

CREATING A MODEL HAZARD ANALYSIS
CRITICAL CONTROL POINT (HACCP) SYSTEM
WITHIN THE FLOUR MILLING INDUSTRY

By

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Abstract: Foodborne illnesses and diseases have been a major concern to the food industry worldwide. Foodborne illnesses are caused by several disease-causing germs that have contaminated food. Researchers have identified over 250 foodborne diseases. Most of them are infectious, caused by various bacteria; and parasites. Chemicals and harmful toxins are other factors that can contaminate food and cause foodborne illnesses. The top viruses that cause foodborne illnesses in the US are norovirus, salmonella, clostridium perfringens, campylobacter, and staphylococcus aureus (staph). Some germs do not cause as many illnesses. However, when they do, they have a higher risk of causing individuals to end up hospitalized. Those viruses include *Clostridium botulinum* (botulism), *listeria*, *Escherichia coli* (E. coli), and *vibrio* (Hedberg, 1999). According to the Centers for Disease Control and Prevention (CDC), they estimate that 48 million people get sick from a foodborne illness, 128,000 get hospitalized, and 3,000 die each year (FDA 2022). The purpose of this study is to show how the Hazard Analysis Critical Control Point (HACCP) system has been proven to be effective in the food industry. It is a food safety tool that manages the hazards associated with food production plants and farm-to-table within the past three decades, the U.S. government agencies have issued a succession of regulations that require a HACCP plan development for certain types of foods. The HACCP plan system is a proactive control approach and is globally accepted for manufacturers to prevent recalls and outbreaks, along with reducing financial losses (Gillion 2005).

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CHAPTER I

INTRODUCTION

While the American food supply is among the safest in the world, the Federal government estimates that there are about 48 million cases of foodborne illness annually. The equivalent of sickening is one in six Americans each year. Each year, these illnesses result in an estimated 128,000 hospitalization and 3,000 deaths (FDA 2022). More than 250 known diseases are transmitted through food. Biological, chemical, and physical hazards are responsible for foodborne illnesses. The symptoms of foodborne illnesses range from mild gastroenteritis to life-threatening neurologic, hepatic, and renal syndromes. In the United States, foodborne diseases have been estimated to cause six million illnesses and up to 48 million deaths each year. Ongoing changes within the food industry/supply, have identified new foodborne diseases. Therefore, the availability of new surveillance data has made these figures obsolete. New and more accurate estimates are needed to guide prevention efforts and assess the effectiveness of food safety regulations (Hedberg 1999).

The lack of reporting foodborne illnesses is one of several factors why monitoring them is difficult. Although foodborne illnesses can be severe and even fatal, milder cases are often not detected through routine inspections. Many pathogens transmitted from food are also spread through water and person to person. This factor eliminates the probability that it is transmitted through food. Several proportions of foodborne illnesses are caused by pathogens or agents that have not been identified yet and therefore, cannot be diagnosed (Hedberg 1999).

Food poisoning symptoms in the mild stages go unnoticed because the individual will get treated for the symptoms versus getting tested for what the cause may be. These symptoms include diarrhea (sometimes bloody), vomiting, nausea, or stomach cramps. The immunocompromised such as pregnant women, the elderly, and young children are classified as the high susceptible group because they can get foodborne illnesses easier and, in some cases, have fatal results. The top five germs that cause foodborne illnesses are *Norovirus*, *Salmonella*, *Clostridium perfringens*, *Campylobacter*, and *Staphylococcus aureus* is formally known as staph (CDC 2020).

Food safety receives minimal attention although it has been suggested that; food should be safe from farm to fork. Therefore, it is advised that food safety should be controlled by having a total quality management system in place. This system should include pre-requisite programs and a HACCP plan to ensure all factors that could affect the safety of the product are under control (Sun and Ockerman 2005; NACMCF 1998). Because HACCP aims to identify and control hazards, time is saved; and the consumer's perception of safe food is met.

The HACCP concept is also based on prevention rather than detection. Testing the end product is not a reliable method of ensuring a product is safe. HACCP systems do not guarantee zero risks but, it helps to minimize them. In some cases, the reasons for HACCP failure are incomplete hazard analysis and reliance on HACCP only which results in negligence of the general hygiene management. HACCP is excellent to use especially, to focus on food safety issues. However, it does not guarantee against ignorance or mishaps of any kind (Heggum 2001).

HACCP was first introduced by the Pillsbury Company, NASA, and the US army laboratories at Natick to ensure the food the astronauts would consume was safe for consumption in space. (Trujillo 2000; Sperber 2005). The Codex Alimentarius Commission has identified seven principles for HACCP mainly structured into three main elements. The first element refers to hazard analysis (principle one), element two refers to the measures of hazard control (principles 2-5), and element three refers to the documentation and verification of the HACCP system (principles 6-7) (Untermann 1998).

To implement the HACCP plan, it is important to have a pre-requisite program in place. These programs are described as the HACCP support network (Mortimore and Wallace 1995). These programs refer to “the universal steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable for the production of safe food” and include elements such as the Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Hygiene Practices (GHP) (Mortimore and Wallace 1995). The pre-requisite programs are the backbone of the HACCP system and help to simplify the HACCP plan. In the long run, the HACCP plan is simplified and will be easier to manage for food facilities.

The flour milling industry is considered a low-risk area within food handling enterprises since the flour is mainly used for baking purposes. Pathogens such as *Bacillus* and *Staphylococcus* produce toxins that are heat stable and therefore; can cause illness even after the product has been baked. (Gillion 2005). In some cases, the flour does not undergo heat treatment (cooking or baking) and is used as a coating for candy which in return causes consumers to be at risk of contracting food poisoning. In other cases where the flour is used in sauces, the heat treatment sometimes is not as extreme, and micro-organisms are not killed off completely (Gillion 2005). As a result, outbreaks of foodborne illnesses have occurred throughout North America along with recalls.

There was a need within the milling industry for controlling food safety especially due to customer demands and government regulations. The best way to ensure food safety was with the implementation of a HACCP-based food safety system. Therefore, the principal

aim of this study is to develop a generic HACCP model for the flour milling industry.

This generic model could be adapted for each specific mill and its needs (Gillion 2005).

The specific project objectives are to develop pre-requisite programs for the flour milling industry, develop a generic flow diagram, conduct a hazard analysis, identify the critical control point(s), identify the critical limits, identify monitoring and verification procedures, and investigate the microbial safety of wheat and flour (Gillion 2005).

CHAPTER II

LITERATURE REVIEW

2.1 Wheat and the Microbial Load on Wheat

2.1.1 Wheat

Wheat originated in the Middle East thousands of years ago in the areas now known as, Israel, Egypt, Syria, and Jordania. The wheat plant is adaptable to various climates and geographical areas. When a seed is planted and becomes warm, it absorbs moisture which causes specific metabolic processes to occur, initiating growth. This includes the development of the shoot and root. If weather conditions are favorable, the wheat plant will continue to grow and within the stem of the plant, ahead of wheat will start to develop. Wheat is ready for harvest when the plant becomes an amber color which is caused by the loss of water (Food Trust 2019).

2.1.1.1 Wheat Types

Six types of wheat are commonly grown in the United States. Hard Red Winter Wheat, Hard Red Spring Wheat, Soft Red Winter Wheat, Hard White Winter Wheat, Soft White Spring Wheat, and a specialty variety called; Durum. The soft and hard terms refer to the hardness of the kernel. Hard wheat requires more energy to mill because more force is needed to crush it. Red and white refer to the reddish pigment in the outer layers of the wheat kernel which can be seen. Winter and spring describe the growth period when the wheat type is planted and grows. Winter wheat is planted in autumn because cold temperatures are needed for the wheat head to produce, and then it is harvested in the summer. Spring wheat is planted in the spring and harvested in late summer-early autumn time (Precision Ag. 2019).

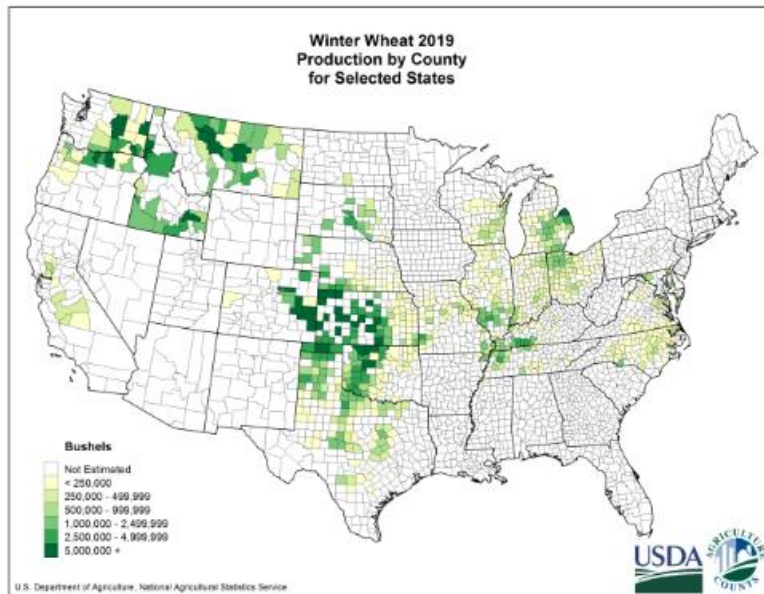
Hard Red Winter Wheat is mostly grown in the state of Kansas and other Plains states such as; Oklahoma and Texas. The protein content is very popular because it is approximately 10.5%, making it preferred among commercial mills for making all-purpose mixes (Precision Ag. 2019). Hard White Winter Wheat is also common for flour mills because the protein is like Hard Red Winter Wheat, but it has more of a sweet flavor to it. This wheat is often used for the same types of products from which they make Hard Red Winter Wheat (USDA 2021).

2.1.1.2 Growth Regions

In America, the main areas where winter wheat is grown are indicated in Fig 2.1 below. Winter wheat is spread out within the United States, but the primary areas are in the northwest and central regions. The states in the northwest area that predominately grow

winter wheat are northern Oregon, Washington, Idaho, and Montana. In the central area, lightly starting in South Dakota moving south, Nebraska, Oklahoma, and Texas. Some other states in the northeast region include Wisconsin, Illinois, Indiana, Ohio, Minnesota, Kentucky, Missouri, and Tennessee. The expected wheat production will total 50.0 million metric tons (MMT) for the 2020/21 year.

Fig. 2.1 Areas for growing wheat in North America



2.1.1.3 General uses of wheat

Hard red winter (HRW) wheat is primarily grown in the Great Plains such as northern Texas through Montana and used for producing bread flour. Hard red spring (HRS) wheat is mainly grown in the Northern Plains such as North Dakota, Montana, Minnesota, and South Dakota. HRS is highly valued for its high protein levels which makes it suitable for making various kinds of bread products. Soft red winter wheat (SRW) is grown in states along the Mississippi River and eastern states. Flour produced from milling-grade SRW is used to produce cakes, crackers, and cookies. White wheat (both winter and spring) is

grown in Washington, Oregon, Idaho, Michigan, and New York. This flour is produced for making noodle products, crackers, cereals, and white crusted bread. Lastly, Durum wheat is mainly grown in North Dakota and Montana, and it is used to produce pasta.

2.1.1.4 Structure of the wheat kernel

The wheat kernel structure is made up of three essential components: the endosperm, germ, and bran (Atwell 2001). The wheat kernel is also known as a wheat berry. The kernel is the seed from which the wheat plant grows and produces. Each seed contains three distinctive parts that are separated during the milling process to produce flour indicated in Figures 2.2 and 2.3. The endosperm is about 83% of the kernel weight and is the source of white endosperm flour (NZFMA 2021). The endosperm contains the biggest portion of protein, carbohydrates, iron, as well as B-vitamins such as riboflavin and niacin. It is also a source of soluble fiber. The germ consists of the embryo and scutellum which comprises 3% of the wheat kernel. Most of the lipids and other essential nutrients are concentrated in the germ (NZFMA 2021).

The outer protective layer of the wheat is the bran. It is mainly divided into the pericarp, testa, and nucellar epidermis. The latter is subdivided into several layers (Mousia and Pandiella 2004). Bran is about 14% of the kernel weight (Atwell 2001). Between the bran and the endosperm, a layer of highly specialized endosperm cells the aleurone layer is found. This layer is considered to contain a high enzyme activity, making it more biologically active. This layer is also generally removed during milling operations as part of the bran. Bran is included in whole wheat flour and can also be sold separately. Bran contains a small amount of protein, trace minerals, and dietary fiber which is primarily

insoluble (NZFMA 2021). Germ is about 2.5% of the kernel weight. The germ is the embryo and/or sprouting section of the seed. It is often separated from flour due to the fat content (10%) and limits shelf life. The germ contains minimal quality protein but a greater share of B-vitamins along with trace minerals. Wheat germ is also a part of whole wheat flour and can also be bought separately (NZFMA 2021).

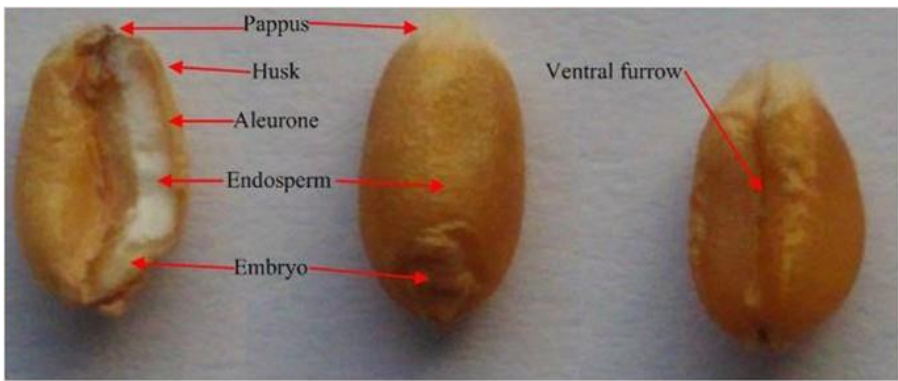


Fig. 2.2 Wheat Kernel Structure

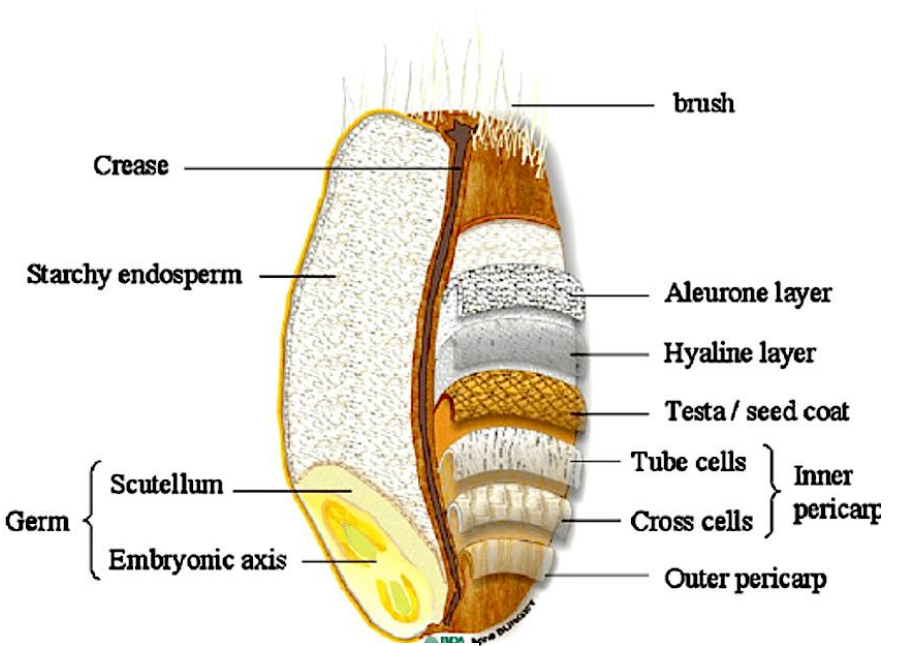


Fig. 2.3 Wheat Kernel Structure

2.1.2 Microbial load on wheat

Right after wheat has been harvested, the wheat gets contaminated by micro-organisms from various sources such as dust, water, soil, fertilizers, animal feces, human handling, and other sources. The bacteria commonly found on grains mainly belong to the *Pseudomonadaceae*, *Micrococcaceae*, *Lactobacillaceae*, and *Bacillaceae* families. The molds are common to the *Alternaria*, *Fusarium*, *Helminthosporium*, and *Cladosporium* families (D’Mello et al 1993; Mousia et al. 2004; Anon. 2005f). Although others may also be present, these are the most common. The wheat should be stored under appropriate conditions to prevent these micro-organisms from flourishing and altering the properties of the product.

In North America, an updated list of grading rules by the Department of Agriculture is available to the wheat grader to accept or reject a load of wheat upon arrival at the mill. Under Principles Governing the Application of Standards, regulation code, 810.2203 Basis of determination states,

Each determination of heat-damaged kernels, damaged kernels, foreign material, wheat of other classes, contrasting classes, and subclasses is made based on the grain when free from dockage and shrunken and broken kernels. Other determinations not specifically provided for under the general provisions are made based on the grain when free from dockage, except the determination of odor is made on either the basis of the grain as a whole or the grain when free from dockage” (pg. 4 US Dpt. Of AG).

2.2.1.1 Wheat receiving

Wheat is mainly received by truck or rail. A well-trained and experienced wheat grader with the relevant qualification on site takes a representative sample of a whole load of wheat and does grading according to the latest national grading rules (Anon. 1993). The sample is inspected and tested for impurities, moisture content, protein content, hectoliter mass, cultivar, insect infestation, and sprout damage (Anon. 1993; Anon. 2004b). The optimum moisture content of grains before storage should be +/- 14.0% (Anon. 1977). In rare cases where high moisture wheat is stored for long periods, it is important that drying or aeration of the wheat should take place to minimize the risks of sweating, sprouting, heat damage, and spontaneous combustion (Anon. 1977). If the quality is acceptable as stated on the grading certificate received, the wheat can be unloaded. If the quality of the wheat differs from the grading certificate, the wheat grader has the authority to reject or re-grade the wheat. The accepted wheat is unloaded into the pit and then goes to the leg which is then transferred to the aspirator for cleaning.

2.2.1.2 Cleaning house

Before cleaning occurs, a process called gristing takes place, where different types of wheat are mixed into different proportions to produce the right quality of the flour. When the flour undergoes the cleaning process, it helps to remove any foreign materials and impurities (Gillion 2005). Aspirators, de-stoners, combi-cleaners, seed removers, truer cylinders, and carter disks are used in various mills to remove any foreign materials. In North American mills, when wheat is transferred from the elevator to the mill, it goes through a dirty surge bin. During the wintertime, the wheat will go through a wheat

heater to raise the temperature for milling purposes (Gillion 2005). At this point, the wheat is then weighed and passes through a magnet to remove any metal objects. The wheat then goes through a separator/aspirator to remove foreign material such as corn, rocks, sticks, etc. The aspirator will remove light chaff and/or possibly infested kernels that have become lighter than the non-infested kernels. A color sorter identifies irregular wheat/coloring and removes them, then; passes through a scour/aspirator. The scour will contribute to removing dirt and any infested kernels that may have passed through the aspirators (Gillion 2005). Before going to the temper bin, the wheat will go to a dampener, and water is added to facilitate the efficient separation of the endosperm from the bran. This conditioning phase usually takes place in two stages where 60% of the water is added during the first conditioning and 40% during the second conditioning phase (Anon. 1993). The rest time for hard wheat is a minimum of 12 hours and for soft wheat, 7 hours at ambient water temperatures. The advantages of proper conditioning are a better flour product. Less stress on the reduction rolls due to the mellowed endosperm and consistent milling performance (Gillion 2005).

2.2.1.3 Milling

Once the wheat has been tempered for a couple of hours in the tempering bins, the wheat passes through a scourer and aspirator to remove any mud formed (Anon. 2004b). The wheat is then ready to go through to the first break roller and first break scale. During the milling process, the endosperm is separated from the bran and the germ by breaking the kernel into smaller fragments (Mousia and Pandiella 2004). The break rolls are fluted rolls that are designed to break each grain into three parts known as the endosperm, germ, and bran. A continuous process of grinding, conveying, and sifting takes place whilst the

endosperm is sent through reduction rolls, scales, and sifters to produce the final product, flour (Fig. 2.5). The bran and wheat germ were also sifted into different streams and separated by sieves so when the milling process is complete, these products are also separated.

2.2.1.4 Finished flour

The different types of flour depending on the variety of wheat as well as the percentage of bran removed before the milling process. As shown in figure 2.5, each type of flour milled has a different color, consistency, and outcome. When whole wheat flour is produced, the whole grain is used. White bread flour is more refined because the bran is separated from the rest of the grain. Brown bread flour has a higher extraction rate than white bread flour since it contains more bran thus giving the flour a darker color and a stronger flavor and odor (Anon. 2004a; Anon. 2005e).



Fig. 2.5 Final Product Samples

2.2.2 Debranning or Pearlizing of wheat

Until recently, the aleurone layer which is considered the most nutritious part of the cereal grain since it is rich in vitamins, minerals, and other nutrients was removed with the bran layers because it is very difficult to separate with conventional milling processes. The aleurone layer refers to the inner part of the bran layers closest to the endosperm. However, debranning opened new doors in the milling industry since it removes the layers from the cereal grain from the outside inwards which means the aleurone layer can remain attached to the endosperm (Mousia and Pandiella 2004). Other advantages of the debranning system are improvements to the ash and color results, improved flour quality, more valued-added food, and non-food products since the aleurone is used, removal of

microbial contaminants, reduced stress on the milling process resulting in an increased yield and reduced bran that improves the bread-making performance (Mousia and Pandiella 2004). The debranning system has proven it efficiently removes the bran from the wheat kernel thereby improving the flour quality since bran has a negative effect in the baking industry due to its particle size and content. The bread quality is affected in terms of color, volume, and texture (Mousia and Pandiella 2004). Bran particles also disrupt the gluten-starch network and restrict the gas cell expansion within the matrix; it absorbs water, restricting the hydration and development of gluten (Mousia and Pandiella 2004). The presence of bran in the final product, therefore, can have a negative effect on the flour stability during storage.

2.3 Food Safety Management Systems

Foodborne diseases are a major concern worldwide to every food manufacturer, health official, researcher, and many others. Customers expect only the best quality when purchasing a product and when unsatisfied, it can result in a downfall within the greatest food handling enterprises. Food that does not cause harm to the consumer when prepared or eaten according to its intended use, is regarded as safe for human consumption therefore, every food manufacturer must produce safe food that meets the in-house specifications and conform to local health regulations. Therefore, Food Safety Management Systems within the food industry are important. Most of the quality assurance programs are designed to discover the problems once it has already occurred whereas HACCP is a food safety tool based on prevention rather than detection (Bauman 1991). With traditional inspection, it is possible to evaluate current sanitation and food safety conditions, but it is not possible to see that plants are operating under conditions

that continuously prevent problems from occurring (Trujillo 2000). Other food safety management systems include the ISO series and others less known.

2.3.1 Pre-requisite programs

The actions that take place before the layout of a HACCP plan can influence the hygiene; quality and safety of the food under production are referred to as the pre-requisite programs. Concepts such as cleaning, hygiene, design of the plant and building, and preventative maintenance are very well-developed and are known to the food industry as Good Manufacturing Practices; therefore, it is not new to most of the food handling enterprises (Wallace and Williams 2001). It is of utmost importance that pre-requisite programs such as the Good Manufacturing Practice (GMP), Good Agricultural Practices (GAP), Good Hygiene Practices (GHP), and Good Laboratory Practices (GLP) should be in place before an attempt can be made to implement HACCP. Therefore, formalizing the pre-requisite programs alongside HACCP to control the identified hazards is a new concept (Wallace and Williams 2001). With the implementation of the pre-requisite programs, all the critical areas are covered. However, if HACCP is implemented before the pre-requisite programs are in place, it could lead to a complicated HACCP system with too much critical control points (Mitchell 1992).

Of all these pre-requisite programs the Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) are the most important and should be documented, monitored, confirmed, and reviewed frequently. If these practices are well-developed and frequent auditing shows consistency, the food safety plan (in this case the HACCP plan), is noticeably simplified (Gillion 2005).

There are 10 elements within the program standards which are, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each element has self-assessment worksheets while certain standards have supplemental worksheets and forms for determining a level of conformance with these standards (FDA 2017).

The Food and Drug Administration (FDA) uses these programs as a tool to help improve contracts with the States. The goal is to implement a risk-based food safety program to measure and improve the performance of manufactured food regulatory programs within the United States. These program standards will help Federal and State programs to better direct their regulations toward reducing the risks of foodborne illness hazards within food plants (FDA 2017).

Key model pre-requisite programs

2.3.1.1 Establishment design and facilities

2.3.1.1.1 Design

2.3.1.1.1.1 The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:

2.3.1.1.1.2 Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food (FDA 2022).

2.3.1.1.1.3 Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, airflow systems, dust control systems, enclosed systems, or other effective means (FDA 2022).

2.3.1.1.1.4 Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that isles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact (FDA 2022).

2.3.1.1.1.5 Facilities

2.3.1.1.1.6 Each plant must be equipped with adequate sanitary facilities and accommodations including Water supply. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure, as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or employee sanitary facilities (FDA 2022).

2.3.1.1.1.7 Plumbing must be of adequate size and design and adequately installed and maintained to: carry adequate quantities of water to required locations throughout the plant. Properly convey sewage and liquid disposable waste from the plant. Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition. Provide adequate floor drainage in all areas where floors are subject to flooding–type cleaning or where normal operations release or discharge water or other liquid waste on the floor. Provide that there is no backflow from, or cross-contamination between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing (FDA 2022).

2.3.1.1.1.8 Sewage disposal. Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means (FDA 2022).

2.3.1.1.1.9 Toilet facilities. Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a

potential source of contamination of food, food-contact surfaces, or food-packaging materials (FDA 2022).

2.3.1.1.2 Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature (FDA 2022).

2.3.1.2 Equipment and utensils

All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable and must be adequately maintained to protect against allergen cross-contact and contamination (FDA 2022).

2.3.1.2.1 Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants (FDA 2022).

2.3.1.2.1.1 Food-contact surfaces must be corrosion-resistant when in contact with food. Food-contact surfaces must be made of non-toxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures. Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives. Seams on food-contact surfaces must be smoothly bonded or maintained to minimize the accumulation

lation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact (FDA 2022).

2.3.1.2.2 All operations in the manufacturing processing, packing, and holding of food (including operations directed to receiving, inspecting, transportation, and segregating) must be conducted by adequate sanitation principles. Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function. Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and contamination from any source. Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination. All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination (FDA 2022).

2.3.1.3. Warehouse and distribution

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container (FDA 2022).

2.3.1.4. Personal hygiene

2.3.1.4.1. All persons working in direct contact with food, food-contact surface, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and contamination of food (FDA 2022). The methods for maintaining cleanliness include:

- (1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and the contamination of food, food-contact surfaces, or food-packaging materials (FDA 2022).
- (2) Maintaining adequate personal cleanliness (FDA 2022).
- (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated (FDA 2022).
- (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand (FDA 2022).
- (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition (FDA 2022).
- (6) Wearing, where appropriate, and effectively, hair nets, headbands, caps, beard covers, or other effective hair restraints (FDA 2022).

2.3.1.5. Training

2.3.1.5.1. All personnel should be trained in food handling and should have the knowledge that enables them to protect food from contamination (CAC 1997; Anon. 2004c).

(1) Training programs for personnel should comprise the following: the nature of the food, the handling, and packaging of the food, the ability to sustain the growth of pathogenic microorganisms, processing before final consumption, storage conditions, expected length before consumption, basic personal hygiene, and sanitary requirements of the equipment (CAC 1997; Anon. 2004c).

(2) The effectiveness of the training should be checked by periodic assessments and routine supervision (CAC 1997; Anon. 2004c).

(3) Systems to ensure that food handlers are aware of all procedures necessary to maintain the safety and suitability of the food should be in place (CAC 1997; Anon. 2004c).

2.4 Hazard Analysis Critical Control Point

2.4.1 The history of HACCP

The HACCP concept was first introduced to the food industry by the Pillsbury Company, NASA, and the US army laboratories at Natick in the 1960s (Efstratiadis and Arvanitoyannis 2000; Trujillo 2000; Sperber 2005). At first, it was developed to ensure the safety of foods for astronauts in the NASA space program. The food products that were being produced for space use had to be free from pathogens. At that stage, quality

systems were mainly based on end-product testing, which obviously would not have worked for such a mission because by the time results were received for the product tested on earth, the possibility that the product would have been used up in space already, existed. To find a solution to their problem, they decided to take control over the process, raw materials, environment, and people as early as possible in the food production system (Mortimore and Wallace 1995). A preventative system with a high level of food safety guarantee namely the HACPP system was born. HACCP concepts were used during the seventies in the production of low acid canned foods after the FDA published a mandatory regulation because botulism became a major problem in canned mushrooms (Trujillo 2000; Sperber 2005). Thereafter, the use of HACCP concepts was not visible until the 1990's when the seafood industry voiced concerns regarding microbiological, chemical, and physical hazards (Trujillo 2000). The National Academy of Sciences (NAS) recommended in 1991 that HACCP should be used to ensure food safety. In 1994, the FDA after numerous consultations with the seafood industry, the public, and academics, issued a mandatory regulation requiring all seafood processors in the USA as well as those exporting to the USA, to implement HACCP (Trujillo 2000). In 1992, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in the USA, issued guidelines for the use of HACCP based on the draft prepared by the HACCP working group of the Codex Committee (Trujillo 2000). These guidelines were re-issued in 1997 with a detailed explanation of the HACCP principles (Trujillo 2000).

The Codex Alimentarius Commission which was established in 1962 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) should ensure fair international trade in food (Trujillo 2000). Codex adopted seven principles for

the HACCP system in 1997 (CAC 1997). This is a step-by-step procedure on how to develop a HACCP plan.

2.4.2 HACCP

HACCP for in long, Hazard Analysis Critical Control Point System identifies hazards within the food production system and implements control and management systems to ensure the safety of the product (Mortimore and Wallace 1995). The HACCP system is based on the principle that food safety issues can be prevented or minimized by prevention rather than detection in the final product (Vail 1994). It is an internationally recognized food safety system and can be applied effectively to all types of food businesses from production through to the end-product or even the final stage, consumption (Forsythe 2000). By developing, implementing, and effectively managing the hazard control program, HACCP assures food safety (Vail 1994). The benefits of a HACCP system are the maximization of product safety as well as consistent food safety, cost-effectiveness, better use of resources, and well-timed reaction to problems (Mortimore and Wallace 1995). HACCP also has a few downfalls including being an expensive, technically complex, and time-consuming process (Unnevehr and Jensen 1999).

2.4.3 Total Quality Management

Total Quality Management (TQM) is the organization's cultural approach toward quality which is based on all members within the organization participating to continually improve the quality of the product manufactured in the long run (Forsythe 2000). It has been mentioned that a food safety plan such as a HACCP plan is just as good as the

commitment of the personnel implementing and managing the program (Vail 1994). To maximize quality, productivity, and food safety, a combination of HACCP, quality management systems (e.g., ISO 9000), TQM, food safety management systems, and business excellence is needed (Forsythe 2000). Therefore, the generic requirements for the food safety management systems such as the pre-requisite programs should be in place before the food safety assurance plan or HACCP plan can be developed.

2.4.4 Preliminary steps of HACCP

The following five principles are preliminary HACCP steps used to develop a successful HACCP plan.

Table 2.1 The five preliminary HACCP steps (*Developing a HACCP Plan the Five Preliminary Steps*, 2019).

Pre-HACCP Step 1: Bring together the HACCP resources/assemble the HACCP team

Pre-HACCP Step 2: Describe the product and its method of distribution

Pre-HACCP Step 3: Develop a complete list of ingredients and raw materials

Pre-HACCP Step 4: Develop a process flow diagram

Pre-HACCP Step 5: Meet the regulatory requirements for sanitation

2.4.5 Principles of HACCP

The following seven principles are the Codex guidelines and outline specifically how to implement a HACCP study.

Table 2.2 The principles of HACCP (CAC 1997; NACMCF 1998; Unnevehr 1999; Efstratiadis and Arvanitoyannis 2000; Boccas et al. 2001).

Principle 1	Conduct a hazard analysis
Principle 2	Determine the critical control points (CCPs)
Principle 3	Establish critical limits
Principle 4	Establish monitoring procedures
Principle 5	Establish corrective actions
Principle 6	Establish verification procedures
Principle 7	Establish record-keeping and documenting procedures

2.4.6 The 12-step procedure for a HACCP system set up

Step 1: Assemble the HACCP Team

The first task in developing a HACCP plan is to assemble a HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process (NACMCF 1998; Forsythe 2000; Higuara-Ciapara and Noriega-Orozco 2000; Trujillo 2000). It is the team's responsibility to develop the HACCP plan. The team should be multi-disciplinary and include individuals from areas such as engineering, production, sanitation, quality assurance, and food microbiology. The team should also include local personnel who are involved in the operation as they are more familiar with the variability and limitations of the operation. Additionally, this fosters a sense of ownership among those who must implement the plan. The HACCP team may need assistance from outside experts who are knowledgeable in the potential biological, chemical, and/or physical hazards associated with the product and the process. However, a plan which is developed totally by outside sources may be erroneous, incomplete, and lacking in support at the local level (FDA, 2017).

Due to the technical nature of the information required for hazard analysis, it is recommended that experts who are knowledgeable in the food process should either participate in or verify the completeness of the hazard analysis and the HACCP plan. Such individuals should have the knowledge and experience to correctly: (a) conduct a hazard analysis; (b) identify potential hazards; (c) identify hazards that must be controlled; (d) recommend controls, critical limits, and procedures for monitoring and verification; (e) recommend appropriate corrective actions when a deviation occurs; (f)

recommend research related to the HACCP plan if important information is not known; and (g) validate the HACCP plan (FDA, 2017).

Step 2: Describe the food and its distribution

The HACCP team first describes the food. This consists of a general description of the food, ingredients, and processing methods. The method of distribution should be described along with information on whether the food is to be distributed frozen, refrigerated, or at ambient temperature (FDA, 2017).

Step 3: Describe the intended use and consumers of the food

Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g., infants, immunocompromised individuals, the elderly, etc.) (FDA, 2017).

Step 4: Develop a flow diagram that describes the process

The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process which are directly under the control of the establishment. In addition, the flow diagram can include steps in the food chain which are before and after the processing that occurs in the establishment. The flow diagram need not be as complex as engineering drawings. A block-type flow diagram is sufficiently descriptive. Also, a simple schematic of the facility is often useful in understanding and evaluating product and process flow (FDA, 2017).

Step 5: Verify the flow diagram

The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modifications should be made to the flow diagram as necessary and documented.

After these five preliminary tasks have been completed, the seven principles of HACCP are applied (FDA, 2017).

Step 6: Conduct a hazard analysis (principle 1)

After addressing the preliminary tasks discussed above, the HACCP team conducts a hazard analysis and identifies appropriate control measures. The purpose of the hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. Hazards that are not reasonably likely to occur would not require further consideration within a HACCP plan. It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns. A hazard is defined as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Thus, the word hazard as used in this document is limited to safety. A thorough hazard analysis is key to preparing an effective HACCP plan. If the hazard analysis is not done correctly and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed (FDA,

2017). The hazard analysis and identification of associated control measures accomplish three objectives: Those hazards and associated control measures are identified. The analysis may identify needed modifications to a process or product so that product safety is further assured or improved. The analysis provides a basis for determining CCPs in Principle 2 (FDA, 2017).

Step 7: Determine critical control points (CCPs) (principle 2)

A critical control point is defined as a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. The potential hazards that are reasonably likely to cause illness or injury in the absence of their control must be addressed in determining CCPs (FDA, 2017).

Complete and accurate identification of CCPs is fundamental to controlling food safety hazards. The information developed during the hazard analysis is essential for the HACCP team in identifying which steps in the process are CCPs. One strategy to facilitate the identification of each CCP is the use of a CCP decision tree. Although the application of the CCP decision tree can be useful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. A CCP decision tree is not a substitute for expert knowledge (FDA, 2017).

Critical control points are located at any step where hazards can be either prevented, eliminated, or reduced to acceptable levels. Examples of CCPs may include thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing product for metal contaminants. CCPs must be carefully developed

and documented. In addition, they must be used only for purposes of product safety. For example, a specified heat process, at a given time and temperature designed to destroy a specific microbiological pathogen, could be a CCP. Likewise, refrigeration of a precooked food to prevent hazardous microorganisms from multiplying, or the adjustment of food to a pH necessary to prevent toxin formation could also be CCPs. Different facilities preparing similar food items can differ in the hazards identified and the steps which are CCPs. This can be due to differences in each facility's layout, equipment, selection of ingredients, processes employed, etc. (FDA, 2017).

Step 8: Establish critical limits (principle 3)

A critical limit is a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Critical limits should not be confused with operational limits which are established for reasons other than food safety (FDA, 2017).

Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated, or reduced to acceptable levels. Each control measure has one or more associated critical limits. Critical limits may be based upon factors such as temperature, time, physical dimensions, humidity, moisture level, water activity (a_w), pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information such as aroma and visual appearance. Critical limits must be scientifically based. For each CCP, there is at least one criterion for food safety that is to

be met. An example of a criterion is a specific lethality of a cooking process such as a 5D reduction in *Salmonella*. The critical limits and criteria for food safety may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental results, and experts (FDA, 2017).

Step 9: Establish monitoring procedures (principle 4)

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Monitoring serves three main purposes. First, monitoring is essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs. Second, monitoring is used to determine when there is a loss of control and a deviation occurs at a CCP, i.e., exceeding, or not meeting a critical limit. When a deviation occurs, appropriate corrective action must be taken. Third, it provides written documentation for use in verification (FDA, 2017).

An unsafe food may result if a process is not properly controlled, and a deviation occurs. Because of the potentially serious consequences of a critical limit deviation, monitoring procedures must be effective. Ideally, monitoring should be continuous, which is possible with many types of physical and chemical methods. For example, the temperature and time for the scheduled thermal process of low-acid canned foods are recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the product

from the retort is retained and the disposition determined as in Principle 5. Likewise, pH measurement may be performed continually in fluids or by testing each batch before processing. There are many ways to monitor critical limits on a continuous or batch basis and record the data on charts. Continuous monitoring is always preferred when feasible. Monitoring equipment must be carefully calibrated for accuracy (FDA, 2017).

Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs and control measures and the complexity of monitoring. Personnel who monitor CCPs are often associated with production (e.g., line supervisors, selected line workers, and maintenance personnel) and, as required, quality control personnel. Those individuals must be trained in the monitoring technique for which they are responsible, fully understand the purpose and importance of monitoring, be unbiased in monitoring and reporting, and accurately report the results of monitoring. In addition, employees should be trained in procedures to follow when there is a trend toward loss of control so that adjustments can be made promptly to assure that the process remains under control. The person responsible for monitoring must also immediately report a process or product that does not meet critical limits. All records and documents associated with CCP monitoring should be dated and signed or initialed by the person doing the monitoring (FDA, 2017).

With certain foods, processes, ingredients, or imports, there may be no alternative to microbiological testing. However, it is important to recognize that a sampling protocol that is adequate to reliably detect low levels of pathogens is seldom possible because of the large number of samples needed. This sampling limitation could result in a false sense

of security for those who use an inadequate sampling protocol. Additionally, there are technical limitations in many laboratory procedures for detecting and quantitating pathogens and/or their toxins (FDA, 2017).

Step 10: Establish corrective actions (principle 5)

The HACCP system for food safety management is designed to identify health hazards and establish strategies to prevent, eliminate, or reduce their occurrence. However, ideal circumstances do not always prevail and deviations from established processes may occur. An important purpose of corrective actions is to prevent foods that may be hazardous from reaching consumers. Where there is a deviation from established critical limits, corrective actions are necessary. Therefore, corrective actions should include the following elements: (a) determine and correct the cause of non-compliance, (b) determine the disposition of non-compliant products, and (c) record the corrective actions that have been taken. Specific corrective actions should be developed in advance for each CCP and included in the HACCP plan. At a minimum, the HACCP plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken.

Individuals who have a thorough understanding of the process, product, and HACCP plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining the disposition of non-compliant products (FDA, 2017).

Step 11: Establish verification procedures (principle 6)

Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The NAS (1985) [\(2\)](#) pointed out that the major infusion of science in a HACCP system centers on proper identification of the hazards, critical control points, critical limits, and instituting proper verification procedures. These processes should take place during the development and implementation of the HACCP plans and maintenance of the HACCP system (FDA, 2017).

One aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. An effective HACCP system requires little end-product testing since sufficient validated safeguards are built in early in the process. Therefore, rather than relying on end-product testing, firms should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, and review of CCP monitoring and corrective action records (FDA, 2017).

Another important aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified, and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Information needed to validate the HACCP plan often include (1) expert advice and scientific studies, and (2) in-plant observations, measurements, and evaluations (FDA, 2017).

Subsequent validations are performed and documented by a HACCP team, or an independent expert as needed. For example, validations are conducted when there is an unexplained system failure; a significant product, process, or packaging change occurs; or new hazards are recognized (FDA, 2017).

Step 12: Establish record-keeping and documentation procedures (principle 7)

Generally, the records maintained for the HACCP System should include the following:

2. A summary of the hazard analysis, including the rationale for determining hazards and control measures.
3. The HACCP Plan: Listing of the HACCP team and assigned responsibilities, description of the food, its distribution, intended use, and consumer, and verified flow diagram.

HACCP Plan Summary Table that includes information for: Steps in the process that are CCPs, the hazard(s) of concern, critical limits, monitoring*, corrective actions*, verification procedures and schedule*, and record-keeping procedures*

4. Support documentation such as validation records.
5. Records that are generated during the operation of the plan (FDA, 2017).

Benefits of auditing a HACCP system would include the following: evidence of suitable thoroughness in the management of food safety, independent and objective reviews of the effectiveness of the HACCP system, confidence in the HACCP system can be maintained by verifying the effectiveness of the controls, areas for improvement can be identified,

awareness of food safety management is continually being reinforced and obsolete control mechanisms removed (Mortimore and Wallace 1995).

An audit is a verification procedure that is an essential part of any quality and safety management system. Auditing is the tool used to make sure the system complies with the requirements.

2.4.7 Auditing

An audit is defined as a systematic and independent examination to determine whether activities and results comply with the documented procedures, in addition to whether these procedures are implemented effectively and are suitable to achieve the objectives (Mortimore and Wallace 1995). The auditor is the individual who exercises judgment based on the estimation of the facts obtained in the audit. Three types of audits are identified namely first party, second party, and third-party audits. A first-party audit is where a food handling enterprise relies on its own staff to verify its own system internally. Second-party audits are carried out by employees from a government agency when food safety auditing is required by the government and provides a more focused, in-depth inspection of the operation. The third-party audit is carried out by an independent, external individual, or organization and usually investigates a specific problem area (Souness 2000). During the implementation and maintenance of a HACCP plan, all three types of audits may be used either in combination with each other or alone. The auditor should present a true and fair view of the efficiency, status, and implementation of the HACCP plan.

CHAPTER III

PRE-REQUISITE PROGRAMS

The existence and effectiveness of prerequisite programs should be assessed during the design and implementation of each HACCP plan. All prerequisite programs should be documented and regularly audited. Prerequisite programs are established and managed separately from the HACCP plan. Certain aspects, however, of a prerequisite program may be incorporated into a HACCP plan. For example, many establishments have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production. During the development of a HACCP plan, the HACCP team may decide that the routine maintenance and calibration of an oven should be included in the plan as an activity of verification. This would further ensure that all the food in the oven is cooked to the minimum internal temperature that is necessary for food safety (FDA, 2017).

3A. Premises

Premises refer to the actual property and building as well as its surroundings where production takes place. The condition of the premises such as the outside property and building, the design, construction and maintenance, lighting, ventilation, air quality, and compressed air, waste disposal, inedible areas, sanitary facilities, water quality, and supply can have a major impact on the quality of the product. Therefore, specifications for these factors must exist.

3A.1 Building Exterior

3A.1.1 *Outside property and building* (Mills and Pedersen 1992; CAC 1997; SABS 2001a; Anon. 2004; Du Toit 2004; Fisher 2004; CFR - Code of Federal Regulations Title 21, 2022).

3A.1.1.1 The mill should be located away from environmentally polluted areas and industrial activities that can contaminate the food source (i.e., odors, dust, and/or aerosols); areas subjected to flooding unless sufficient safeguards are provided; areas where wastes, either solid or liquid, cannot be effectively removed, they should be clean and free from excessive levels of bacteria, yeast, and molds as well as areas which are prone to the infestation of pests. The neighboring roadways should be free from debris, adequately drained, and maintained to minimize environmental health hazards.

3A.1.1.2 The mill should be designed, sized, constructed, and maintained to prevent the entry of contaminants and pests (i.e., no unprotected openings, air intake should be

located, the roof, walls, and foundation should be maintained to prevent leakages) as well as to allow proper cleaning. The building materials used shall be permitted as easily cleanable and disinfecting surfaces. To satisfy the performance of all operations, adequate working space shall be provided.

The building should conform in all respects to the Department of Health regulations but also FDA requirements.

3A.1.1.3 Raw material receiving, and distribution areas should be isolated from the other process steps. These areas are more or less sensitive areas in terms of raw materials, products and personnel should be separated. Within the milling environment, the less sensitive areas could be defined as the reception, processing, and distribution areas whereas the more sensitive areas could be the packing areas. The raw product storage and packing area should be separated physically.

3A.1.1.4 An external facility for the disposal of waste should be located well away from the production areas and where possible, in its enclosed building.

Suitable containers that can be cleaned thoroughly shall be used for the storage of litter and waste. If these containers cannot be stored in an enclosed waste room, they should be fitted with tight-fitting lids.

3A.1.1.5 Appropriate facilities approved by the local authority should be available for the disposal of sewage and wastewater. It should remove all wastewater and sewage from the premises, and it should be constructed to that there will be no contamination of the product, the premises, or the water supply. It should be located far away from the production areas.

3A.1.1.6 Protection from the weather for the receiving and distribution areas as well as for all materials and products in transit should be provided.

3A.1.1.7 A perimeter wall or fence should prevent unauthorized persons from accessing the mill and should keep stray animals out. If the milling facility is located in a rural area, cattle guards or other appropriate measures shall be taken to prevent cattle from entering the milling grounds.

3A.1.1.8 No animals shall be allowed on the milling grounds. Exceptions can be made for a person who is blind in the sales or servicing department accompanied by a guide dog or when it is used for security purposes. Security dogs are not allowed in production or packing areas.

3A.1.1.9 Take precautions to eliminate, as much as possible, birds from nesting or perching on the grounds of the plant, while still complying with the regulations of the conservation of the wildlife department. Frequent inspections to eliminate the invasion of these contaminants are of utmost importance.

3A.1.1.10 A clean condition shall be maintained in the yards, outside structures, and pathways. The grounds should be kept free from uncut weed and grass, litter, waste, and other foreign materials. The defecation from birds and animals should be removed to avoid foodborne soil and harmful microorganisms from being carried into the plant. All outside structures shall be kept clear of debris, bird droppings, etc. to prevent the contamination of the food product.

3A.1.1.11 All outhouses, service buildings, unused buildings, etc. shall be kept tidy and clean to avoid the harborage and breeding of micro-organisms, insects, rodents, and/or birds.

3A.1.1.12 All equipment should be installed and located in an orderly manner so that adequate maintenance and cleaning are permitted. Equipment and engineering materials should be stored in a manner that would not provide breeding sites for micro-organisms, insects, rodents, and/or birds.

3A.1.1.13 All engineering materials shall be stored in an orderly manner on elevated racks or pallets in clearly defined areas.

3A.1.1.14 Gutters, open drains, potholes, and pools shall be monitored very carefully and on regular basis to prevent water from becoming stagnant. Inadequate drainage and incorrectly sloped surfaces cause water to become stagnant and stagnant water should be eliminated. The capacity of the drainage system must be sufficient to cope with the maximum process requirements placed on it.

3A.1.1.15 Roofs, valleys and gutters shall be maintained and kept clear of debris to prevent the contamination of food or materials, by rainwater or other impurities. Also, to prevent walls and floors from becoming damp or wet due to rain. It should be inspected at appropriate intervals and the inspections recorded.

3A.1.1.16 All drains should be fitted with debris traps to ensure the retention of heavy debris. Any manhole covers should be properly greased and sealed. Drainage entry and exit points into the building should be pest proofed. To prevent blockages and

accumulation of debris, damaged drains should be replaced as soon as possible. Records of the maintenance of drains should be kept.

3A.1.1.17 Openings for piping, conduits, conveyors, vents, etc. should be well-grouted and the edges should be smooth. It is advised that openings at and/or near ground level should be covered with a screen.

3A.1.1.18 External doors shall be constructed in such a way as to prevent the entry of rainwater into the facility. Tight windows and doors, barriers such as elevated docks, metal flashings, overhangs, and rung steps discourage and prevent rodent access. Cracks and crevices should be sealed.

3A.1.1.19 Hard paving should surround the exterior of all the production and storage buildings. Parking, walkway, and traffic areas should be paved to avoid excessive dust. Areas that serve the establishment shall have hard, paved surfaces which should be suitable for wheeled traffic. Provision for adequate drainage and cleaning should be made.

3A.1.1.20 Trees should be more than 30 feet away from the production and storage buildings. Grounds should be kept free from uncut weeds, grass, litter, waste, and miscellaneous materials.

3A.1.1.21 Precautions shall be taken to prevent contamination from trucks, vehicles, forklifts, or foot traffic.

3A.1.1.22 Records should be kept of all the inspection, maintenance, and corrective action procedures done on the exterior of the plant and at defined intervals.

3A.1.1.23 Holes drains, and other places where pests are likely to occur must be kept sealed.

3A.2 Building Interior

3A.2.1 Design, Construction and Maintenance (SABS 2001a; Anon. 2004; Du Toit 2004; Fisher 2004; Meyer 2004).

3A.2.1.1 Toilets and changing rooms should be located separately from the production areas.

3A.2.1.2 All surfaces of walls, partitions, and floors should be made of impervious, durable materials with no toxic effect in the intended use. Walls and partitions should have a smooth surface; all cracks and crevices should be sealed and easily cleaned. The edges should be sloped to minimize dust accumulation. Walls should be kept free from cobwebs, dampness, condensation, and molds.

3A.2.1.3 Junctions between walls and walls as well as between floors and ceilings should be closed and ideally coved. Joints on paneled walls should be sealed. Acrylic or epoxy-based paint should be preferably used for the finish of walls. Where tiles are used, only the industrial type should be allowed and the joints between the tiles should be sealed with non-absorbent material. Horizontal ledges and windowsills should be avoided but in cases where they are present, they should be kept free from soil and other items.

3A.2.1.4 All openings for conveyors, services, vents, etc. should be smoothly finished and sealed. Walls such as those in the packing area should be protected from damage by moving equipment. Galvanized guard rails could be used for this purpose.

3A.2.1.5 Proper maintenance of walls including the replacement of damaged tiles, sealing of cracks, and joints on wall surfaces as well as getting rid of flaking paint should be done regularly. Avoid placing fixtures, signs, switch boxes, etc. on internal wall surfaces, but, if they are present, they should be properly sealed to avoid the accumulation of soil. Attachments such as shelves shouldn't be allowed as far as possible to prevent any horizontal surface to act as a dust trap.

3A.2.1.6 Walls should always be maintained in a clean condition and finished with a hygienic easy-to-clean surface. Temporary walls should not be a hazard to the process or product and should give adequate protection from contamination.

3A.2.1.7 Floors should be constructed of durable, water-resistant material such as concrete or approved synthetic material. Only industrial-type tiles that are properly sealed should be considered where floor tiles are used. A wood policy should be in place that allows proper cleaning and fumigation of wooden floors where present, to avoid the infestation of pests such as weevils.

3A.2.1.8 Floors should be resistant to attack by-product spillage, cleaning agents, and cleaning solutions. Floors should be smooth to facilitate easy cleaning and they should be safe to walk on when wet, dry, or greasy. It should also always be maintained in good condition, e.g., free from cracks, holes, and corrosion. Concrete floors should be suitably constructed in a way that prevents the build-up of soil or the release of dust alternatively they should be sealed. Floors should be kept free from litter, oil, accumulated water, etc. Disinfectants should be used to clean the floors of sensitive production areas.

3A.2.1.9 Stairways in production areas especially overproduction or packing lines should be completely sealed. Metal stairways should be constructed from non-corrosive material to be protected from corrosion. Mezzanine floors, bridges over equipment, and bridges to mezzanine floors should have sidewalls in all instances where the absence of it could lead to contamination of the area below. Floors should be free from cracks and open joints and should be constructed to allow adequate drainage and cleaning where needed. The damaged flooring should be repaired as soon as possible.

3A.2.1.10 Doors, windows, and window frames should be free from mold, flaking paint, etc., and kept clean as well as in good condition. The frames of exterior windows should fit properly, and they should be completely sealed to prevent insect ingress. Windows that may be opened in the production area should be fitted with removable and cleanable insect-proof screens. Doors leading into the production areas other than the emergency exits shall be fitted with self-closing devices, air curtains, or plastic strips. Doors, windows, and window frames should be always tight fitting.

3A.2.1.11 Glass windows in the production areas should be protected or constructed of alternative materials such as PVC to ensure that the product is not contaminated by breakages. Cracked or broken windows should be replaced immediately. Glass should be avoided as far as possible within a milling environment and should be replaced with PVC to avoid glass splinters in the final product. Therefore, the cover of the roller stands and sight glasses should be replaced.

3A.2.1.12 Internal windowsills shall be kept free from dust and debris. If newly built stills, it should have a slope of 45° degrees.

3A.2.1.13 External doors should be kept closed and constructed in a manner to prevent the entry of rainwater and pests into the facility.

3A.2.1.14 Wooden doors should be avoided, but, if used, flush doors are allowed to prevent the accumulation of soil and should be coated with a non-toxic, easily cleanable material.

3A.2.1.15 Doors should be easily cleaned and disinfected, should have smooth non-absorbent surfaces, and have automatic closing devices, overlapping plastic strip curtains, or rubber swing doors to avoid the entrance of pests.

3A.2.1.16 Ceilings should be smooth, impervious to water and dust, and easily cleanable.

3A.2.1.17 Overhead pipework and structures should be minimized to facilitate cleaning and shall be fixed above ceilings, into walls, or fixed at least 40mm away from ceilings, walls, and floors. If present, it should be free from dust, rust, mold, flaking paint, cobwebs, and other extraneous material.

3A.2.1.18 The ceiling should be sealed where there is no space above the ceiling. Where skylights are present, they shall be clean and unable to open. Openings in ceilings for conveyors, vents, piping, etc. should be properly sealed and the edges should be smooth. Canopies that cover equipment, air vents, air vent covers, and screens should be kept clean and dust-free.

3A.2.1.19 Any internal point of access to the outside such as roofs and structures should be controlled to prevent soil from entering the plant. The access door should be locked unless otherwise required by fire regulations.

3A.2.1.20 False ceilings should be smooth, adequately supported, and impervious to water and dust. It should preferably be constructed of materials not likely to disintegrate.

3A.2.1.21 Stairs and elevators should be designed constructed and maintained in a hygienic condition to prevent contamination of the product. The maximum allowable load for an elevator should be clearly posted inside the elevator. The elevator should have an intercom system that should be always maintained in proper working condition.

3A.2.1.22 Elevators should be kept clean. Elevators should be maintained in a hygienic condition free from conditions that could present a risk of contamination to the food. The well of the elevator should be kept free from any condition that could present a risk of contamination to the product.

3A.2.1.23 Electrical cables and wires should, where possible, be enclosed in conduit or orderly arranged on screens. Electrical trunking and cable trays should be kept free from dust, cobwebs, etc.

3A.2.1.24 Electrical equipment should be appropriate and if possible, all defective equipment identified, repaired, or removed unless a complete cleaning schedule exists for that specific piece of equipment.

3A.2.1.25 Washstand(s) with hot and cold water, paper towels, antibacterial soap, and plastic-lined litter disposal bins should be present at the entrances to the mill, outside or next to toilets, and lunchrooms.

3A.2.1.26 Battery charging stations must be separated from product handling areas and always kept clean.

3A.2.1.27 To avoid contamination and accidents, pedestrian gangways should be available.

3A.2.1.28 Special signs should be present in the plant to inform and remind the personnel about the smoking policy. No eating and drinking signs should also be posted in areas where such activities are prohibited. Signs to guide personnel to fire exits, stairs, elevators, etc. during emergencies should also be present.

3A.2.1.29 More sensitive areas are identified as areas where the product is exposed, and the subsequent processing does not contain a step that effectively destroys all harmful micro-organisms. The packing department within a milling environment would be regarded as such an area. It is, therefore, important that these areas should be separated by partitioning, location, or any other effective means. Only hand washbasins and no toilet facilities should be located in the packing department.

3A.2.1.30 All furnishings should be in good condition, of solid construction, and the inner and outer surfaces of furnishings always are kept clean. It should be constructed of either metal or plastic and in cases where it is wood-based; it should have a non-toxic and easy to clean finish as well as a cleaning schedule to avoid the infestation of pests. Where

necessary, the furnishings should be very well ventilated, sloped, and the tops kept clean from dust and extraneous material.

3A.2.1.31 The entrance doors to the production area should have openings less than 1cm between the walls, floor, and appropriate barriers to prevent insect ingress.

3A.2.2 Lighting (Mills and Pedersen 1992; SABS 2001a; Anon. 2004; Fisher 2004)

3A.2.2.1 Lighting (whether natural or artificial) should be appropriate so that production or inspection could be effectively conducted safely and hygienically. It is important that the food color should not be altered and that the respective commodity standards should be met.

3A.2.2.2 Adequate natural or artificial lighting of the intensity of at least 220 lux in general product handling areas, as well as artificial lighting of at least 540 lux at inspection points throughout the product handling areas, would be provided. Fluorescent strip lights should be protected by shatterproof diffusers or sleeve covers in production areas. The artificial lighting should not alter colors and white light should be used where the color of the food is a critical quality parameter, and it must be monitored.

3A.2.2.3 Light bulbs and fixtures located in areas where there is an exposure to the product or packing materials, should be of the safety type or should be protected to prevent contamination of the product in the case of breakage. Fixtures shall be constructed and situated so that they would be easily maintained and cleaned when the department is not in production.

3A.2.2.4 Skylights should not be directly above exposed raw materials or finished products and should be designed in such a way as to prevent access by pests. Lighting in pesticide storage areas should be adequate so that pesticide labels could be read easily.

3A.2.2.5 The exterior plant ground should have proper lighting so that the facility would be well lit at night. It is recommended that yellow sodium lamps should be used on the outside of the building, but they should be located away from doors to minimize pest attraction.

3A.2.3 Ventilation, Air quality, and Compressed air (Mills and Pederson 1992; SABS 2001a; Anon. 2004)

3A.2.3.1 Proper ventilation (naturally and mechanically) that provides sufficient air exchange to prevent unacceptable accumulation of dust as well as to remove contaminated air, is of utmost importance in the milling environment.

3A.2.3.2 Air-intake points shall be fitted with fly screens which should be fitted with dust filters. These air-intake points shall be located to avoid the intake of air contaminated by micro-organisms, dust aerosols, chemicals, and smoke. The air-intake levels should be at least 1 m above the internal floor levels and outside surfaces.

3A.2.3.3 The design of all ventilation and extraction systems should be of the sort that allows proper cleaning.

3A.2.3.4 Compressed air should be dry when it comes into contact with the product to prevent micro-organisms from building up in the airlines. Air should be free from micro-organisms, chemicals, dust, and soil that could contaminate food or be hazardous

to health. Compressed air supplies must be filtered and passed across water and oil traps which should be regularly drained.

3A.2.3.5 Non-return valves shall appropriately be fitted in the airlines to prevent the entry of food into the lines.

3A.2.3.6 Clean, dry, filtered air should be used for pneumatic conveying of dry bulk ingredients including wheat.

3A.2.3.7 Within a dusty environment such as a mill, it is advised that dust extractors should be installed where necessary; the units should be inspected and maintained to ensure their functionality.

3A.2.3.8 Ventilation systems should be kept clean and maintained in good condition to avoid the introduction of contaminants into the process environment.

3A.2.3.9 Compressed air should not be used for cleaning purposes since it will cause soil and dust to spread around the mill.

3A.2.3.10 In cases where relative humidity or the control of the air is important to protect the quality of the product, these parameters should be measured and recorded. Unwrapped foods should be handled and processed in areas with an ample supply of filtered air.

3A.2.3.11 External air used in the process area should be dry, filtered, and clean.

3A.2.4 Waste disposal (SABS 2001a; Anon. 2004; Fisher 2004)

3A.2.4.1 Waste storage facilities shall be designed to eliminate the entry and harborage of pests and to avoid the contamination of the product, potable water, equipment, buildings, and roadways on the premises as well as the environment in general. There should be no cross-connection between the sewage system and any other waste effluent system in the mill, nor should it pass directly over or through production areas unless it is properly controlled to prevent contamination. The system should be appropriately equipped with traps and vents.

3A.2.4.2 Waste material containers should be covered, and food waste should be emptied at least daily whereas non-food waste could be emptied once weekly to minimize pest infestation.

3A.2.4.3 Waste material containers shall be located as far as practicable from processing areas and must be sited on proper hard standing with adequate drainage and access for cleaning and pest control.

3A.2.4.4 Waste material containers shall be provided in appropriate locations in the mill. Only bonafide waste containers shall be used for waste disposal and these containers shall be of such that they cannot be mistaken for food containers, leak-proof, appropriately covered, and shall be emptied daily. Packing material even when damaged shall not be used for waste material.

3A.2.4.5 Waste should be removed, and facilities and containers cleaned and sanitized frequently to minimize contamination. Regular cleaning and disinfecting of the area and receptacles are essential.

3A.2.4.6 Product and non-product debris should be handled separately in easily identifiable enclosed containers.

3A.2.4.7 Waste disposal should be monitored, and records kept.

3A.2.4.8 No glass should be allowed into the production area. All glass breakages should be cleared up immediately and the broken pieces placed in a lidded bin for that specific purpose. A written Glass Policy should exist.

3A.2.4.9 Waste disposal bins should be available, identified; preferably not hand-operated, covered and must have a plastic bag inside.

3A.2.5 Inedible Areas (Mills and Pedersen 1992; SABS 2001a; Anon. 2004; Fisher 2004)

3A.2.5.1 It is advised that a separate facility should be provided for the cleaning and sanitizing of equipment used for inedible materials e.g., the cleaning of brushes or sampling equipment used for raw materials.

3A.2.5.2 In the case where canteen facilities are provided, these areas should be located, ventilated, and refrigerated in a manner to ensure no cross-contamination of the products produced.

3A.2.5.3 Where the company has its microbiological laboratories on-site; it is strongly advised that they should be physically separated from the production area.

3A.2.5.4 A central garbage collection point should be located outside the raw materials and production building.

3A.2.5.5 A pesticide storage area, large enough for proper and efficient storage of pesticides should be separated from the production area or a separate building on the premises secured by lock and key. The room should be well ventilated and away from raw materials, supplies, or finished products. It shall be constructed to contain pesticide leaks or spills. All application equipment should be identified and a procedure for the disposal of empty pesticide containers shall exist. This area should also be equipped with safety and first aid equipment.

3A.3 Sanitary Facilities

3A.3.1 Employee facilities (SABS 2001a; Anon. 2004; Fisher 2004; Hooper 2004; Van Schalkwyk 2004; Visser 2004)

3A.3.1.1 Change rooms, toilets, and ablution facilities should be provided at all mills. Male and female toilets should be separated. These facilities should be adequate, suitable, conveniently located, well lit, well ventilated, and appropriately heated. It should be completely separated from the food processing areas and should not open into the food processing areas. A lobby with wash hand basins should be between toilets and the food processing areas. The door between such a lobby and food processing areas should be equipped with a self-closing device and the doors of the lobby supplied with push plates on both sides. The lobby should be big enough and facilitated to enable personnel to hang up their protective clothing before entering the toilet. The number of toilets and wash hand basins should be adequate and by the requirements of the administering authority.

3A.3.1.2 Hot and cold running water, as well as hand cleaning and antibacterial hand foams or soap, should be provided at each hand washing point next to the toilets. These hand-washing facilities should be positioned in such a manner that the employee must pass them when leaving the toilet area. A suitable, hygienic means of drying the hands should also be provided close to the hand-washing facility such as disposable towels or air hand-dryers. Air hand-dryers should not be used in sensitive production areas to preclude the possible spread of aerosolized bacteria.

3A.3.1.3 Well positioned notices directing employees to wash their hands after using the toilet, by the urinal area, in break areas, a sink, and on every entrance door to the production area should be posted in these areas.

3A.3.1.4 Suitable refuse containers and ample supply should be provided in or near each change-room, hand-washing facility, and toilet area.

3A.3.1.5 Wash-hand basins should be provided in production areas where if they are absent, a food safety risk can occur. Access to such hand-washing facilities should always be unobstructed. They should be supplied with hot and/or cold water and preferably be knee, foot, or automatically operated.

3A.3.1.6 Restrooms should be provided, and provisions made for facilities where staff could lock away their food, eating, and drinking utensils, outdoor clothing, and valuable possessions. Adequate seating facilities should be provided to meet the maximum usage. Lockers should facilitate easy cleaning and should be inspected frequently to discourage the growth of micro-organisms.

- 3A.3.1.7 Handwash sinks, and drying facilities should not be used for utensils or general purposes.
- 3A.3.1.8 A medical room with the adequate equipment for the first aid treatment of illness or injury is essential.
- 3A.3.1.9 Facilities for the disposal of smoking materials should be provided at exits of smoking areas.
- 3A.3.1.10 Where drinking within the mill is allowed, the proper option would be a drinking fountain as it can be easily controlled, cleaned, and tidied.
- 3A.3.1.11 Where canteen facilities are available, the food preparation area should be of good design with adequate storage, well run, and properly maintained.
- 3A.3.1.12 Automatic vending machines are allowed as long as they are suitable located, adequately cleaned, and maintained. Proper disposal facilities for cans and papers should be provided.
- 3A.3.1.13 Changing facilities only for the change of clothing shall be provided in cases where uniforms are changed on-site.
- 3A.3.1.14 Hand-washing facilities with antibacterial soap and disposal towels for personnel should be available in or near the pesticide storage area as well.

3A.3.2 Equipment cleaning and sanitizing facilities (Du Toit 2004; Fisher 2004; Van Schalkwyk 2004)

3A.3.2.1 Facilities where equipment such as sieves are replaced should be separate from production areas.

3A.3.2.2 Separate facilities for utensil washing and general-purpose cleaning should be appropriately identified and where possible, segregated from production areas.

3A.3.2.3 Adequate, designated storage space should be provided to allow for the complete segregation of clean, dry utensils. Cleaned utensils should be stored in a clean, well-maintained storage area and the utensils stacked in a manner to prevent recontamination.

3A.3.2.4 To prevent mold growth, good draining and drying of equipment and utensils should be present, and where necessary adequate ventilation should be provided.

3A.4 Water quality and supply

3A.4.1 Water (Mills and Pedersen 1992; SABS 2001a; SABS 2001c; Anon. 2004; Marais 2004)

3A.4.1.1 Potable water, free from hazardous substances and in ample supply should be available at the point of use. Where water is used in the milling process as an ingredient as in conditioning, it shall comply with the regulations.

3A.4.1.2 If any form of water treatment occurs on-site, the system should be checked routinely and the results recorded (i.e., Cl₂, O₃, ClO₂, Sodium hypochlorite plant). The minimum chlorine levels in treated water should be between 0.1mL and

0.2mL per liter at the point of use. At least 20 minutes should be allowed for the chlorine to come into contact with the water before use. A responsible person should be assigned to check that the chlorination equipment is working effectively. They should make sure that no leakages occur and that the pump is in working condition. The chemicals used for the treatment of the water should also be always in ample supply. Regular samples should also be taken and tested to make sure that the water is safe and within the specifications of the regulations. Records should be kept by trained personnel.

3A.4.1.3 Data from periodic testing should be available to show compliance with chemical and microbiological standards.

3A.4.1.4 Water storage tanks or reservoirs should be constructed of a suitable material and covered properly to prevent contamination of the water by birds, rodents, and organic and inorganic matter and should be inspected weekly. The air vents of these tanks/reservoirs should be insect-proof as well as rodent-proof. Frequent inspections should occur regularly to ensure that no contamination took place. These water reservoirs should be on a cleaning schedule.

3A.4.1.5 Where back-siphoning of contaminated water can occur such as in places where pesticides are mixed to appropriate concentrations, vacuum breakers should be included in the system.

3A.4.1.6 Analysis of water samples should be obtained from the municipal authorities regularly to prove that the water used complies with the standards of the regulations taken place.

3A.4.1.7 Non-potable water systems could be used for fire control but shall be separate, identified, and shall not connect into the potable system.

3A.4.1.8 A potable supply of hot and cold water should be available from raw material to dispatch for cleaning purposes.

3A.4.1.9 Where a mill is using borehole water, it is advised that the water should also be tested at least every month. If it doesn't conform to the regulation standards, a filtration or chlorination system should be considered.

3A.5 Certificates/Documentation required concerning the premises

3A.5.1 Certificate of Acceptability

The food premises should have a valid certificate of acceptability. The person in charge of the food premises should apply in writing to their local authority for such a certificate and the local authority should after thorough inspection and approval, issue the certificate in the name of the person in charge. If the person in charge is replaced by someone else, a new certificate should be issued within 30 days in the name of the new responsible person. The certificate of acceptability should be displayed for the information of the public on the food premises, or a hard copy thereof shall be available on request where the display thereof is impractical. No person may make any changes to the certificate of acceptability. (Anon. R918).

3B Purchasing, Transportation, and Storage

The main raw ingredient within a milling environment is the wheat received from corporations that received it directly from the farm. On our local farms, growing specialty

crops in today's marketplace are becoming more complex. Farmers cannot simply plant a crop, nurture it to maturity, harvest it, and get it to market. They also must incorporate a culture of food safety into their operations to gain market access. Whether it is acquiring an understanding of the Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA) Produce Safety Rule or ensuring their compliance with buyers' demands for food safety audit verification, producers are increasingly being required to spend additional time and resources on food safety. This is the case for growers of all sizes, from a small family farm that sells products to a local supermarket to a producer who grows and distributes products nationally and internationally. Being able to assess and mitigate food safety issues is just as important as understanding how much fertilizer to use or when to harvest a crop. With that in mind, USDA recently advanced its USDA Good Agricultural Practices (GAP) food safety verification program in two very significant ways. The changes to the GAP program streamline food safety requirements for the specialty crop industry and provide new options for specialty crops producers to attain food safety verification to the FSMA Produce Safety Rule or a Global Food Safety Initiative (GFSI) benchmarked audit to access markets. The advancements to the USDA GAP program build on USDA's long-standing work with the Produce GAP Harmonization Initiative.

3B.1 Purchasing

3B.1.1 Suppliers (CAC 1997; SABS 2001a; Carelse 2004; Fisher 2004; Marais 2004)

3B.1.1.2 A suitable, qualified person should be used to identify, list, and establish the appropriate chemical, functional, and organoleptic specifications for all raw materials, and in-process materials. Raw materials should be purchased from approved suppliers and a list of the approved suppliers should be available and maintained.

3B.1.1.3 Written specifications for all materials purchased as well as for the finished product should be established by the manufacturer to ensure the food source is free from foreign bodies.

3B.1.1.4 A certificate of analysis (COA) for ingredients, raw materials, and packaging materials should be received with each delivery. The certificate received of the graded wheat can act as a COA for raw wheat.

3B.1.1.5 A system should be in place to evaluate the delivered ingredients such as the raw materials and packaging materials. No raw material or ingredient should be accepted if it is known to contain insects, micro-organisms, pesticides, veterinary drugs, and/or toxic substances that would not be reduced to an acceptable level by further processing downstream. The incoming materials should be inspected to prevent contaminated and/or damaged goods that could result in spillage, and are rejected from entering the facility without taking precautions against such contaminants.

3B.1.1.6 Suppliers should have effective pre-requisite programs in place and should be verified annually. Audits should be carried out on suppliers of raw materials.

3B.1.1.7 Certificates of acceptability for raw materials should be maintained.

3B.2 Transportation and Distribution

3B.2.1 Food carriers (Mills and Pedersen 1992; SABS 2001a; Anon. 2004; Fisher 2004; Hooper 2004)

3B.2.1.1 Vehicles used for transportation and/or distribution of foodstuffs should be clean, free from odors, weatherproof, free from foreign objects, and pests, and easily cleanable. Inspection for interior damage is essential and protruding objects capable of damaging the product, should be eliminated.

3B.2.1.2 Food carriers should be loaded, arranged, and/or unloaded in a manner that prevents damage, contamination, and/or deterioration of the food and packaging materials.

3B.2.1.3 Vehicles used for transportation should be inspected before loading to ensure cleanliness, weatherproof, and to certify the absence of foreign odors, pests, humidity, and material incompatible with a food product, and dirt. Doors and latches should be tight to prevent the entry of moisture, and pests, and to ensure proper fumigation when needed. Appropriate warning signs should be posted to the vehicle after fumigation that took place, and to only be removed when it is safe to do so. After proper aeration, the vehicle could be used, and the warning signs removed. Records should be kept of daily checks and maintenance.

3B.2.1.4 The internal surfaces of the vehicle body should be impervious to water, and easy to clean, and the vehicle body should be sealed to avoid the entry of pests, exhaust fumes, and/or other sources of contamination.

3B.2.1.5 The outside of an insulated container and/or vehicle body should be weatherproof, clean, and in good condition.

3B.2.1.6 Transportation of product and non-product items in the same container should not take place unless it can be demonstrated that no risk of contamination to the food is present.

3B.2.1.7 In cases where bulk units and/or tankers are used for transportation of the food and the food comes into direct contact with the inner surfaces, these tanker and/or bulk units should not be used for non-food items unless harmlessness can be demonstrated. These tankers and/or bulk units should also be cleaned at appropriate intervals and should be suitable for food use.

3B.2.1.8 Cleaning in place washing units and/or washing units containing a recirculation system for washing food tankers and/or bulk units should not be used to wash tanker and/or bulk units that contained non-food products.

3B.2.1.9 Conveyances and containers used in transporting food should be kept in a clean and repaired condition. Effective cleaning and disinfection should take place in cases where these conveyances are used for the transportation of different foods and/or non-foods. In some cases, such as for bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose. It should protect the product against weather conditions.

3B.2.1.10 Receiving and unloading of foodstuffs must be performed by adequately trained personnel.

3A.2.1.11 Where a damaged product is accepted onto a vehicle also carrying the sound finished product, the damaged product should be clearly labeled and separated from the rest. It should also be handled in such a manner as to reduce the likelihood of contamination.

3A.2.1.12 The load should be equally distributed in the vehicle.

3A.2.1.13 In the case where a contractor distribution company is used, their vehicles and administrative procedures should be checked and accepted before signing the contractual agreement.

3B.2.1.14 The loading area should be free from trash, insects, rodents, birds, and dust. Preferably sealed and/or proofed against pest infestation. Any spillage should be cleaned up to discourage pest ingress.

3B.2.1.15 The receiving company should establish proper receiving and unloading procedures to ensure the product is not contaminated at the point of receipt. Damaged and/or infested goods shall not be accepted until action has taken place.

3B.2.1.16 Conveyances, containers, and bulk transport should be suitable for food use.

3B.2.17 The dead-ends in bulk tankers where the old product can accumulate, should be cleaned regularly.

3B.2.2 Temperature control (Mills and Pedersen 1992; Du Toit 2004; Fisher 2004)

3B.2.2.1 Samples taken for microbial analysis should be transported at regulated and/or acceptable temperatures to the laboratory where it is to be tested.

3B.2.2.2 The finished product should be transported under conditions to prevent damage and deterioration to the product.

3B.2.2.3 The temperature in the pesticide storage areas should be controlled sufficiently to protect the types of pesticides stored.

3B.2.2.4 The temperature in various sections of the mill should be controlled and well ventilated to protect the quality of the product.

3B.3 Storage

3B.3.1 Incoming material receiving and storage (Mills and Pedersen 1992; Anon. 1993; Anon. 1994; SABS 2001a; Du Toit 2004; Fisher 2004).

3B.3.1.1 Adequate storage facilities (silos/elevators) should be provided for the storage of incoming wheat. Separate storage areas should be provided for processed and unprocessed foods.

3B.3.1.2 No wheat should be accepted by a mill if it does not meet specifications. Physical and biological tests will be done to grade the incoming wheat. If it is known that the wheat contains high levels of undesirable substances (impurities) such as toxins,

micro-organisms, pesticides, parasites, insects, etc. the raw material should be rejected.

Where appropriate, raw materials should be identified.

3B.3.1.3 Different grades of wheat shall be stored separately in different silos.

3B.3.1.4 Wheat storage silos/elevators should be rodent, insect, and bird-proof.

They should be kept in a hygienic condition, cleaned, and fumigated regularly. Therefore, maintenance of silos/elevators should take place regularly.

3B.3.1.5 Silos/elevators should be constructed of suitable materials such as cement and fitted with suitable close-fitting covers are kept in place at all times. The interior of these grain storage bins should be smooth and free from cracks and crevices. In cases where these storage tanks are vented, the venting should be maintained and designed to not contaminate the contents. Inlet valves and pipework should be kept in a hygienic condition and precautions taken to avoid access to the pipework by rodents, insects, and/or birds.

3B.3.1.6 Conveyances should be designed and constructed so they do not contaminate foods and can be cleaned effectively and permit effective separation of different grades of wheat.

3B.3.1.7 Incoming materials such as fortificants and packaging materials should be handled and stored in a manner to prevent damage, deterioration, and contamination.

Where appropriate, rotation is also required.

3B.3.2 Non-food chemicals receiving, storage, and usage (Mills and Pedersen 1992; SABS 2001a; Fisher 2004).

3B.3.2.1 All non-food chemicals, water treatment chemicals, chemicals for sanitation, pesticides, paints, lubricants, etc. should be approved for the food premises and together with the associated application equipment should be segregated from the food source to prevent contamination.

3B.3.2.2 All non-food chemicals received should be inspected and the procedure documented to ensure that damaged goods that could cause spillage are not brought into the mill without appropriate measures being taken to avoid contamination. Damaged goods shall not be taken to the storage facility unless it has been inspected for evidence of pest and/or insect infestation and appropriate measures have been taken accordingly.

3B.3.2.3 Emergency procedures should be in place in the case of an accident or spillage.

3B.3.2.4 Only when a substance that could contaminate the food product is necessary for hygiene and/or processing purposes can the substance be stored in food-handling areas. No hazardous substance may be used and/or stored in food-handling areas.

3B.3.2.5 First aid equipment should be kept secure in a locked cupboard and should only be issued by trained staff. All treatments should be fully recorded in a medical record book together with the patient's name, date, disease, and the medical supplies issued.

3B.3.2.6 All raw materials, as well as the packaging materials, should have a batch code (lot number) and accompanying documentation to identify them in storage and processing.

3B.3.2.7 A formalized procedure for the issue of food ingredients such as fortificants from stores shall exist. The amount issued, batch code (lot number), and date of issue should be documented. When these ingredients are moved it should be done in such a way that their identities are not lost.

3B.3.2.8 Where an operator adds an ingredient manually to a batch, the addition of each ingredient to the batch should be recorded at the time of manufacturing to ensure traceability of ingredients and to minimize the risk of accidental omission.

3B.3.2.9 Cleaning and disinfecting agents should be used by the manufacturer's instructions and their use kept to a minimum when production is in progress.

3B.3.2.10 Clothing, gloves, approved aspirators, and other safety and monitoring equipment (personal protective equipment PPE) should not be stored with pesticides.

3B.3.3 Finished product storage (Mills and Pedersen 1992; Anon. 1993; Anon. 1994; SABS 2001a; Anon. 2004; Fisher 2004; Meyer 2004; Van Schalkwyk 2004).

3B.3.3.1 The finished product should be stored in containers constructed of suitable materials, fitted with suitable close-fitted covers, and kept in place at all times.

Containers shall be designed to ensure proper cleaning and maintenance.

3B.3.3.2 Finished products shall be stored away in separate areas from other chemicals, raw materials, and/or materials used in the process.

3B.3.3.3 The finished product should be palletized and stored on pallets with cardboard and/or plastic layer (slip sheet) to avoid splintering and not be placed directly on the floor.

3B.3.3.4 Finished product should be stored, rotated where possible on a first in first out basis (to maintain shelf life for client/customer), and handled under conditions to prevent damage or deterioration.

3B.3.3.5 The finished products should be stored in a manner that allows inspection, cleaning, and pest control. (It is recommended that the finished product should be stored at least 45-50cm from walls and other materials and 2cm off the floor).

3B.3.3.6 Finished products should be stored in a manner that provides physical protection and restricted access in closed storage areas under the appropriate conditions as was agreed on within the finished product specification.

3B.3.3.7 Broken and/or contaminated pallets should not be used to transport the finished product. A physical inspection of the pallet before it is used is advised.

3B.3.3.8 Storage areas should be maintained in a dry, clean conditioned, and well-ventilated state. All materials should be stored off the floor, on clean pallets, and at least 20cm from the wall to allow proper cleaning, pest control, and ventilation.

3B.3.3.9 Packing materials should be stored in a separate area that is dust-free and pest-proof. Specifications for packing materials should exist but most importantly, they should be able to protect the food. It should also be free from contamination and should not taint the food or impart off-flavors and/or off-odors to the product.

3B.3.3.10 Loading areas should be sealed and pest-proof to prevent contamination during the loading operation. All loading areas should also be kept clean, tidy, and well maintained to prevent the ingress of pests.

3B.3.3.11 Before the release of the finished product, the finished product should be checked and approved by the quality assurance department. Examples of tests that could be done on the final product: test for moisture percentage, protein percentage, color, falling number, alveograph, mixograph, particle size, vitamins, and baking quality. Records should be kept.

3B.3.3.12 Batches of the finished product that has been approved by the quality assurance team should be stored in separate areas and under appropriate conditions.

3B.3.3.13 Batches of the finished product that does not meet the required specifications, should be quarantined, labeled clearly, and held in a separate area to prevent accidental use.

3B.3.3.14 As damaged goods are discovered, they should be stored in a designated area to not expose other products within the storage facility to contamination or probable infestation.

3B.3.3.15 If a batch of the approved finished products is stored unlabeled temporarily, it should be labeled and coded at a later stage; extreme caution should be taken to guarantee its exact identity.

3B.3.3.16 Returned, damaged or goods segregated for reprocessing should be physically segregated from other finished products to avoid contamination. An entirely different storage facility for recall work shall be preferred.

3B.3.3.17 Where damaged goods should be disposed of, all labeling should be removed to prevent the products from re-entering the distribution chain.

3B.3.3.18 A formalized procedure should exist that deals with the consequences of accidents or damage during storage and distribution.

3B.3.3.19 Management controls should ensure that all products should be easily accessible, all aisles are kept clear, and products are stored in designated areas, movement around the area should be unimpeded, products should be released or used in proper stock rotation, maximum utilization of the available space should occur, and the suspect product should be identified.

3C. Equipment

Equipment in any food manufacturing facility is essential to produce the food product therefore, it is of utmost importance that the equipment should be able to fulfill its intended role, it should be properly designed, maintained, calibrated, and should always be in proper working condition.

It should not add any contaminants to the process therefore, guidelines for the milling industry are listed below.

3C.1 General Equipment

3C.1.1 Design and installation (Mills and Pedersen 1992; Anon.1993; Anon. 1994; SABS 2001a; Middleton *et al.* 2003; Anon. 2004; Carelse 2004; Fisher 2004; Godrich 2004; Meyer 2004; Mousia and Pandiella 2004; Van Schlkwyk 2004).

3C.1.1.1 When purchasing new equipment, it should be of hygienic design. Equipment should be designed, constructed, and installed so that: all parts are accessible for cleaning, inspection, and pest control; they can deliver the requirements of the process; contamination of the product during operations is prevented; all food contact surfaces are smooth, non-corrosive, non-absorbent, non-toxic, free from cracks and crevices, and capable of withstanding repeated cleaning.

3C.1.1.2 The material used for equipment should not transmit toxic substances, odor, taste, or color changes. Stainless steel or inert materials should be used. Materials such as wood cannot be properly cleaned and disinfected therefore should be avoided except for when their use would not be a source of contamination and/or when a proper wood policy is in place. Surfaces coming into contact with food shall comply with regulations from the Health Act.

3C.1.1.3 Different metals should not be used where electrolytic deterioration can take place.

3C.1.1.4 No dead ends in pipework because it cannot be cleaned adequately.

3C.1.1.5 Storage and blending bins should be fitted with suitable, close-fitting covers kept in place at all times.

3C.1.1.6 Food conveyors to and from filling and closing machines, carrying open containers should have suitable covers to protect the open food containers and products from overhead contamination.

3C.1.1.7 For service and cleaning purposes, access under, inside, and around the equipment should be provided. Mounting of equipment could take place directly on the floor or walls as long as they are adequately sealed to prevent the infestation of micro-organisms. Equipment mounted to the floor should be at least 60 cm from the adjacent walls and other equipment and at least 30 cm from the floor to give easy access to all parts for cleaning and should be elevated or properly sealed to prevent the harborage of micro-organisms.

3C.1.1.8 Equipment should not have screws, screw nuts, rivets, etc. which can become loose and can lead to a food hazard. If screws, nuts, and bolts are used inevitably, it should be self-locking, and precautions are taken to prevent interruption of the smooth operation of the piece of equipment of the plant. It should also be covered or protected to prevent product contamination.

3C.1.1.9 Only electrical or battery-operated forklift trucks in enclosed areas should be allowed to prevent fume contamination.

3C.1.1.10 Furnishings should be of solid construction and in good repair.

3C.1.1.11 The inner and outer surfaces of furnishings should be kept in a clean condition. Ideally, furnishings should be constructed of metal or plastic but in cases where it is a wood-based product, it should be non-toxic and easy to clean. Where necessary, furnishings should be ventilated. The tops of furnishings should be kept free from dust and extraneous material and where appropriate, they should be sloped.

3C.1.1.12 Glass should be strictly prohibited in the food production and storage areas. A glass and foreign body policy should exist. If glass pipes, flow meters, or other glass equipment are used, a documented procedure for routine inspection for cracks and splinters should be in place. Broken glass windows should be reported and replaced immediately. In the case where the product was contaminated by the breakage, the contaminated product should be dealt with.

3C.1.1.13 All pumps should be constructed of suitable materials, the pumps should be capable of being stripped down for ease of cleaning and inspection, and they should be in good condition and have the power to ensure proper circulation. The frequency of stripping down should be according to a cleaning schedule.

3C.1.1.14 All connecting pipework should be made up of sections that can be easily dismantled to remove any trapped debris and for effective cleaning purposes. They should be in good condition, impervious, and have an easily cleanable surface to

minimize foreign body contamination. Regular swabs should be taken to analyze the degree of contamination.

3C.1.1.15 Stainless steel is the preferred material for the use of food equipment surfaces.

3C.1.1.16 Only fully enclosed products protected by outer packaging are allowed to be packed on wooden pallets. A wood policy should be in place.

3C.1.1.17 Agitator motors should be fitted with oil catch trays that cannot overflow into the storage or blending vessel and controls to prevent excessive leakage of lubricants should exist.

3C.1.1.18 Equipment such as sieves, carter disks, truer-cylinders de-stoners, separators, combiners, scourers, magnets, and metal detectors should be used to control foreign body contamination by cleaning the incoming wheat as well as to protect the final product. It is advised that the following equipment should be the minimum requirements within the cleaning house of a mill. Aspirator to control the separation of light impurities. Separator to separate large coarse material and small finer materials from the grain. Gravity selector to separate stones and other heavy impurities, low density and damaged kernels, and dust from whole clean grain. Scourer to remove dirt, mud balls, etc. Magnets to remove ferrous material. This equipment should be on a cleaning schedule.

3C.1.1.19 Utensils used in production areas such as brooms, brushes, dust mops, and vacuum cleaning systems should be made of materials such as metal and plastic and should be color-coded to prevent contamination.

3C.1.1.20 Because of potential microbiological and foreign body contamination the use of cleaning cloths is not recommended but in cases where it is used, they should be replaced or washed regularly. Disposable cleaning cloths are a good option.

3C.1.1.21 Wire wool is not accepted and scouring pads should only be used if simple brushing is inadequate. The pads should be color-coded and used in conjunction with the daily sanitation procedure and renewed before any signs of deterioration.

3C.1.1.22 Vacuum systems are preferred above compressed air hoses in cleaning systems and in inaccessible areas air jet is recommended.

3C.1.1.23 Proper equipment such as a flashlight, equipment opening tools, spatula, sample containers, sieves, pans, etc. should be available for inspection for pest infestation purposes.

3C.1.1.24 To prevent cross-contamination, color or shape coding of the equipment could be used in pesticide applications.

3C.1.1.25 Elevators and conveyors should be designed to permit easy cleaning through drop-bottoms, clean-out doors, etc. Dead ends can be designed out of the equipment through installation or by reducing the length of the conveyor.

3C.1.1.26 Equipment such as the tempering bins used for high moisture conditions should be supplied by suction devices. The equipment should be designed properly to eliminate dead spots.

- 3C.1.1.27 All equipment should be of hygienic design. Equipment such as bucket elevators, boots, and screw and drag conveyors should be accessible through clean-out openings or even through easy disassembly, especially for in-house cleaning purposes.
- 3C.1.1.28 Equipment such as sifters, purifiers, roller stands, etc. should be designed in such a manner as to allow both inspection and cleaning simultaneously.
- 3C.1.1.29 Magnets should be used throughout the milling system to remove ferrous metals.
- 3C.1.1.30 Entoleters (impact machines)/sterilators should also be used to break open kernels of wheat that have been infested with insects.
- 3C.1.1.31 Feed-in sifters with at least a 30-wire sieve or finer should be used in mix-back systems or where feed-in sifters are used within a milling environment.
- 3C.1.1.32 Dust collectors should be kept enclosed since it provides ideal locations for infestations.
- 3C.1.1.33 Bulk storage bins should not allow condensation and therefore when constructed of concrete, should have double-constructed or heated outside walls. Steel bulk storage bins should be enclosed in a structure where temperatures around the outside of the bin can be regulated.
- 3C.1.1.34 A wheat debranning system is useful to remove the aflatoxins and micro-organisms from the outer surface of the wheat kernel.

3C.1.1.35 Ideally, it would be recommendable that the finished product should go through a metal detector with the capability of detecting ferrous material of 2 mm in diameter and non-ferrous material of 2.5 mm in diameter. A trained person should also check the sensibility of the search head and record the results. These results should be kept for at least the shelf life of the product.

3C.1.1.36 The metal separation system should be positioned as close to the end of the process as possible. It is recommended that the metal detection system be fitted with an automatic rejection system that rejects contaminated products into a locked, inaccessible container. This system should be checked when the metal detector is checked. An alternative would be to stop the line.

3C.1.1.37 Miro feeders should be installed to control the amount of fortifiacnt mix added to the flour.

3C.1.1.38 Equipment with interior surfaces that are in direct contact with the product should be self-emptying or self-draining.

3C.1.1.39 All mills should at least have a redress system in place to eliminate any physical hazards that might be added to the final product by human error or operation deficiency.

3C.1.1.40 It is advised that in cases where mills mix-back returns, a re-bolt sifter, impactor system, and metal detector should be in place to remove any form of physical contamination that might have escaped other methods of detection.

3C.1.2 Equipment maintenance and calibration (Mills and Pedersen 1992; SABS 2001a; Anon. 2004; Du Toit 2004; Fisher 2004).

3C.1.2.1 Reparation of equipment should take place after they have been inspected regularly for cracks because micro-organisms could grow in cracks and might not be killed by normal cleaning procedures. Defective equipment should be identified and repaired. Temporary repairs and modifications that might affect the quality of the product are not recommended.

3C.1.2.2 Only approved lubricants for food production should be used and the bearings inside and outside the product zones should not be excessively lubricated and the leaking oil seals repaired frequently.

3C.1.2.3 All motors where there is a possibility that oil could leak onto the product should be fitted with oil catch trays because no oil of any kind may leak onto the product.

3C.1.2.4 The sieves, filters, and gaskets should be checked and maintained regularly. Filters of ventilation systems should be cleaned and replaced appropriately.

3C.1.2.5 A list of equipment that requires regular maintenance should be available. The maintenance procedures and frequency as well as the reasons for the activity should be recorded.

3C.1.2.6 All equipment that may have an impact on food safety and quality should have an inventory with an effective calibration and verification program.

3C.1.2.7 Equipment in the production area shall be cleaned after every maintenance procedure.

3C.1.2.8 Challenge tests should be carried out on all metal detectors and in the case where such a challenge test fails, all products produced since the last successful test shall be quarantined, isolated, and evaluated. Records should be kept of these challenge tests.

3C.1.2.9 All metal detectors should be calibrated to maintain the sensitivity to detect metal foreign objects. This should be scheduled as part of the preventive maintenance program and records should be kept.

3C.1.2.10 Documented contingency plans should exist in case metal detectors fail such as a spare replacement unit, product transferal, adequate raw material sieving, etc.

3C.1.2.11 The calibration and verification of scales should be done according to a program and the results recorded. During automatic mixer feeding, it should be verified that the pipelines and automatic scales are completely emptied for each batch.

3C.1.2.12 Adequate systems to control volume and/or weight should be in place to meet legal and specified requirements.

3C.1.2.13 Equipment should be maintained in good working order and appearance and should be free from product debris, flaking paint, or other contaminated hazards.

3C.1.2.14 Records of equipment used for the product manufacturing and maintenance of the plant should be available when required.

3C.1.2.15 Metal surfaces if not stainless steel should be kept in good condition, free from flaking paint and free from rust.

3C.1.2.16 Agitator motors, their mounting frames, and oil trays should be kept free from rust and flaking paint.

3C.1.2.17 Equipment should only be used for its intended purpose and should not serve as shelving, storage, and/or food preparation surface.

3C.1.2.18 Maintenance and inspection records should exist, and staff should observe all precautions while working on the equipment. For instance, all screws, bolts, nuts, washers, etc. should be checked and fastened; a record of all tools used in maintaining the piece of equipment should be kept and removed from the area; all spare parts or fittings should be removed from the area; equipment and surrounding areas should be left clean and tidy before production could start again; the machine operator should check that all machine parts are intact, and all necessary guards fitted.

3C.1.2.19 Magnets in the cleaning house should be cleaned and checked daily and these processes recorded so that accumulations of metal can be removed. Magnets further downstream in the production line should be on a cleaning schedule.

3C.1.2.20 Maintenance on a production line is not allowed while production is in progress however it is allowed on adjacent non-functional lines provided that the process operation is properly screened.

3C.1.2.21 All measuring equipment used in laboratories should be calibrated regularly against a given standard. Results of calibration should be formally documented.

3C.1.2.22 In cases where equipment is taken off-site for calibration, provision should be made for “reserve” equipment, which is also accurate, maintained, and calibrated to be available.

3C.1.2.23 Brooms and hand brushes should be maintained in good condition and free from deterioration and soiling and when not in use, hung in storage facilities provided. Brushes should also have colored, easily detectable synthetic bristles which cannot become loose easily through continuous use.

3C.1.2.24 When cleaning implements become badly worn and become a foreign body risk, they should be discarded.

3C.1.2.25 Pesticide application equipment should be checked for proper operation and calibration before use.

3C.1.2.26 Handling and cleaning equipment in the mill should be inspected and cleaned frequently to ensure that the grain that goes through to the milling side is properly cleaned and that further contaminants are not added. The interior of cleaning equipment should be checked, and static grain and dust removed. At the same time, the mechanical condition of the equipment should be checked.

3C.1.2.27 Equipment containing dead spots such as screw conveyors and milling equipment should be checked regularly.

3C.1.2.28 Bulk flour bin inspection lids should be sealed at all times to prevent the introduction of contaminants to bulk storage flour.

3C.1.2.29 The rotors of the impact machines should be checked at regular intervals for their efficiency as well as to make sure that it is operating at the recommended speed.

3C.1.2.30 Micro feeders should be calibrated and maintained regularly to prevent overdosing.

3C.1.2.31 To verify the cleaning equipment is in good working condition, it is advised the percentage screenings that are associated with a certain load of wheat should be controlled and always documented. Each mill should make sure they lay down the minimum percentage screenings limit and that it is revised regularly. Whenever the minimum percentage of screenings drops, it is a very good indication that some or all the cleaning equipment are not in proper working condition.

3C.1.2.32 the wheat debranning system must be cleaned and maintained on schedule. Where these systems are in use, the management of that specified mill needs to lay down minimum and maximum requirements for the offal screenings. Once the minimum limit was not achieved for a certain time, it should be evident the system is not in effective working condition.

3C.1.2.33 The redress/re-bolt system should be cleaned, checked, and the results recorded on schedule. Any sign of over tails is an indication that upstream in the production process, there could be a defect in the equipment.

3D. Personnel

Without human labor, it is difficult for any mill to operate therefore, personnel in all departments are necessary. To produce a product of good quality and safe to consume, the personnel need to know what they are doing. That is the reason why training of all food handlers especially in personal hygiene and the safety of the product is very important.

3D.1 Training

3D.1.1 General food hygiene training (SABS 2001a; Anon. 2004; Fisher 2004).

3D.1.1.1 Management is responsible to arrange training for all food handlers regarding the hygienic handling of food as well as personal hygiene (good hygiene practices). It should be clear to all food handlers what precautions to take in order not to contaminate the food source.

3D.1.1.2 Training should be done by competent personnel; it should be updated appropriately, and records of training should be kept.

3D.1.1.3 The training program includes appropriate training on the company's Hygiene Code of Conduct at the beginning of employment. It also comprises how foodstuffs are handled and packed, the probability of contamination, the nature of the

food, the food's ability to sustain the growth of pathogenic or spoilage microorganisms, awareness of food safety issues, basic personal hygiene, and hygienic and sanitary requirements of the equipment.

3D.1.1.4 It is advisable that employees should be informed in writing of the company's policy on personal hygiene when work commences as well as the disciplinary actions that could be taken against them in cases of non-conformances.

3D.1.1.5 All production and quality assurance personnel should be fully trained in good manufacturing practices.

3D.1.1.6 Training records should be kept on each member of staff.

3D.1.1.7 Routine checks and supervision should be in place to ensure the effectiveness of the training and instruction programs and to confirm that designated procedures are being followed. Verbal and/or oral tests are advisable means of testing.

3D.1.1.8 Systems that ensure employees remain aware of all necessary procedures to maintain the safety and wholesomeness of the food should be in place.

3D.1.1.9 Personnel employed as drivers should be adequately trained to meet the specific quality to the hygienic and safety requirements of the transported goods.

3D.1.1.10 Engineers should be adequately trained in hygiene procedures such as personal hygiene and product protection. When entering the production and packaging areas they should adhere to the same rules such as hand washing as the other operators.

3D.1.1.11 Off-site engineers brought into the plant should be shown the company's personal hygiene code of practice and taken through it. To overcome language problems, picture-based guides could be of good use.

3D.1.1.12 By implementing regular hand swabs or contact plates before and after washing hands, the effectiveness of handwashing could be monitored. These results could then be used in hygiene training. This is advisable for the more sensitive areas where can be direct contact with the product.

3D.1.1.13 New employees should be informed at recruitment of the company's "No smoking policy."

3D.1.1.14 Cleaning operatives should be adequately trained so they fully understand: the cleaning schedules; chemicals listed, and safety precautions required; the need for protective clothing; the appropriate dilutions of cleaning agents; the personal hygiene standards expected of them as well as the use and care of cleaning equipment.

3D.1.1.15 Personnel employed to only fulfill a cleaning role should be identified by either the use of different colored protective clothing, design, and/or color of the hat, or by overall symbols.

3D.1.1.16 Production supervisors or junior managers should be trained in at least a basic food hygiene qualification (one day) whereas senior and middle production management should have gained advanced food hygiene qualification (three days).

3D.1.1.17 Personnel in the packing areas of mills should be extra cautious to prevent accidental finished product contamination. Proper hair restraints should be in place; only

shirts without pockets should be allowed or in cases where shorts do have pockets, nothing in the shirt pocket should be allowed and no jewelry should be allowed.

3D.1.1.18 Employees should have the necessary knowledge and skills enabling them to implement the standards contained in this document.

3D.1.2 Technical training (Anon. 1993; Anon. 1994; Du Toit 2004; Fisher 2004).

3D.1.2.1 Training should be provided to address the complexity of the manufacturing process and the tasks assigned to employees. (Employees should know what their responsibilities are and how to monitor their performances. They should also know what actions to take in certain cases). It is of utmost importance that work instructions and procedures exist and that the personnel are trained to deal with chokes due to poor operations efficiency in the milling machinery. It is also advisable the product was exposed to the floor or the open environment, when the choke was being cleared, should not be mixed back directly into the system. If it is mixed back, the mix-back procedure should be controlled.

3D.1.2.2 Training for maintenance personnel in the calibration and fixation of equipment that could affect product safety is essential.

3D.1.2.3 Personnel and supervisors responsible for sanitation should be trained to understand the principles and methods required for effective cleaning and sanitation.

3D.1.2.4 Personnel responsible for pest control should be qualified otherwise the services should be outsourced to a pest control company. Qualifications should be kept on record.

3D.1.2.5 Provision should be made for a fully trained nurse on-site or suitable staff should be trained in first aid.

3D.1.2.6 The person in charge of receiving the grain (wheat grader), should be well trained to do so, knowledgeable, and dependable to do his specified task. A suitable wheat grading certificate that shows the wheat grader is qualified should be kept on record. The wheat grader should have the authority to reject wheat if it does not conform to the minimum requirements or re-classify it into another class if necessary.

3D.2 Hygiene and Health Requirements

3D.2.1 Cleanliness and conduct (Mills and Pedersen 1992; SABS 2001a; Anon. 2004; Du Toit 2004; Fisher 2004; Marais 2004; Meyer 2004; Visser 2004; Wessels 2004).

3D.2.1.1 All employees should be medically fit. If the administering authority requires it, any food handler should be medically examined, and the records of such examinations kept in confidential files.

3D.2.1.2 All staff should behave in a manner so as not to contaminate the food and wear clean, protective clothing when entering or working in the production area. They should adhere to the company's hygiene policy.

3D.2.1.3 Visitors and contractors should also be required to wear suitable protective clothing (e.g., laboratory coat) when entering the mill to prevent them from being a source of contamination to the food. No jewelry should be allowed, a hairnet and/or hat, and earplugs provided. No loose hanging clothes should be allowed to avoid them from getting stuck into machinery.

3D.2.1.4 Attention should be paid to ensuring that maintenance and subcontractors do not carry soil on their clothes into production areas or areas sensitive to contamination.

3D.2.1.5 Personal garments should not be worn in overprotective clothing and no part of any personal garment should protrude from protective clothing above the knee.

3D.2.1.6 Clean prescribed clothing and covering that covers hair (long hair should be tied), including beards (beard nets), should be worn by personnel in the mill including engineers, management, and other casual visitors. Clothing should have no external pockets above the waistline and if internal pockets are provided, it should be at hip level. It should be free from loose fastenings such as buttons but when available; it should be securely fastened.

3D.2.1.7 Headwear should retain all hair; it should be of generous size and comfortable to wear. A hat worn together with a hairnet is a good option.

3D.2.1.8 Earplugs or earmuffs for ear protection against noises of machinery should be worn at all times in the mill.

3D.2.1.9 A protective clothing and footwear policy should be in place according to the standards set.

3D.2.1.10 Footwear should be clean, and workers should have separate footwear for use in the factory to preclude the introduction of pathogenic micro-organisms. Safety boots or trainers should be provided to employees.

3D.2.1.11 Protective clothing such as laboratory coats and uniforms should be kept in a clean condition and should be cleanable and not used outside the factory or worn to and from work unless authorized to do so. Uniforms should be replaced when necessary and laundering should be done by a competent service provider with acceptable standards. Management should be responsible for an adequate supply of laundered protective clothing.

3D.2.1.12 Protective workwear should be color-coded to identify service operators with different roles.

3D.2.1.13 The frequency of changing uniforms should take place on a more regular basis in the more sensitive areas. In less sensitive areas uniforms can be changed with a lesser frequency.

3D.2.1.14 The hygienic transfer of laboratory coats and uniforms from the laundry to the food premises is essential. The vehicle should be properly cleaned, and the uniforms protected from contamination especially after it has been laundered.

3D.2.1.15 Gloves should only be used where the workers' hands need to be protected against physical, chemical, or temperature harm. Disposable gloves should be used where

possible and non-disposable gloves should be thoroughly cleaned and disinfected. If they become damaged or torn, they should be removed and discarded.

3D.2.1.16 Clothing and personal items should not be stored in food-handling areas.

3D.2.1.17 No jewelry should be worn although plain wedding bands and wristwatches could be allowed in some cases. Fingernails should be kept short, clean, and free from varnish and lacquer (no false and/or acrylic fingernails). Adequate supervision to ensure compliance is needed.

3D.2.1.18 No eating, drinking, smoking, or any unhygienic practice such as spitting, sneezing, or coughing over unprotected foods should be allowed in food-handling areas. Eating, drinking, and smoking should only be allowed in designated areas.

3D.2.1.19 Hands should be washed before work is started, immediately after the toilet has been used, after handling debris, and food waste; after they became soiled or visibly contaminated when blowing the nose or touching the mouth, after handling money, a handkerchief, or reuse container and after smoking. Also, after handling any material capable of transmitting disease and when on duty in a food-handling area hands should be kept clean by frequent washing with disinfectant and running water. Hands should be thoroughly dried. Adequate supervision to ensure compliance with this provision is needed.

3D.2.1.20 Facilities such as change rooms, toilets, etc. should be kept clean and odor-free and in good condition to preclude the establishment of sites for the harborage of micro-organisms, insects, rodents, and/or birds.

3D.2.1.21 Only metallic pens should be used in the raw material, production, and packaging areas to allow for detection by metal detectors if lost. The use of other stationery such as pencils, pens, etc. should be minimized in the production area.

3D.2.1.22 Management should set the example by abiding by the personal hygiene requirements.

3D.2.1.23 Restrooms should be properly maintained and kept clean at all times.

3D.2.1.24 The interiors of bins should be inspected, cleaned, and repaired when empty. Static deposits of grain could be a source of contamination.

3D.2.1.25 More frequent inspection and cleaning should take place in situations where high moisture conditions exist.

3D.2.1.26 The chemical, functional, organoleptic, and microbiological tests and procedures and frequencies used for cleaning and sanitation should be identified and listed.

3D.2.1.27 Contact lenses are not permitted in the raw material and production areas.

3D.2.1.28 Employees engaged in raw material and production areas should refrain from smoking, spitting, chewing, and/or eating as well as from sneezing and/or coughing over unprotected food products.

3D.2.2 Communicable diseases (CAC 1997; SABS 2001a; Fisher 2004).

3D.2.2.1 Any food handler who is infected with a disease that can be transmitted through food, a carrier of such a disease, and/or who have infected wounds, boils, skin

infections, sores, gastro-intestinal disorders, vomiting, diarrhea, or any other abnormal sources of microbial contamination should immediately report his illness to management. Management should ensure that any known or the suspected person suffering from the above illnesses would not be allowed to work in any food-handling area where the likelihood can occur where the food product can be directly or indirectly contaminated or where the disease can be transmitted to other workers.

3D.2.2.2 Staff should make sure that the requirements are met.

3D.2.2.3 Before any person who suffered from an infectious disease returns to work, he should be declared medically fit by his doctor, especially when the person still can contaminate the food source. Records should be kept for each case.

3D.2.2.4 No open cuts wounds should be allowed and a person suffering from them should only be allowed to handle the foodstuff or food contact surfaces when the injury had been dressed and treated to avoid contamination.

3D.2.2.5 After treatment of a cut, sore, or graze, the area should be covered by a trained first aider or nurse with a colored waterproof dressing containing a metal strip and of a different color than the food produced. A check-out and check-back register should exist for the records.

3D.2.2.6 All employees should report any food poisoning symptoms they had during their holiday before returning to work. They should also be screened by a doctor before work.

3D.2.2.7 Employees with chronic pathogenic infections should be allowed in high-risk areas but should be transferred to other parts of the facility.

3E. Sanitation and Pest Control

Sanitation includes plant cleanliness, personnel cleanliness, respect for the food produced, and good overall appearances. This should be maintained within the food industry and a mandatory routine practiced throughout any food manufacturing facility. Good manufacturing practices should also include control over all pests which can be carriers of disease, and this should be regulated with a successful pest control program.

3E.1 Sanitation

3E.1.1 Sanitation program

3E.1.1.1 Buildings, equipment, utensils, and all other physical facilities of the mill shall be maintained in an orderly condition and should be cleaned at regular intervals to prevent them from becoming a source of contamination.

3E.1.1.2 The plant grounds should be inspected frequently as part of the overall inspection program but during particular seasons or in areas where particular products are discovered, it should be done more regularly. Attention should be given to places where housekeeping is difficult or impossible.

3E.1.1.3 The building exterior, roof, drainage troughs, exhaust vents, and air intakes should also be inspected to achieve the overall objective to produce a quality product by excluding sources of contamination.

3E.1.1.4 Materials and equipment used for cleaning should be suitable for use in a food plant, supplied by a reputable company, and should not be a source of contamination itself.

3E.1.1.5 An established, documented cleaning procedure for the cleaning of all food contact surfaces such as equipment, walls, floors, windows, etc. should exist. Cleaning should include dry cleaning, wet cleaning, disinfection, and sterilization. Cleaning inaccessible areas in mills should be done by dry cleanings such as vacuum systems or compressed air and in inaccessible areas by air jet.

3E.1.1.6 A cleaning program for each room, group of rooms, production area, walls, floors, windows, surfaces, utensils, equipment, fixtures, fittings, and drains should exist. This program should state the frequency, method, contact time, temperature, and strength of cleaning solutions to be used for each item of equipment. Evidence that the cleaning was adhered to such as records should exist. Where necessary, these areas should be disinfected.

3E.1.1.7 An area separate from the food area should be allocated, clearly labeled, and marked for the storage of detergents and disinfectants.

3E.1.1.8 Personnel handling detergents and disinfectants which in most cases are hazardous should be informed of the appropriate treatment in case of an accident. Safety goggles, face shields, and gloves should be available and should be used as safety measures when handling detergents and disinfectants.

3E.1.1.9 Avoid household chemicals as well as those from non-reputable suppliers. It is recommended that only chemicals that were approved for food industries are used.

3E.1.1.10 In cases where hazardous materials are mixed or dispensed, an eye-washing and shower facility should be close to the mixing or dispensing point.

3E.1.1.11 Brooms and brushes in the production area should not be made of wood. It should have colored nylon bristles that are easily detectable in the food source, be clean, in good condition, and when not in use should be hung upside down to aid the drying process. Brushes used for the cleaning of floors should not be used on equipment surfaces.

3E.1.1.12 Cleaning clothes and scouring pads should not be a source of contamination and it is advised that disposable or single-use cloths be used. Cleaning cloths of a woven fabric should be used only when they were disinfected or sterilized by a documented schedule. Disposable clothes should be the alternative option: they should be of a contrasting color to the food produced.

3E.1.1.13 Equipment such as sampling utensils should be cleaned before use. Equipment that has been wet cleaned and especially where there is a possibility that the product can be contaminated should not be used unless it's dry.

3E.1.1.14 Vacuum cleaners should be emptied outside the processing areas.

3E.1.1.15 Cleaning of floors and equipment with water under force should not take place during production as soil might contaminate the food. Only approved and adequate cleaning agents and disinfectants should be used. Any food contact surface that has been

cleaned by such products should be rinsed thoroughly with potable water to remove any residues before it is used again.

3E.1.1.16 After a day's work or during a change of shift, floors, drains, and walls of food handling areas should be cleaned.

3E.1.1.17 Change rooms and toilets should be kept clean at all times. All internal and external areas should be kept clean.

3E.1.1.18 Roadways and yards in the immediate vicinity should be kept clean.

3E.1.1.19 Color-coded equipment should be used for cleaning, so the same brushes won't be used in both the restrooms and processing areas. Each department should have an inventory of all color-coded equipment or otherwise uniquely used equipment that is checked daily. Damaged or broken items should be replaced immediately.

3E.1.1.20 Contamination of food, potable water, and the environment should be avoided by proper storage and disposal of waste material. Waste should be removed from the food handling areas at least once daily. In the case of hazardous waste, it should be disposed of by the Hazardous Substances Act, 1973. Immediately after the disposal of the waste, receptacles used for the storage of waste and any equipment that came into contact with the waste should be cleaned and disinfected.

3E.1.1.21 Avoid construction materials that cannot be properly cleaned and disinfected unless their use would not be a source of contamination.

3E.1.1.22 All cleaning operatives should be trained and retained to continually meet the required upgraded standards.

3E.1.1.23 The sanitation program should be carried out in a manner that does not contaminate food or packaging material during cleaning and sanitizing.

3E.1.1.24 Where required, operations begin only after sanitation requirements are met.

3E.1.1.25 Clear, legible, and easy-to-follow cleaning procedures and schedules should be available for every department within the factory.

3E.1.1.26 The cleaning schedules should dictate the frequency, method of cleaning, and disinfecting agents that are to be used for all plant equipment and surroundings.

3E.1.1.27 In cases where companies employ different ethnic groups, the cleaning procedures should also be explained in a language that is understandable to the workers.

3E.1.1.28 A clean as you go philosophy should be adopted throughout production to minimize the amount of food debris and soil left for cleaning at the end of a shift.

3E.1.1.29 Cleaning practices should be supervised, and checklists should be available for each department to ensure that every piece of equipment has been properly cleaned. The supervisor in charge should sign the checklist after inspection and only when it has been cleaned to an acceptable standard.

3E.1.1.30 The cleaning supervisor should also have an inventory of all cleaning equipment within the department which should be checked daily, and any damaged or broken utensils should be replaced immediately.

3E.1.1.31 It's also the job of the cleaning supervisor to check the dilutions of cleaning agents and to take corrective action if it is either too weak or too strong.

3E.1.1.32 Physical inspection of the equipment should reveal clean, smooth, surfaces.

3E.1.1.33 It is of utmost importance that good housekeeping procedures as well as "clean as you go" procedures are in place at all times. The entire site, buildings, perimeter, staff facilities, etc. should be cleaned and tidied throughout the day.

3E.1.1.34 Throughout the mill, it is important to be alert of any source of overhead contamination but more so in the packaging area where the system is not enclosed.

3E.1.1.35 Bulk flour conveyors should be cleaned, and all dead stock removed at least monthly. Filters on pneumatic conveyors should also be cleaned monthly.

3E.1.1.36 Bulk storage bins should be cleaned on an observed need basis.

3E.1.1.37 Any material that may lodge in the rotor of impact machines such as string, paper, etc. should be removed regularly.

3E.1.1.38 Packing bins should be cleaned regularly and where needed; they should be fumigated monthly.

3E.1.1.39 Daily cleaning of the adhesive applicators on small package lines is required. The entire unit should be cleaned every week.

3E.1.1.40 Accidental spills in or on the sealing unit should be on a shift basis or immediately after the glue was spilled to prevent hard-to-clean situations.

3E.1.1.41 Areas where portable bulk storage units are filled should be in an enclosed area such as the warehouse areas but, should be separated from other activities. These areas should be cleaned regularly. Daily cleaning of the floors and monthly cleaning of overhead structures are suggested.

3E.1.1.42 Housekeeping in bulk loading areas for trucks and railcars is just as important as within the mill. The overhead areas should be cleaned at least once monthly, and the drive areas should be swept or wet cleaned on a more regular basis.

3E.1.1.43 In cases where the services of external cleaning contractors are rendered, they must be given clear, concise, written instructions on what should be done. Their performance should also be assessed regularly.

3E.1.1.44 To facilitate the cleansing and sanitation operations, adequate preventive and corrective maintenance should be carried out on buildings, equipment, and installations.

3E.1.2 Cleaning chemicals, disinfectants, and detergent-disinfectants (SABS 2000; SABS 2001b; Fisher 2004).

3E.1.2.1 Raw materials used in the manufacturing of cleaning chemicals, disinfectants, or detergent-disinfectants shall not contain potentially harmful or toxic products nor shall they form toxic or potentially harmful byproducts. Chemicals, disinfectants, or detergent- disinfectants that are known to leave residues that could be harmful to humans, shall not be used.

3E.1.2.2 Cleaning chemicals, disinfectants, and detergent-disinfectants shall not contain perfumes and should not leave intolerable odors. The color, flavor, or odor of the product shall not be affected by it.

3E.1.2.3 Cleaning chemicals and detergent-disinfectants shall effectively remove soils for which they are claimed to be effective when it is used by the manufacturer's recommendations. The pH of products intended for personal use (on unbroken skin), shall be in the range of 4 to 9.

3E.1.2.4 Disinfectants and detergent-disinfectants shall kill the organisms for which they are claimed to be effective when it is used by the manufacturer's recommendations.

3E.1.2.5 The cleaning chemicals used shall comply with the requirements for storage as is set out in the latest version of regulations.

3E.1.2.6 The disinfectants and detergent-disinfectants used shall comply with the requirements for storage as is set out in the latest version of regulations.

3E.1.2.7 Cleaning agents that are purchased in solid or powder form shall be readily soluble in water at the temperature and quality as was recommended by the manufacturer.

3E.1.2.8 The manufacturers of cleaning chemicals, disinfectants, and detergent-disinfectants should be able to provide certification by a recognized body, material safety data sheets by the regulations relating to certificates of analysis, and any other significant information.

3E.2 Pest Control

3E.2.1 Pest Control Program (Anon. 1993; Mills and Pedersen 1992; Anon. 1994; SABS 2001a; Anon. 2004; Fisher 2004).

3E.2.1.1 To deter and destroy the infestation of pests on the premises, there should either be trained personnel on-site, or the services of an approved pest control organization should be rendered. Where an outside contractor is used, a staff member should always accompany him/her.

3E.2.1.2 Pest control companies should at least visit the site six times per year at regular intervals but where evident problems occur, daily visits should be specified until the problem is cleared.

3E.2.1.3 After fumigation and capture, the disposal of the pests is required to be hygienic and safe. Documented procedures are therefore needed.

3E.2.1.4 Pest control inspections should be recorded in the on-site Report Book with the correct date of inspection.

3E.2.1.5 A responsible member of the management team must be made responsible to ensure that all the recommendations made in the report are acted upon within an agreed time scale.

3E.2.1.6 Rodents, birds, animals, and insects should be excluded as far as practicable from the milling grounds. Pest control should be scheduled regularly with records of the activities maintained.

3E.2.1.7 Access to pests should be prevented by keeping buildings in good repair and good condition. The factory grounds should be maintained to avoid the establishment of breeding sites for micro-organisms, insects, rodents, and/or birds. Animals should be excluded from factory grounds. The surrounding areas and establishments should be regularly examined for evidence of infestation.

3E.2.1.8 An effective and continuous program for pest control of the premises and equipment shall exist. This includes a pest control protocol, the name of the person at the manufacturer-assigned the responsibility for pest control, the name of the pest control company, a list of chemicals used, the concentration of the chemicals used, the location of application, the method and frequency of application used by the label instructions, a map of pest control devices and self-inspection program. Material safety data sheets of the chemicals used should also be kept.

3E.2.1.9 Fixed equipment on floors should be 0.3m from the ground and 0.5m from the walls or it should be adequately sealed to prevent the build-up of soil behind or under the equipment.

3E.2.1.10 Air-take points and windows that open should at least be fitted with a fly screen or removable wire mesh screens.

3E.2.1.11 External doors should be fitted with self-closing devices or protected by an internal lobby with a self-closing door. It should also be rodent-proof.

3E.2.1.12 Trained personnel should carry out a monthly inspection for evidence of the infestation by insects and rodents as well as for the presence of birds, and wild and domestic animals.

3E.2.1.13 Raw material deliveries should be inspected for the presence of infestation by defined written procedures.

3E.2.1.14 If evidence of the infestation of pests is found in or around the mill, action to remove and/or control the infestation should be taken. Treatment with chemical, physical, or biological agents should be taken by or under the strict supervision of trained personnel. Control measures should be carried out by the recommendations of the administering authority. Pesticides and pest-control agents should be registered for use in the United States, environmentally acceptable, and should be applied to the provisions of regulations.

3E.2.1.15 Insecticides or rodenticides with a similar appearance to the food being manufactured or that are in similar containers to those used for packaging should not be

used. Before the application of pesticides food, equipment, and utensils should be safeguarded against contamination. After pesticide application, contaminated equipment and utensils should be thoroughly cleaned to remove any residue before being re-used. Only when preventative measures cannot be used effectively, should approved pesticides be used.

3E.2.1.16 Birds should be excluded from all production and storage areas and adequate steps taken to ensure this exclusion is enforced, subject to legal requirements for the conservation of wildlife. A recommendation is the installation of mirrors on the outside of the building to scare away birds with their reflections.

3E.2.1.17 A site drawing and register of bait stations should be kept up to date. Open bait should not be used in processing areas, ingredient storage areas, or packaging stores unless the bait station is suitably demarcated and there is no possibility of affecting the product. Each bait station should be adequately labeled and the bait boxes date marked at each site inspection.

3E.2.1.18 Pest-proof containers should be used for the storage of potential food sources, or they should be stacked above the ground and away from walls. Inside and outside areas of the food premises should be kept clean.

3E.2.1.19 External bait stations should be tampered resistant and situated around the external area of the factory site as well as marked. Internal bait stations should be located on an accurate site map and held in the Report Book.

3E.2.1.20 Where products are being stored, insects are considered a risk and the appropriate treatment should be included in the control program and fumigation applied as required.

3E.2.1.21 Domestic animals should be excluded from the premises and should not be used for pest control purposes.

3E.2.1.22 An ideal clear perimeter zone free from rubbish, packaging materials, raw materials, pallets, etc. should exist and ideally it should be fenced for security purposes.

3E.2.1.23 Good housekeeping standards should be maintained to control pest infestation. I.e., controlling the accumulation of food and packaging debris; keeping passages clean and clear; removing redundant equipment; ensuring good stock rotation; keeping the exterior of the facility in good condition, and proper waste disposal procedures.

3E.2.1.24 If pest infestation is found on incoming materials, it should be isolated from the factory, the pest control contractor called immediately, and the infestation treated before it spreads.

3E.2.1.25 Pest control documentation should be kept up to date, clear, concise, legible, and regularly reviewed by the technical department.

3E.2.1.26 Datasheets relating to the safety and application of approval baits and pesticides should be available. Information regarding the control of hazardous substances to health should also be readily accessible.

3E.2.1.27 All documentation detailing the safe use and application of pesticides requires the signature or identification of the checker to ensure accountability.

3E.2.1.28 If a logical Code of Practice for pest control is adhered to, then freedom from pests should be evident on site. This should be further clarified in the pest prevention record book.

3E.2.1.29 If evidence of pest infestation is available then the action taken to free the site from the problem should be thoroughly documented and dated until the infestation is removed.

3E.2.1.30 Physical methods for pest control could include the use of pheromones and food attractants in bait traps; forced aeration; heat; moisture manipulation; impact machines and abrasion equipment (scourers); rodent traps; magnets; metal detectors; equipment design and construction; keeping the building rodent-proof and the doors closed.

3E.2.1.31 Chemical methods include the use of pesticides, insecticides, fumigants; rodenticides; avicides, etc.

3E.2.1.32 Rubber gloves, protective outer garments, and respirators should be used when handling or applying chemical forms of pest control.

3E.2.1.33 Phosphine-producing fumigants in tablet or pellet form are usually used for fumigation of wheat during storage. Adequate concentrations of the fumigant, sufficient contact time, and a tight enclosure are needed for successful fumigation.

3E.2.1.34 In cases where electrocution devices are used, they should be located in areas where they cannot be a source of contamination to the product, it should have effective catch pans to retain the insects collected, located away from entrances. The insect traps should be cleaned every week, the bulbs replaced at least annually, and the results recorded.

3E.2.1.35 Insecticides and poisons used in the mill should be approved by regulatory authorities for usage by the food industry, it should be properly identified, controlled, and used according to instructions.

3E.2.2 Pesticides and pesticide storage (Anon. 1972; Mills and Pedersen 1992; SABS 2001a; Anon. 2004; Fisher 2004).

3E.2.2.1 Hazardous substances, chemicals, cleaning chemicals, or pesticides should be suitably labeled with directions for use and a warning about their toxicity. It shall be stored in a dry, adequately ventilated area where no possibility for cross-contamination can occur of the food or food contact surfaces. This area shall be equipped with power ventilated exhaust to the outside and never cross ventilate with food processing or food container storage areas. It should be stored in a locked room or cabinet for that purpose only and should only be dispensed and handled by authorized and properly trained personnel or under the strict supervision of trained personnel. Whenever chemicals should be mixed, it should be done in clean, correctly labeled containers. No old food containers should be used for this purpose.

3E.2.2.2 Pesticide storage areas should be completely enclosed by walls and the door locked to prevent unauthorized entry. If a wire fence forms any of the walls, it should extend to the ceiling.

3E.2.2.3 Special warning signs should be placed on the entrance to warn the user of the contents of the storage area.

3E.2.2.4 Pesticides should be stored off the floor on pallets, racks, or shelves with catch or drip pans underneath.

3E.2.2.5 Pesticide containers should be stored with the label visible. In the case where a label is damaged, it should be replaced with a sample label from the supplier.

3E.2.2.6 A continuous inventory of pesticides should be kept, and regular inspections should check the accuracy of the inventory as well as the condition of the storage containers and overall facility.

3E.2.2.7 A “first in first out” schedule of use should be followed for all cleaning agents, pesticides, packaging material, etc.

3E.2.2.8 Pesticides that are canceled, not in use, or suspended should be labeled and disposed of according to specified guidelines.

3E.2.2.9 Highly toxic pesticides such as certain fumigants or rodenticides should be kept under separate security and should be approved for targeted pests.

3E.2.2.10 Pesticide application equipment may be stored and secured in the pesticide storage area.

3E.2.2.11 For the maximum limits for pesticides residues that may be present on wheat, refer to the updated Foodstuffs, Cosmetics, and Disinfectants Act.

3F. Recall

Recall refers to the actions taken to remove or correct a product by the supplier of the product to protect the end user from an identified hazard that could be harmful to the consumer. A good recall system should be in place to ensure proper traceability of the product.

3F.1 Recall System

3F.1.1 Recall Program (Anon. 2004; Fisher 2004).

3F.1.1.1 An effective Health and Safety recall program should exist which will include tracking, analysis, actions taken as well as the records of product complaints; the responsible person(s), the roles and responsibilities of coordination and implementation of a recall; methods to identify, locate and control the recalled product; a requirement to investigate other products produced that might be affected and that should be included in the recall; a procedure for monitoring the effectiveness of the recall; procedures to verify the capability of the program to rapidly identify and control a code lot of potentially affected product and reconcile the amount of product produced, in inventory and distribution. A mock recall should take place at least annually.

3F.1.1.2 The local Health Department should be notified immediately in the case of a recall and information such as the amount of product produced, in inventory, and

distributed; the name, size, code, or lot number of foods recalled; the area of the distribution of the product and the reason for the recall should be available.

3F.1.1.3 The operator and supervisor should be traceable and such records should be available.

3F.1.1.4 Sufficient documentation should exist so that in case of a recall, the finished product can be linked to the raw materials used as well as to the corresponding laboratory records.

3F.1.1.5 If a person other than the quality assurance manager has been allocated the responsibility to deal with all product complaints, that person should have sufficient product knowledge, experience, and authority to implement the appropriate corrective action.

3F.1.1.6 All quality complaints should be recorded when received and investigated within a certain time according to their urgency, and a corrective action report prepared for company records.

3F.1.1.7 Corrective action includes responding to the complainant and the local enforcement authority involved. Copies of these letters should be kept on file and procedures should be implemented to remove the cause of grievance and avoid its reappearance.

3F.1.1.8 Complaints reports should be used to observe trends and should be reviewed frequently. This could be an indication of a potential product recall or specific problem.

3F.1.1.9 A designated authorized person should organize the activities of the recall team under complete confidentiality. That person should be the link with the competent authority. If the media becomes involved, the company must have a designated spokesperson.

3F.1.1.10 The recall procedure should be workable and effective within a reasonable time frame but, must be reviewed regularly in the event of changing circumstances.

3F.1.1.11 The recall procedure should include the exact method of notifying all distribution networks and retailers involved as well as the contact names' details. The procedure should be able to stop the transit of products at any stage in the distribution chain.

3F.1.1.12 Full product details, the batch code, the nature of the defect, the action required, and the degree of risk concerned should be given in the announcement of a recall.

3F.1.1.13 Records of equipment that could affect the quality of a product should be available when required.

3F.1.1.14 Reference samples of flour should be kept for at least a year after the shelf-life, the re-evaluation date, or for one year after the distribution is completed, whichever one is longer.

3F.1.1.15 The sample size should be double the amount required for the specified testing and should be identified with product name, lot number, and sampling date.

3F.1.2 Product code identification and distribution details (Anon. 2004; Fisher 2004).

3F.1.2.1 Each pre-packaged food should have lasting, understandable code marks, or lot numbers on the packages. The code has to identify the organization, the day, month, and year of production. Code marks and the exact meaning of the code should be available. Where applicable, case codes should be legible and represent the container within. Classification of a product must declare the name, shelf life, lot number, warning (where applicable), storage instructions, and distributor.

3F.1.2.2 For each lot of product produced, the producer should have records of customer names, addresses and telephone numbers as well as records of production, inventory, and distribution. The records should be accessible, organized, and filed for at least 2 years after the shelf life of the product or by legislation.

3F.1.2.3 Finished products should be sealed. Labeled with information on its shelf life and protected against moisture. Only knotting or thermal sealing are allowed unless the customer requires otherwise. Packaging should protect the product during its expected life under normal conditions.

3F.1.2.4 Implement efficient measures to safeguard against the suspect; returned or damaged finished product being accidentally released.

3G. Quality Assurance

Quality is an important factor when purchasing a product therefore, quality must be defined within a company by developing predefined standards. “Quality assurance means to give to the customer the warranty the company works for based on these requirements” (Scipioni *et al.* 2002). Customers will buy a specific product because of the quality but, if they are not satisfied with the product, they could have drastic actions taken against the manufacturer. The power of the media and product liability lawsuits could lead to major economic losses. To avoid situations that could affect the whole company, the quality of the product should be assured at all times.

3G.1 Quality Control

3G.1.1 Quality Function (Anon. 2004; Fisher 2004).

3G.1.1.1 The company should have a quality assurance and monitoring structure to guarantee consistent production of a safe, legal product that complies with the agreed specifications.

3G.1.1.2 The quality assurance team should consist of sufficient properly trained personnel with clearly defined responsibilities that can maintain the agreed quality standards.

3G.1.1.3 Whenever production is in progress, the quality assurance team should be productive.

3G.1.1.4 The quality function should be included in all activities and decisions regarding product quality and should not be limited to laboratory operations only.

3G.1.1.5 The quality function should be independent of production and purchasing functions and should have the responsibility and authority to approve or reject all components in the process, packaging materials, and finished product.

3G.1.1.6 Resources such as offices, laboratories, and other designated areas within the factory should be available for the quality assurance team to fulfill its tasks effectively.

3G.1.1.7 The responsibility and authority for the management and final approval of process changes, specifications, and assays for raw materials, intermediate product and packaging materials, specifications and assays for process control purposes, sampling procedures, instructions regarding hygienic and sanitation practices, processes for reprocessing of rejected materials and the investigation of failures and complaints lies within the quality function.

3G.1.1.8 Accept/reject criteria, method of testing, sampling techniques, safety precautions and characteristics to be inspected should be included in the inspection instructions. The quality assurance department should be authorized to accept or reject raw materials, packaging materials, work in progress, and finished products against an agreed specification.

3G.1.1.9 The product may not be released for sale until all the final inspection and testing is completed, confirming the product is sound for consumption.

- 3G.1.1.10 A strict policy about quarantined stock should exist to state whether the product should be reworked or disposed of.
- 3G.1.1.11 A quality assurance manual with details of the type and frequency of checks carried out, as well as the documentation records to be filed, is essential.
- 3G.1.1.12 The results of tests, together with any corrective action taken in response to adverse results should be documented and kept for at least a year or longer depending on the shelf life of the product.
- 3G.1.1.13 Quality assurance systems have to consider all the relevant legislation and good manufacturing practices.
- 3G.1.1.14 The quality assurance department should also have the power to stop production in cases where good manufacturing practice was not exercised or where the product is at risk.
- 3G.1.1.15 The reasons for stopping production should be explained by the quality assurance department and proper corrective action taken before restarting the line.
- 3G.1.1.16 A signed, dated agreement between manufacturer and customer should exist and all products manufactured on-site should conform to this written specification.
- 3G.1.1.17 No alteration to the product specification should be allowed without the consent of the customer. Amendments made after consultations should be signed, dated, and recorded.

3G.1.1.18 All manufactured products should be according to written specifications. Non-conforming raw materials or finished products should be identified and dealt with accordingly.

3G.1.1.19 Reports of all the processes required to ensure the safety of the food should be inspected by an experienced and appropriate individual at least daily. The records should be signed off to demonstrate the process has been carried out under the required conditions.

3G.1.2 Inspections and Testing (SABS 2001a; Anon. 2004; Fisher 2004; Vorster 2004; USDA 2014).

3G.1.2.1 Incoming wheat shall be graded according to its moisture content, cultivar, odors, taste, and color as well as the presence of the following factors that could affect food safety: toxins, chemicals, noxious seeds, *ergot sclerotia*, and molds. Wheat with more than 0.02% *Ergot Sclerotia*, is classified as contaminated. Wheat is graded into four classes: Class bread wheat, class biscuit wheat, class durum wheat, and class other wheat.

3G.1.2.2 The latest revised version of the Bread wheat grading table can be obtained from the following website: [Subpart M -- United States Standards for Wheat \(usda.gov\)](#) Click on the following links: Local and import regulations, agronomy, wheat, latest revised version. The wheat grading table would be attached as an annexure to the latest regulation from the Department of Agriculture relating to the grading, packing, and marking of wheat intended for sale in the RSA.

3G.1.2.3 Microbiological testing will depend on the nature of the product to be tested for example the shelf life, composition, and degree of risk.

3G.1.2.4 Laboratory facilities on site should implement good laboratory practices, should have adequate space, and should also have the appropriate equipment required for tests to be done. Laboratory personnel should be competently trained to take the analysis, interpret the results, and deal with problems as they arise. Standards for microbial limits should be defined. Access to laboratory areas should be restricted to authorized personnel only.

3G.1.2.5 Protective clothing such as laboratory coats worn in microbiological laboratories should not be used in production areas.

3G.1.2.6 Laboratory waste should be stored by existing legislation.

3G.1.2.7 Stringent precautions should be taken while sampling to avoid contamination which could result in inaccurate test results.

3G.1.2.8 The microbiological laboratory and quality assurance department should communicate daily through designated staff to ensure that corrective action is taken in response to specification results.

3G.1.2.9 A sample that previously gave a non-conforming test result and was retested, cannot be released based on the re-test results only. This would only be appropriate if it can be proved that the original and re-test data could then be used to release the lot.

- 3G.1.2.10 Finish product testing should conform to written specifications.
- 3G.1.2.11 All laboratory methods should be written up including an assessment of the hazards of each chemical used and all test methods should be readily available for analysis. Test methods should be followed as written and without modification.
- 3G.1.2.12 All laboratory equipment should be clean, well maintained, serviced, and calibrated regularly to ensure functionality and accuracy. Maintenance reports should be kept for laboratory equipment. All calibrated instruments should be labeled with the date and next date of calibration.
- 3G.1.2.13 All reagents and microbiological media should be controlled and monitored to assure that they are periodically replaced, and old reagents are not used.
- 3G.1.2.14 Positive and negative controls are of utmost importance in microbiological testing to avoid false positives.
- 3G.1.2.15 All results should be recorded at all times.
- 3G.1.2.16 In cases where outside laboratories are used for the testing of samples, the premises should be audited before the commencement of the contract.
- 3G.1.2.17 All expired or spoiled products should be rejected.
- 3G.1.2.18 The raw materials, in-process materials, and the finished product should be tested by an accredited laboratory.
- 3G.1.2.19 Environmental and microbiological analyses of these samples should be carried out by the manufacturer.

3G.1.2.20 The required levels of fortificant mix that flour should contain is 200g per ton of flour (0.02%) and to make sure these levels are maintained; ring tests should be done regularly for each batch produced.

3H. Management

One of the most important factors of a successful HACCP system is the competency of the people who developed and operated it. The people mentioned here not only refer to those personnel that work directly with the product produced but, also to senior management that plays a very important role in the preparation and planning of such an extensive project. Commitment and visibility from their side could add to the success of the project therefore, the roles of management should be defined within a company.

3H.1 Management Control

3H.1.1 Interest from Senior Management Level (SABS 2001a; Fisher 2004)

3H.1.1.1 It is the management's responsibility to define and document a company's food safety and hygiene policy and these policies should be positioned at strategic points throughout the factory. Management should make sure that the policies are understood, implemented, and maintained at all levels within the organization. Only authorized people with the responsibility for implementing the policy should sign the statement.

3H.1.1.2 It is also important for the manufacturer to establish the chemical, functional, microbiological, and organoleptic specifications for the finished product.

Senior management should be fully committed to the company's quality philosophy and the main board of directors should contribute to the quality management system through their job description or responsibility.

3H.1.1.3 Managers should be involved in the production environment by taking regular factory tours, communicating with "online" operatives, having discussion/review meetings with senior managers, and motivating staff by encouragement and reward.

3H.1.1.4 Senior Management should at all times be fully trained and aware of food hygiene and good manufacturing practices.

3H.1.2 Communication to production level (Fisher 2004).

3H.1.2.1 All levels of management should be present in regular meetings on a daily or weekly basis, dependent on the size and nature of the company. Discussion points to include in such meetings should be the previous day's production target; inline problems and equipment faults; the number of complaints received; rejected raw materials; damaged or returned goods; product development program; pre-production trials, and a summary of non-conformances. By discussing these areas, all levels of management will be fully aware of the company's activities and progress and will be able to distribute this information to their departments.

3H.1.2.2 Communication to the production level is essential to ensure consistent quality of the products as well as to involve online operatives in taking corrective actions.

3H.1.2.3 This two-way communication should give evidence that there is sufficient, properly trained production staff to ensure all quality criteria are met.

3H.1.3 Internal Audits (Anon. 2004; Fisher 2004)

3H.1.3.1 Internal auditing should take place to identify strengths and weaknesses in the operating system and to shed light on proper, corrective actions.

3H.1.3.2 To ensure objective auditing, managers should not be allowed to audit their departments.

3H.1.3.3 All managers should be responsible for an ongoing audit and review of the production process to ensure the safe and legal production of products of an agreed specification.

3H.1.3.4 The attitude and response to all types of audits should be enthusiastic, dedicated, and positive. Corrective actions should be completed within the agreed time scales.

3H.1.3.5 Internal audits should be carried out at least on a six-month basis and an action plan for resolution should be agreed on by the site manager.

3H.1.3.6 The internal assessments should be verified annually by a suitable, qualified employee.

3H.1.4 Hygiene Management (SABS 2001a; Fisher 2004).

3H.1.4.1 To implement and maintain the food hygiene management system, a suitable, qualified, and experienced hygiene officer should be appointed. Written policies

and procedures for hygiene and good manufacturing practices should be compiled by a qualified person and kept in a hygiene manual. The hygiene policy should be understood, implemented, and maintained at all levels of the organization.

3H.1.4.2 To ensure the safety of the food produced, the policy statement should contain a commitment to maintaining the hygiene level at least by the standards and regulations in place.

3H.1.4.3 It is recommended that the hygiene management should be responsible to the Quality Management Team, who in return should be entirely liable for the hygiene standards of the equipment and factory premises.

3H.1.4.4 Hygiene management should be a controlled, organized system, effectively completing a daily program of duties that have been prioritized in liaison with the Quality Management Department.

3H.1.4.5 Managers specifically responsible for areas such as hygiene should be adequately trained and qualified. They should report directly to a senior manager and should possess a degree in organizational, people management, and time management skills.

3H.1.4.6 A hygiene team should be available to cover all departments on a split shift or single shift basis.

3H.1.4.7 The team should be appropriately trained in the use of cleaning chemicals, dispensing equipment, cleaning schedules, and safety precautions.

3H.1.4.8 All hygiene staff should have undertaken basic hygiene training that matches the level of their responsibility.

3H.1.4.9 Management at all levels should be dedicated to producing safe, legal products of the specified quality. To achieve this, specialist expertise should be available in all departments to achieve.

3H.1.4.10 Departmental managers' responsibilities regarding hygiene and quality should be defined and understood. Their commitment to Good Manufacturing Principles should never be in doubt and they should be able to demonstrate and communicate them to their staff.

3H.1.4.11 It is also highly recommended that key management and managerial positions should have designated deputies to cover for absence and to ensure the standards are maintained.

3H.1.4.12 Revision of the hygiene system should take place at least on an annual basis or on a more frequent basis to correct shortcomings due to poor hygiene implementation or by changes in legislation. Records should be kept.

3H.1.5 Reports and Corrective procedures (Fisher 2004)

3H.1.5.1 All reports issued should include a program of corrective action within an agreed time frame.

3H.1.5.2 Named managers should be listed and lead times are given in the corrective action program.

3H.1.5.3 A specific manager should be designated the task of checking that corrective actions have been completed on time by the appropriate personnel.

3H.1.5.4 The HACCP system should be reviewed at planned intervals by senior management to ensure its continued suitability, adequacy, and efficiency to improve continually. Records of management reviews shall be always maintained.

3H.1.6 Clear definition of responsibility (Fisher 2004)

3H.1.6.1 A major responsibility of managers is to ensure compliance with all appropriate legislation.

3H.1.6.2 Personnel at all levels should have a job description explaining their duties and responsibilities. A more detailed job description is needed at the management level which includes their specific tasks, reporting procedures, and any specific safety requirements.

3H.1.6.3 Personnel allocated responsible positions should have sufficient authority to discharge their responsibilities effectively.

3H.1.6.4 The production and quality assurance managers should be two different people who should not be responsible to each other but to their direct senior. They must join forces to achieve the agreed quality specification.

3H.1.6.5 Management should be committed to implementing as well as participating in the improvement of the HACCP system. The HACCP system should also be reviewed frequently for its efficacy, appropriateness, and continued sufficiency.

Management is also responsible for the communication and understanding of the HACCP system within the organization.

3H.1.6.6 A representative from management shall be responsible to establish a clear route for communication throughout the organization as well as establishing a forum for resolving conflict.

CHAPTER IV

GENERIC HACCP PLAN FOR THE FLOUR MILLING INDUSTRY

4.1 INTRODUCTION

The HACCP plan is the formal document that contains and pulls together the key information that is critical for the management of food safety (Mortimore and Wallace 1995). The plan is drawn up by the institution's HACCP team and should contain the flow diagram and the HACCP control chart as well as the additional supporting documentation (Mortimore and Wallace 1995). The process flow diagram for the wheat milling process was explained in chapter four.

Effective preparation and planning should take place for the application of the HACCP principles (Mortimore 2001). Prerequisite programs should be in place before the HACCP plan can be implemented. Therefore, the team must determine beforehand what elements are required and what are already in place (Mortimore 2001). The pre-requisites that needed to be in place were covered in chapter three.

To simplify the HACCP study, it can be approached as a twelve-stage procedure as shown in Table 4.1. (CAC 1997; NACMCF 1998; SABS 1999; Uys 2000; Forsythe 2002).

Table 4.1 Logic sequence for application of HACCP (CAC 1997; NACMCF 1998; Boccas et al 2001; Sjoberg et al. 2002)

Stage 1	Assemble HACCP team
Stage 2	Describe products
Stage 3	Identify the intended use
Stage 4	Construct flow diagram
Stage 5	On-site confirmation of flow diagram
Stage 6	List all potential hazards; Conduct a hazard analysis; control measures
Stage 7	Determine CCPs
Stage 8	Establish critical limits for each CCP
Stage 9	Establish a monitoring system for each CCP
Stage 10	Establish corrective actions
Stage 11	Establish verification procedures
Stage 12	Establish documentation and record-keeping

4.2 Stage 1: Select the HACCP Team

To effectively implement HACCP, it is of utmost importance that senior management from all disciplines be involved and show their support by being committed. HACCP should not be carried out by one person alone but should be the result of a team effort. Depending on the size of the organization, one or even two teams should be assembled to assist with the implementation, management, maintenance, and review of the HACCP plan (Mortimore and Wallace 1995). There must at least be experts from the following areas within the organization: production, quality, and engineering (Mortimore and Wallace 1995; NACMCF 1998; Forsythe 2002). The competency of the people who

develop and operate the HACCP plan, as well as the pre-requisite programs that support it, is required to have a HACCP plan that truly works in practice (Mortimore 2001).

Written proof of a person's assignment and commitment to the HACCP team should be kept on record for every team member (Fisher 2004). The three main goals of such a team must be to ensure that management's commitment is visible, communication channels are open, and a forum for conflict resolution is established.

The core HACCP team should consist of personnel with specific knowledge and expertise regarding the process and product. The necessary HACCP studies shall be conducted by the core team, and they should supervise the implementation and maintain the HACCP plan (SABS 1999). The core team shall consist of:

4.1.1 A team leader should be part of management with enough management experience and should be a natural leader with defined responsibilities, authority, and sufficient HACCP training. This person should be appointed by management to lead the HACCP team. The team leader should also have the authority to ensure the HACCP system is established, implemented, and maintained according to the requirements of FDA 2017. He or she should also report to management on the performance of the HACCP system for review purposes and as a basis for improving the system. The team leader also must assess which resources such as time, people, equipment, and funding are needed for the implementation, maintenance, and continual improvement of the HACCP system (SABS 1999).

4.1.2 A facilitator should also have formal HACCP training provided by registered, certified, or accredited organizations or persons as well as a validated training

curriculum. This person should be responsible for the organization of meetings and training and should act as the secretary during such activities. The facilitator will also be responsible for ensuring that specialist advice is available when required, the progress throughout the organization is communicated, any obstacles regarding the implementation and maintenance of the system are removed, follow-ups are completed on time as well as organizing experimental studies when required (SABS 1999). The team leader and facilitator can be the same person. In some cases, the facilitator can also contribute as a specialist to the team.

4.1.3 A quality controller should contribute to the team by providing expertise in microbiological, chemical, and physical hazards associated with the product.

Understanding the hazards and the knowledge to know control measures to prevent the hazards from affecting the product (Mortimore and Wallace 1995; NACMCF 1998; SABS 1999).

4.1.4 A production expert with detailed knowledge of the production of the product should also be part of this team (Mortimore and Wallace 1995; NACMCF 1998; SABS 1999).

4.1.5 An engineer that would provide the team with knowledge of the process equipment and environment concerning hygienic design and process capability (Mortimore and Wallace 1995; NACMCF 1998; SABS 1999).

4.1.6 Additional expertise could be either internal or external depending on the availability within the organization. For example, a person from the suppliers' quality assurance side could provide the team with details of supplier activities and the hazards

and risks associated with raw materials purchased (Mortimore and Wallace 1995; NACMCF 1998; Forsythe 2002).

4.1.7 A Research and Development expert should provide knowledge of any new product or process development (Mortimore and Wallace 1995).

4.1.8 A Distribution expert should have expert knowledge of storing and handling food products (Mortimore and Wallace 1995).

4.1.9 A Purchasing expert would help to answer any questions regarding purchasing (Mortimore and Wallace 1995).

4.1.10 A microbiologist would be able to provide knowledge on microbiological hazards (Mortimore and Wallace 1995; NACMCF 1998).

4.1.11 A toxicologist would provide knowledge of chemical hazards (Mortimore and Wallace 1995).

4.1.12 Food Scientist or Technologist would provide knowledge of the food source and new product development (SABS 1999).

4.1.13 An Industrial chemist should provide knowledge of the production of a wide range of important chemicals and materials and can help when a process needs to be modified (SABS 1999).

4.1.14 Work Study officer would provide problem-solving advisory service to all management levels to increase productivity, profits, cost-effectiveness, quality, and efficiency (SABS 1999).

4.1.15 A risk assessment expert would be the ideal person to help whenever the need arises for doing risk assessments (SABS 1999).

4.1.16 HACCP consultants could assist the team by training team members in HACCP techniques, assisting them in the implementation of HACCP, assessing the HACCP studies and implementation, assisting in documentation development, and assisting with the ordering and structuring of meetings (Mortimore and Wallace 1995).

The HACCP team is responsible to define the terms of reference of the HACCP system of the company (SABS 1999). Reference should be to a specific product, product line, or process, and the microbiological, chemical and physical hazards associated with the product should be discussed. The safety of the product at the point of consumption or the point of manufacture should also be declared. At the point where the product is supposed to be judged as a safe product, hazards that could affect the product at that point should be listed and considered. Whether only product safety hazards will be included or whether nonsafety requirements will also be included should also be discussed (SABS 1999; Uys 2000).

4.3 Terms of Reference for Flour

This HACCP study considers biological, chemical, and physical hazards throughout the entire wheat milling process. The biological hazards could affect the safety of the final product especially if it is consumed by the high-risk group of the population such as the elderly, infants, and the immunocompromised especially if the product was not subjected to extreme heat or cold conditions.

Biological hazards of wheat include micro-organisms such as bacteria and fungi (Mills and Pedersen 1992). Field fungi such as *Ergot sclerotia* produce mycotoxins and *Fusarium gramineous* that produce vomitoxin (deoxynivalenol) (Mills and Pedersen 1992). Storage fungi include *Aspergillus spp.* Another commonly found bacteria are the *Bacillus* species. These species produce a highly heat-stable toxin that is associated with the characteristic food poisoning symptoms such as nausea and vomiting. *Bacillus subtilis* causes ropiness in bread (Mills and Pedersen 1992).

Yeasts are divided into two groups, true yeasts, and false yeasts. True yeasts form endospores. A typical example is bread yeast. These types of yeasts are usually not a problem on grain or flour unless the moisture is high and oxygen levels are non-existent (Mills and Pedersen 1992).

Vegetative pathogens such as *Salmonella*, *Listeria*, and *Staphylococcus* are not excluded from the raw product.

Chemical hazards could be associated with raw materials such as the pesticides used. Chemical contamination can also take place during the cleaning process due to the use of cleaning materials that might leave residues or during the fumigation of the plant. Examples of chemical hazards within a milling environment would be pesticides, insecticides, avicides, fungicides, cleaning agents, lubricants, antibiotics, fortificants, and heavy metals (Mills and Pedersen 1992).

Physical hazards include all foreign bodies such as sticks, stones, sand, glass, plastic, metal, insects, hair, wood, paint, noxious seeds, etc. (Mills and Pedersen 1992). Most of these hazards would be removed by the cleaning house section in the mill where a lot of

specialized equipment is used to separate the wheat kernel from the foreign bodies. Examples of common machinery would be separators, cleaners, carter disks, truer cylinders, scourers, aspirators, magnetic separation, sieves, seed removers, and combi-cleaners.

Physical hazards could also affect the safety of the product if it is to go through to the final stages where the cleaning equipment failed, sieves broke, or metal detectors and magnets failed.

4.4 Stage 2: Describe the Product

Wheat flour is found in three forms – whole wheat meal, brown bread flour, and white bread flour (Lockwood 1960; Anon. 2004a).

The whole grain is used in the production of a whole wheat meal including the fiber-rich bran (outer layer), endosperm (middle layer), and the nutrient-packed germ (inner layer) (Lockwood 1960; Anon. 2004a; Anon. 2005). Wheat flour contains dietary fiber, B vitamins (thiamin, riboflavin, niacin, and folate), calcium, iron, magnesium, phosphorus, potassium, and zinc and is also a good source of complex carbohydrates. The bran component of a wheat kernel contains fiber, the endosperm contains protein, carbohydrates, and small amounts of B vitamins, and the germ contains trace minerals, unsaturated fats, B vitamins, antioxidants, and phytonutrients (*Flour / Food Source Information*, 2022).

White bread flour is refined meaning the bran is removed from the rest of the grain and in the process, many nutrients are removed. According to government legislation, white

flour must be fortified with nutrients such as vitamins and minerals to compensate for losses resulting from the milling process. Other variants such as self-rising flour can also be produced by just adding baking powder to the white bread flour. White bread flour has an extraction rate of 70-75% and up to 30% of the bran germ fat, and minerals are removed (Lockwood 1960; Anon. 2004a; Anon. 2005).

Brown bread flour contains a little more bran than white flour which adds a darker color, stronger flavor, and odor to the flour. Brown bread flour should be fortified according to law, it has an extraction rate of 85% - 90%, and 10-15% of the bran is removed. It is light brown in appearance (Lockwood 1960; Anon. 2004a; Anon. 2005).

Flour is a very dry product meaning that it has a low water activity and a moisture content of between 13 and 14 %. It is packed into bulk containers, bags, or smaller paper bags and should be stored in a cool dry place. Flour is prone to pest infestation if it is kept for very long periods therefore, it is suggested that flour should not be stored for a period longer than six months. The natural oils in the flour can oxidize therefore the flour goes rancid after a while and the odor and flavor are affected. The storage conditions, insect activity as well as the type of flour stored, all influence the shelf life of flour.

Typical flour storage should be at ambient temperature and humidity in a clean dry area. Whole grain flour will have a shorter shelf life than white flour because it still contains the wheat germ. The average shelf life for a whole wheat meal and brown bread flour would be 3 to 4 months depending on the temperature. For white bread flour, it is usually 6 months (Anon. 2004b).

In most cases, the product will be consumed only after it was subjected to extreme heat conditions such as baking or boiling, which make the product a medium care product. Such foods are defined because they are a potential source of micro-organisms; they are intended for consumption after a cooking step that is adequate to kill off the pathogens (SABS 2001). In some instances that should be described by the different manufacturers to which it is applicable, the raw product is being used as-is and can be classified as a high care product. Such foods do not have a cooking step before consumption that is adequate to kill off pathogens and destroy their toxins (SABS 2001). For this study, we will look at flour as a high care product.

The final product before packaging is tested for some or all the following: moisture content, protein content, ash content, strength, water absorption, vitamin content, bran content, particle size, color, falling number, and baking quality.

4.5 Stage 3: Identify the Intended Use of the Product

Strong flour has a high protein content and is used in the making of bread whereas wheat with a lower protein content produces soft flour used mainly for making cakes and biscuits. Soft or weak flour with a protein content of +/- 8% is suitable for making cakes. Plain flour containing +/- 10% protein is suitable for making biscuits and sauces. Self-rising flour with a protein content of 10% and added raising agent is suitable for sponge cakes and scones. Strong flour with a protein content of between 11 and 14% is used for yeast dough, flaky, and puff pastry. Whole grain flour is used to make a variety of whole-grain products which are a very important part of one's diet. It contains nutrients such as fiber, starch, minerals, and vitamins which are in short supply in our diet. Antioxidants

and phytoestrogens which are important in disease prevention can also be found in this type of flour.

Consumers of wheat products cover a very large spectrum of our population, from babies to the elderly. The only exceptions that do not consume products containing wheat are the people suffering from wheat allergies. Examples of products produced by flour are bread; biscuits; cakes; breadcrumbs; cereals; pasta; sauces; baby foods and many more.

4.6 Stage 4: Construct a Product Flow Diagram

It is important to realize that for each mill, a unique process flow diagram and floor plan should be constructed and verified on-site (NACMCF 1998; SABS 1999; Forsythe 2002). The critical control points should also be indicated on the process flow diagram (Fisher 2004; Marais 2004).

4.7 Stage 5: Arrange On-site Confirmation of the Flow Diagram and Floor Plan

The flow diagram should cover all areas from intake through to the final production stages and should be confirmed on-site during all hours of operation (NACMCF 1998; SABS 1999; Forsythe 2002). All relevant information should be included on the flow diagram e.g., indicate the Critical Control Points. The floor plan should consider all the entrances, exits, walkways, equipment, and their location. It is the responsibility of the HACCP team to verify both the flow diagram and floor plan on site.

Therefore, it is best to take the flow diagram into the process area and observe it at each step and during all stages and hours of the operation (Mortimore 2001). The same should be done with the floor plan.

4.8 Stage 6: List All the Hazards Associated with Each Step in the Process and List Measures that Will Control the Hazards

A hazard is defined as a biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect (CAC 1997; NACMCF 1998). It is important during the hazard analysis, that the likelihood of the hazard occurring, and the severity of the hazard should be considered (Mortimore 2001). All the hazards that could be present in the wheat milling process are covered in the following tables at various stages in the process.

Table 4.2 Hazards associated with the intake of wheat and applied control measures (Gillion 2005).

Hazards	Type	Control measures
Glass, stones, sticks, metal, bone, wood, noxious seeds, broken grains, plastic, rubber straw, dust, hair, sand mud balls, paint flakings, insects: grain weevils, lesser grain borers, grain moths, flour, and grain beetles, rodents, insulation	Physical	Preliminary cleaning, aspiration, removal of unmillable material, intermediate cleaning, cleaning house: aspirator separator, combinator, combi-cleaners, de-stoner, carter disk, truer cylinder, scourer, magnets, metal detectors, pest control

material, fruit pits
(Forsythe 2002)

program

Residues of pesticides
or heavy metals due to
industrial pollution of the
environment.

Chemical

Wheat grading specifications

Micro-organisms:
Aspergillus spp.
Penicillium spp.
(Can produce mycotoxins

Biological

Store grain in a dry place,
aerate, if possible, control
temperature and moisture
conditions, temperature

as by-products.)
Fusarium graminearum

should not exceed 25°C,
moisture should not exceed
grading specifications (13 -

(produce vomitoxin /
deoxynivalenol / DON) *Bacillus* spp. (Mills
and Pedersen 1992)

14%), a_w should be <0.90 to
prevent *Fusarium* from growing
and producing DON/NIV (Hope
and Magan 2003)

Table 4.3 Hazards associated with the fumigation of wheat and applied control
measures

Hazard(s)	Type	Control Measure
Chemical residues of fumigant (Forsythe 2002)	Chemical	Control the fumigation process

Table 4.4 Hazards associated with the conditioning of wheat and applied control measures

Hazard(s)	Type	Control Measure
Bacteria, Yeasts & Molds	Biological	Making sure the water used
Overdosage of chemical	Chemical	Regular testing of the water and maintenance of the water treatment plan. Records should be kept of the pH of the water etc. making sure no overdosing can take place.

Table 4.5 Hazards associated with the milling process and applied control measures

Hazard/s	Type	Control Measures
Foreign materials added by human error or equipment deficiencies.	Physical	GMPs, sieves, redressers, metal detectors.
Overdosage of fortification or other additives.	Chemical	Use only the prescribed number of additives. Store appropriately and label correctly. Record all manual additions. Make sure that scales are calibrated regularly in cases where it is added automatically.
Foreign materials added by mix-back.	Physical	Accept/reject criteria, sieves, redressers.

Micro-organisms
added by mix-back.

Biological

Accept/reject criteria.
It is strongly advised that
returns should not
be mixed back into
the system mainly
because no
guidelines or criteria for
microbiological
specifications of flour
exist at present.

4.9 Stage 7: Determine Critical Control Points (CCPs)

Mortimore and Wallace (1995) define a critical control point as a point, step, or procedure at which control can be applied and a safety hazard can be prevented, eliminated, or reduced to acceptable levels. People often make the mistake of “choosing to manage” some pre-requisites as CCPs to “be on the safe side” (Mortimore 2001). Critical control points could be raw materials, processes, procedures, and practices. By making use of a decision tree such as the one included in this document as fig. 5.1, critical control points for the milling industry were identified. For the generic model, decision tree number 2 according to SABS 0330: 1999 and Codex Alimentarius was used and only two critical control points were listed. Each step or process within the milling process was carefully considered and the questions were answered consecutively. The first CCP is the rebolt sifter, metal detector, and impactor system before packaging (Mills and Pedersen 1992), and the second one, is the mix-back system (Marais 2004; Uys 2004). If, however, a mill does not mix back any returns into the system, that specific

mill would have only one critical control point and will be audited mainly on their pre-requisite programs and the one CCP (Marais 2004; Uys 2004).

Various control points within a milling environment exist. These were covered in the pre-requisite programs and are covered in Table 4.6

Table 4.6 Control points and associated types of hazards

Step / Procedure	Hazards
Wheat grading	Physical, Biological & Chemical
Wheat cleaning	Physical
Conditioning	Biological & Chemical
Wheat Debranning System	Biological
Redress system	Physical Hazards

It is advised that mills should not mix back returns especially if they do not have control over the process (Du Toit 2004; Fisher 2004). The returns could be used in animal feeds or for another purpose. The main reasoning behind this is the fact that no guidelines or specifications for micro-organisms in the final product exist now.

If, however, a mill continues to mix back for some or the other reason, it is strongly advised that a rebolt sifter, impact detacher, and the metal detector should be in place to control at least the physical hazards (Mills and Pedersen 1992; Du Toit 2004).

4.10 Stage 8: Establish Target Levels and Tolerances for Each Critical Control Point

By establishing target levels and tolerances for the critical control points, one can distinguish between a safe and an unsafe product, identify the actual operating limits and

identify the degree of latitude allowable (Von Holy 2004). Often experimental activity and reference data are needed to lay down critical limits (Mortimore 2001). For both the critical control points zero tolerance is allowed (Du Toit 2004; Fisher 2004). This means that no foreign objects or physical hazards should be detectable in the returned product. No insect eggs or signs of an infestation should be allowed neither should any strong odors be detected. No signs of infestation or adulteration in tailings of the redress sifter. Any product with any of the above deficiencies should be immediately rejected. Therefore, very strict accept/reject criteria should exist. To prevent micro-organisms such as *Fusarium* that produce toxins, from growing, it is important that returns accepted as mix-back should be kept at temperatures lower than 15°C and that the wheat-based substrate (flour) should not exceed 0.90 (Hope and Magan 2003).

4.11 Stage 9: Establish A Monitoring System for Each Critical Control Point

By establishing a monitoring system for the critical control points rules are laid down as to who should act when they are to act, and how they are to act (Von Holy 2004). The frequency that was set must be able to detect loss of control of the CCP promptly (Mortimore 2001).

4.11.1 CCP – Metal detector before packaging

The person in charge of the packing department or a designated responsible person should check the redress tailings of the rebolt sifter for signs of infestation or sieves being broken. Act accordingly and replace broken sieves or equipment where appropriate.

Regular challenge tests on the metal detectors should also take place regularly. The metal detector should be replaced as soon as it is found that it is faulty.

4.12 Stage 10: Establish Corrective Action Plans

Corrective action plans for the CCPs could be an action that could be taken to bring the process back into control before the deviation could lead to a safety hazard (Mortimore 2001; Von Holy 2004). Or action to deal with the product manufactured while the process was out of control (Mortimore 2001; Von Holy 2004). The procedures should correct the nonconformity and deal with the product that was produced while the process was out of control (Mortimore 2001). Examples of such actions could be a strict accept/reject criterion, notifying the supervisor, stopping production, isolate the product. In the case of non-conformity, it is advised that re-processing should not take place and that the product should rather be used for animal feeds (Du Toit 2004).

If the hazards associated with the product while the process was out of control are physical hazards, it would be wise to notify the supervisor and stop production especially if the redress system is at fault. If this material is accepted as material for mix-back, then it is advised that the mix-back material is isolated, fumigated, and go through a redress system and impactor (sterilator) that is in proper working condition as well (Du Toit 2004).

4.13 Stage 11: Establish Verification and Review Procedures

It is important at this stage that the HACCP team document how they plan to verify the HACCP plan is working (Mortimore 2001). Typical verification activities would include final product testing where the final product should be tested periodically, and it should conform to the customers' requirements and specifications (Fisher 2004).

Examples of different tests that a mill could do to conform to the customer's requirements are tests for moisture %, protein %, ash %, color, falling number, alveograph, farinograph, mixograph, extensigraph, particle size, vitamins, and baking quality (Atwell 2003). Microbiological analyses on the final product as requested by the customer should also take places such as testing for pathogens such as *Salmonella* and toxins that might be present and also test for total viable counts, coliforms, yeasts, and molds.

Internal audits to verify that the process (HACCP plan) is working effectively (Mortimore 2001). Independent auditing should take place meaning that someone from the packing department is not allowed to audit the packaging area (Fisher 2004).

Other activities for verification include the review of consumer complaints (Mortimore 2001), checking the records of CCP operations, observing the operations at CCP, checking the records of monitoring instrument calibration, having a formal customer complaint procedure in place, and having recall procedures in place.

The HACCP plan should be reviewed periodically because "it is very unlikely that the products produced, the process, the environment, likely hazards or the people in the

facility will remain unchanged over time” (Mortimore 2001). Conditions that automatically trigger a review of the HACCP plan are a client and consumer complaints that indicate that there is a health or spoilage risk associated with the product; a likely change in client and consumer use; a change in raw materials or product formulation; a change in the processing system; a change in the plant design and surroundings; any alteration/replacement to the processing equipment; a change in the cleaning and disinfection program; a change in the packing, storage and distribution system; changes to personnel levels and tasks; legislation changes; the outcome of verification and validation activities (SABS 1999).

4.14 Stage 12: Establish Record-Keeping and Documentation

Records that should be kept include the HACCP plan itself, CCP monitoring records, training records, verification activities as well as records of amendments to the system (Mortimore 2001). A document control procedure should be in place that should address at least the following: approve the adequacy of documents before usage; update and review documents where necessary and re-approve the documents; identify changes to documents and the current revision status; current versions of applicable documents should be available at points of use; documents should be legible and readily identifiable; documents of external origin should be identified and their distribution within the organization should be controlled; the unintended use of documents should be prevented and suitable identification to them should be applied if they were retained for any purpose; no handwritten procedures/documents should be allowed; no handwritten changes to documents/procedures should be allowed.

Records should provide conformance to the requirements of the HACCP system and should address the identification, collection, storage, protection, retrieval, retention times, and disposition of such records. Minimum HACCP records to be kept are company profile; management commitment to safety; cleaning and sanitation records; plant construction and maintenance records; records on the nature, source, and basis for acceptance of raw materials, water quality, additives, ingredients, cleaning chemicals, and packaging materials; processing records including storage, distribution, and recall; summary of hazard analysis; listing of HACCP team and assigned responsibilities; description of the food, its distribution, intended use, and consumer; verified flow diagram; management review; pre-requisite programs; training policy and the HACCP manual format outline in table form, for an example refer to Table 5.7 (SABS 1999; Merican 2000). Records should include supporting documentation such as validation records, records generated during the operation of the plan, HACCP plan modifications, and a distribution list to control documents that need to be circulated amongst the personnel.

After completion of the HACCP study, a fully focused documented system known as the HACCP plan should be achieved (Mortimore 2001). The following stage would be the implementation of the HACCP plan and afterward the maintenance of the system to ensure that the implementation remains successful (Mortimore 2001).

4.15 Assessment of the HACCP Plan

The HACCP plan should then be assessed by a government inspection agency to verify whether the food handling enterprise can manufacture and distribute safe and quality

products. This assessment is mainly two-fold a document review and an on-site verification (Ababouch 2000).

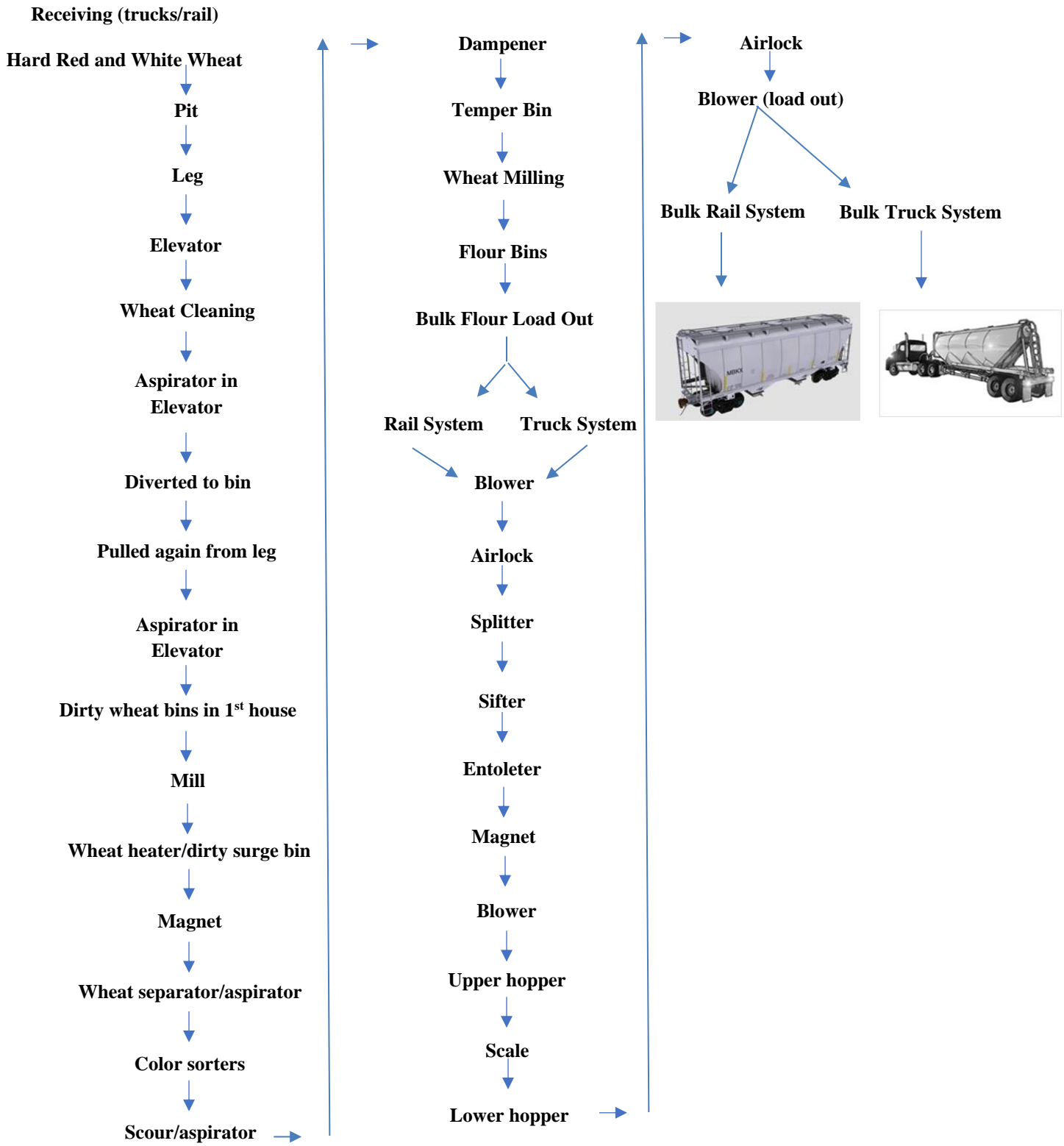
CHAPTER V

FLOW DIAGRAMS

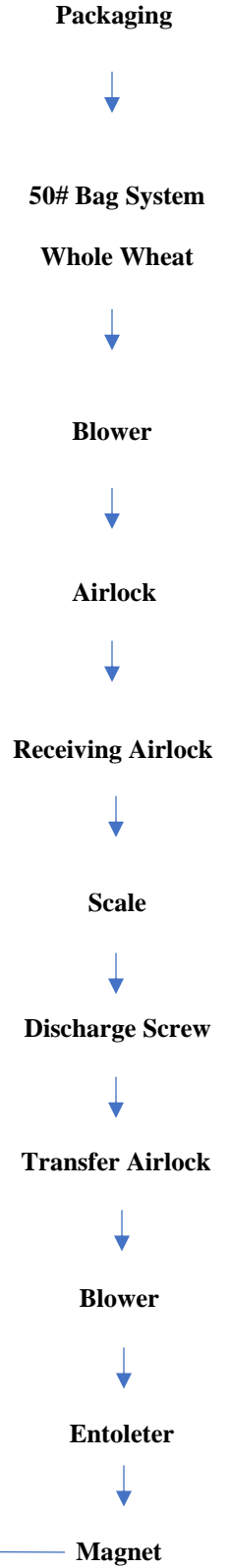
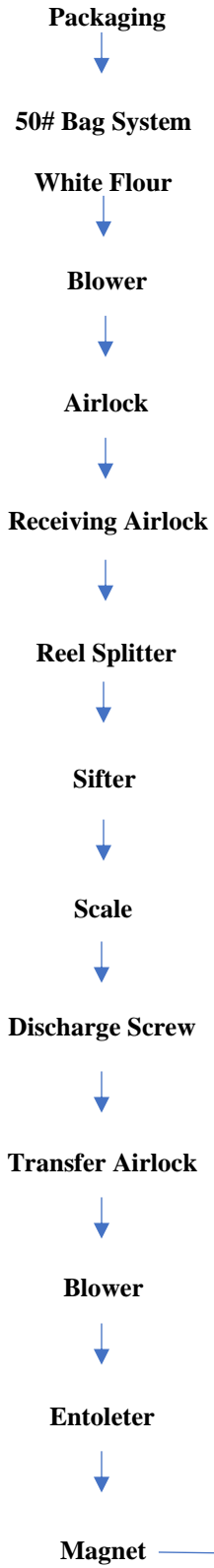
5.1 INTRODUCTION

Step four in the 12-step procedure for the roll-out of a HACCP plan states a product flow diagram should be constructed. This flow diagram should be unique for each food handling enterprise and should have the critical control points indicated on it. It is also important that this flow diagram should be verified on-site during all hours of operation to make sure it is complete. A box-type flow diagram is sufficient but, a more detailed process flow diagram is included (Gillion 2005).

A floor plan should also be constructed by the HACCP team. It should indicate all entrances, exits, and walkways. The floor plan should be unique for each mill which is also the reason why an example is not included in this generic model (Gillion 2005).



(Industry Expert)



→ To Packer or Bulk

←

(Industry Expert)

CHAPTER VI

GENERAL CONCLUSION

It is quite evitable that no food handling enterprise would want to see consumers falling ill from the foods they produce and at the same time losing the trust of the customers and its reputation (Mortarjemi and Mortimore 2005). Globally there has been an increase in the consumers' awareness of food safety due to some major food safety failures however foodborne diseases are still on the increase (Panisello and Quantick 2001).

Factors that contribute to outbreaks are temperature misuse, inadequate handling, inadequate environment, and the ingestion of contaminated raw materials (Panisello *et al.* 2000). However, food handling enterprises cannot always guarantee the absence of pathogens therefore it is insufficient to improve the microbiological quality of foods alone since foods can easily become recontaminated. Extreme pressure from governments, consumers, media, academia, retailers, and the food-service industry as well as the food industry itself also occur (Mortarjemi and Mortimore 2005). In collaboration with all these sectors, and by meeting their expectations, it will be able for the food industry to prepare a safe product for consumer use.

Food safety has been based on end-product testing in the past, but it has its limitations such as time delay, as well as the high cost of the direct monitoring of microbial patho

gens (Unnevehr and Jensen 1999). It can also be extremely costly, especially if the contaminated product is reported once production is already complete. Adding to this economic loss of a company is the recall of the defective product from the retail outlets (Tokatli *et al.* 2005).

Therefore, the most secure and cost-effective method to monitor the physical, chemical, and biological hazards from farm to fork to produce a safe product is the HACCP system (Efstratiadis and Arvanitoyannis 2000; Panisello *et al.* 2000).

Overall HACCP has been regarded as “the magic concept that’s capable of solving all food safety problems” (Heggum 2001) but there are various technical barriers that need to be overcome for the HACCP plan to work effectively (Panisello and Quantick 2001). Barriers that might affect the project before HACCP implementation are the illusion of control, company size, the type of product, the industry sector, and the customer’s food safety requirements. Barriers during the process of HACCP implementation are the lack of HACCP program leadership, lack of co-operation between the industry and the enforcement authorities, personnel persisting with their old habits and attitudes, the lack of time for staff to implement HACCP, the lack of staff motivation and supervision, dealing with a lot of paperwork, lack of equipment or poor design thereof as well as incorrect plant layout. Barriers after HACCP systems have been implemented include difficulties in the verification and validation of the HACCP plans and the lack of equivalence (Panisello and Quantick 2001).

There are numerous reasons why HACCP programs fail and the most important one is because the pre-requisite programs are not in place. In such situations, it can lead to the

complication of the HACCP plan with too many critical control points that could not be managed in the end. Some of them are not even true critical control points. It is advised that only the significant hazards are covered in the HACCP plan and that the general hygiene issues should be covered in the pre-requisite programs (Wallace and Williams 2001). In other cases, HACCP is a paper exercise or once HACCP has been attained, the program is lapsed because of improper maintenance. It is also important that the HACCP plan should be designed, implemented, and verified by an interdisciplinary team and not just an individual such as the quality assurance manager otherwise HACCP is doomed to failure in such a situation (Higuara-Ciapara and Noriega-Orozco 2000).

For a HACCP program to be successfully implemented, managed, and maintained, four stages were identified to make HACCP work in practice (Mortimore and Wallace 1995; Mortimore 2001): Firstly, the proper preparation and planning before the seven principles of HACCP are applied which include proper training and resources such as time and money. Secondly, the application of the seven HACCP principles was identified by the Codex Alimentarius Commission (CAC 1997). Thirdly, the implementation of the HACCP program, and finally, the maintenance of the HACCP program. Maintenance is of utmost importance because most companies are relieved once the HACCP plan is implemented but they forget that to produce safe and quality food, the plan needs to be always maintained.

There is no doubt that the biggest benefit of implementing HACCP in food safety. Food safety is not an option but rather a requirement to keep customers happy and to improve market share. Other benefits that come along with the implementation of HACCP are

fewer customer complaints, maintaining the company's market position, a reduction in liability as well as an increase in efficiency and waste control (Bliedung 1997). Food handling enterprises that adopt the HACCP system whether they're big or small can also boast of improved confidence, a reduction in costs, a more focused approach on what's important, improved team building, more development within the organization, legal protection, and more trading opportunities (Taylor 2001).

Two critical control points were identified for the generic HACCP plan which are: a rebolt sifter, metal detector, and impactor system to control physical hazards as well as the mix-back system that should be managed to control mainly biological hazards as well as physical hazards that enter the mill using returns. If it is considered that not all flour products are used in the baking or cooking process, it is quite evitable that food poisoning problems due to contaminated flour may occur. Therefore, the flour milling industry must adapt HACCP systems to manage the food safety hazards identified.

It is important to note that HACCP is not a stand-alone, but it can be regarded as a supplement to already existing hygiene practices (Heggum 2001). Therefore, food safety is HACCP plus pre-requisite programs (Sperber 2005).

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