typically target success parameters are determined including successful recall percentage and recall time elapsed.

Equipment Performance and Maintenance

- Proper design
- Preventative maintenance
- Contractor control
- Equipment calibration
- Temporary repair procedures

Equipment should be designed to minimize the cross-contamination of food, the accumulation of food residues during the production and for ease of cleaning. If equipment is difficult to clean, or poorly cleaned, microbiological growth can occur that will contaminate the product.

HACCP PREREQUISITE PROGRAMS

Consideration should be given to air intakes into production lines to ensure that the risk of potential contamination via the air flow is managed.

There must be pre-scheduled servicing of all equipment, including replacement of worn parts. Schedules should also be established for equipment calibration.

Pest Control

- The goal of the pest control program is to primarily prevent the entry of pests into the food plant, as well as, eliminate pests that do enter the facility. Pests include (but are not limited to): rodents, insects and birds.
- The pest control activity can be carried out through a combination of pest control contractor and in-house involvement, which meets all regulatory requirements.
- The pest control practices that assist a company in maintaining a pest free environment include (but are not limited to):
 - Regular inspections by a certified/licensed pest control company or employee.
 - A process that eliminates pests and/or circumstances which permitted a pest presence, if pests are found.
 - Follow-up to verify effective elimination of pests and circumstances that permitted a pests presence.
 - Utilization of approved chemicals and baits, according to written procedures.
 - Thorough documentation of pest control activity.
 - Analysis of trends to monitor and optimize performance of the Pest Control Program.
 - On-going training program for company personnel to keep them up to date with regulatory and technical developments in pest control.

Sanitation Program

- The goal of a sanitation program is to maintain a sanitary environment, necessary for the production of food of the highest quality and safety.
- The sanitation program encompasses all working areas and equipment utilized in the manufacture or warehousing of food products.
- A company will maintain documented sanitation procedures.
- Written sanitation procedures and forms for each cleaning task typically include (but are not limited to) the frequencies, sequence of steps involved, tools and utensils used, approved materials and documentation requirements.
- Sanitation procedures will be used as tools for training new personnel, as well as, for refresher training of existing employees.

HACCP PREREQUISITE PROGRAMS

Allergen Control

- The ultimate goal of the Allergen Control Program is to protect consumers with food related allergies.
- This is accomplished through, but not limited to: ingredient review, labeling, rework, segregation, scheduling, sanitation and training.
- Procedure(s) outlining allergen ingredient review, labeling, rework, segregation, scheduling, sanitation and training will be documented.

Process Control

To ensure that the manufacturing environment does not add to the risk of introducing a hazard into the product there can be programs to ensure this contamination controlled or eliminated. Process control procedures can include but are not limited to:

- Bag opening controls – to ensure that raw material packaging does not introduce a potential hazard.
- Knife control programs – to ensure correct sanitation and identification of potential breakage.
- Control of bag stitching needles – to ensure that a broken needle does not get into the product
- Control of magnets – to ensure they are cleaned and maintained correctly
- Control of utensil, such as brushes and scoops, to ensure they remain in good condition and are not a risk for cross contamination (particularly allergens)
- Sampling procedures – to prevent contamination and to ensure that sampled product is correctly sealed
- Control of screens / sieves – to ensure that they do not break and become potential contaminants and to ensure that they remain undamaged.

Personnel

Procedures should be in place to ensure that all personnel entering the manufacturing environment do not pose a risk to food safety. Some of the personnel programs may include:

- Hand washing / sanitation controls
- Protective clothing regimes
- Company hygiene code
- Return to work procedure
- Visitor controls

As an example the company hygiene code may include such items as eating and drinking procedures, smoking controls, illness reporting, removal of jewellery, etc.

HACCP PRINCIPLES

HACCP is a system which identifies specific hazard(s) (i.e. any biological, chemical, or physical property that adversely affects the safety of the food) and specifies measures for their control. 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 hazards to human health that may be introduced into the food product, microbiological, chemical, and physical.

Step 2: Identify preventative 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, pH, etc. 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 to produce the safe effect.

PRINCIPLE 4: Establish Monitoring Procedures

Monitoring procedures are routine tasks, either by 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 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?

HACCP PRINCIPLES

PRINCIPLE 6: Establish Recordkeeping 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 management review and sign off.
- 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.

¹ Codex has step six as Verification and step seven as Documentation

GUIDE FOR HACCP PLAN IMPLEMENTATION

PRELIMINARY STEPS

1. Assemble 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 pre-requisite 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. Describe 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. Develop and verify process flow diagram(s)

- What specific process or production line will be studied?
- At what points does the process begin and end?
- What are the all the steps in the process that could have a hazard risk?
- 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

HACCP PLAN DOCUMENTATION

These documents will not always be available at the beginning of the HACCP study, but you should ensure that they are all documented by the end of the process.

HACCP plan documentation should include:

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

Product description should include:

- Process/product name, type, and general description
- Food safety characteristics
- How the product is used by the customer
- Packaging
- Label instructions
- Special distribution and storage control
- Shelf-life

Process flow diagram should include:

- All processing equipment and steps that affect product characteristics
- Each process step can be assigned a unique number to allow easy reference
- All CCPs clearly labeled and numbered

Hazard Analysis should include:

- Documentation to support the designations of CCPs

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

HAZARD TYPES

There are three primary types of hazards to consider when conducting a hazard analysis. They include the following:

- Chemical Hazards
- Physical Hazards
- Biological Hazards

When undertaking a risk assessment for all of the above potential contaminants, whether physical, chemical, or microbiological, consideration should be given to the potential vectors that can transfer a hazard for one location to another.

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. However, there are chemicals in processing facilities and manufacturing plants that should be rigorously controlled. These include such items as sanitizers, lubricants, pest control chemicals used within a processing facility and water treatment additives, plus chemicals added to the manufacturing process for a specific process. 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.

Some chemical hazards occur in foods due to poor growing or handling conditions or natural conditions that cannot be controlled. Some toxins originating from microorganisms, molds or bacteria, are often considered 'naturally occurring'. Types of chemical hazards found with spices and seasonings, in addition to those used in the processing facilities include:

- Naturally occurring
 - Mycotoxins such as aflatoxin
- Added Chemicals
 - Agricultural products, pesticides, fertilizers, antibiotics, other field chemicals
 - Toxic elements, lead, mercury, and other heavy metals
 - Food additives, such as preservatives, flavor enhancers, color additives

As with pesticides and heavy metals, Mycotoxins will not be affected by the process so their control should take place prior to entering the facility.

In the United States, 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

CHEMICAL HAZARDS (Continued)

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. Please contact the ASTA office for an updated list of pesticide tolerances for spice products.

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 is essential in all manufacturing facilities. It is critical that all routes of cross-contamination must be considered including airborne contaminants, reworked 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.

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.

Recently, the FDA updated their 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. The 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.

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

ASTA prepared a list of equipment capable of removing the physical impurities that can contaminate raw spices. The chart, which matches the spices and typical contaminants to the machines best suited for separation, follows on the next page. The major attributes used for separating impurities include: size and dimension of products, specific gravity, different behavior in air currents (aspiration), and magnetic properties. The following machines are generally used for spices:

1. Aspirator (Air separator)
2. Rotary knife cutter
3. Destoner
4. Vacuum gravity separator (Air table)
5. Clinder separator (Indent)
6. Sifter Aspirator
7. Plain sifter
8. Spiral gravity separator
9. Air screen separator

Contaminants in facilities can be controlled with strict compliance to GMPs and having prerequisite 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.

RECOMMENDED CLEANING EQUIPMENT

This Chart matches the spices and typical contaminants to the machines best suited for separation. (Machines listed on page 14.)

Name of Spice, Seed or Herbs	Whole Insects Dead	Excreta Rodent	Excreta/ Other	Insect Defiled	Extraneous Matter
Allspice	8	8	8	2+9	8
Anise	4	4	4		4
Annatto	4	4	4		4
Sweet Basil	5+3	5+3	5+3		4+3
Caraway	4	4	4		4+3
Cardamom	9	9	9	2+9	9+3
Cassia/Cinnamon	9	9	9	2+9	9+3
Celery Seed	4	4+3	4+3		4+3
Chillies	9	9	9	2+9	9+3
Cloves	9	9	9	2+9	9+3
Coriander	8	8	8	2+9	8
Cumin Seed	4	4	4		4+3
Dill Seed	4	4	4		4+3
Fennel Seed	4	4a	4		4+3
Fenugreek	4	4	4		2+3
Ginger (Whole & Split)	9	9	9	2+9	2+9+3
Laurel (Bay) Leaves	7	7	7	2+7	2+7+3
Mace	9	9	9	2+9	9+3
Marjoram	5+3	5+3	5+3		5+3
Nutmeg (Broken)	9	9	9		9
Nutmeg (Whole)	7	7	7	2+9	9
Oregano	5+3	5+3	5+3		5+3
Parsley	9	9	9		9+3
Pepper, Black	8	8	8		8
Pepper, White	8	8	8		8
Poppy Seed	4	4	4		4+3
Rosemary Leaves	7	7	9		9+3
Sage	9	9	9		9+3
Savory	7	7	9		9+3
Sesame Seed (Natural & Hulled)	6	6	6	6	6+3
Tarragon	7	7	9		9+3
Thyme	4	4	4		4+3
Turmeric	7	7	9	2+9	2+9+3

a. If Rodent excreta has same size and SP.Gr. as Fennel Seed, Use 2+9

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 foodborne 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 foodborne 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.

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 and herbs 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. If the products are not stored and shipped properly, problems may 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 counts, 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:

- **Bacteria**

- *Salmonella*
- *C. perfringens*
- *Bacillus cereus*
- *E. coli*
- *Staphylococcus aureus*

- **Fungi, Yeast and Molds**

- *Aspergillus*
- *Penicillium* ssp.

BIOLOGICAL HAZARDS

■ **Mycotoxins**

Examples of mycotoxins include but are not limited to: Aflatoxin, Ochratoxin and Vomitoxin. Low levels of mycotoxins, when found, are most commonly present in capsicums, turmeric, ginger, nutmeg, mace and white & black pepper.

Sources of microbial contamination are:

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

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
- *E. coli*

Control of Microorganisms in Spices and Herbs

Many methods for controlling microorganisms in spices/herbs during growing, planting, harvesting, storage, and export are outlined in the ASTA Clean Spices Manual. ASTA has presented the Clean Spices Program in a number of spice producing countries over the past few years in an effort to help these countries produce cleaner product.

Many controls for microbiological hazards will be implemented through HACCP prerequisite programs. The most common controls for the biological hazards include:

- Micro specifications for raw material and finished spices and seasonings
- Time/temperature applications, used mainly for seasonings
- Prevention of cross contamination
- Environmental monitoring programs
- Food handling practices
- Equipment sanitation
- Employee hygiene
- Storage/distribution
- Packaging

BIOLOGICAL HAZARDS

However, processes for Microbial Reduction (MRPs) are recommended for imported spice and herb products. Three general treatments are used:

- **Ethylene oxide/propylene oxide fumigation**
Fumigation is the oldest of the MRP treatments. It is widely used in the United States, but is banned in the EU and a number of other countries. Currently, US EPA regulations limit EtO residues to a maximum of 50 ppm and PpO residues to 300 ppm.
- **Steam**
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.

Post-Process Contamination

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

CHECKLIST OF QUESTIONS

(Hazard Analysis Process)

This point in a hazard analysis consists of asking a series of questions that are appropriate to each step in the flow diagram. The hazard analysis should question the effect of a variety of factors on the safety of the food.

1. Ingredients

Does the food contain any sensitive ingredients that are likely to present microbiological hazards (e.g. *Salmonella*, *Staphylococcus aureus*), chemical hazards (e.g. aflatoxin, antibiotic or pesticide residues) or physical hazards (stone, glass, bone, metal)?

2. Intrinsic factors of food

Physical characteristics and composition (e.g. pH, type of acids, fermentable carbohydrates, water activity, preservatives) of the food during and after preparation which can cause or prevent a hazard.

Which intrinsic factors of the food must be controlled in order to ensure food safety?

Does the food permit survival or multiplication of pathogens and/or toxin formation before or during preparation?

Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?

Are there other similar products in the market place? What has been the safety record for these products?

3. Procedures used for preparation/processing

Does the preparation procedure or process include a controllable step that destroys pathogens or their toxins? Consider both vegetative cells and spores.

Is the product subject to recontamination between the preparation step (e.g. cooking) and packaging?

CHECKLIST OF QUESTIONS

4. Microbial content of the food

Is the food commercially sterile (i.e. low acid canned food)?

Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?

What is the normal microbial content of the food stored under proper conditions?

Does the microbial population change during the time the food is stored before consumption?

Does the change in microbial population alter the safety of the food?

5. Facility design

Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods?

Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

Is the traffic pattern for people and moving equipment a potential source of contamination?

6. Equipment design

Will the equipment provide the time/temperature control that is necessary to meet critical limits?

Is the equipment properly sized for the volume of food that will be prepared?

Can the equipment be controlled so that the variation in performance will be within the tolerances required to produce a safe food?

Is the equipment reliable or is it prone to frequent breakdowns?

Is product contamination with hazardous substances (e.g. glass) likely to occur?

What product safety devices such as time/temperature integrators are used to enhance consumer safety?

CHECKLIST OF QUESTIONS

7. Packaging - for food contact

Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?

Is the package clearly labeled “Keep Refrigerated” if this is required for safety?

Does the package include instructions for the safe handling and preparation of the food by the consumer?

Are tamper-evident packaging features used?

Is each package legibly and accurately coded to indicate production lot?

Does each package contain the proper label?

8. Sanitation

Can the sanitation practices that are employed impact the safety of the food that is being prepared?

Can the facility be cleaned and sanitized to permit the safe handling of foods?

Is it possible to provide sanitary conditions consistently and adequately to ensure safe foods?

9. Employee health, hygiene, and education

Can employee health or personal hygiene practices impact the safety of the food being prepared?

Do the employees understand the food preparation process and the factors they must control to ensure safe foods?

Will the employees inform management of a problem that could impact food safety?

CHECKLIST OF QUESTIONS

10. Conditions of storage between packaging and the consumer

What is the likelihood that the food will be improperly stored at the wrong temperature?

Would storage at improper temperatures lead to a microbiologically unsafe food?

11. Intended use

Will the food be heated by the consumer?

Will there likely be leftovers?

12. Intended consumer

Is the food intended for the general public (i.e. a population that does not have an increased risk of becoming ill)?

Is the food intended for consumption by a population with increased susceptibility to illness (e.g. infants, the elderly, the infirm, and immunocompromised individuals)?

HACCP PLAN

PRODUCT DESCRIPTION

Processed Spice: Black Pepper

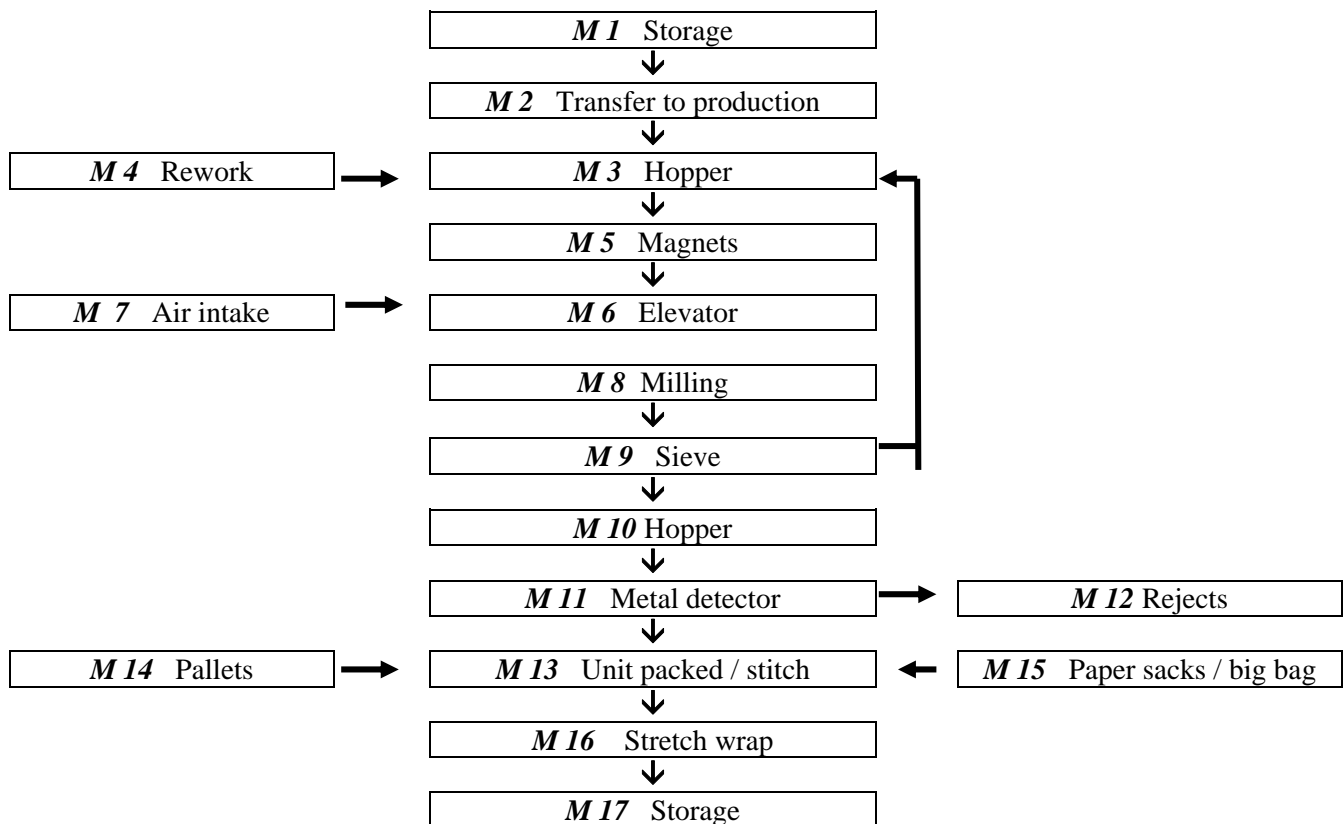
Name:	Black Pepper
Origin:	India/Indonesia
Packaging:	Bags or Boxes
Shelf-life/Temperature:	1 year – ambient temperature
Food Safety:	Microbial control; foreign material control

PRODUCTION OF 30 MESH BLACK PEPPER

Within a HACCP process flow diagram, a process step could be assigned to any action where the product is stored, moved or processed in any way, which may add a risk to the product.

All input and outputs from the process should be included to ensure that their risk is considered.

The following flow diagram is intended to be an example of how a HACCP process step diagram for a milling operation may look.



ASTA HACCP HAZARD ANALYSIS WORKSHEET
Production of 30 Mesh Black Pepper
Ingredient

Ingredient	Potential Hazard	Examples	Type ¹	Is this likely to occur? (Y/N)	Does hazard need to be in HACCP plan (Y/N)	Why?	Can this be controlled by prerequisite program? (Y/N)	What measures can be applied to prevent, eliminate, or reduce hazards
Black Pepper	Metal		P	Y	Y	Material inherent with the growing and collection process. Significant risk of choking for particles between 7-25mm	N	Metal Detection
	Foreign Material	Wood, Glass and other non-metallic material	P	Y	N	Material inherent with the growing and collection process. Also, potential rogue contamination from incoming pallets; dirty containers	Y	Cleaning and sifting
	Micro	Salmonella	M	Y	N	Significant risk of illness	Y	Microbial Reduction Process
	Allergens	Top 8 Soy, Wheat, Milk, Eggs, Nuts, Treenuts, Fish, Shellfish	C	N	N	No evidence of allergenic properties	Y	Program to preclude shipment with allergens

¹ Type – P=Physical; M=Microbiological; C=Chemical

ASTA HACCP HAZARD ANALYSIS WORKSHEET
Production of 30 Mesh Black Pepper
Process Steps

Process Step	Potential Hazard	Type ²	Does hazard need to be in HACCP plan (Y/N)	Why?	Can this be controlled by prerequisite program? (Y/N)	What measures can be applied to prevent, eliminate, or reduce hazards. Define Prerequisite Program that is applicable	Is this a critical control point (CCP)? (Y/N)
Receiving	Physical		N	Although incoming spice items may arrive at the facility with physical contaminants there are cleaning steps further down the process to eliminate or reduce these down to an acceptable level	Y		N
	Biological – Salmonella Spp.		N	Although incoming spice items may arrive at the facility with microbiological contaminants there are microbial reduction steps further down the process to eliminate or reduce the threat to an acceptable level	Y	GMP's SSOP's, Microbial Reduction Process	N
	Chemical – Mycotoxins		N	Mycotoxins have been associated with black pepper or many spices in which there is improper storage or handling.	Y	Vendor Selection and Evaluation. Supplier Certificates of Analysis	N
Storage	Contamination by Pests	M	N	Good prerequisite programs offer control	Y	GMPs and Pest Control Program	N
	Sanitation Chemicals	C	N	Good prerequisite programs offer control	Y	Master Sanitation Programs	N
	Physical		N	The opportunity for additional physical contamination is limited	Y	GMP's, Pest Control and Warehouse Sanitation Programs	N
	Chemical		N	The opportunity for additional contamination is limited	Y	GMP's, Pest Control, Chemical Control Programs and Warehouse SSOP's	N
	Microbiological		N	The opportunity for additional contamination is limited	Y	GMP's	N
Treatment	Physical		N			Preventative Maintenance	N

² Type – P=Physical; M=Microbiological; C=Chemical

ASTA HACCP HAZARD ANALYSIS WORKSHEET
Production of 30 Mesh Black Pepper
Process Steps

						Program, GMP's, Self-Inspection Programs	
	Chemical		N			GMP's Allergen Control Program, Label Control Program	N
	Microbiological		N			GMP's SSOP's, Microbial Reduction Process	N
Cleaning, Milling and Sifting	Physical		N	This step is designed to reduce and or eliminate physical contaminants	Y	Preventative Maintenance Program, GMP's, Self-Inspection Programs, Quality Testing	N
	Chemical		N		Y	GMP's Allergen Control Program, Label Control Program, SSOP's	N
	Microbiological		N		Y	GMP's SSOP's, Microbial Reduction Process	N
Rework	Physical		N	Rework typically re-introduced at the Cleaning, Milling or sifting stage(s)	Y	Preventative Maintenance Program, GMP's, Self-Inspection Programs, Quality Testing	
	Chemical		N	Typically a "same into same" or "like into like" approach	Y	GMP's Allergen Control Program, Label Control Program, SSOP's	
	Microbiological		N		Y	GMP's SSOP's, Microbial Reduction Process	
Metal Detection CCP 1	Physical - Metal	P	Y	Choking and/or laceration hazard	N	Detection at preset levels typically 1.0-1.5mm for ferrous and 2.0-2.5mm for non-ferrous	Y
	Chemical		N		Y		N
	Microbiological		N		Y		N
Filling	Physical		N	The opportunity for additional physical contamination is limited	Y	Preventative Maintenance Program, GMP's, Self-Inspection Programs	N
	Chemical		N		Y	GMP's Allergen Control Program, Label Control Program	N
	Microbiological		N		Y	GMP's SSOP's, Microbial Reduction Process	N

ASTA HACCP WORKSHEET
Production of 30 Mesh Black Pepper
Process Steps

CCP	Process Step	Hazard	Adverse Effects	Control Measures	Critical Limits	Monitoring Procedures	Corrective Actions	Monitoring Records
CCP 1	Metal Detection	Metal	Choking or lacerations	Metal detector	Ferrous – 1.0mm Non-ferrous – 1.5mm Stainless – 2.0mm	On-line detector inspection	Hold and review including inspection of rejects	Metal detector log and inspection results

HACCP PLAN

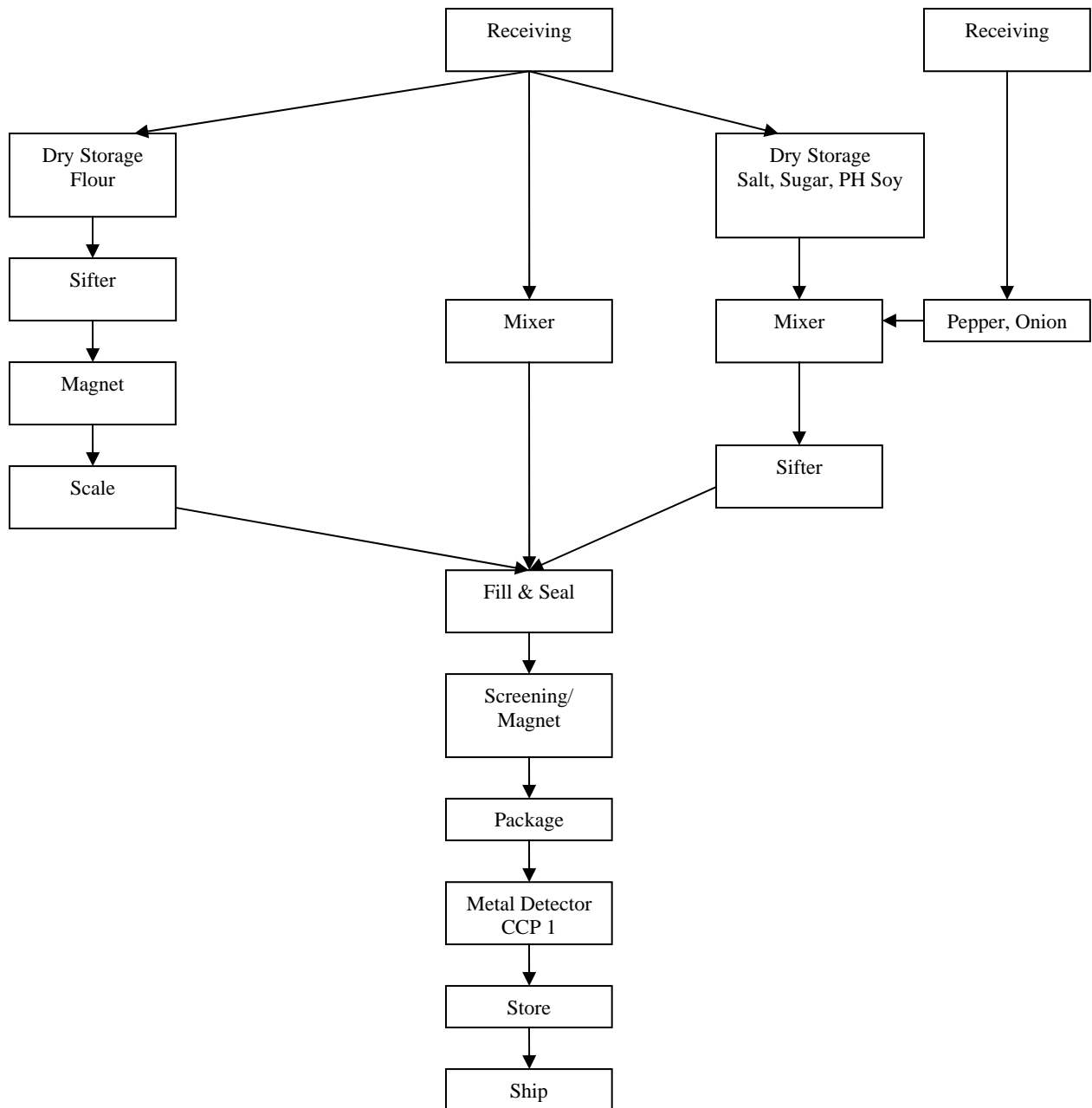
PRODUCT DESCRIPTION

Processed Seasoning

Product Description:	Seasoning for snacks
Food Safety Characteristics:	Spices (microbial control, foreign materials), dry ingredients (foreign material), dairy blends(refrigeration, microorganisms)
Target Customer:	Snack manufacturer Used as a topical seasoning
Packaging:	50 pound multiwall bags or boxes

Production of Seasoning for Snacks

Raw Materials: Flour, salt, sugar, nonfat milk, part hydrogenated soy oil, natural and artificial flavor, MSG, onion powder, black pepper, silicon dioxide.



ASTA HACCP HAZARD ANALYSIS WORKSHEET PROCESSED SEASONING

Ingredient or process step	Potential hazard	Type³	Does the hazard need to be in HACCP plan (Y/N)	Why?	Can this be controlled by prerequisite program? (Y/N)	What measures can be applied to prevent, eliminate, or reduce hazards	Is this a critical control point? (CCP) (Y/N)
Receiving	Salmonella, aflatoxin, mislabeled product, pesticides and/or colorants	P, M, C	N	Salmonella, aflatoxin, mislabeled products can be health concerns	Y	COA's from suppliers, raw material specs, trailer inspections, sampling and raw material testing for pesticides, colorants, micro, label verification	N
Warehouse	Micro contamination, pest infestation	M, P	N	Can be controlled by appropriate programs	Y	GMPs for warehouse including insect and pest programs, sanitation schedules	N
Staging/Mixing	Cross contamination, contamination from employees, use of incorrect ingredients, allergens	P, C, M	N	Can be controlled by appropriate operational and material handling programs	Y	GMPs with stringent cleaning procedures for equipment, process controls, employee training, ingredient verification	N

³ Type – P=Physical; M=Microbiological; C=Chemical

ASTA HACCP HAZARD ANALYSIS WORKSHEET PROCESSED SEASONING

Ingredient or process step	Potential hazard	Type⁴	Does the hazard need to be in HACCP plan (Y/N)	Why?	Can this be controlled by prerequisite program? (Y/N)	What measures can be applied to prevent, eliminate, or reduce hazards	Is this a critical control point? (CCP) (Y/N)
Mixing/Blending	Foreign Materials	P	N	Foreign material hazards addressed with screening, magnets and/or metal detection	Y	Discharge Screening, Magnets post blending	N
Packaging	Foreign material from damaged packaging, cross contamination. Incorrect labels relating to allergens	P, M, C	N	Can be controlled by appropriate programs	Y	GMP's, package inspection, label verification procedures, Allergen Control Plan	N
Metal Detection CCP1	Foreign Materials non-ferrous metal	P	Y	Metal that may not be caught at discharge screening or on magnets	N	Metal Detector	Y
Rework	Foreign material, allergens	P,M,C	N	Rework is typically overseen by management an re-run through the above system(s) reducing or eliminating the threat of physical, microbiological or chemical hazards	Y	GMP's, package inspection, label verification procedures, Allergen Control Plan, Rework Control Procedure	N
Shipping	Hazards due to unsanitary trailers, damaged packaging	P, C, M	N	Can be controlled by appropriate programs	Y	GMPs, trailer and packaging inspection	N

⁴ Type – P=Physical; M=Microbiological; C=Chemical

ASTA HACCP HAZARD ANALYSIS WORKSHEET PROCESSED SEASONING

CCP	Process Step	Hazard	Adverse Effects	Control Measures	Critical Limits	Monitoring Procedures	Corrective Actions	Monitoring Records
CCP-1	Metal Detection	Foreign materials, Metals	Choking or lacerations	Final sifting, Metal detector	Ferrous 1.0mm, Nonferrous 1.5mm Stainless 2.0mm	On-line inspection	Hold and review including inspection of rejects	Inspection results, Metal detector log

LIST OF TYPICAL RECORDS FOR A HACCP SYSTEM IN OPERATION

1. Ingredients

- Records from all monitored CCPs.
- Supplier certification documenting compliance with establishment's specifications.
- Establishment's audit records verifying supplier compliance.
- Storage temperature record for temperature-sensitive ingredients.
- Storage time records for limited shelf-life ingredients.

2. Preparation

- Records from all monitored CCPs.
- Records verifying the continued adequacy of the food preparation procedures.

3. Packaging

- Records indicating compliance with specifications for packaging materials.
- Records indicating compliance with sealing specifications.

4. Finished Product

- Sufficient data and records to establish the efficacy of barriers in maintaining product safety.
- Sufficient data and records to establish the safe shelf-life of the product if age of product can affect safety.
- Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

5. Storage and distribution

- Temperature records.
- Records showing no product shipped after shelf-life date.

6. Deviation and corrective action

- Records of all actions taken following deviations at a CCP.
- Reassessment records and modifications to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

7. Employee training

- Records indicating that employees responsible for the HACCP plan have been trained and understand the hazards, controls, and procedures. Including records for refresher HACCP training.

HACCP VERIFICATIONS

Types:

- CCP Verification: Evaluates day to day compliance to the HACCP plan.
- Audit: Evaluates effectiveness of employee training and plan implementation
- 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. White outs, missing information, etc. will prompt corrective action.
 - All results are within critical limits or any deviating 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.

HACCP VALIDATIONS

- 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.

HACCP VALIDATIONS

(Continued)

- May require retraining
- Does the scientific data still support the Hazard Analysis?
- Reference Study*

* ASTA/FDA Validation procedures for microbial reduction using EtO, Irradiation, and Steam MRP processes are available for members from the ASTA office.

RECOMMENDED HACCP MANUAL LAYOUT

- Title/Location/Effective Date
- HACCP Team Member List, include titles
- Review/Revision History, chronological
- Definition of Terms
- Description of Prerequisite Programs
- HACCP Description
- Hazard Description
- Product Descriptions
 - Name, general description
 - Allergen Statement
 - Intended use/application
 - Storage guidelines
 - Ingredient list
 - Packaging
- Detailed Process Flow Diagram
 - All processing steps that affect product characteristics
 - Clearly identify Critical Control Points
- Process Hazard Analysis
 - Process Step
 - Potential hazard introduced, controlled, or enhanced at this step.
 - Include each type of hazard: biological, chemical, physical. If not present indicate “none”.
 - Why potential hazard must be controlled.
 - Measures to eliminate the hazard(s)
 - Is this step a Critical Control Point?
- Critical Control Point Plan
 - Description of CCP
 - Hazard(s) that are addressed
 - Critical limits
 - Monitoring: what, how, frequency, who
 - Corrective action
 - Verification activities
 - Record keeping procedures
- Deviation Procedure
- Description of Verification and Validation Programs

DEFINITION OF TERMS

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)	<p>A step which, if controlled, will eliminate or reduce a hazard to an acceptable level.</p> <p>A step in any stage in food production and/or manufacture. This includes production of ingredients, or harvesting of raw materials, together with transport to the processing plant and formulation, processing and storage of product. Where appropriate, it includes distribution to the retail outlet consumer, and instructions for safe use.</p>
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 nonconformance 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.
FLOW DIAGRAM	The detailed sequence of operations for the product/process under study.
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 delineates the procedures to be followed.

DEFINITION OF TERMS

HACCP TEAM	A multidisciplinary group of individuals that undertakes a HACCP study. The team should consist of specialists, a chairperson, and a technical secretary.
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.
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.
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.

REFERENCES FOR HACCP TEAMS

1. Agriculture Canada. *Food Safety Enhancement Program - HACCP Implementation Manual*. Camelot Drive, Nepean, Ontario, Canada, 1996.
2. Baker, D.A. *Application of Modeling in HACCP Plan Development*. Int. J. Food Microbiol. 25: 251-261, 1995.
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.
4. Corlett, D.A., Jr. *HACCP User's Manual*. Chapman & Hall, New York, 1990.
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.
8. Environmental Protection Agency. *Tolerances for Pesticides in Foods*. Title 40, Code of Federal Regulations, Part 185. U.S. Government Printing Office, Washington, D.C., 1998.
9. Food and Drug Administration. *The Food Defect Action Levels*. FDA/CFSAN. Washington, D.C., 1998.
10. Food and Drug Administration. Section 555.425: Foods – Adulteration Involving Hard or Sharp Foreign Objects Compliance Policy Guides Manual, FDA, Washington, DC.
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.

REFERENCES FOR HACCP TEAMS

13. Hefle, S.L. et al. *Allergenic Foods. Critical Reviews in Food Science and Nutrition*, 36(s), S69-S89, 1996.
14. Mortimer, S. E. and Wallace, C.A. *HACCP: A Practical Approach*. 2nd Edition. Chapman & Hall, London, 1998.
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*

SELECTED WEB SITES FOR FOOD SAFETY INFORMATION

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

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/>