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A Review on Hazard Analysis Critical Control Point in Milk and Milk Products

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Abstract: Hazard Analysis and Critical Control Point system is a preventive system for assuring the safe production of food products. It is based on a common sense application of technical and scientific principles to a food production process. HACCP program deals with control of factors affecting the ingredients, product and process. It is a risk management system in which food safety is addressed through the analysis and control of biological, chemical and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. The hazard analysis process involves identifying hazards that are reasonably likely to occur in the absence of control and their preventive measures. Milk and dairy products form a significant part of the human diet. They are rich sources of nutrients such as protein, fat, vitamins and minerals; it is because of this, that these products are susceptible to rapid microbial growth. Milk is sterile when secreted into the alveoli of the udder, but microbial contamination occurs mainly during and after milking. Safe food is a composite of all of the views and descriptions held by consumers, special interest groups, academicians, regulatory authorities and industry. Food safety in the early twenty-first century is an international challenge requiring close cooperation between countries in agreeing standards and in setting up transnational surveillance systems. Modern systems of food health quality assurance are based on the concept of creating production conditions which guarantee optimal quality products.

Key words: Food safety · HACCP · Milk and milk product

INTRODUCTION

Milk and milk products are the most important and necessary products in the food supply chain. The dairy industry is highly susceptible for incidents affecting the public image of their products. It means that all efforts have to be directed toward the quality features of the product and the production process that have direct association with the consumer concern. As stated above, this refers first of all to food safety, public health, animal health and animal welfare and next, to the more classic, technological quality measures like milk cell counts, bacteria counts, antibiotic residues and freeze point decrease [1].

Milk can show large quality differences, which milk processors, must take into account. Two types of criteria are used for paying by quality physiochemical and biological. Physiochemical criteria usually relate to the fat and protein content, the basic rate of which per kilo of milk varies from one to another. Testing for better biological quality could result in finding specific bacteria such as *Coliforms, Staphylococcus, Listeria* and Butyric spores. Similarly, the presence of antibiotics and the milk temperature during collecting can be used as quality criteria and for price reduction. In addition, the presence of chemical residues could alter the process of elaboration of derived fresh milk products [2]. Due to physical, chemical or microbiological hazards of possible contamination, many people in the world are exposed to these risks quite clearly. Therefore, sufficient quality and food safety practices are important for food security in the dairy industry. The most effective way to achieve food safety is to focus on prevention of possible hazards and to improve the process [3].

Putting in place of a functional quality control system is an important tool to bring about improvement in food safety. Several quality management systems such as International Standard Organization (ISO 9000), Total Quality Management and Hazard Analysis Critical Control Point (HACCP) were developed for the food industry. The dairy industry has implemented HACCP systems to enable the quality assurance of final products via a chain

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management approach. The quality and safety of raw milk is essential for the quality and safety of milk and dairy products The HACCP system has been indicated as one of the most effective ways to guarantee high quality and safe food [4].

A food safety management system based on HACCP principles contains many of these elements and provides a comprehensive framework by which an operator can effectively control the occurrence of foodborne illness risk factors. Hazard Analysis and Critical Control Point program is a system which identifies and controls the critical steps in producing safe and wholesome dairy products. It is a food safety control system that can minimize the likelihood of food safety hazards but cannot guarantee zero tolerance for all food hazards 100% [5]. The factors which impact HACCP effectiveness may fall into three main groups; personnel factors, operational management factors and environmental factors. Active managerial control through the use of HACCP principles is achieved by identifying the food safety hazards attributed to products, determining the necessary steps that will control the identified hazards and implementing on-going practices or procedures that will ensure safe food [6].

In Ethiopia there is no standard hygienic conditions followed by producers during milk production. The hygienic conditions are different according to the production system, adapted practices, level of awareness and availability of resources. In most of the cases under small-holder condition, the common hygienic measures taken during milk production especially during milking are limited to letting the calf to suckle for few minutes and/or washing the udder before milking [7].

Food-safety risks at the point of consumption may vary between countries or areas within countries. Major differences occur between a largely industrialized dairy sector where pasteurization technologies are routinely applied and regulated and a dairy sector where there are many small scale dairy farmers and milk may be sold through informal channels. The challenge to all food safety policy makers is to ensure that appropriate measures are taken to prevent food borne illnesses and to support implementation of safe food practices including hygiene and education for dairy farmers, suppliers and consumers while at the same time promoting economic development of the dairy sector [8].

Therefore the objectives of this paper were:

- ✓ To highlight the food safety hazards specific to milk.
- ✓ To review the basic principles of HACCP.

Food Safety Hazards Specific to Milk and Milk Products: Milk, being a nutritious medium, presents a favorable physical environment for the multiplication of microorganisms and being an animal product is subjected to widely differing in production, handling and processing methods, results in its contamination by a broad spectrum of microbial types, chemical residues and foreign bodies. To effectively reduce the occurrence of foodborne illness risk factors, operators of retail and food service establishments must focus their efforts on achieving active managerial control. The term “active managerial control” is used to describe industry’s responsibility for developing and implementing food safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors [9].

There are many tools that can be used by industry to provide active managerial control of foodborne illness risk factors. Regulatory inspections and follow-up activities must also be proactive by using an inspection process designed to assess the degree of active managerial control that retail and food service operators have over the foodborne illness risk factors. In addition, regulators must assist operators in developing and implementing voluntary strategies to strengthen existing industry systems to prevent the occurrence of foodborne illness risk factors [10].

A food-safety hazard is defined as a biological, chemical or physical agent in a food, or condition of food with the potential to cause an adverse health effect.The main risks to human health associated with milk and dairy products fall into three main categories: biological, chemical and physical [11].

Biological Hazards: Milk and dairy products can harbor a variety of microorganisms, including many zoonotic bacteria and some viruses (e.g. retroviruses and cytomegalovirus). Where an animal is healthy, the microbiological quality of milk at the time of milking is generally good; milk from the udder contains very few bacteria (although it may include human pathogens) and the natural inhibitory systems in milk prevent a significant rise in microbial cell counts for the first three or four hours at ambient temperatures (Table 1) [12].

Although milk produced from the mammary glands of healthy animals is initially sterile, microorganisms are able to enter the udder through the teat duct opening. Once milk is secreted from the udder, it can be contaminated from many sources (air, faces, bedding material, soil, feed, water, equipment, animal hides and people). The prevalence of pathogens in milk is influenced

Table 1: The Main causes of food safety hazards

Biological hazards	Chemical hazards	Physical hazards
•Pathogenic bacteria (including toxin-producing bacteria)	•Naturally occurring toxins	•Metal fragment
•Toxigenic moulds/fungi	•Direct and indirect food additives	•Glass pieces
•Parasites	•Pesticide residues	•Hair
•Viruses	•Heavy metals	•Insect parts/fragments
	•Chemical contaminants from packaging material	•Stones
	•Environmental contaminants (e.g. dioxins)	•Bone fragments
	•Allergens	•Jewellery
	•Veterinary drug residues	

Source: [19].

by numerous factors such as farm size, number of animals on the farm, dairy herd health and hygiene in the dairy farm environment, farm management practices, geographic location and season [13].

Quality control occurs at every step in the production, as a raw material on farm condition. Consumers, processors and regulatory agencies are increasingly interested in the safety and wholesomeness of milk resulting in increased emphasis on the farm management to insure the production of milk quality [10].

On arrival at the processing site, the milk is transferred to bulk storage tanks, or silos, prior to processing. The milk may be stored in the silos for 2-3 days and further growth of psychrotrophic bacteria is likely during this period. The degree of growth is dependent on the initial microbial load and the storage time and temperature. Pseudomonads are the predominant organisms present in stored raw milk, with *Pseudomonas fluorescens*, *Pseudomonas fragi* and *Pseudomonas lundensis* being commonly isolated. The growth of psychrotrophic bacteria may also be accompanied by the production of heat-stable, extracellular proteolytic and lipolytic enzymes. These enzymes are often capable of surviving pasteurization and, in some cases, ultra high temperature (UHT) processing and they may subsequently cause spoilage in the processed milk [14].

In most cases, pathogens must grow or multiply in food to certain levels in order to cause

Food Borne Illness. The Following Factors Can Affect the Growth of Pathogens

Nutrients: Bacteria require food and water to carry on their life processes. Since what you are producing is a food product, nutrients are going to be available. Equipment that contains food residue can also be a nutrient source for bacteria.

Temperatures: Another essential factor that affects the growth of bacteria is temperature. Growth can occur over a wide range of temperatures from about 14°F to 194°F, but individual bacteria have much narrower temperature ranges for growth.

Time: It's not just the temperature that's the problem; it's the time at these temperatures that can affect growth of bacteria. The goal is to minimize the time of exposure of foods to temperatures where bacteria grow most quickly.

Moisture: The amount of available moisture in a food is measured as water activity. When substances like salt and sugar are added to water is tied up and is less available to the bacteria. The water activity of some foods is listed below:

Inhibitors: Foods can contain chemicals that are either natural or added that restrict or prevent growth of microorganisms. Salt is a good example of an added chemical that can inhibit growth of bacteria. Chemical preservatives like sodium nitrite, sodium benzoate and calcium propionate can also inhibit the growth of microorganisms.

pH: pH shows how acid a food is. pH ranges from 0 – 14 with 7 being neutral. Foods with a pH of 4.6 and below are considered acid foods, like most fruit juices. Foods with a pH above 4.6 are said to be low acid, like meats and vegetables. Most bacteria don't grow very well in acid foods, so you can use pH to control the growth of bacteria. Generally, food is considered to be in a safe pH range when the fi nal pH is 4.6 or below.

Atmosphere: Some bacteria require a specific type of atmosphere for growth. Microorganisms are categorized as aerobes, anaerobes, facultative anaerobes and microaerophilic Aerobes require oxygen and include such bacteria as Bacillus. Anaerobes grow only in the absence of molecular oxygen. These organisms include Clostridium. Facultative anaerobes can grow whether the environment has oxygen or not. Micro aerophilic is a term applied to organisms, which grow only in reduced oxygen

environments. Knowledge of the atmosphere surrounding the food is an especially important consideration in determining which pathogens are likely to be a problem.

Chemical Hazards: Chemical hazards include contaminants (heavy metals, radionuclides, persistent priority pollutants, e.g. polychlorinated biphenyls (PCBs) or dioxins and mycotoxins) and residues of other chemicals that are used or added during the animal production or manufacturing processes, such as veterinary drugs, pesticides, substances migrating from packaging materials (e.g. isopropyl thioxanthone (ITX) and bisphenyl) [15]. The source of chemical hazards varies and may include air, soil, water, substances used in animal husbandry practices and animal feedstuffs. Special attention should be given to chemical food safety hazards as once they are present in concentrations greater than the acceptable daily intake (ADI) or acute reference dose it may be difficult to reduce them to an acceptable level during processing (Table 1) [16].

Problems may still exist where highly or moderately persistent pesticides are used in malaria control programmes and against agricultural pests and livestock endo- and ecto-parasites. This may result in contamination of air, water and soil with residues and their subsequent transfer to milk producing animals such as cows and buffaloes if they feed on contaminated grass or hay, drink contaminated water or inhale them as aerosols. Being highly lipophilic, organochlorine pesticides accumulate in the fat of animals and are excreted through milk. Several health effects of such pesticides have been reported, ranging from systemic effects on cardiovascular and respiratory function to genotoxic effects. It is therefore imperative that, the level of pesticide residues is kept well below recommended tolerance levels to minimize the risk to human health [17].

Physical Hazards: A physical hazard may be defined as any physical material not normally found in a food which may cause illness or injury to the individuals using the product. The potential health costs of a physical hazard are likely to be greater if the company is producing a sensitive product, such as infant formula and infant foods that contain milk. These manufacturers have some of the best programmes in the world for ensuring that foods produced are free of foreign material, especially glass and are scrupulously clean and processed to exacting standards of safety (Table 1) [18].

Physical contaminants like dirt particles, hair, leaves, rubber and mettle particles, paper pieces etc can get into the milk at the time of milking. The dirt particles from air even, an unclean udder or body of the cow, unclean utensils and water supply can also contaminate the milk. The hair of the body of the cow can also fall into the milk. The habits of the milker can also add some harmful contaminants like smoking tobacco, which can introduce physical contaminants into the milk [16].

Haccp in Milk and Milk Products

Definition: HACCP is a science-based analytical tool that enables management to introduce and maintain a cost-effective ongoing food safety program. It involves the systematic assessment of all the many steps involved in a food operation and identification of those steps that are critical to the safety of the product. It is an operation-specific, internally managed systems of preventative control that identifies, evaluates and controls hazards of signicance to food safety. While it has a relatively long history, originating as a means of assuring the safety of meals produced for the first USA astronomical space program in the 1960s, it is only in the last 10 years that, it has emerged as the primary approach to securing the safety of the food supply [20].

It is a process that identifies and assesses the hazard and risk associated with the manufacture, storage and distribution of foods and implements the appropriate control aiming at the elimination or reduction of these hazards at specific points of production line. The ultimate goal of HACCP program in the dairy plant is to eliminate all public health risk. Most steps and procedures required for a HACCP program are likely already being monitored in dairy plants. Many dairy plants need only to reorganize their record keeping system to facilitate full implementation of the HACCP program. As such, the actual cost of implementation of a HACCP program is usually quite small [21]. Prerequisite Programs of HACCP: Prior to the implementation of a HACCP Plan, there is a requirement for dairy plants, receiving stations and transfer stations to develop, document and implement written prerequisite programs. PP's provide the basic environment and operating conditions that are necessary for the production of safe, wholesome food. In order for a HACCP system to be effective, a strong foundation of procedures that address the basic operational and sanitation conditions within an operation must first be developed and implemented. These procedures are collectively termed prerequisite programs. When prerequisite programs are in place, more attention can be given to controlling hazards associated with the food and its preparation. Pps are the universal procedures used to

Table 2: Examples of common prerequisite programs

Maintenance	416.1–3. 416.6	Equipment is designed and constructed with sanitary practices in mind. Preventive maintenance and calibration schedules established and documented
Personal Hygiene	416.1, 416.5	All employees and other persons who enter and work in the manufacturing plant must follow the proper hygienic practices
Pre-operational Sanitation	SSOPs 416.1, 416.11-17	This program documents that food is produced using sanitary practices in a sanitary facility using sanitary equipment prior to the start of daily operations
Operational Sanitation	SSOPs 416.1,416.11-17	This program documents that sanitary practices are maintained during processing
Pest Control	416.2	Effective pest control programs should be in place and monitored
Storage and Shipping	416.1-416.4	All raw materials and products should be stored under sanitary conditions and proper environmental conditions to assure their safety
Traceability and Recall	Requirement of the Bioterrorism Act of 2002, Section 306	All raw material and finished products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary
Supplier Control		Facility should ensure that supplier has in place effective Good Management Practices and food safety programs.

Source [25].

control the condition of the plant environment that contribute to the overall safety of the product. They represent the sum of programs, practices and procedures that must be applied to produce and distribute safe products in a clean, sanitary environment [22].

PP's differ from CCP's in that they are basic sanitation programs that reduce the potential occurrence of a food safety hazard. Frequently, both HACCP Plan CCP's and PP's control measures are necessary to control a food safety hazard. The exact set of PP's will vary since their application is product and process specific. The existence and effectiveness of PP's should be assessed during the design and implementation of each HACCP Plan. PP's should be documented and regularly audited. An audit review consists of verifying that the company has a program implemented that indicates how the company monitors and controls each of the PP's. PP's are established and managed separately from the HACCP Plan [23].

The basis for HACCP programs is PP's. These programs include food temperature control, cleaning and sanitizing, employee personal hygiene and pest control. These programs should be formally documented and implemented through Standard Operating Procedures (SOP). The SOP will include several of the prerequisites including supplier control, specifications, cleaning and sanitation, personal hygiene, chemical control, receiving and storage, transportation (shipping), traceability and recall and pest control. The SOP will be presented by functional areas, including each of these aspects of the production system. If SOP currently exist, they need to be reviewed Carefully to determine if food safety controls and monitoring are included adequately (Table 2) [24]

The five preliminary steps of HACCP as outlined by the National Advisory Committee of Microbiological Criteria for Foods (NACMCF) will help the producers in conducting hazard analysis and developing the HACCP plan and will prove valuable for other HACCP functions. The steps that should follow are: Assemble a HACCP Team. Describe the food and its distribution. Identify the intended use and consumers of the food. Develop a flow diagram that describes the process. And verify the accuracy of the flow diagram [21].

Assembly of a HACCP Team: The formal method of HACCP requires a multi-disciplinary team approach. This should include representatives from a range of disciplines and have personnel who have expertise in areas such as Production, Technical/Quality, Engineering/Maintenance and Hygiene. The team should have specific knowledge of HACCP and relevant knowledge of product, processes and associated hazards [23]. An effective HACCP team is empowered by management, multidisciplinary and knowledgeable of their product and process being evaluated. Appropriate multidisciplinary team member selection is the first step in the process. Once selected, team members must receive foundational HACCP training. Additionally, it is important that the team have a depth and breadth of knowledge of the product being produced and the specific production system [26].

Flow Diagram: The flow diagram is made of four parts: raw material, processing, critical limits and adjustment. The reason is the producer needs to check the condition of each step during processing. If it is inside the critical limits, the process continues; otherwise the process is stopped and the proper adjustment is made. The adjustment is determined based on the temperature, time and salt change. If the condition cannot be controlled the product will be rejected (Fig 1) [27].

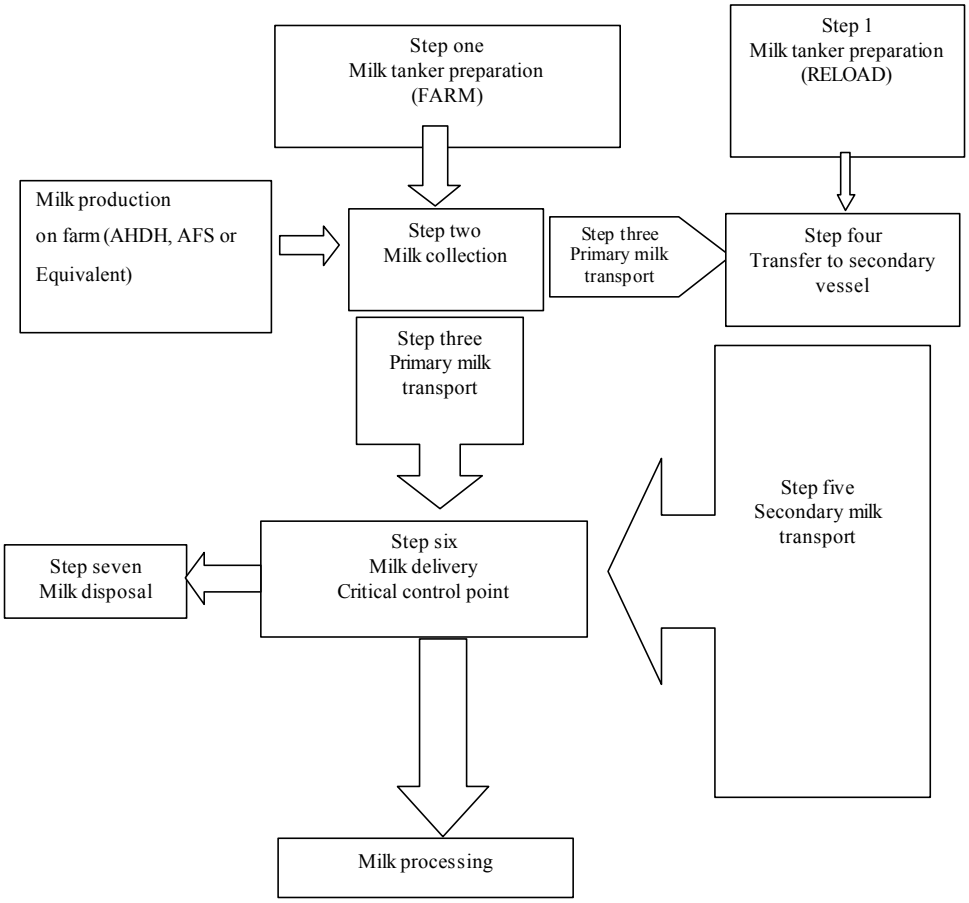

Fig. 1: Flow diagram, source [25].

Principles of HACCP: HACCP is a preventive system for the production of safe food products. It is based on technical and scientific principles applicable to every step of the food production chain, from growing/breeding activities, to production and distribution systems, to the moment the food reaches the final consumer. The HACCP procedure is generally targeted at food safety management (control of pathogenic microorganisms and their toxins), but, as an approach in the context of broader quality management, it can be effectively applied to microbiological spoilage, foreign body contaminations or pesticide contamination. It is preferable to conduct a HACCP program with a narrow scope (a single pathogen or possibly pathogens) rather than attempt to cover an extended list of hazard areas when documentation will become complex [26].

However, an experienced team might choose to cover the whole spectrum of hazards which is depending on the resources available to produce and maintain a composite HACCP plan and the way in which it is to be incorporated into the local quality plan and quality system. The emphasis within quality assurance has turned to the avoidance of problems, a concept that forms the basis of HACCP. There are seven principles in establishing an effective HACCP plan, which is used in conjunction with the prerequisite programme and other associated parts of the entire HACCP programme [28 *Principle one: Conduct a hazard analysis:* A thorough hazard analysis addressing food safety hazards is the key to preparing an effective HACCP plan. The hazard analysis is necessary to identify hazards whose elimination or reduction to acceptable levels is essential to the production of a safe food. All biological, chemical and physical hazards should be considered. This step can be used to go through the process systematically, identify the hazards which might occur at each step in the process and measures which can be used to prevent, eliminate or reduce each hazard to an acceptable level [29].

Principle two: Identify the critical control points: A Critical control point (CCP) is defined as a step at which control can be applied and is essential to prevent or

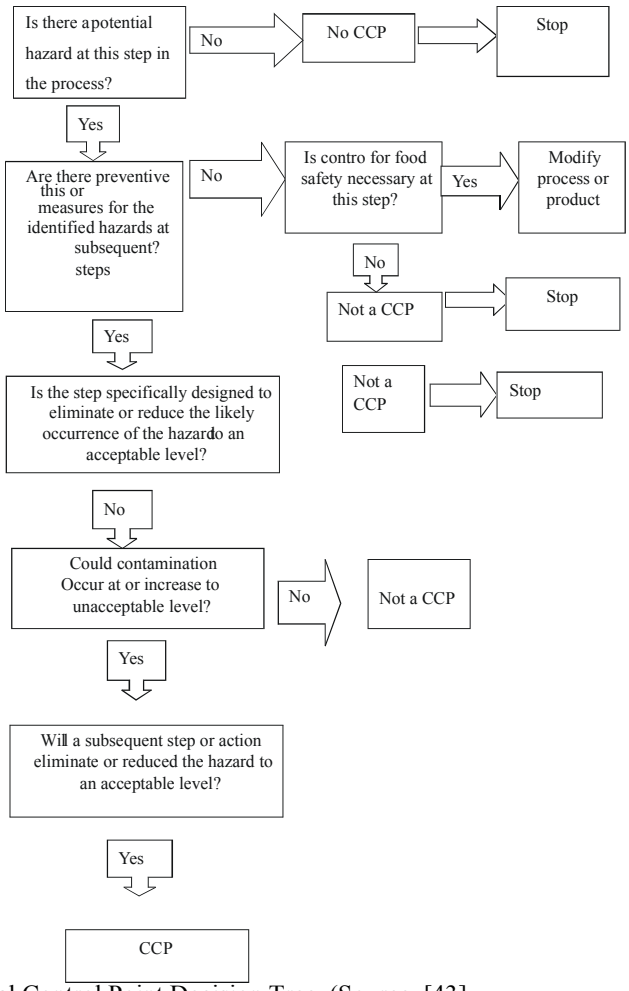

Fig. 2: Example of a Critical Control Point Decision Tree, (Source, [43]

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. Complete and accurate identification of CCPs is fundamental to control 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 [30].

CCP are located at any step where hazards can be prevented, eliminated, or reduced to acceptable levels. For each food safety hazard that is likely to occur, a preventive measure must be identified at a point or points in the process where these preventive measures should be applied Common examples of CCPs include cooking, cooling, hot holding and cold holding of ready to drink potentially hazardous foods (time/temperature control for safety foods). Due to vegetative and spore- and toxin-forming bacteria that are associated with raw animal foods, it is apparent that the proper execution of control measures at each of these operational steps is essential to prevent or eliminate food safety hazards or reduce them to acceptable levels [31].

The main objective of Critical Control Points (CCP) is to identify problems before they occur and establishing control measures that are critical to maximizing food safety at each stage in the production process. In this study, the identification of critical control points in dairy sector, the identification of all potential hazards in raw milk, pasteurized milk, Ultra High Temperature (UHT) milk, cheese, ice-cream, butter and yoghurt production are reviewed. Description of critical control points, evaluation and orientation applied to prevent and control the critical points were presented [2].

One strategy to facilitate the identification of each CCP is the use of a CCP decision tree, to provide a logical, structured approach to decision making. However, application of the decision tree should be flexible and its

use may not always be appropriate (Fig 2) [32]. It is also essential that the HACCP team has access to sufficient technical data to determine the CCPs effectively. If a significant hazard has been identified at a step where control is required for safety, but for which no control exists at that step or any other, then the process must be modified to include a control measure [33].

Unless a suitable, separate place is provided for the cooling, handling and storing of milk and for the washing, sanitizing and storage of milk utensils, the milk or the utensils may become contaminated. Construction, which permits easy cleaning, promotes cleanliness. A well-drained floor of concrete or other impervious material promotes cleanliness. Ample light promotes cleanliness and proper ventilation reduces the likelihood of odors and condensation. A milk house that is separated from the barn, stable or parlor and the living quarters provides a safeguard against the exposure of milk and milk equipment and utensils to contamination [34].

All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milk house in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as milker claws, inflations, weight jars, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria, may be mechanically cleaned, sanitized and stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution contact surfaces from contamination at all times. Some of the parameters to be considered in determining protection are: Proper location of equipment, Proper drainage of equipment; and Adequate and properly located lighting and ventilation [35].

The milking barn or parlor must be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of animals. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milk house. Provided, in the case of a milking parlor that opens directly into an enclosed housing area, through a covered holding area, the holding area may be seasonally enclosed when: There are no manure pit openings in the parlor, holding area or in the housing area close enough to affect the milking parlor, the cattle holding and housing areas are maintained in good repair and reasonably clean and with respect to dust, odors, rodents and insects, the entire area meets milking parlor standards and the parlor is free of evidence of birds [36].

Adequate hand washing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent and individual sanitary towels, convenient to the milk house, milking barn, stable, parlor and flush toilet. Adequate hand washing facilities are essential to personal cleanliness and minimize the likelihood of contamination of the milk. Hand washing facilities are required in order to increase the assurance that milker's and bulk milk hauler/sampler's hands will be washed. Hand washing facilities are located convenient to the milk house, milking barn, stable, parlor and flush toilet. Hand washing facilities include soap or detergent, hot and cold, or warm running water, individual sanitary towels and a lavatory fixture. Hands are washed, clean and dried with an individual sanitary towel immediately before milking; before performing any milk house function; and immediately after the interruption of any of these activities. Milkers and bulk milk hauler/samplers wear clean outer garments while milking or handling milk containers, utensils or equipment [61], Raw milk for pasteurization shall be cooled to 10°C (50°F) or less within four hours or less, of the commencement of the first milking and to 7°C (45°F) or less, within two hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F) [38].

Effective measures shall be taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents and by chemicals used to control such vermin. Milk houses shall be free of insects and rodents. Surroundings shall be kept neat, clean and free of conditions, which might harbor or be conducive to the breeding of insects and rodents. Feed shall be stored in such a manner that it will not attract birds, rodents or insects. Proper manure disposal reduces the breeding of flies, which are considered capable of transmitting infection by physical contact or through excreta to milk or milk containers, utensils or equipment. Insects visit unsanitary places, they may carry pathogenic organisms on their bodies and they may carry living bacteria for as long as four weeks within their bodies and they may pass them on to succeeding generations by infecting their eggs [38].

Effective screening tends to prevent the presence of flies, which are a public health menace. Flies may contaminate the milk with microorganisms, which may multiply and become sufficiently numerous to present a public health hazard. The surroundings of a dairy should be kept neat and clean in order to reduce insect and rodent harborages [39]. Rooms in which milk or milk

products are handled, processed, stored, condensed, dried and packaged, or in which containers, utensils and/or equipment are washed or stored, shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes. Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged milk and milk products [40]. The floors of all rooms in which milk or milk products are handled, processed, packaged, or stored; or in which milk containers, utensils and/or equipment are washed, shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped, provided with trapped drains and kept in good repair. Provided, that cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Provided further, that storage rooms for storing dry ingredients, packaged dry ingredients, packaged dry milk or milk products and/or packaging materials need not be provided with drains and the floors may be constructed of tightly joined wood [41].

Floors constructed of concrete or other similarly impervious material can be kept clean more easily than floors constructed of wood or other pervious or easily disintegrating material. They will not absorb organic matter and are; therefore, more apt to be kept clean and free of odors. Properly sloped floors facilitate flushing and help to avoid undesirable conditions. Trapping of drains prevents sewer gas from entering the milk plant [42].

Principle Three: Establish Critical Limits: CCP requires establishing critical limit(s) for criterion separating acceptability from unacceptability, validating the critical limit(s), making the measurements that are needed to monitor criterion and timely detect deviations [44]. 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 of 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. Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated or reduced to acceptable levels and control measure has one or more associated critical limits. Critical limits are conducted based upon factors such as: temperature, time, pH, salt concentration, preservatives, or sensory information such as aroma and visual appearance [45].

Principle Four: Establish Monitoring Procedures: 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 loss of control and a deviation occurs at a CCP, i.e., exceeding or not meeting a critical limit. When a deviation occurs, an appropriate corrective action must be taken. Finally, it provides written documentation for use in verification [46].

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. P^H 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 [47].

The workers responsibility for monitoring is an important consideration for each CCP. Specific responsibility 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 should 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 towards loss of control. So that adjustments can be made in a timely manner to assure that the process remains under control [48].

Principle Five: Establish Corrective Actions: The purpose of corrective actions is to prevent foods which may be hazardous from reaching to consumers. Where there is a deviation from established critical limits,

corrective actionns are necessary. Therefore, corrective actions should include the following elements: determine and correct the cause of non-compliance, determine the disposition of non-compliant product and 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 [49].

As 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. Corrective actions must ensure that, the CCP has been brought back under control. They must also include appropriate disposition of any affected commodity or product. Whenever possible an alarm system should be introduced which will activate when monitoring indicates that, the critical limit is being approached. Corrective action can then be applied to pre-empt a deviation and prevent the need for any product disposition [50].

Principle Six: Establish Verification Procedures: 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 National Academy of Science pointed out that a HACCP system centers on proper identification of the hazards, critical control points, critical limits and instituting proper verification procedures to control food safety. These processes should take place during the development and implementation of the HACCP plans and maintenance of the HACCP system [51].

One aspect of verification is evaluating whether the facilities of 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 [52].

In addition, a periodic comprehensive verification of the HACCP system should be conducted by an unbiased, independent authority. Such authorities can be internal or external to the food operation. This should include a technical evaluation of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from operation of the plan. A comprehensive verification is independent of other verification procedures and must be performed to ensure that the HACCP plan is resulting in the control of the hazards. It is important that individuals doing verification have appropriate technical expertise to perform this function [53]. Principle seven: Establish effective record keeping procedures**:** Efficient and accurate documentation and record keeping are essential to the application of a HACCP system and should be appropriate to the nature and size of the operation. Examples of activities for which documentation is required include: hazard analysis, CCP determination, HACCP plan and critical limit determination. Another examples of activities for which records are required include: CCP monitoring activities, process steps, associated hazards, critical limits, verification procedures and schedule, deviations, associated corrective actions and modifications to the HACCP system [54].

Benefits of HACCP System: HACCP is a systematic method, preventive and science based, which first priority is the safety of the products through risk identification and risk management in the production process. It has a proactive, rather than reactive approach, emphasizing food hazard prevention rather than the detection of harmful defects in finished food products. Its main objective is to identify problems before they occur, establishing control measures that are critical to maximizing food safety at each stage in the production process [55].

The key benefits of HACCP in the food and dairy industry includes: the potential to identify all hazards in the manufacturing process so that controls can be established to assure food safety. It is a systematic approach relevant to all stages of food processing covering agriculture and horticultural practices, harvesting, processing, product distribution and customer practices, is the preferred risk management tool in total quality management, focuses technical resources on critical parts of the process and provides a cost effective control of food borne hazards and facilitates the move from retrospective end-product testing to a preventative quality assurance approach enabling the producer to produce safe food and reduce reject waste [56].

Effectiveness of HACCP: Hazard analysis critical control point begins with the understanding that, if one opens a retail food establishment that serves food to consumers, one must know that, the raw food coming from the

wholesale system is normally contaminated with enough vegetative pathogens to cause a customer foodborne illness and put an operation out of business [47]. The preventative nature of the HACCP approach to the management of food safety comes through its identification, evaluation and control of hazards thatcould cause harm to the consumer. It proactively identifies potential food safety hazards and implements control systems before the hazards are realized. Hazard analysis critical control point cannot guarantee zero tolerance for all food hazards 100% of the time due to variability in materials and processes in conjunction with the potential for control procedure failure and human error, so it should be considered as a risk management system that can minimize the likelihood of food safety hazards occurring [58]

However a rigorously designed, fully and securely managed and controlled HACCP System should come as close to zero tolerance as technically and operationally feasible in a food operation. There are very few records of foodborne disease outbreaks, in which a food company operating with effective HACCP system has been implicated [59]. Verification is also 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 includes: expert advice and scientific studies and in plant observations, measurements and evaluations [60].

Hazard analysis critical control point needs to be built on 4 Pillars, i.e. management commitment, education and training, availability of resources and external pressures and that sustainable HACCP can only be built as a result of internal pressure and support (i.e. the decision to apply HACCP is internal to the company and its management), the alternative being an unsustainable model that is the result of external pressure (i.e. the company is pushed into HACCP application by others, e.g. customers or regulator [61].

Factors which impact HACCP effectiveness falls into three main groups: personnel factors, operational management factors and environmental factors. Personnel Factors; Knowledge and understanding of the principles of HACCP are normally achieved through training, which is believed to be a key aspect of successful HACCP. Operational management factors relating to management commitment, resources and management support for the ongoing functioning of HACCP systems have been widely identified as key requirements for effective HACCP development, implementation and maintenance. Lack of employee motivation is also one of the most frequently barriers identified to implement an HACCP based food safety management system [62].

Environmental factors; are the items that may influence the operation from the outside, e.g. legislative requirements for HACCP and other outside pressures such as customer specifications. It is possible that other general factors operating at a local business level, such as dimensions of national and regional culture, might impact the HACCP process and HACCP effectiveness [55].

CONCLUSIONS AND RECOMMENDATIONS

Hygienic milk production is not only important with respect to the quality of the bulk tank milk, but also for animal welfare. Microorganisms in bulk tank milk at the farm originate from the interior of teats, the farm environment and surfaces of the milking equipment. Different microorganisms have different origins and, hence, require different control measures. The use of food safety and quality assurance in farms and plants is very important to reduce chemical and microbiological hazards in milk and dairy products. A regulatory law implementation in milk and dairy industries and long term planning is required to achieve milk safety. HACCP is an improved system compared to the traditional sampling and testing of quality control. Not only because it is a prevention instead of a reaction which reduces the risk of processing and selling unsafe products, but also because it is a cost-effective program which is fairly useful in milk and milk products production. Operational pre-requisite programs and risk analysis need to be established for the effective applicability of HACCP that determine physical, chemical and microbiological hazards in dairy industry. The promotion of HACCP by government agencies worldwide as the panacea for foodborne disease control is relatively subjective. Perception of management commitment and its importance by the workforce along with its potential impact on the HACCP process requires further study. There are no internationally agreed tools and methods for the measurement of HACCP effectiveness and the factors impacting HACCP success.

Therefore based upon the above conclusion the following recommendations are forwarded:

- Workers participated in milk production sector should be well trained in the monitoring technique of HACCP principles.
- The HACCP system should be promoted by government agencies worldwide as a cure for foodborne disease control.

- Internationally agreed tools and methods for the measurement of HACCP effectiveness should be developed.

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