GAP ANALYSIS AND EVALUATING RECOMMENDATIONS FOR THE IMPLEMENTATION OF ISO 22000 IN KEELLS FOOD PRODUCTS FACTORY

By

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DECLARATION

The work describe in this thesis was carried out by me at the Department of Food Science & Technology, Faculty of Applied Sciences, Sabaragamuwa University of Sri Lanka, under the supervision of, Mr. A.L.C.J. Liyanage and Mr. Lasath Ratnayake. The report on this has not been submitted to another university for another degree.

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Affectionately Dedicated

To My Parents

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ABSTRACT

Ensuring food safety is increasingly important in our Global market. Food safety is linked to the presence of food– born hazards in food at the point of consumption. Since food safety hazards can occur at any stage in the food chain it is essential that adequate control be in place. ISO 22000 standard dealing with food safety and effective implementation of the ISO 22000 in Keells factory they willing to continually improve its manufacturing facility, process control systems and the supplier base for the realization of safe processed meat/fish products. The present study was focused on the perform Gap analysis and evaluating recommendations for the implementation of ISO 22000 in Keels Food factory.

First approach was compliance assessment of document requirement with ISO 22000 FSMS and external communication, hazard analysis of cut meat range products, validation plan and the procedure and internal audit plan identified as documentation gap. To fulfill the above documentation gap procedures and the plan were developed.

Evaluation of PRP was used as the universal procedure to control food safety and as ISO 9001 certified company of KFPL, GMP and PRP currently established for factory critically evaluated in preliminary study and analyzed weakness and area would have to modify. Modification of factory lay out and the accommodation of equipment in suitable places cause reduction of the cross contamination. Possibility of food contamination by workers hand was high and should monitor the personnel hygiene.

Emergency preparedness program was evaluated by referring factory evacuation plan and the procedure manual and lack of training and awareness of workers about emergency procedure (fire drill & training) in factory cause gap in implementation. Recover the gap of ISO 22000 requirements in KFPL hazard analysis of cut meat range product was carried out. Onsite verification of flow diagrams of different kind of products flow in factory was carried out and Ham and Bacon Process flow diagrams were updated. OPRP and the CCP were identified and developed plan for the validate OPRPs and CCPs.

Achieving 72^0C and maintain 72^0C for 1 minute was identified as adequate core temperatures for chamber cooking process. It is expected that developed internal audit plan ISO 22000 carried out every six month. Evaluation of individual verification of raw meat chills and other cold storage conditions indicated needed for maintaining temperature at 0^0C - 4^0C and freezers below -18^0C. An effective implementation and maintaining of PRPs of personal hygiene, lighting levels of factory and cleaning procedure and the cleaning frequency of deboning section need to be conducted as further improvements measures

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LIST OF ABREVIATIONS

AMI	Anti Mortem Inspection
AQAM	Assistant Quality Assurance Manager
CCP	Critical Control Point
CR	Critical
CO_2	Carbon dioxide
CS	Cleaning and sanitation
FSMS	Food Safety Management System
GMP	Good Manufacturing Practices
HEM	Harmful Extraneous Matter
HACCP	Hazard Analysis Critical Control Point
ITI	Inspection and Testing Institute
IT-RM	Inspection & Testing Incoming Raw Material
ISO	International Organization for Standardization
KFPL	Keells Food Products PLC
Kg	Kilogram
LDPE	Low Density Poly Ethylene
MA	Major
MI	Minor
OPRP	Operational prerequisite programs
PMI	Post Mortem Inspection
PRP	Prerequisite programs
SA	Satisfactory
SLSI	Sri Lanka Standard Institute
SLS	Sri Lankan Standard
SSOP	Standard Sanitary Operating Procedure
Sec	Seconds
TPC	Total Plate count
TS	Technical Specification
TPC	Total Plate Count
US	Unsatisfactory
QM	Quality Manual
QMS	Quality Management System

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CHAPTER 01

INTRODUCTION

1.1. Background:

Industrialization together with mass production leads to increased risk of food contamination and a considerably larger number of people affected in food borne disease outbreaks as a result of changing lifestyles demand from vast number of people to eat outside the home every day in food service or catering establishments at street food stalls or in fast-food restaurants.

The International Organization of Standardization (ISO) created the very successful quality management system standard ISO 9001 used worldwide companies. Therefore, as the need for an international standard for the food industry became apparent, ISO started a working group to develop a Food Safety Management System (FSMS).

Therefore today, ISO 22000 standard developed by the International Organization for Standardization deal with food safety. The ISO 22000 international standard specifies the requirements for a food safety management system that involves the elements of interactive communication, system management, prerequisite programmes & HACCP principles.

Keells Food Products PLC is presently Sri Lanka's market leader in the processed meat industry and enjoys a market share of approximately 70%. A subsidiary company of John Keells Holdings, KFP PLC started its operations in the year 1983, and today takes the pride being solely responsible in developing the Sri Lankan Processed Meats industry to its current heights.

Keells factory manufactures a wide range of Sausages, Meat Balls, Hams, Bacons and more. It incorporates some of the most modern semi-automated machinery, conforming to international standards for hygiene and safety, such as sausage linking machine (to automate the portioning and hanging process, at high speed), peeler machine, slicer machine (high speed, automated slicing and stacking) and a Thermoform Packaging Machine.

KFP PLC holds ISO 9001 certification awarded by the Sri Lanka Standards Institution (an accredited organization of RVA, Netherlands) and obtains the SLS mark for the category of "Sausages". However ISO 22000 standard has not yet been implemented. Hence the Keells Food Products PLC plans to implement ISO 22000 FSMS with the aim of providing wholesome, quality products with ensuring the consumer safety related to their wide range of products of processed meat, fish meat & raw meat products.

Ensuring food safety is increasingly important in our global market. Food safety is linked to the presence of food-borne hazards in food at the point of consumption. Since food safety hazards can occur at any stage in the food chain, it is essential that adequate control be in place. Therefore, a combined effort of all parties through the food chain is required.

Through effective implementation of the ISO 22000 at Keells factory, the management plans to continually improve manufacturing facilities, process control systems and the supplier base for the realization of safe processed meat/fish products. Gap Analysis is the fastest, most efficient way to assess how organization measures up to the requirements of a particular standard (HACCP, ISO 2200 etc.) and to define the corrective actions required for being compliant. It is expected to perform a gap analysis & presents recommendations of ISO 22000 in Keells factory in line with the existing process.

1.2. Overall Objective:

- To perform a gap analysis & evaluating recommendations for the implementation of ISO 22000 in Keells food products Factory

1.3. Specific Objectives:

- To assess the compliance of documentation requirements with ISO 22000 FSMS standard.

- To evaluate of the pre requisite programs (PRP's).
- To identify & evaluate of selected key procedures in the standard.
    - Emergency Preparedness and Response (ISO 22000 Clause No:5.7)
    - Planning and evaluation of safe Products (ISO 22000 Clause No 7)
    - Validation of Control measure combinations (ISO 22000 Clause No 8.2)
    - Internal Audit (ISO 22000 Clause No 8.4.1)
    - Evaluation of individual Results (ISO 22000 Clause No 8.4.2)
- To propose recommendations for filling the identified gaps in order to implement ISO 22000.

CHAPTER 02

LITERATURE REVIEW

2.1. General overview

2.1.1 International Organization for Standardization

The International Organization for Standardization widely known as ISO is an international-standard-setting body composed of representatives from various national standards organizations. The organization promulgates worldwide proprietary industrial and commercial standards. While ISO defines itself as a non-governmental organization, its ability to set standards that often become law, either through treaties or national standards, makes it more powerful than most non-governmental organizations. ISO's main products are the International Standards. ISO also publishes Technical Reports, Technical Specifications, Publicly Available Specifications, Technical Corrigenda, and Guides. The work of preparing International Standards is normally carried out through ISO technical Committees (Wikipedia, ISO, 2008). Publication as an International Standards requires approval by at least 75% of the member bodies casting a vote. ISO 22000 was prepared by technical Committee ISO/TC 34, Food Products.

2.1.2. ISO 22000

ISO 22000 is a generic food safety management system standard. It defines a set of general food safety requirements that apply to all organizations in the food chain. This is a general derivative of ISO 9000 (Wikipedia, ISO 22000, 2008).

2.1.2.1. Food safety

Food safety is a scientific discipline describing handling, preparation, and storage of food in ways that prevent food borne illness. This includes a number of routines that should be followed to avoid potentially severe health hazards. Food can transmit disease from person to person as well as serve as a growth medium for bacteria that can cause food poisoning. Debates on genetic food safety include such issues as impact of genetically modified food on health of further generations and genetic pollution of environment, which can destroy natural biological diversity (Wikipedia, Food Safety, 2008)

2.1.2.2. Food Safety Management System

The Food Safety Management System combines Good Management Practices, Hazard Analysis and Critical Control Point (HACCP) principles and effective supplier verification and validation, ensuring that all actions possible are taken, recorded and verified to ensure safe food, which is based on the HACCP principles (Praxiom, ISO 22000 definitions, 2008).This requires a company policy definition and quality manual, with definition of responsibilities for management and employees, prerequisite programs and HACCP plan implementation, and preparing SSOP programs and measures for implementing the food safety program. Preparing the HACCP team and effective recording systems, and a combination of self assessment with application of internal auditing, management review, application of all legal requirements and supplier evaluation, are other concerns in this system.

2.1.3. ISO 22000 family of standards

- ISO 22000:2005 – Food safety management system - Requirements for any organization in the food chain.
- ISO 22001 - Guidelines on the application of ISO 9001:2000 for the food and drink industry (replaces: ISO 15161:2001).
- ISO TS 22003 - Food safety management systems for bodies providing audit and certification of food safety management systems
- ISO TS 22004 - Food safety management systems - Guidance on the application of ISO 22000:2005.
- ISO 22005 - Traceability in the feed and food chain - General principles and basic requirements for system design and implementation.
- ISO 22006 - Quality management systems - Guidance on the application of ISO 9002:2000 for crop production (Wikipedia, ISO 22000, 2008).

2.1.4. Relationship with ISO 9001

ISO 22000 has been designed to work in harmony with ISO 9001 and its supporting standards. ISO 9001 provides requirements for a quality management system that can

be used for internal application by organizations, or for certification, or contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements. ISO 9001 provides the essential elements of a food safety management system for similar purpose (ISO/TS 22004:2005(E)).

2.1.5. Key elements of ISO 22000 standard

The ISO 22000 international standard specifies the requirements for a food safety management system that involves the following elements:

- Interactive communication;
- System management;
- Prerequisite programmes;
- HACCP principles (SLS ISO 22000:2005).

2.1.5.1. Interactive communication

Communication along the food chain is essential to ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain. This implies communication between organizations both upstream and downstream in the food chain. Communication with customers and supplies about identified hazards and control measures will assist in clarifying customer and supplier requirements (SLS ISO 22000:2005).

2.1.5.2. System management

The most effective food safety systems are designed, operated and updated within the framework of a structured management system and incorporated into the overall management activities of the organization. This provides maximum benefit for the organization and interested parties. ISO 22000 will take due consideration of the requirements of ISO 9001: 2000 in order to enhance compatibility of the two standards and to allow their joint or integrated implementation (Wikipedia, ISO 22000, 2008).

2.1.5.3. Prerequisite programs

Prerequisite programs (PRPs) are the conditions that must be established throughout the food chain and the activities and practices that must be performed in order to

establish and maintain a hygienic environment. PRPs must be suitable and be capable of providing food that is safe for human consumption. PRPs are also referred to as good hygienic practices, good agricultural practices, good production practices, good manufacturing practices, good distribution practices, and good trading practices. PRPs support HACCP plans (Praxiom, ISO 22000 definitions, 2008).

2.1.5.4. HACCP Principles

HACCP stands for Hazard Analysis and Critical Control Point. It was developed by the Codex Alimentarius Commission. HACCP is a methodology and a management system. It is used to identify, prevent, and control food safety hazards. HACCP management systems apply the following methodology:

1. Conduct a food safety hazard analysis.
2. Identify your critical control points (CCPs).
3. Establish critical limits for each critical control point.
4. Develop procedures to monitor critical control points.
5. Design corrective actions to handle critical limit violations.
6. Create a food safety record keeping system.
7. Validate and verify your system. (Praxiom, ISO 22000, 2008)

2.1.6. Benefits of ISO 22000:2005

Benefits of ISO 22000:2005 certification include,

- Clear communication across the entire supply chain.
- Traceability – identification of an organisation's impact on food safety within the supply chain.
- Cost reduction due to a more efficient system.
- Continuous improved business performance in line with the ISO 22000 food safety policy and objectives.
- Better planning, less post process verification.
- Filling the gap between ISO 9001 and HACCP.
- Meets food industry expectations.
- Based on system management, not on inspections or a product approach.
- Provides an opportunity for international recognition through 3rd party registration.
- Saves resources by reducing overlapping system audits.

2.2. ISO 22000:2005 – Food safety management system requirements

2.2.1. General Requirements

The organization establish, document, implement and maintain an effective food safety management system and update it necessary in accordance with the requirements of this International Standard. The organization defines the scope of the food safety management system that is specify the product or product categories, process and production sites that are address by the food safety management system. FSMS develop an effective system that meets the requirements of the standard, document, implement and maintain the system. The system must be evaluated and updated to stay current (ISO/TS 22004:2005(E)).

2.2.2. Documentation Requirements

A food safety management system needs to be documented. The organization must have, as a minimum, a written food safety policy and related objectives, the procedures and records required by ISO 22000 and any other documents that need to ensure the effective development, implementation and updating of the system. (ISO/TS 22004:2005(E)). The following diagram explains the documentation requirements of ISO 22000.

Figure2.1: Documentation requirements hierarchy of food safety management system

2.3. Management Responsibility

2.3.1. Management commitment

Management must be involved in and committed to the FSMS. They will write the Food Safety Policy and be responsible for making sure it is communicated and implemented. Top Management must be involved in the design and implementation of the FSMS. Many specific responsibilities are assigned to Top Management to ensure their input and participation. After implementation Management will conduct management review to ensure continued effectiveness of the system (Praxiom, ISO 22000, 2008).

2.3.2. Food safety policy

A food safety policy statement formally defines an organization's commitment to food safety. It expresses, in general terms, what top management intends to do about food safety and describes the direction the organization wishes to take. More precisely, a food safety policy statement should express an organization's commitment to the implementation and ongoing maintenance of its food safety management system (FSMS). The food safety policy should drive the establishment of the FSMS should also encourage people to update and improve its overall effectiveness (Praxiom, ISO 22000, 2008).

2.3.3. Food safety management system planning

ISO 22000 status that planning of food management system carried out to meet general requirements and the objectives of the organization that support food safety and implementation and maintain done by top management.

2.3.4. Responsibly and authority

Responsibly and authority define by top management and communicated within organization to ensure effective operation and maintenance of FSMS (SLS ISO 22000:2005).

2.3.5. Food safety team leader

Food safety team leader is a central to the food safety management system of any organization and should be a member of the organization and should understand its

food safety issues. Where the food safety team leader has other responsibilities within the organization, these should not conflict with food safety responsibilities (ISO/TS 22004:2005(E)).

2.3.6. Communication

The purpose of communication is to ensure that the necessary interaction occur.ISO 22000 requires that both external and internal communication takes place as part of the FSMS. External communication aims to exchange information in order to ensure that any relevant hazard is controlled at one step through the food chain by interaction (ISO/TS 22004:2005(E)).

2.3.7. Emergency Preparedness and response

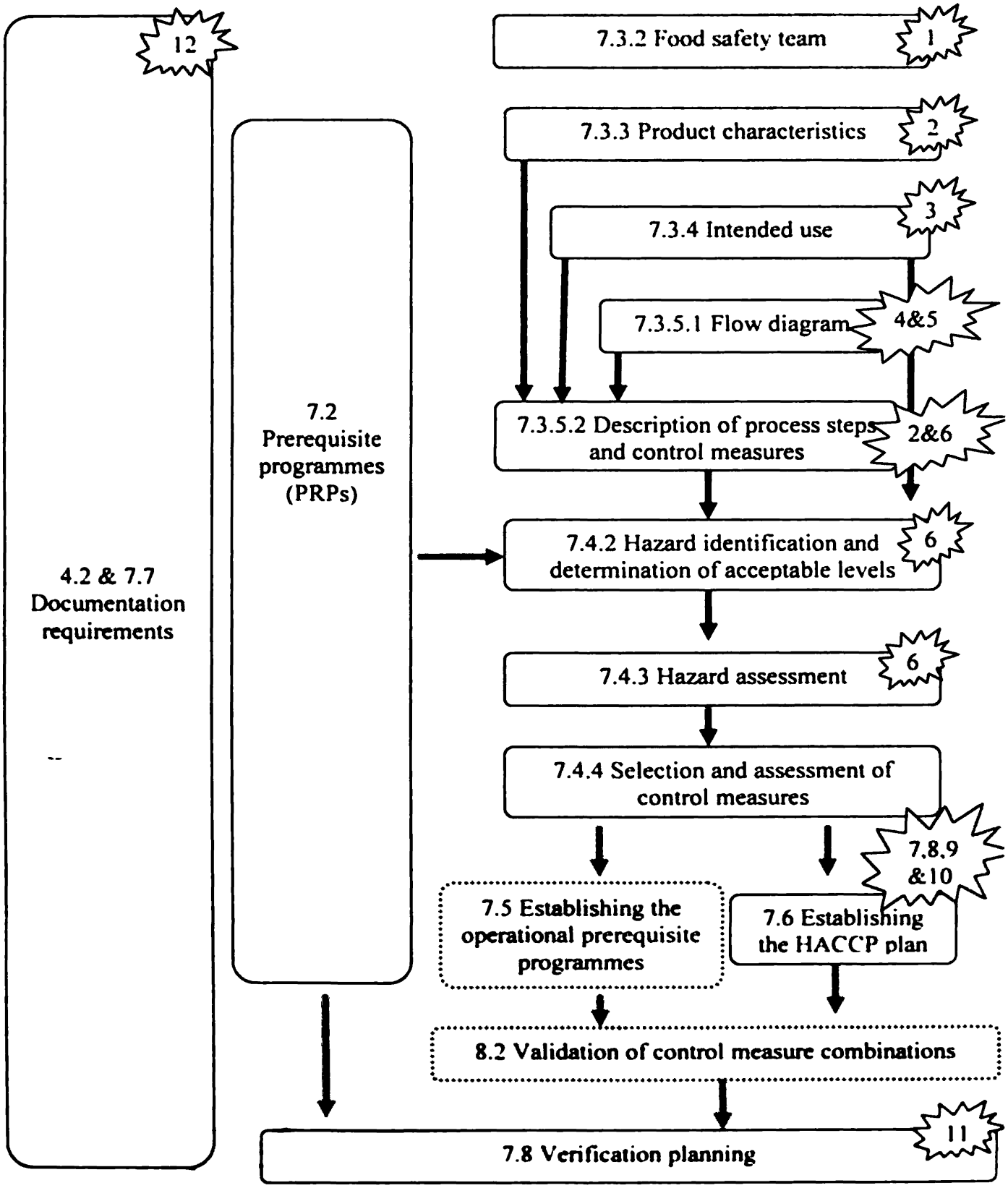
According to ISO 22000 meat base company should aware contaminations, fire, power failure, accidents, incidents and disasters and sudden illnesses or outbreaks like potential food emergency situations and top management must be prepared to respond to these situations.

2.3.8. Management Review

Management must review the food safety management system to ensure its continuing suitability, adequacy and effectiveness. The review also facilitates the assessment of opportunities for improvement and the need for change to the system, including the food safety policy. This review should take place at planned intervals. In the early stages of implementation, these intervals may be shorter than when the system is mature (ISO/TS 22004:2005(E)).

2.4. Planning and realization of safe products

Company shall establish and maintains documented plans and procedures to ensure that processes and sub-processes are conducted under controlled conditions and yield safe products. Planning of the realization processes is consistent with the other requirements of Company's food safety management system (Figure 2.2).Company shall implement, operates and ensures the effectiveness of the planned activities and any changes to those activities. This includes PRP(s) as well as operational PRP(s) and/or the HACCP plan (ISO/TS 22004:2005(E)).



Key

Step addressed by the codex Alimentarius HACPP Guidelines

Step specific to ISO 22000

Figure 2.2.: Planning of safe foods (Source: ISO/TS 22004:2005)

2.4.1. Preliminary step to hazard analysis

2.4.1.1. Food safety team

The food safety team is comprised of multi-disciplinary members that posses the required knowledge and experience in developing and implementing the food safety management system. This includes, but is not limited to, company's products, processes, equipment, and food safety hazards within the scope of the food safety management system. Records that demonstrate that the food safety team has the required knowledge, skills, and experience are maintained per the Control of Records Procedure (Praxiom, ISO 22000 definisions, 2008).

2.4.1.2. Product Characteristics & Intended use

All the raw material, ingredients and product contact material described and identify the statutory and regulatory requirements related to above details. Reasonably expected group of uses or appropriate group of consumers for product described to the extent needed to conduct the hazard analysis (SLS ISO 22000:2005).

2.4.1.3. Flow diagrams

On site confirmation of Flow diagrams

The efficiency of the HACCP plan depend on the expertise used during its development, and the correctiveness of the data used. Assessment therefore starts with an evaluation of these two points. As has been mentioned before, not only should HACCP be assessed, but also the prerequisite. The accuracy of several data can only be checked during on site inspection. This should be check the correctness of the information and ensure that nothing crucial was overlooked. It is important to inspect the site and the practices applied during all the hours.

2.4.2. Hazard analysis

A food safety hazard analysis is done in order to determine which hazards need to be controlled, how much control is needed, and which combination of control measures should be used in order to make sure that food is safe.

2.4.2.1. Food safety hazard

A food safety hazard is an agent or condition that could potentially cause an adverse human health effect. Agents are either in or on food and can be biological, chemical, or physical. Furthermore, the condition of the food itself can also be hazardous (Codex, Food Hygiene, 2008).

- Biological Hazards

Mainly consist of contamination of the product with pathogenic bacteria such as *salmonella*, *Escherichia coli*, *Listeria monocytogens* and parasites, such as *Trichinella sprialias*. Raw ingredients must be properly treated, stored and handled.

Escherichia coli

E-coli is a gram negative bacterium that is commonly found in the lower intestine of warm-blooded animals. *E. coli* strains are harmless, but some, can cause serious food poisoning in humans, and are occasionally responsible for costly product recalls (Wikipedia, Escherichia coli 2009) E-coli contamination of sausage and other meat products can cause serious diarrheal illness, sometimes resulting in contamination that can lead to death.

Salmonella

Salmonella infection is a food borne illness caused by the salmonella bacteria carried by some animals, which can be transmitted from kitchen surfaces and can be in water, soil, animal feces, raw meats, and eggs (Maclandsborough, 1995) Salmonella infections typically affect the intestines, causing vomiting, fever, and other symptoms that usually resolve without medical treatment. Salmonella also can be spread through cross-contamination, so when you're preparing meals, keep uncooked meats away from cooked and ready-to-eat foods. Most salmonella bacteria appear in animal products and can be killed by the heat from cooking. Microwaving is not a reliable way to kill the salmonella bacteria.

Staphylococcus aureus

Staphylococcus aureus is a facultatively anaerobic, Gram-positive coccus, which appears as grape-like clusters when viewed through a microscope and has large, round, golden-yellow colonies, often with hemolysis, when grown on blood agar plates. *Staphylococcus aureus* is the most common cause of staph infections. It is a spherical bacterium, frequently found in the nose and skin of a person. Staph bacteria can spread through the air, on contaminated surfaces, and from person to person.

Listeria monocytogens

Listeria monocytogens is a bacterium found in soil and water that can contaminate meat, and can cause a serious infection in human, called listeriosis. The organisms can be found in many foods processing environment, and has been isolated from floor drains and refrigeration drip pans. From this niches the organisms gets moved throughout the facility, and can end up on food contact surfaces (Wikipedia, *Listeria monocytogens* , 2008). Detection of post processing product contamination by *Listeria monocytogens* can include sampling the processing lines and environment. In world about 4216 person become seriously ill with *Listeria* each year, resulting in about 425 deaths (Codex, Food Hygiene, 2008).

- Chemical Hazards

Consist of contamination of the product approved chemicals or ingredients. Chemical contamination could include fertilizers, cleaners, lubricants and paints food chemicals such as preservative and processing acid and naturally occurring chemicals such as aflatoxin, lead and arsenic.

- Physical Hazards

Consist of contamination of the product by foreign objects, such as rocks, wood, metal glass, and screw, plastic or jewelary that inadvertely enter the product mixture.

2.4.2.2. Hazard identification and determination of acceptable levels

Potential biological, physical and chemical hazards are identified for each step/activity of the product flow diagram. For each potential hazard the hazard assessment is conducted according to health- risk assessment model and control measurers are determined (SLS ISO 22000:2005).

Hazard assessment

According to the information gathered from hazard identification, determine the severity and risk associated with hazard.

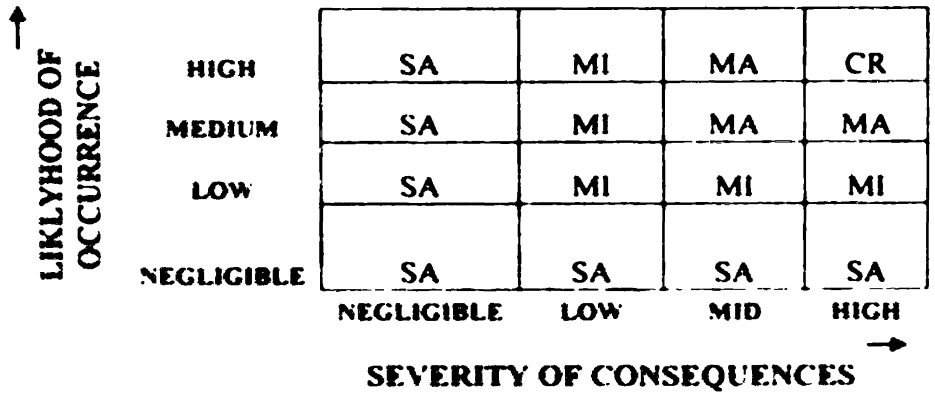
- **Severity**

Severity is the magnitude of a hazard or the degree of consequences that can result when the hazard exists.

- **Risk of hazard**

Risk is a function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard in food

Each food safety hazard evaluate according to the possible severity of adverse health effects and the likelihood of their occurrence using Health risk assessment model (Figure 2.3).



Significance of hazards.
SA = Satisfactory(Negligible)
MI = Minor
MA = Major
CR = Critical

Figure 2.3: Hazard assessment (Source: Exiting documentation of ISO 22000 in keells factory)

Hazard evaluation is used for determine PRPs and OPRPs.

Value	Status	PRP / OPRP/ HACCP
< or = 4	Satisfactory	No control measure
< 4 >9	Minor	PRP
< or = 9>16	Major	OPRP
> or = 16	Critical	HACCP

Table 2.1: Hazard evaluation (Source: Exiting documentation of ISO 22000 in keells factory)

2.4.2.3. Establishing operational prerequisite programmes (OPRPs)

Operational prerequisite programs (OPRPs) are prerequisite programs (PRPs) that are essential. They are essential because a hazard analysis has shown that they are necessary in order to control specific food safety hazards. OPRPs are used to reduce the likelihood that products will be exposed to hazards, that they will be contaminated, and that hazards will proliferate. OPRPs are also used to reduce the likelihood that the processing environment will be exposed to hazards, that it will be contaminated, and that hazards will proliferate in that environment (Praxiom, ISO 22000, 2008).

2.4.2.4. Establishing HACCP plan

Critical Control Point

CCP is a point, step or procedure at which controls can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable (critical) levels. The most common CCP is cooking, where food safety managers designate critical limits (Praxiom, ISO 22000 definisions, 2008).

Identify critical control points

A Critical Control Point (CCP) is a point, step, or procedure in a food manufacturing process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level (Praxiom, ISO 22000 2008).

Determination of critical limits for critical control point.

A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level (Praxiom, ISO 22000, 2008).

System for the monitoring the critical control point.

Monitoring activities are necessary to ensure that the process is under control at each critical control point. In the United States, the FSIS is requiring that each monitoring procedure and its frequency be listed in the HACCP plan (Praxiom, ISO 22000, 2008).

Establish corrective actions.

These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce (Praxiom, ISO 22000, 2008).

2.5. Validation, verification and improvement of the food safety management system

2.5.1. Validation

Validation is an element within the verification process and seeks to establish the technical validity of the control and limits within the FSMS. Validation focuses on the scientific and technical inputs and seeks to identify justification for the decision made within the FSMS. It involves looking at the original design of the FSMS and it's validity over time as changes occur. There are several methods by which the validity of the safety management system can be tested (ISO/TS 22004:2005(E)).

2.5.1.1. Approaches for validation

- Reference to previous validation studies or historical knowledge of the performance of control measure.

Scientific literature government regulations, guideline on the good hygienic practices, international standard or guide lines, equipment manufactures validation studies and FSMS validated by a recognized authority are taken to validate control measure.

- Scientifically valid experimental trials of the control measures.

Laboratory challenges testing designed to mimic process conditions as designed as a pilot test.

- Collection of biological, chemical and physical hazard data during normal operating conditions in the food operation.

Validation measures through the use of intermediate and finish product sampling and testing based on the use of statistical sampling plan and validated testing methodology.

- Statistically designed surveys.

This approach can be used to document control measure that cannot otherwise be measured. The extent of variability in area such as equipment performance and reliability, environmental conditions and potential for recontamination may impact significantly the performance of control measure.

- Mathematical model.

This approach can be used to estimate the predicted performance of a control measure or combination of control measure.

2.5.2. Control of monitoring and measuring

It is a procedure to detect any failures in the control measures. Organization provides evidence that the specified monitoring methods and measuring equipments are adequate to ensure the expected performance (SLS ISO 22000:2005).

2.5.3. Internal audit

An internal audit is a systematic evidence gathering process that is carried out in order to determine how well a food safety management system (FSMS) meets a set of expectations. According to standard, your internal audits should determine how well your FSMS complies with the ISO 22000 requirements as well as your organization's own requirements and arrangements. In addition, expects internal

auditors to evaluate how well the FSMS has been implemented and how well it is being updated and improved (Praxiom, ISO 22000 audit, 2008).

2.5.4. Food safety Management System Verification

Verification of Food safety Management System assure that it is functioning as designed and is updated based upon currently available information. A Food safety Management System that is functioning properly minimizes the need for extensive product sampling and testing. Verification occurs in two stages that may be loosely classified as ongoing and periodic (Praxiom, ISO 22000, 2008).

Ongoing activities use methods, procedures or test separate from, and in addition to those used in monitoring of the system. Verification reports should include information about,

- The system
- The person administering and updating it
- The status of records associated with monitoring activities
- Certification that monitoring equipment is properly calibrated and in work order
- Results of records review and any samples analyzed

2.5.5 Gap analysis of ISO 22000

Gap Analysis is the fastest, most efficient way to assess how your organization measures up to the requirements of a particular standard (HACCP, ISO 22000) and to define the corrective actions required for being compliant (Praxiom, ISO 22000 gap analysis,2008).

The Gap Analysis Report is used to

- Assess compliance to the standard
- Highlight the missing elements required by the standard
- Determine the corrective measures required
- Verify if resources used are adequate
- Indicate the need for additional resources

2.6. Meat and meat products

Comminuted meat products are a term collectively used for the Luncheon meat, Meatballs, Chicken Roll, Burger, Sausages and other meat products (SLS 1218:2001).

2.6.1. Types of comminuted meat products

Comminuted meat products seasoned with salt and spices and enclosed in a natural or synthetic casing or formed by other means into a cylindrical or similar shape (SLS 167: 1998).

- **Sausages**

Sausages are usually defined as comminuted seasoned meats, stuffed into casings; they may be smoked, cured, fermented and heated. They are made from any edible part of the slaughtered, veterinary-inspected animal, and a series of nonmeat ingredients (I.V. Savic, sausage production).

- **Fresh sausages**

Sausages prepared from fresh / cured meat.

- **Cooked sausages**

Sausages prepared from fresh / cured meat, which has subject to boiling or heating with steam and are ready to-serve.

- **Smoked & cooked sausages.**

Sausages prepared from fresh / cured meat, which has been seasoned, smoked and cooked, smoked and cooked sausages are ready to serve (SLS 167: 1998). Smoked sausage is a simple seasoned product. Black pepper is the major spice flavor in smoked sausage. Red Pepper is used at very low levels. Coriander is sometimes used. Smoke and the sweet burnt flavor of dextrose are the major flavors of smoked sausage (Animal range- Meat ingredients).

- **Dry and semi-dry sausages**

Sausages prepared from fresh / cured meat and dried with out boiling or dried after boiling. These sausages may be fermented with lactic acid bacteria to produce a characteristic flavor.

- **Meat balls**

A meat ball of fish balls is a generally spherical mass of ground meat or fish and other ingredients, such as bread or bread crumbs, minced onion, various spices and possibility eggs, cooked by frying, baking steaming or braising in sauce. (Wikipedia Meat balls: 2006)

SI No	Characteristics	Requirements	Method of test
1	Lean meat content, % by mass, min	40	SLS 1218
2	Total meat content, % by mass, min	60	SLS 1218
3	Fat content, % by mass, min	20	SLS 779
4	Starch content, dry basis % by mass, max **	4	SLS 840
5	Total solid content, % by mass, min	33	SLS 294
6	Sodium chloride content, % by mass, max	2.5	SLS 330
7	Sulfur dioxide content, mg/Kg max	500	SLS 1218
8	Acid insoluble ash content, % by mass, max	0.5	SLS 1218
9	Nitrates & nitrites, calculated as $NaNo_2$, mg/kg, max	125	SLS 384 & SLS 396

Table 2.2: Requirements for comminuted meat products (Source: SLS 1218:2001)

Microorganism	Limit		Method of test
	Raw/Semi Processed product	Cooked product	
Staphylococcus aureus	< 1000/g	< 100/g	SLS:516 part 5
E.coli	< 100/g	Absent in 1g	SLS:516 part 3
TPC count	10^7/g	10^6/g	SLS:516

Table 2.3: Microbiological limits of comminuted meat products (Source: SLS 1218:2001)

SI No	Heavy metals	Limit	Method of test
I.	Arsenic, mg/kg, max	1.0	SLS 312
II.	Copper, mg/kg, max	20.0	SLS 301
III.	Lead, mg/kg, max	1.0	SLS 311

Table 2.4: Limits for heavy metals (Source: SLS 1218:2001)

2.6.2. Ham

Smoked ham is a popular serving of meat, cut from the pork leg. It is cured with salt and spices, and then subjected to slow and steady heat for varying periods. The

smoking is carried out in a special chamber called a kiln. The product made of meat from the hind leg of a pig carcass (SLS 1146:2001).

- **Shoulder ham**

The product made of meat from the shoulder of a pig carcass.

- **Ham loaf**

The product made of meat from suitable muscles of a pig carcass.

- **Cooked ham**

Ham prepared from cured meat which has been subjected to boiling or heating with steam and ready-to-serve.

- **Cooked and smoked ham**

Ham prepared from cured meat which has been, smoked and cooked. Smoked and cooked ham is ready-to-serve or may require slight warming before serving.

Sl No	Characteristics	Requirements	Method of test
1	Moisture content, % by mass, min	75	SLS 1218
2	Meat protein (on fat free basis) %	16.5	SLS 1218
3	Fat content, % by mass, min	10	SLS 779
4	Nitrates & nitrites, calculated as $NaNo_2$, mg/kg, max	125	SLS 384 & SLS 396
5	Acid insoluble ash content, % by mass, max	0.5	SLS 1218
6	Sodium chloride content, % by mass, max	3.0	SLS 330

Table 2.5: Requirements for Ham (Source: SLS 1146:2001)

Sl No		Limit	Method of test
i.	Staphylococcus aureus	< 100 /g	SLS:516 part 5
ii.	*E.coli*	Absent in 1g	SLS:516 part 3
iii.	Salmonella	Absent in 25g	SLS:516 part 6

Table 2.6: Microbiological limits of Ham (Source: SLS 1146:2001)

The tolerance limits of heavy metals same as the comminuted meat products.

2.6.3 Bacon

- **Traditional bacon**

The product obtained by curing and with/ without smoking, the properly trimmed pork loins and bellies, which are processed in accordance with this specification and conforming to the requirements of this specification (SLS 342:2001).

- **Back bacon**

Bacon prepared from pork loins

- **Streaky bacon**

Bacon prepared from pork bellies.

SI No	Characteristics	Requirements	Method of test
1	Total fat content, % by mass, min	40	SLS 779
2	Sodium chloride content, % by mass, max	3.0	SLS 330
3	Nitrates & nitrites, calculated as $NaNo_2$, mg/kg, max	125	SLS 384 & SLS 396
9	Protein content, (N* 6.25) % by mass, max	9.0	SLS 295
5	Acid insoluble ash content, % by mass, max	0.5	SLS 1218

Table 2.7: Requirements for Bacon (Source: SLS 342:2001)

The tolerance limits of heavy metals and microbiological limits same as the ham products.

2.6.4. Raw materials

2.6.4.1. Meat ingredients

The flesh and fat, skin, rind gristle and sinew in amounts naturally associated with the flesh of animal or bird, which is normally used for human consumption and include edible parts (SLS 167:1988).

Cattle	Hogs	Veal	Sheep
Boneless primal cuts(chucks, plates, flanks and navels)	Boneless primal cuts(Ham loins shoulders and bellies)	Boneless primal cuts	Boneless primal cuts
Trimmings from primal cuts	Trimmings from primal cuts	Hearts	Hearts
Checks	Checks	Head	Checks
Head meat	Head meat	Checks	Tongues
Hearts	Hearts	Tongues	
Tripe	Stomachs		
Livers	Tripe		
Tongues	Livers		
Lips	Tongues		
Giblet meat	Lips		
Weasand meat	Giblet meat		
	Weasand meat		

Table 2.8: Raw meat materials Used for preparation of comminuted processed meat (source: Pearson, 1997)

2.6.4.2. Non Meat Ingredients

- **Salt**

Salt is basic to most curing mixtures. It is the only ingredient necessary for curing. Salt acts by dehydration and altering of the osmotic pressure so that it inhibits bacterial growth and subsequent spoilage. Originally salt served as a preservative and for that matter, still does in the "country-style" cured meat products. Salt when used alone gives a harsh, dry, salty product that is not very palatable. In addition, salt when used alone results in a dark undesirable colored lean that is unattractive and objectionable to consumers (Montana, Meat ingredients, 2008). Salt is used in most instances as a flavor enhancer but it is also important to water binding ability of meat

and extraction of meat proteins necessary for the manufacture of boneless or chopped and formed hams (Hamm, 1960).

- **Ascorbate and erythorbate**

These reductants react with nitrite to give nitric oxide, thus fastening development of the pink-red colour in cured sausages. Only sodium ascorbate and erythorbate (isoascorbate) are used in practice since ascorbic and isoascorbic acids react directly with the nitrite. Sausage emulsions containing ascorbate or erythorbate may be heat treated immediately after stuffing and a uniform red colour results throughout the product (Montana, Meat ingredients, 2008).

- **Nitrite / Nitrate**

Nitrates and nitrites must be used with caution during curing. Both are poisonous and therefore, strict limits on their use have been established. Excessive use of nitrates and nitrites not only presents a health hazard but may also result in nitrite burn that is a green or white discoloration in the cured meat. In addition to the color role these products perform other very critical functions in cured meats. Nitrates and nitrites have a pronounced effect on flavor. Without them a cured ham would simply be a salty-pork roast. The bacteriostatic properties of nitrites are also important in cured meats, particularly in canned hams. Sodium nitrite is a very effective inhibitor of the growth of *Clostridia*, particularly *Clostridium botulinum*, the bacteria that causes botulism (Jay, 1986). The level is highly regulated in many countries. United States regulations allow only 200 ppm in hams and 120 ppm in bacon.

- **Phosphates**

Phosphates are added to the cure or brine to increase the water-binding capacity and thereby the yield of the finished product. Its increased water binding capacity, product yields increases, product surfaces are drier and firmer, and emulsions are more stable at higher temperatures. Excessive levels have been accused of causing a "soapy" taste, especially at levels above 0.5% (Montana, Meat ingredients, 2008).

- **Sugar and Sweeteners**

The sugar is added to cures primarily for flavor. Sugar softens the products by counteracting the harsh hardening effects of salt especially at high levels. Sugar also

interacts with the amino groups of the proteins and, when cooked, forms browning products that enhance the flavor of cured meats. Sugar provides food for reducing bacteria, yeasts and molds. Sugar (in this case usually dextrose) also provides food for some of the lactic acid fermenting bacteria that provide the characteristic flavor of some dry cured and fermented sausage products (Montana, Meat ingredients, 2008).

- **Gums**

Carageenans and xanthan gum are thickening and gelling agents. Carageenan can be used in cured pork products at a level of 1.5% but if used in combination with xanthan gum or locust bean gum then the amount can not exceed 0.5% of the product formulation. If gums are used no other binding agent is allowed in the product (Montana, Meat ingredients, 2008).

- **Starches**

Starches are long chains of glucose molecules that hold water. Most unmodified starches need heat to thicken, however, some modified and natural starches will thicken at room temperature. These products work well in marinates to help coat the product. Starches aren't, however, allowed in hams or roast beef but can be used in non-standard products (Montana, Meat ingredients, 2008).

- **Flavorings**

Adding various flavorings and spices to cured meat products is becoming increasingly popular. Originally a few spices such as pepper, allspice, etc. rubbed on the surface of dry cured hams. The most common flavorings are pepper cloves, allspice and cinnamon. Garlic and onion flavors as well as fruit juices may also be added. Additions of flavorings are an easy way for product differentiation in a finite market. The use of flavoring is a matter of taste. Care should be used so as not to overpower the natural cured meat flavor (Montana, Meat ingredients, 2008).

- **Non-meat proteins**

Soy proteins and deheated mustard flour are used as protein sources to allow for further extension and as binders for added water. Soy isolate can bind between seven and ten times its weight in water while soy concentrate will bind less water (approximately five times its weight) while imparting a more beany flavor (Pearson, 1997).

- **Colouring agents**

Colour is a very important attribute of meats and is subject to great changes during processing. Therefore, the addition of artificial dyes or natural pigments is often required to make meat products attractive to the consumer. However, artificial colouring of sausages is not usually permitted. Meat, particularly beef, contains enough natural red pigment so any addition of artificial colour is not technologically justifiable (Montana, Meat ingredients, 2008).

- **Spice blends**

Spice blends can be either a mixture of natural spices, of natural spices and extractives (preparations) or combinations of extractives themselves. Each of them may be produced with or without the addition of some carriers or stabilizers such as sugar, dextrose, salt, starch, some proteins etc. They are marketed in batch-packaged units suitable for direct use in sausage production (Montana, Meat ingredients, 2008).

2.6.5. Important processing steps of comminuted meat production

- **Curing**

Meat curing was used originally almost entirely as a means of preserving meat during times of plenty to carry over to times of scarcity. Although a variety of compounds can be used in curing meat, the basic curing ingredients are salt, sugar or some other sweetener, and nitrite and /or nitrate. Method of curing primal or sub primal cuts of meat; they are all modification or combinations of two fundamental procedures; dry curing and pickle curing (Pearson, 1997).

- **Grinding, chopping and mixing**

Methods of grinding and chopping vary widely with the different types of comminuted meat production. In a general way it can be said that the finer the degree of grinding and chopping the more complete will be the extraction of protein while the spreading or slicing properties of the finished product will be improved. The same is true for bacterial contamination. Beef is normally chopped first and then the pork components and other ingredients are added. Salt is added at the very end of chopping (Pearson, 1997).

- **Stuffing**

After remixing again in the mixer, the meat mix is packed in the stuffer as firmly as possible to exclude air pockets. Stuffing into casings should also be done firmly and carefully to exclude air. Air inside the casing will discolour the meat and reduce the shelf life of the sausage. After the sausage has been stuffed, the open end is tied (or clipped) and a loop is formed so the sausages can be suspended on rods. The air pockets under the casings are punctured wherever they are visible to eliminate air.

Raw sausages have historically been produced in natural casings. Many of them are identified by the casing used or by the manner in which string is tied around them. Casings, natural or artificial, should be prepared with great care. Sewn beef casings are also used for some large diameter semidry sausages (Pearson, 1997).

- **Smoking and cooking**

The smokehouse operation is essentially a specialized drying and cooking operation in which meat products emulsion coagulated. The important factors relating to smokehouse performance as dimension, time cycle, temperature range, thermal requirements, relative humidity, air flow and smoke density. These factors control the environment to which the sausage will be exposed during smoking and cooking (Pearson, 1997).

- **Chilling**

After smoking and cooking the sausage product showered with cold water. Then chill by refrigerator. On large-volume, continuous operations chilling are frequently done with a brine solution by dipping or spraying the products (Pearson, 1997).

- **Peeling and packaging**

After chilling sausage products, usually an internal temperature of 35°F -40°F, the cellulosic casing and slicing bologna are removed. For packaging used special packaging machinery (Pearson, 1997)

CHAPTER 03

MATERIALS AND METHODOLOGY

3.1. Preliminary Study Manufacturing processes of keells factory.

Study about the company lay out, production process, raw materials, ingredients and all the relevant information. Swab testing and relevant past records were used to evaluate existing manufacturing process. Cross contamination areas of Keells factory was identified and recommendations were given for modification of factory lay out to reduce the cross contamination in production process.

Swab sampling Technique

Materials and Equipments

Non absorbent cotton wool
Wooden sticks
Test tubes (16 mm diameter)
Auto claves (Automated and portable autoclaves)
Box of disposal gloves, Lab coats and boots
Peptone powder (20g)
Distilled water (1000ml)
Pipettes (1ml, 10ml)
Incubator (35^0C +/- 0.5^0C)
Petrifilm- 3M ™ petrifilm Aerobic plates
E-coli
Staphylococcus aureus

Preparation of materials for swab sampling Technique.

Cotton wool swab were prepared from non-absorbent cotton wool with wooden sticks. They were placed in the test tubes, which were then plugged & sterilized 121^0C for 20 minutes. Counts were made from $25cm^2$ surface of the areas. Test tubes containing 10ml of peptone water were prepared and sterilized.

Swab testing

Sterile swab removed from aluminum foil and 25 cm^2 areas was swabbed with sterile rectangular block. Swab was break into the sterile diluents. Samples were taken before and after cleaning of each location in factory. Inoculated swab were relied upon to determine *E-coli* and *Staphylococcus aureus* counts. Containers were shaken and 1ml of inoculated peptone was inoculated directly to petri film. 3M ^{IM} petrifilm E-coli, *Staphylococcus aureus* and incubated at 36^0C for 48 hours and colonies were countered and calculated the organisms present in $1cm^2$.

3.2. Assess the Compliance of documentation Requirements with ISO 22000 FSMS Standard.

ISO 22000 existing documentation of KFPL was studied and assess the compliance of documentation requirement with ISO 22000 FSMS standard using check list (Appendix. I) and recommendations were given.

3.3. Evaluation of prerequisite programs of keells factory.

Measure the effectiveness of the existence manufacturing practices by monitoring and inspection, of personal hygiene & health requirement, cleaning & sanitation, hygienic processing, waste management, pest management and supplier material etc. (Appendix II- VIII). Swab testing was carried out for food contact surfaces (Machineries and tables) and workers hands to measure the effectiveness of cleaning and disinfection procedures

3.4. Evaluation of selected key procedures, Emergency preparedness Hazard evaluation, Internal Auditing and validation.

3.4.1. Evaluation of Emergency preparedness and Response Procedure.

Emergency preparedness procedure was evaluated by using checklist, ISO 22000 documentation and past records with related to it. Evacuation plan of KFPL was on site verified and recommendations were given.

3.4.2. Evaluation of Hazard analyzes.

The gap between hazard identification of ISO22000 requirement and exiting documentation in Keells factory was analyzed.

Hazard analysis of the raw cut range product was developed to fulfill the ISO22000 requirement.

3.4.2.1 Product characteristics and intended use of raw cut range product.

Product characteristics were understood and raw materials, ingredients, end product characteristics, labeling instructions, special distribution control of product and intended use recorded. Raw cut product range was also described.

3.4.2.2. Construction of flow diagram of raw cut range product.

Flow diagrams of the different product range of Keells factory were onsite verified with the support of exiting documentation of ISO 22000 of KFPL. Analyzed gap and developed new flow diagrams for process of cut meat range products.

3.4.2.3. Hazard assessment by identifying significant hazards in raw cut range products.

A hazard assessment was conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels was essential to the production of safe food, and whether its control is needed to enable the defined acceptable levels to be met. Decision tree was used to find out answers for above questions (Figure 3.1). Hazard assessment model diagram of KFPL was used to assess the severity of each hazard.

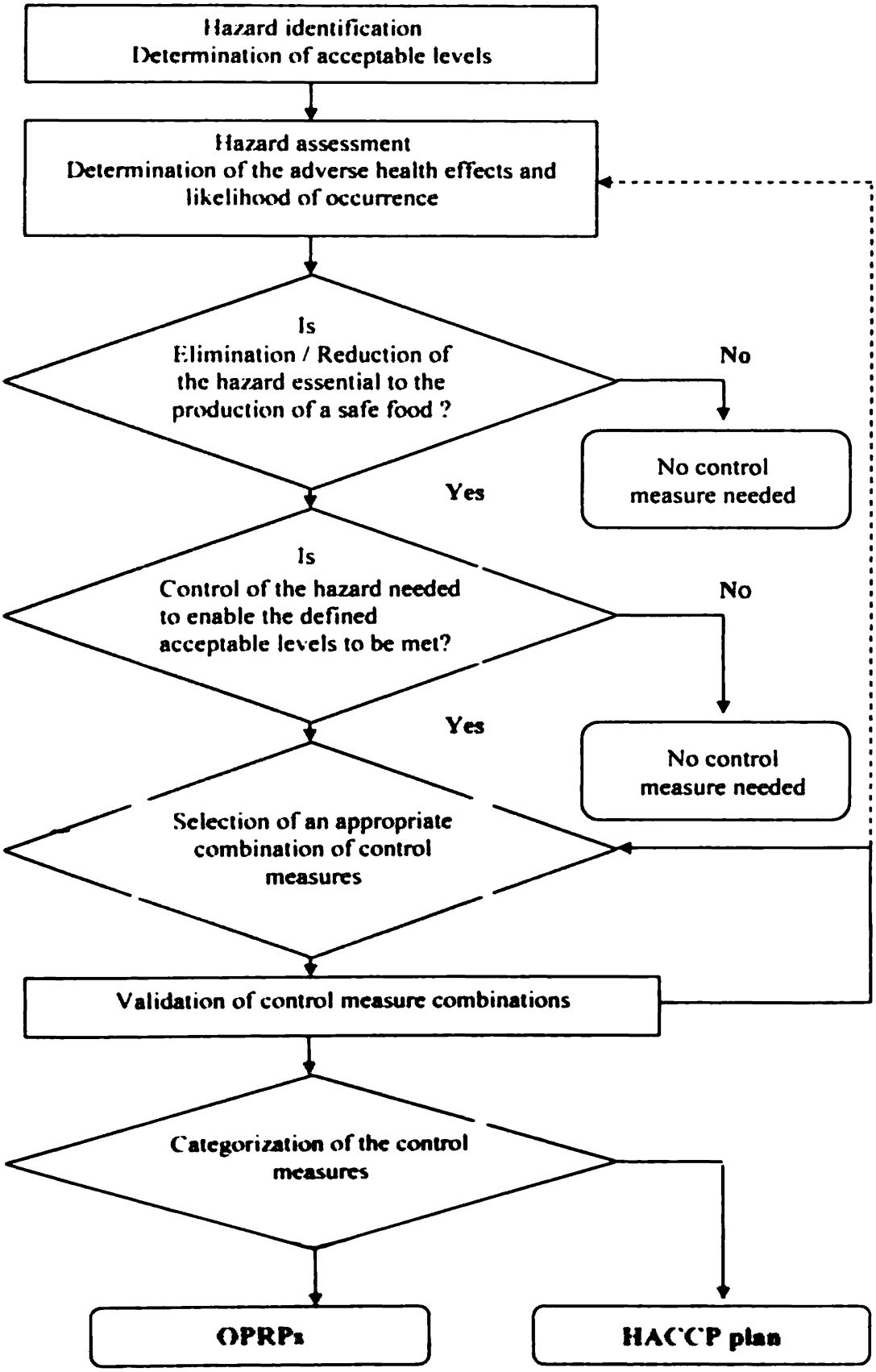


Figure 3.1: Hazard assessment decision tree.

3.4.2.4. Selection and assessment of control measures.

Based on the hazard assessment appropriate combination of control measure was selected to elimination or reduction of food safety hazard.

3.4.2.5. Establishment of the Operational Prerequisite programs (OPRPs) for raw cut range products.

Determined OPRPs were established by considering food safety hazard control measures, monitoring procedures, corrections and corrective actions, responsibilities and authorities.

3.4.2.6. Updated the preliminary information and documents specifying the PRP and the HACCP plan.

Flow diagrams, HACCP plan and OPRP plan of different type of product range of KFPL were on site verified with support of existing documentation. Then establishment of OPRP, HACCP plan of Ham and Bacon products were updated the information of on site verified result of flow diagrams.

3.4.3. Established validation procedure.

Validation procedure was developed to measure the effectiveness of selected control measures which capable of achieving the intended control of food safety hazards.

Swab testing and microbiology testing were carried out for validate the selected control measures and measure the effectiveness control measures. Depending on the microbiological testing results and using relevant past records validate the OPRP and CCP in production process.

3.4.3.1. Microbiological analysis.

Materials and Equipments

Water bath ($44^{0}C$ +/- $0.5^{0}C$)

Distilled water apparatus

Stomacher blender

Electric balance (0 to 2kg range, 0.01sensitivity)

Pipettes (1ml/10ml)

Stomacher bags (Sterlized)

Cotton wool

Beaker (1000ml)

Test tubes (16 mm diameter)

Auto claves (Automated and portable autoclaves)

Box of disposal gloves, Lab coats and boots

Peptone powder

Distilled water

Incubator (35^0C +/- 0.5^0C)

Petrifilm- 3M ™ petrifilm Aerobic plates

E-coli

Staphylococcus aureus

Methodology

Media preparation

Buffered peptone water	20.00g
Distilled water	1000ml

Weighted Buffered peptone was dissolved and poured into bottle and closed the mouth by inserting cotton wool plug or Aluminum screw cap. Then it was autoclaved at 121^0C for 20 minutes.

Sample Inoculation and preparation

90ml of pre-sterilized buffered peptone water was taken into a stomacher bag (sterilized) and 10g of test sample was introduced aseptically. Then blend the sample by using stomacher blender at high speed for 30 seconds.

1ml of the (1/10 dilution) was introduced aseptically to at test tube containing 9m of peptone water. Dilution series was prepared as above for requirement.

Total plate count, *E-coli* and *Staphylococcus aureus* Determination.

TPC, *E-coli* and *Staphylococcus aureus* counts were determined by using 3M petrifilm ™ plates. For that purpose, 1ml of inoculated peptone was inoculated directly to petri film. 3M ™ petrifilm E-coli, *Staphylococcus aureus* and aerobic

plates were used for colony enumeration and incubated at 36^0C for 48 hours. Colonies were countered and calculated the organisms present in $1cm^2$

- Total plate count- All colonies in red colour
- E-coli Blue colonies with associated gas bubbles
- *Staphylococcus aureus* Purple colonies with associated gas bubbles

3.4.4. Established Internal audit plan for ISO 22000 documentation.

Internal audit plan of Keells factory which capable to ISO 9001was study and requirement of ISO 22000 internal audits were identified and then analyzed gap between two of them. According to Requirement of ISO 22000 new internal audit plan was developed for Keells factory.

3.4.5. Analysis of results of verification activities.

PRP, OPRP and the non conformity reports of microbiology records were evaluated statistically.

CHAPTER 04

RESULTS AND DISCUSSION

4.1. Preliminary evaluation manufacturing process.

Swab testing was carried out for whole factory and evaluated the cleaning procedure of factory. Microbes evaluation was carried out with referring to following evaluation standard.

Colony count	Remark	
	Staphylococcus aureus	E-coli
0	Satisfactory (S)	Satisfactory (S)
0-100	Satisfactory (S)	Unsatisfactory (US)
<100	Unsatisfactory (US)	Unsatisfactory (US)

Table 4.1: Microbes evaluation Standard (Surface of 25 cm^2 area) (source: Procedure manual KFPI.)

Swab testing records and conclusions were given in the following table.

Location	While working		Before cleaning		Remarks for after cleaning(Satisfactory (S), Unsatisfactory (US)	Conclusion
	Staphylococcus aureus	*E-coli*	*Staphylococcus aureu*	*E-coli*		
Unloading bay work surface	0	10000	0	100	US	Cleaning frequency should increase
Unloading bay workers hands	0	800	0	100	US	"
Knife	0	2000	0	<10	S	Cleaning sufficient
Slaughter	0	4300	0	<10	S	"

sticking knife						
Dress pig carcass cavity	0	3000	0	<10	S	"
Slaughter chill door	0	<10	0	<10	S	"
Bonning hall chopping board	0	4600	0	40	US	Cleaning frequency should increase
Bonning hall Knives	0	<10	0	<10	S	Cleaning sufficient
Bonning hall baskets	0	3100	0	<10	S	"
Bonning hall workers steel gloves	0	310	0	<10	S	"
Processing section baskets	0	60	0	<10	S	"
Pro.Sec Knives	0	810	0	<10	S	"
Processing section Auto mincer	0	<10	0	<10	S	"
Processing section chopping bowl	0	900	0	<10	S	"
Processing section Filler nozzel	0	<10	0	<10	S	"
Processing section Sausage peeler blade/cavity	0	20	0	0	S	"

Sausage sticks	0	0	0	0	S	"
Trolley surface	0	0	0	0	S	"
Basket inside	0	10	0	0	S	"
Basket out side	0	<10	0	0	S	"
Packing slicer guard	0	230	0	0	S	"
Packing slicer blade	0	10	0	0	S	"
Packing slicer table	0	20	0	0	S	"
Packing table workers gloves	0	50	0	0	S	"
Packing thermoform film	0	<10	0	0	S	"

Table 4.2.: Swab testing records

Unloading bay work surface, workers hands and bonning hall chopping board were found to be unsatisfactory for *E-coli* after cleaning. *Staphylococcus aureus* number in all areas (while working and after cleaning) was had in satisfactory level.

Cross contamination areas of Keells factory was identified by evaluating existing factory layout. Identified cross contamination areas and modified factory lay out were showed in the following figures.

Existing Factory layout

Figure 4.1.: Existing factory layout of Keells

1. Foot dip
2. Meat/fish receiving area
3. Foot dip
4. Slaughter area
5. Washing room
6. Corridor
7. Holding chill
8. Casing chill
9. Salami chill
10. Air compressor
11. Generator room
12. Meat cutting area
13. Processing area
14. Raw product chill
15. Washing room 2
16. Plant room
17. Cooking area
18. Showering area
19. Thawing chill
20. Cut meat chill
21. Spice room
22. Corridor
23. Processing area
24. Corridor
25. Meat cutting room
26. Foot dip
27. Dispatch room
28. Dispatch room office
29. Airlock
30. Cooked product chill
31. Box freezer
32. Tunnel freezer
33. Production freeze
34. Bundle chill
35. Corridor
36. Peeling room
37. Hand washing area
38. Bag making area
39. Packing area
40. Plate freezer
41. Changing room
42. Foot dip
43. Plant room
44. Production office
45. Human Resource Office (HR)
46. Plant room

Cross contamination area

Processing and Packing area

Workers Entrance flow

Modified factory lay out

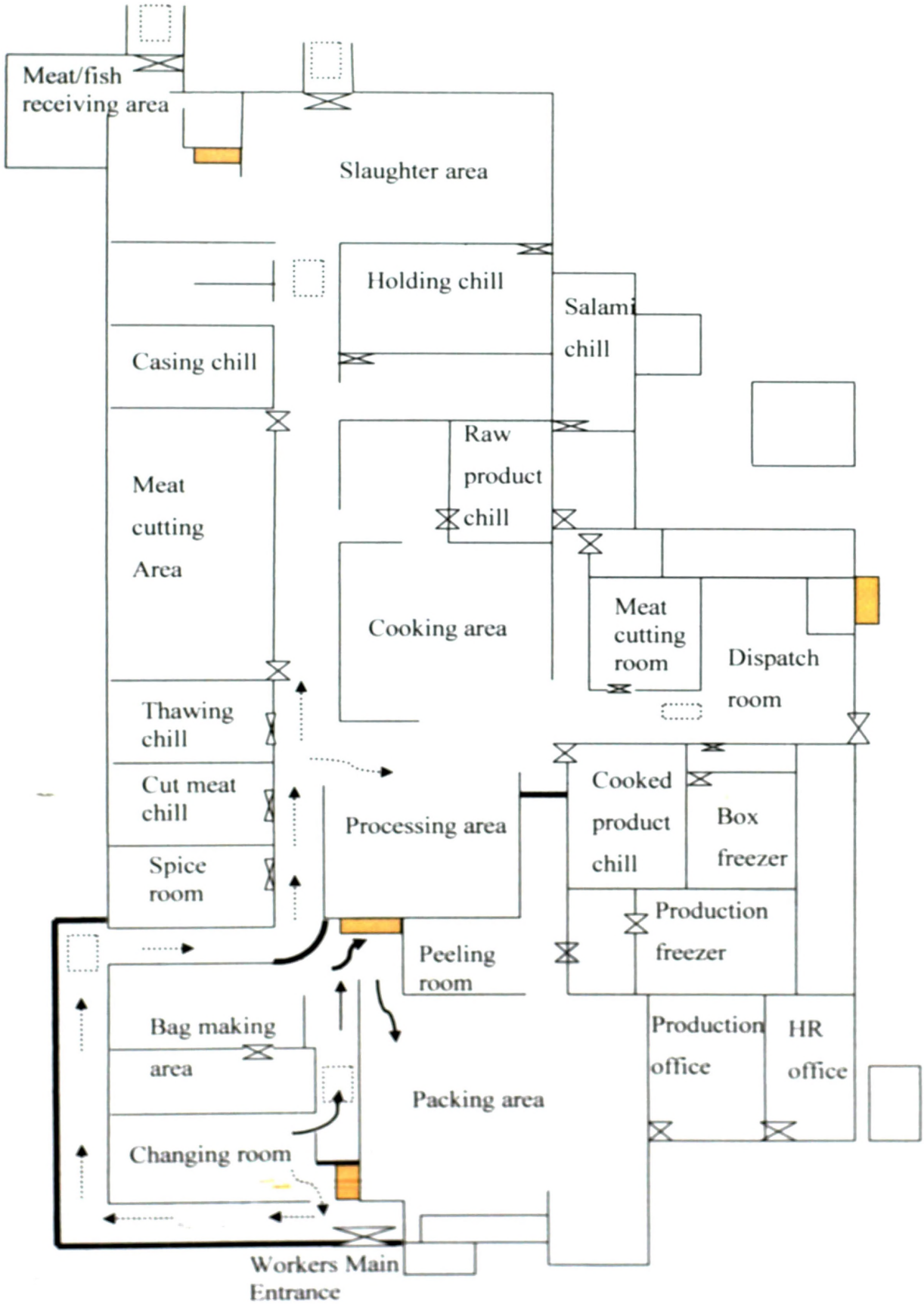


Figure 4.2 Modified factory lay out

4.2 Compliance of ISO 22000 existing documentation of KFPL.

By studying the ISO 22000 existing documentation of KFPL with ISO 22000 documentation requirement compliance were identified (Appendix I). According to assessment; external communication, hazard analysis of cut meat range products, validation plan and the procedure and internal audit plan identified as documentation gap. General requirement, Management commitment, management responsibility, management review, resource management and corrective action clauses were addressed in Quality manual of KFPL and integrated to Food Safety Management System to fulfill the requirement of ISO 22000.
To fulfill the above documentation gap, procedures and the plan were developed.

- **External communication**

The management identifies and ensures that an effective external communication system is prerequisite for the effective FSMS of KFPL. The KFPL has established, implemented and maintained effective arrangements for communicating with suppliers and contractors, customer, statutory and regulatory authorities and other organizations having an impact on food safety. The management shall assure the ways of communication with external bodies. The medium of communication such as telephone (mobile phones), e-mail (lotus notes) , external mailing system, meetings, internal publishing (advertisements in television and radio, news paper, poster, sticker advertisements), meetings , presentations , reports (project reports) , training and opportunity to direct speech are used as the systems/processes in order to fulfills this requirements. The food safety team shall ensure that information obtained through external communication included as input to system updating and management review.

4.3. Evaluation of prerequisite programs of Keells factory.

Analyzed the current existing procedures and practices of PRP's of Keells factory and identified their weakness, areas which would have to modify. Summarized details were in the following table.

PRP	Analyzed gap	Recommendation	Gap analysis reference
PRP's -1 Design lay out and facilities	Cross contamination in production flow and lack of some facilities. Lighting level not maintain proper manner.	Modify the design lay out and accommodation of some equipment should be change. Lighting facility should maintain in factory.	Appendix II
PRP's– 2 Personnel Hygiene	Gap in implementation	Improve the workers behavior of processing area.	Appendix III
PRP's – 3 Cleaning and sanitation	There is gap in cleaning procedure and the implementation	Should modify the cleaning frequencies in machinery specially peeler machine and slicer and Cleaning procedure of deboning section	Appendix IV
PRP's – 4 Hygienic Processing	Existing documentation of ISO22000 addressed all the SLS requirements but gap in implementation.	Should maintain temperature between 22-24 °C In packing area	Appendix V
PRP's – 5 Pest control	Gap in implementation	Holes, drains & other places where pests are likely to gain access should be kept seal	Appendix VI
PRP's – 6 Waste Management	Waste removing pathway could be make cross contaminations	Waste removing pathway should be change.	Appendix VII
PRP's– 7 Potable water Quality	Potable water colour there is gap with the SLS requirement	Should modify the water treatment procedure	Appendix VIII

Table 4.3: Gap analysis of prerequisite programs of Keells

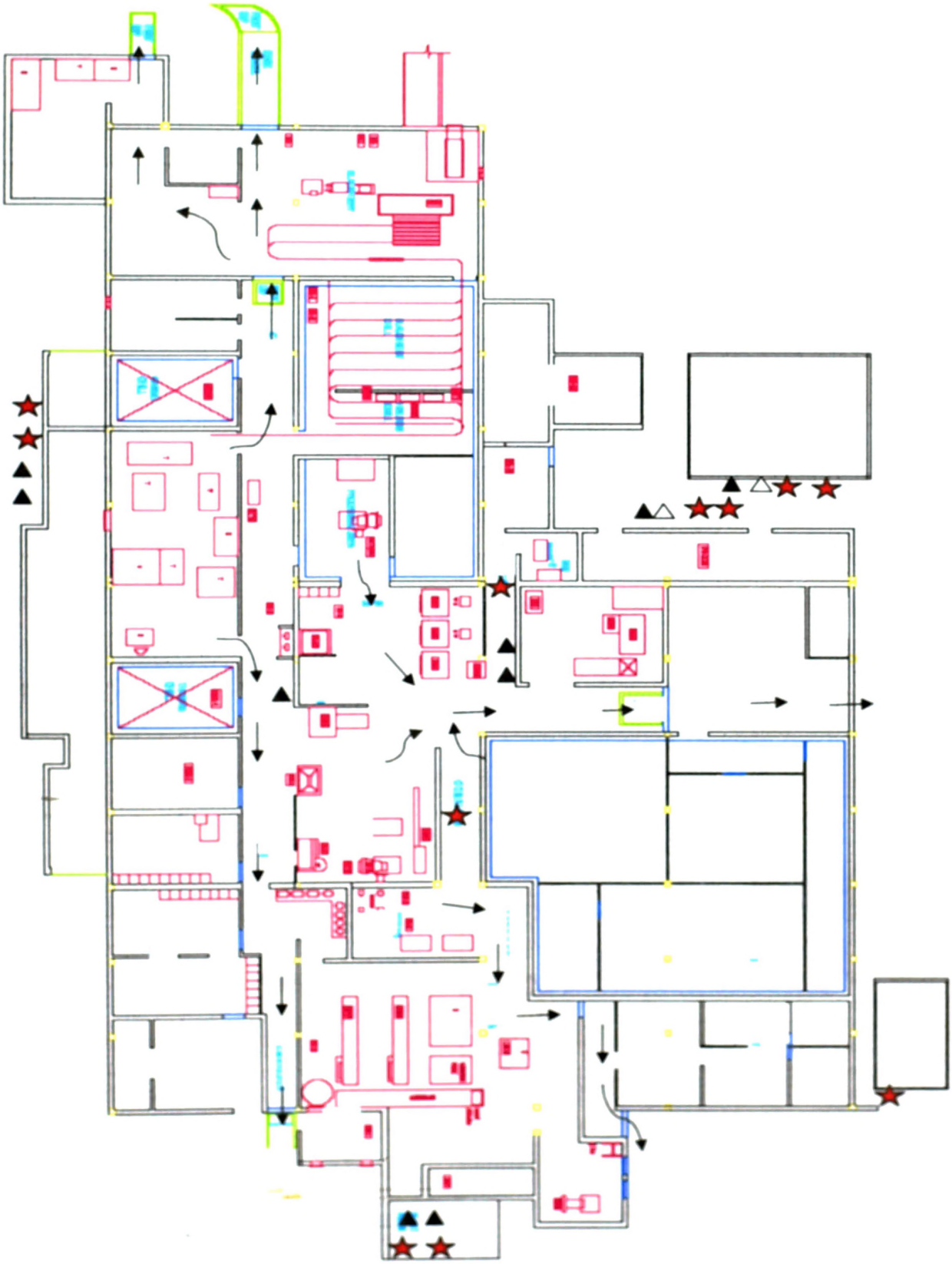
4.4.1. Evaluation of Emergency preparedness and Response Procedure in Keells factory.

During the evaluation of emergency preparedness conducted for Keells Food Products, the attention has been mainly paid to implementation of emergency preparedness plan. According to factory emergency preparedness plan main objective to identify potential food safety emergencies quickly and accurately if possible, to eliminate the exposure of consumers to hazardous products and for mitigating environmental impacts associate with them.

Emergency situations	Sub Emergency situations	Analyzed gap	Recommendations
Sudden illnesses or outbreaks		No Gap	-
Accidents, incidents and disasters		No gap in both documentation and implementation	-
Power failure		No gap in both documentation and implementation	-
Fire	Fire team	Documentation support all the requirement but gap in implementation	Should establish fire team and should maintain it.
	Fire training/ Fire drills	Within 2 years period fire training not held.	Fire training should hold once a year.
	Fire evacuation plan	There is gap in drawn up Fire evacuation plan and the establishment of fire extinguishers	Fire extinguishers establishment should maintain according to drawn up fire evacuation plan
Mitigation of the environment effect of fire		Documentation support all the requirement	-
Natural Disasters		No Gap (Natural disasters are very unlikely in the area)	-
Tampering or sabotage		Documentation support all the requirement but gap in implementation	Should prohibit to Carrying cleaning chemicals food handling areas without permission.

Table 4.4: Evaluation of Emergency preparedness and Response of Keells

Gap analysis of Fire evacuation plan



△ Fire extinguishers (H_2O) Establishment according evacuation

▲ Fire extinguishers (CO_2) Establishment according evacuation plan

★ Actual Fire extinguishers Establishment in plant

→ Emergency Exit Flow

Table 4.3.: Gap analysis of Fire evacuation plan

4.4.2. Evaluation of Hazards analyzed.

4.4.2.1. Product description and intended use of Cut meat range products.

1. Product name	**Raw cut meat**
2.Important product characteristics of end product	Microbiological parameters *Staphylococcus aureus* and coliforms below the acceptable levels Absence of *Salmonella* Chemical Maximum residual limit of antibiotics,lower than upper limit of chemical residues. Physical Absence of Foreign Materials.
3.How the product is to be used	Raw meat cubes wash and cook properly.
4.Packaging	Carcasses-None, Organs-Nylon & LLDPE bags.
5.Shelf- life	6 months at $-18\ ^{O}C$, Organs 3 months, 2-5°C for 3 days
6.Where the product will be sold	Retail Institutions, Food services and hotels
7.Labeling instructions	Storage Instructions(for best results stored at -18°C) Production date(Lot Identification) Traceability Expiry date (Lot identification) Traceability Batch no. Contact Details of Manufacturer
8.Special distribution control	No physical damages , Temperature extremes. Below -15 °C Will be transported by freezer trucks. Direct and through Island wide dealers
9.Intended use	General consumption/May be consume by the high risk groups (Elderly, immune suppressed).
10.Composition	100% meat

Table 4.5.: Product description of raw cut range products

Product Range of raw cut meat product

Long Leg
Beef for Cubing
Premium Pork Loin
Beef Fillet
Boning neck fillet
Oxtail
Pork fillet
Ox liver
BBQ Spare Ribs
Mutton
Bone in curry pork
Mutton Leg Local
Pork cubes (Low fat, Rind\B. less)
Mutton Cub
Pork leg B. In
Pork shoulder Loin
Pork Loin Boneless
Pork Chops
Pork for roasting
Pork Knuckle
Pork picnic Shoulder
BBQ Spare Ribs sheet
Pork Leg- Rind less Chump on B.L
Pork Belly
Pork Premium Loin B/ In
Pork Side
Pork Leg Slice
Schnitzel
Pork for Roasting
Baby Back Ribs
Pork Trotters
Top Sides
Osuboku
Mutton cubes
Curry Mutton
Beef cubs
Minced Beef
Beef Strip loin
Aust. Beef T. Bone Steak
Aus Strip loin Steak

4.4.2.2 Construction of process flow diagram.

Process flow diagram for Raw cut meat range

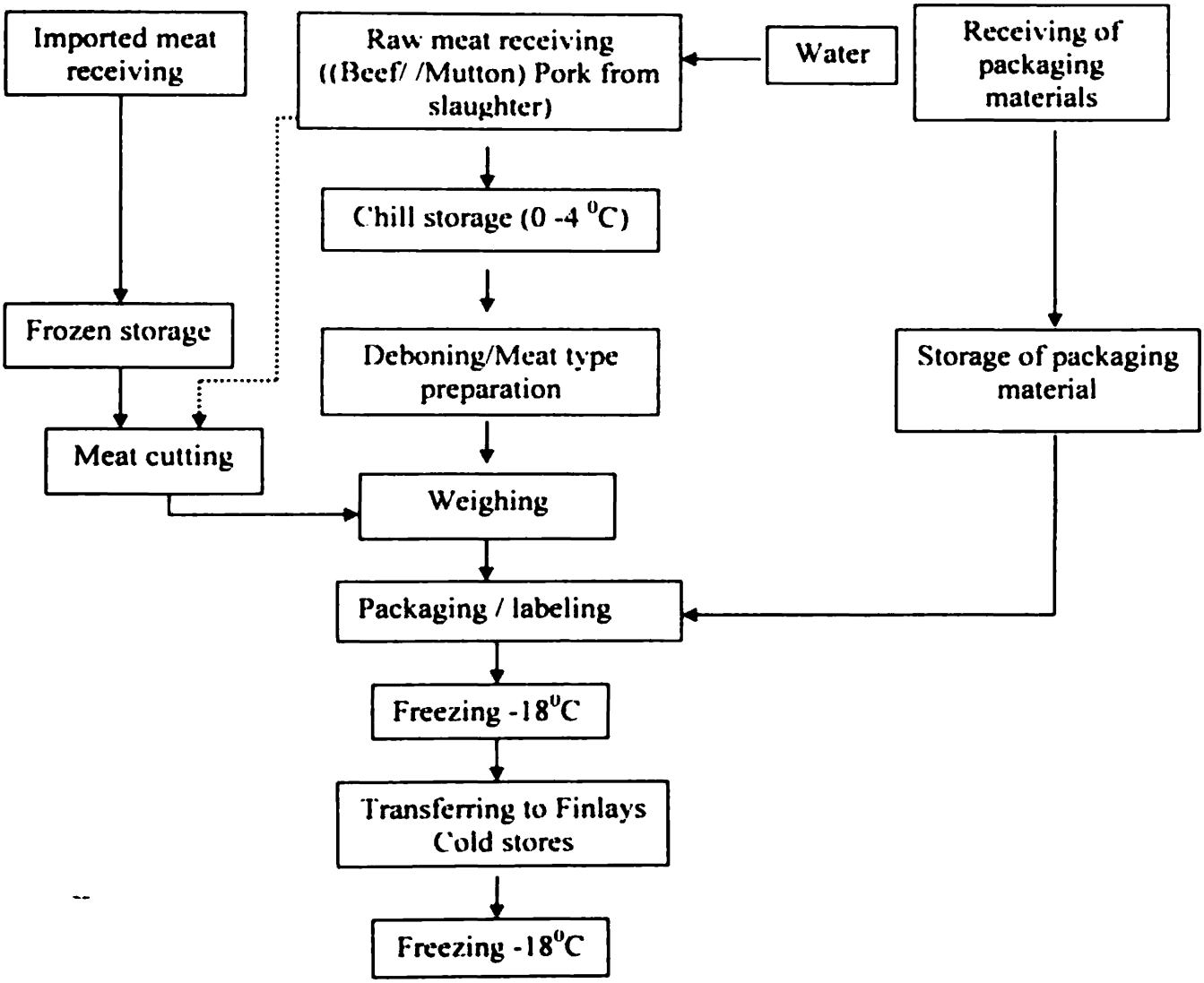


Figure 4.4: Process flow diagram for Raw cut meat range

Construction of process flow diagram using standard icons

Standard Key	Description	standard Key	Description
	Input /Output		Delay
	Operation		Decision
	Measurement		Storage
	Operation & measurement		Transportation

Process flow diagram for Raw cut meat range in standard icons

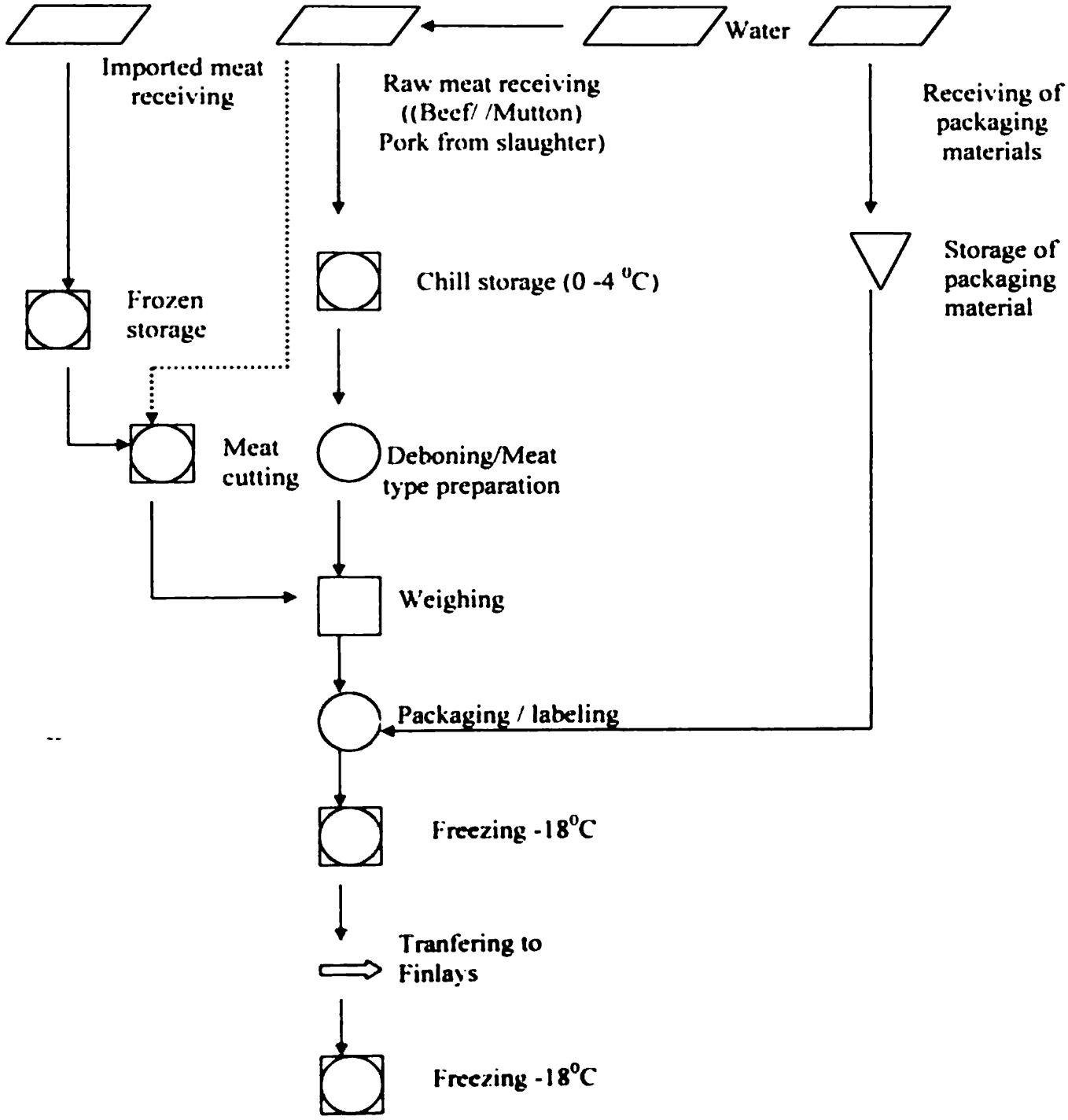


Figure 4.5: Process flow diagram for Raw cut meat range in standard icons

4.4.2.3. / 4.4.3.4. Hazard assessment by identified significant hazards in raw cut range products and control measures.

Process step	Potential Hazard	Score of Hazard evaluation	Significance of Hazard Assessment				Is elimination/reduction of the hazard essential to the production of a safe food?		Is control of the hazard needed to enable the defined acceptable levels to be met?	Control measure
			Sa	Mi	Ma	Cr	Elimination	Reduction		
1.Raw Meat receiving (Pork From slaughter)	**Biological** -Excessive time slaughter to plant could result survival & growth of bacteria • *Salmonella sp.* • *E.coli* -Long storage times in the receiving bay could result build up of bacteria • *Salmonella sp.* • *E.coli* -St.aureus could contaminate through hand.	12			Yes Yes Yes			√ √ √	Yes	OPRP(1B) Ensure minimum Storage time
	Chemical -Could be contaminated by cleaning chemicals -Could contain veterinary drug residues	6							Yes	PRP
	Physical -Could be contaminated with HEM (Harmful Extraneous Matters)	6							Yes	PRP

2.Imported meat receiving (Frozen)	**Biological** -Inadequate temp. When receiving could result survival &growth of pathogenic bacteria.(*Salmonella/E.coli*) -*S.aureus* could contaminate through hands. -Damaged pack could result contamination	8		Yes				√	Yes	**PRP** Supplier certification with necessary records Quarantine Reports of Microbiology
	Chemical - Contaminated by cleaning chemicals	8	Yes				√		Yes	**PRP** Ref:PRP-CS
	Physical - Could Contain foreign matters	8		Yes				√		PRP Visual observations
3. Water as intake	**Biological** -Could contain pathogenic bacteria /Spores	12			Yes			√	Yes	**OPRP(2B)**
	Chemical - contains ,chemical residues	9			Yes		√		Yes	**OPRP(1C)**
	Physical - contaminated by HEM	4	Yes					√	Yes	**PRP**

4.Packaging material receiving	**Biological** -Physical damages could result post process contamination by pathogenic& spoilage bacteria	6		Yes				√	Yes	**PRP** Visual observation on receiving process
	Chemical - contain chemical residues (Non food- grade packaging material)	8		Yes			√		Yes	**PRP**
	Physical -Could contain HEM	6		Yes				√	Yes	**PRP**
5.Chill storage(Beef,Pork)	**Biological** -Improper storage temp. & time could result growth of bacteria (pathogenic & spoilage bacteria). -Cross contamination due to improper storage practices.	9			Yes			√	Yes	**OPRP(3B)** Ref:PRP-HP
	Chemical -Could be contaminated by cleaning chemicals	4			Yes		√		Yes	**PRP** Ref:PRP-CS
	Physical -Could be contaminated with HEM	6	Yes				√		Yes	**PRP** Ref:PRR-HP

6.Deboning/meat type preparation	**Biological** - contaminate by improperly sterilized/cleaned knives and other equipments(Pathogenic & spoilage bacteria)	**6**		Yes			√		Yes	**PRP** Ref.ISO manual PC-WI for boning hall
	Chemical Could contaminate by cleaning chemicals cleaning chemicals	**4**		Yes			√		Yes	**PRP** Ref:PRP-CS
	Physical Could contaminate by remaining bone particles. Could contaminated by HEM	**8**		Yes				√	Yes	**PRP** Visual observation during deboning & 95% skilled workers
7.Frozen storage	**Biological** Improper storage tem. time could result increase of bacterial load(Pathogenic & spoilage bacteria). -Cross contamination due to improper storage practices.	**9**		Yes	Yes			√	Yes	**OPRP(4B)**

	Chemical cleaning chemicals	**4**	Yes					√	Yes	**PRP** Ref:PRP-CS
	Physical HEM	**4**	Yes				√		Yes	**PRP** Ref:PRP-
7.Storage of packaging material	**Biological** contaminated with rodent and pest excrement Natural casings /Improper temperature could results pathogens to multiply	**8**		Yes				√	Yes	**PRP** Ref:PRP-PC
	Chemical pest control residues & Cleaning chemical residues	**4**		Yes				√	Yes	**PRP** Ref:PRP-CS
	Physical HEM	**6**		Yes			√		Yes	**PRP** Ref:PRR-
8.Meat cutting	**Biological** contaminate by improperly sterilized/cleaned knives and other equipments(Pathogenic & spoilage bacteria)	**6**		Yes				√	Yes	**PRP**
	Chemical Cleaning chemical residues	**4**		Yes				√	Yes	**PRP** Ref:PRP-CS

	Physical HEM	**8**		Yes			√		Yes	**PRP**
9.Weighing	**Biological** - contaminate by improperly cleaned crates & other equipments(Pathogenic & spoilage bacteria)	**6**						√	Yes	**PRP** Ref:PRP-CS
	Chemical Cleaning chemical residues	**4**		Yes				√	Yes	**PRP** Ref:PRP-CS
	Physical -None	**-**							Yes	
10.Packaging/Labeling	**Biological** Could contaminate by hands	**9**		Yes				√	Yes	**OPRP(5B)**
	Chemical Cleaning chemical residues	**3**		Yes				√	Yes	**PRP** Ref:PRP-CS
	Physical -None	**-**							No	
11.Freezing	**Biological** Improper storage tem. times could result increase of bacterial load	**9**		Yes				√	Yes	**OPRP(6B)**

	Chemical -None	-							No	-
	Physical -None	-							No	-
Trans porting to Finlays stores	**Biological** Damages due to improper loading -Improper tem. inside the vehicle -long storage time in the dispatch area could result lower the temperature(Pathogenic & spoilage bacteria increase	**12**			Yes			√	**Yes**	**OPRP(7B)**
	Chemical -None	-							No	-
	Physical -None	-							No	-
Frozen Storage	**Biological** -Improper storage tem. Time could result increase of bacterial load. -Cross contamination due to improper storage practice				Yes			√	Yes	**OPRP(8B)**
	Chemical -None	-							No	-
	Physical -None	-							No	-

Table 4.6: Hazard assessment raw cut range products and control measures

4.4.2.5. Establishment of the Operational Prerequisite programs (OPRPs)

Process step	OPRP NO:	Potential Hazard	Control measures	Monitoring procedure				Deviation /Corrective action procedures
				What	Who	How	Freq.	
Raw Meat receiving	OPRP (1B)	Presence of pathogenic bacteria, Diseases	Anti /post mortem inspection, Incoming Inspection -free of defects -gas test satisfactory	PHI certificates Goods	Ex.live stock	Visually	Every Batch	# Reject/hold the batch according to Incoming inspection & live stock purchasing procedure #Plat visits/farm further actions
Receiving of treated Water	OPRP (2B)	Presence of pathogens	water complying to SLS potable water requirements(Microbiological)	Microbiological test reports	Operator	Visually	Every day	#Operator inform AQAM to recommend corrective action
	OPRP (1C)	Presence of harmful chemical residues	water complying to SLS potable water requirements(Chemical)	Chemical test report	Operator	Visually	Once a year	#Operator take corrective action
Chilling	OPRP (3B)	Inadequate time/tem result increase of bacterial growth(pathogens)	Temperature maintained between 0-4°C	Temperature, (cooler)Time	Operator	Visually indicator	Every 2 hrs	#Operator does the corrective action

Freezing /Frozen storage	OPRP (6B)&(4B)	Inadequate load of bacteria and presences of pathogens	Temperature Below-18°C	Tem, (,cooler) Time	Operator	Visually indicator	Every 2 hrs	#Operator inform AQAM to recommend corrective action
Packing	OPRP (5B)	Improper cleaning and sanitary practices could result survival of bacteria	Sterilization of contact surfaces and equipments using 60% IPA.	Tem, (,cooler) Time	Operator	Visually indicator	Every 2 hrs	#Inform supervisor
Transporting to Finlays	OPRP (7B)	Inadequate time/tem result increase of bacterial growth(pathogens)	Product is fast frozen in the freezer truck to reach -15°C	Tem, (,cooler) Time	Operator	Visually indicator	Every 2 hrs	#AQAM/QAE will reject or hold product until time/tem deviation & its implicated are reviewed

Table 4.7: Operational Prerequisite programs

4.4.2.6. Updated the preliminary information and documents specifying the PRP and the HACCP plan.

By the studying of production process of Ham, Bacon and sausage/ Meatballs and salad and Sandwich range of product the gap was analyzed and developed new flow diagrams of Ham and Bacon were developed.

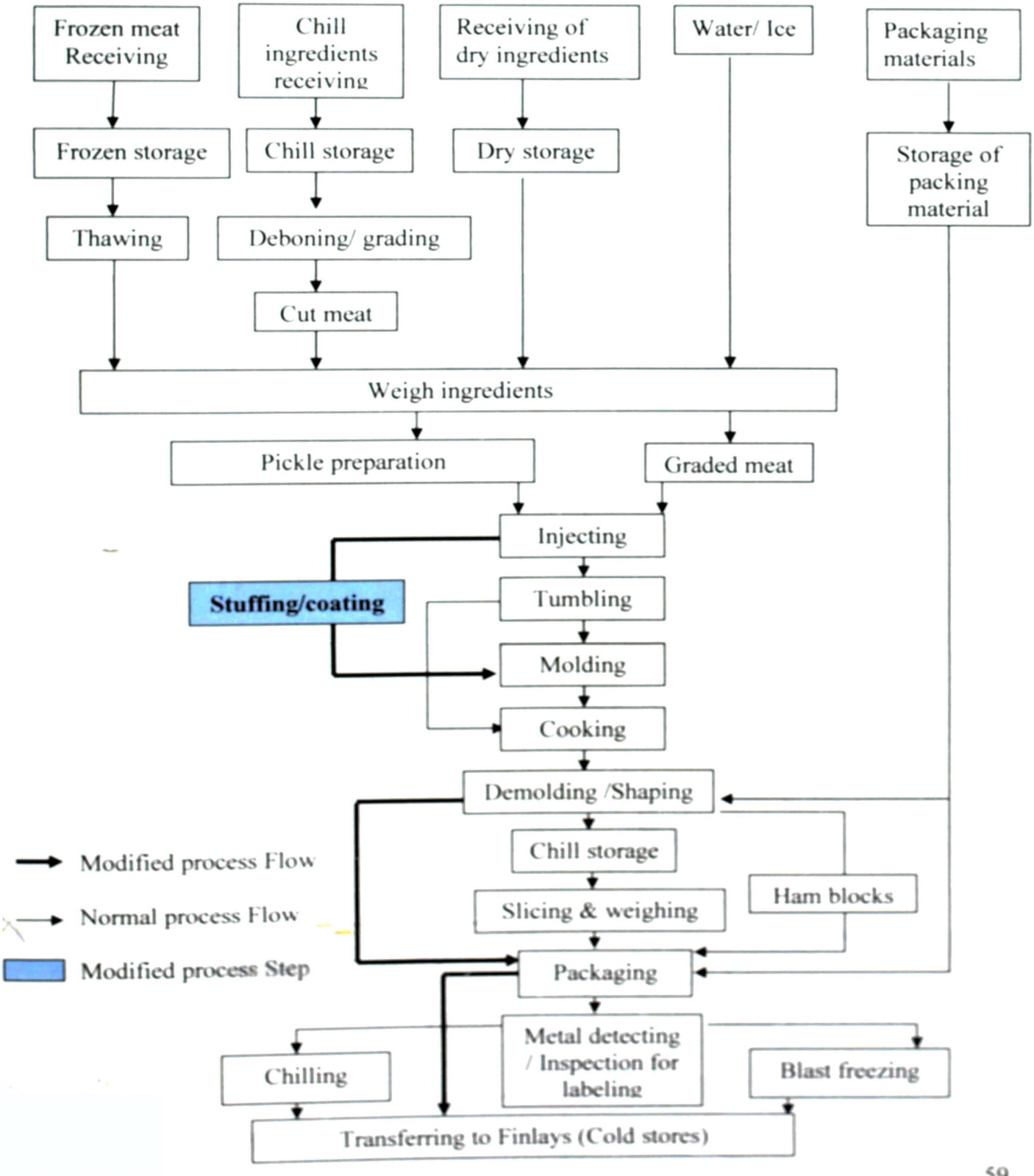


Figure 4.6: Gap analysis of Ham range product flow diagram

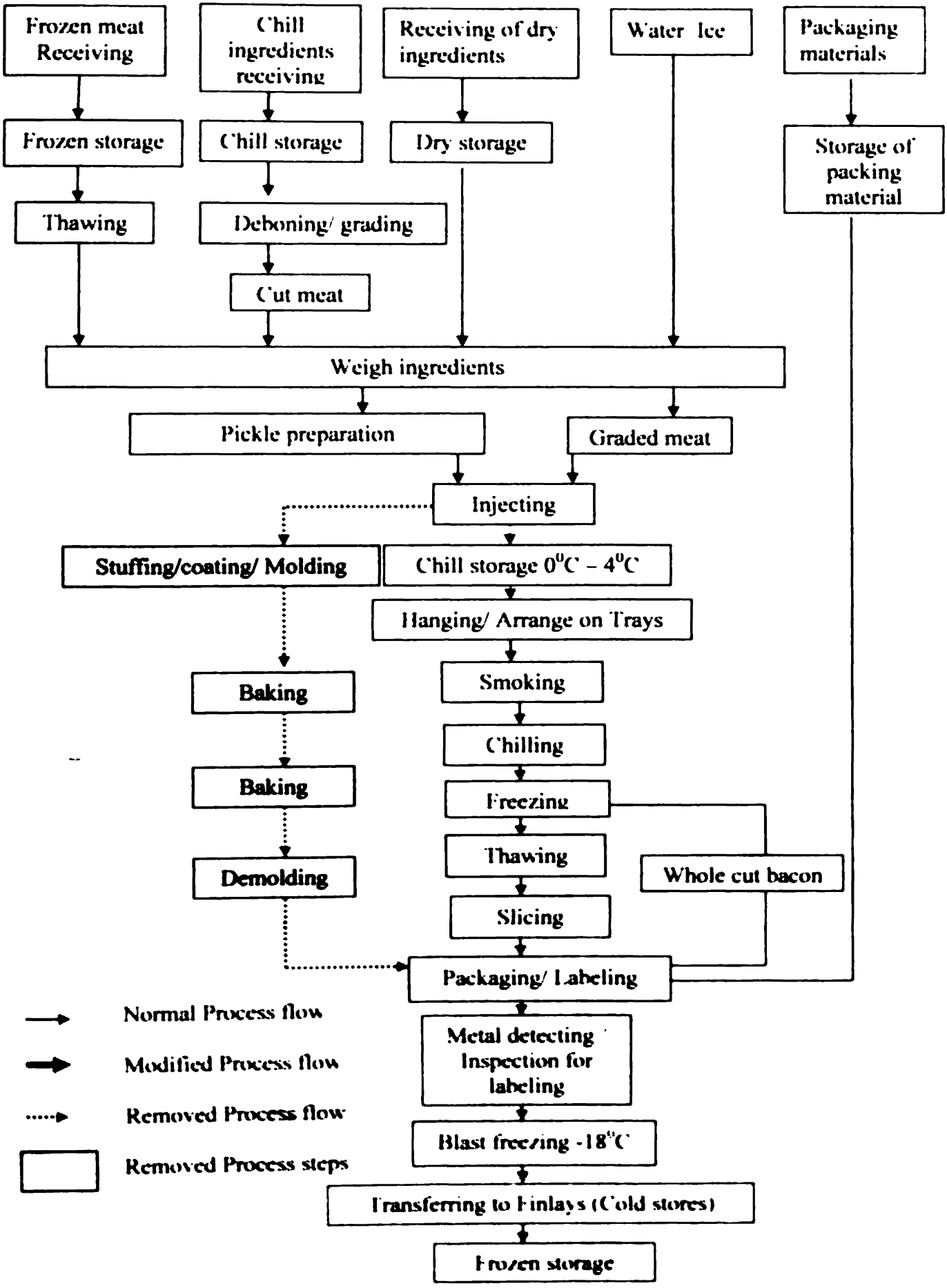


Figure 4.7: Gap analysis of Bacon range product flow diagram

3.4.3. Establishment of validation procedure.

Process step	OPRP / CCP	Hazard description	Validation procedure	Validation Frequency	Responsibility	Validation records
Chill meat receiving(Beef,Pork, Fish)	OPRP (B)	Excessive time, slaughter to plant could result survival &growth of pathogenic bacteria	Historical knowledge of the performance of the control measure. Go through Supplier certificates	Every 3 months	AQAM	supplier test report / Supplier certificates
Frozen meat receiving	OPRP (C)	Inadequate temp. when rece. could result survival &growth of pathogenic bacteria For chicken, damaged pack could result contamination (Anti-Post mortem Inspection)	Go through Supplier certification with necessary records (for Chicken) and Collection of biological hazard data of final test reports	Every 3 months	AQAM	supplier test report Microbiological Test Reports
Receiving of treated water	OPRP (B) OPRP (C)	Could contain pathogenic bacteria /Spores Presence of harmful chemicals	Comply with SLS potable water requirements(Water Microbiology requirements(SLS 614) Comply with SLS potable water requirements (Chemical parameters SLS 614))	Once a year	AQAM	Micro biological test reports of Potable water, ITI test reports & Potable water test report from Water board
Chill Ingredient storage	OPRP (B)	Improper storage tem. time could result growth of bacteria	Comply with SLS standard no 143 & SLS 1065 (Chill storage temperature maintained between 0^0C to 4 ^{0}C)	Every 3 months	AQAM	Microbiological test reports / Temperature

						Monitoring records
Weighing	OPRP (C)	Inadequate weighing of Nitrite could result chemical toxicity	Go through NO_2 salt check list.	Every 3 months	AQAM	NO_2 salt addition to vacuum salt check list
Frozen ingredient storage	OPRP (B)	Improper storage tem. time could result growth of bacteria	Comply with SLS standard SLS 143 & SLS 1065 (Froze product shall be below -18 ^{0}C temperature)	Every 3 months	AQAM	Microbiologic al test reports
Blast freezing/Fin al storage (Chill/ Frozen)	OPRP (B)	Inadequate time/temp. result increase of bacterial growth(pathogens)	Comply with SLS standard SLS 143 & SLS 1065 (Froze product shall be below -18 ^{0}C temperature)	Every 3 months	AQAM	Microbiologic al test reports
Cooking	CCP(B)	Inadequate time, Time during cooking could result increase and survival of bacteria (Pathogenic & spoilage bacteria).	Collection of biological hazard data during normal operating conditions in food operation and validate Microbiological reports (Core temp. to be maintained at least 72 ^{0}C for15 Sec-)	Every 6 months	AQAM	Validate Microbial Test Result of Chamber Processing
Metal detecting	CCP(P)	Metal particles can pass through this step	Go through Metal detecting records (No Metal particles not exceeding 2.5 mm)	Every 3 months	Metal detector operator	Metal detecting records (DA-KE-00)
Anti-mortem Inspection	OPRP (B)	Pathogenic Microorganisms/Parasit es from disease animals.	Go through monitoring records and final product Microbiology test reports	Every 3 months	AQAM	Anti-mortem inspection report

		Cross contamination from/Inspectors /handler				
Post - mortem Inspection	OPRP (B)	Admission of unacceptable carcass/Organs due to parasitic and larval migrations ,Further contamination by microbial growth(pathogens)	Go through Post mortem inspection report and final product Microbiology test reports	Every 3 months	AQAM	Post mortem inspection report Microbiological test reports
peeling	OPRP (B)	Inadequate steam, improper cleaning & sanitary practice could result survival of bacteria	Collection of biological hazard data during normal operating conditions in food operation and validate swab sample reports	Every 3 months	AQAM	Peeler machine cleaning & sanitary practice Validation Records(Swab sample test)
Packaging	OPRP (B)	Improper cleaning & sanitary practice & result bacteria	Collection of biological hazard data during normal operating conditions in food operation and validate swab sample reports	Every 3 months	AQAM	Packing area cleaning & sanitary practice Validation Records(Swab sample test)

Table 4.8: Validation Plan

4.4.4. Establishment of Internal audit plan for ISO 22000 documentation.

Internal audit plan shows when the different parts of the Quality & food safety System (based on processes) are to be audited. The Plan is drawn up on the basis that the whole System will be audited at least two times over a whole year. Amendments will be done to the Audit Plan, from time to time in the light of experience with auditing.

Main Process	Sub Process	According to ISO 22000 / ISO 9001 requirement	Auditee	Auditor	Date	Time
Opening Meeting						
1. Management Processes	General management process	i. Management commitment ii. **Quality manual** iii. Food safety & policy iv. **Quality & food safety objectives** v. **Control of documents** vi. Control of records				
		i. Responsibility & Authority ii. Internal audits iii. Internal communication				
	Resource management & Training	i. Human resource ii. Provision of resource				
2. Realization of safe products	Pre Requisite programs	i. Design, lay out & facilities ii. Temperature monitoring records iii. Infrastructure iv. Prevent of cross contamination				
		i. Waste & Water quality management ii. Personal hygiene(Annual medical reports) iii. Cleaning & Sanitation iv. Pest Control				
	HACCP & OPRP Plan	i. Hazard analysis ii. Critical control point iii. Critical limit iv. Monitoring v. OPRP records vi. HACCP records				

		vii. Product Characteristics				
	Other procedures	i. Control of CCP ii. Work environment iii. Emergency preparedness & response				
	Purchasing process	i. Purchasing- Live stock ii. Purchasing- Dry goods				
3. Control Validation & verification of systems	Quality Assurance Process	i. Control of non conformity ii. FSMS & QMS verification iii. Handling of potentially unsafe products iv. Customer complains records v. Corrections vi. Corrective action vii. Preventive action viii. **Design & Development** ix. **Preservation of Product**				
–		i. Analysis of verification & activities ii. Control of monitoring & measuring & devices iii. Preventive Maintenance				
		i. Withdrawals ii. Traceability				
4. Improvement		i. Procedure for continual improvement ii. Management review				

• All Audits will be held at KFPL in the respective departments.

• Bold Area specifically related to ISO 9001 QMS auditing

Auditors

Table 4.9: Internal Audit Plan

The study was aimed at gap analysis & evaluating recommendation for the implementation of ISO 22000 in Keells food products Factory. As ISO 9001 certified company of KFPL already has GMP and PRP currently established for the factory. But the evaluation of PRP was very essential to control food safety condition of the factory. Existing procedure and practices of PRP of the company were analyzed and their weakness and area would have to modify were identified. Therefore swab testing was carried out for monitoring the effectiveness of cleaning procedure. According to result of swab test and the related records of company PRP procedure evaluated.

Factory flow and the production flow was very important tool to control food safety in factory. Affected studying the factory and dealing with workers, cross contamination areas in factory were identified. Those were supported to establish modified factory lay out. Lighting facility in factory was not examined last years and it was examined. Hand washing area, peeling area, production freezer, raw meat cutting section and spice room, etc. were identified as insufficient lux levels (Appendix IX).

The cleaning procedure of deboning section was not according to SLS required level. Therefore it was informed to construct new cleaning procedure and frequencies. Implementation of personnel hygienic practices and waste management procedures gap can identified due to improper practices of the workers.

ISO 9001 Quality manual and the procedure manuals of KFPL recovered majority of the documentation requirement of ISO 22000. But validation plan and the procedure, internal audit plan and hazard analysis of cut meat range products were mainly identified as documentation gap in ISO 22000 documentation of KFPL.

Emergency preparedness program was evaluated by referring factory evacuation plan and the procedure manual. On site verified result was identified that the existing evacuation plan and establishment of fire extinguishers in plant differ from each other. The main requirement and weakness found through the study is the lack of training and awareness of workers about emergency preparedness procedure (fire drill & training) in factory

To recover the gap of ISO 22000 requirement in KFPL hazard analysis of cut meat range product was carried out with indicating product characteristics, intended use, shelf life, production flow, hazard determination and the assessment of control measures and OPRP plan were established

Onsite verification of flow diagrams of different kind of products flow in Keells factory were carried out and Ham and Bacon Process flow diagrams were updated. HACCP plan and the OPRP plan of above product ranges were simultaneously modified.

Validation procedure for OPRP and the CCP were identified and developed plan for the validate OPRPs and CCPs. Most of OPRP and the CCP control measures, validation records currently maintain for the KFPL were critically evaluated and lack of records of cooking and the peeler machine cleaning validation records established.

It is expected to validate cleaning procedure & frequency of Peeler machine and swab samples were obtained from while working and after cleaning and then swab samples were obtained from every 15 minutes within one hour.

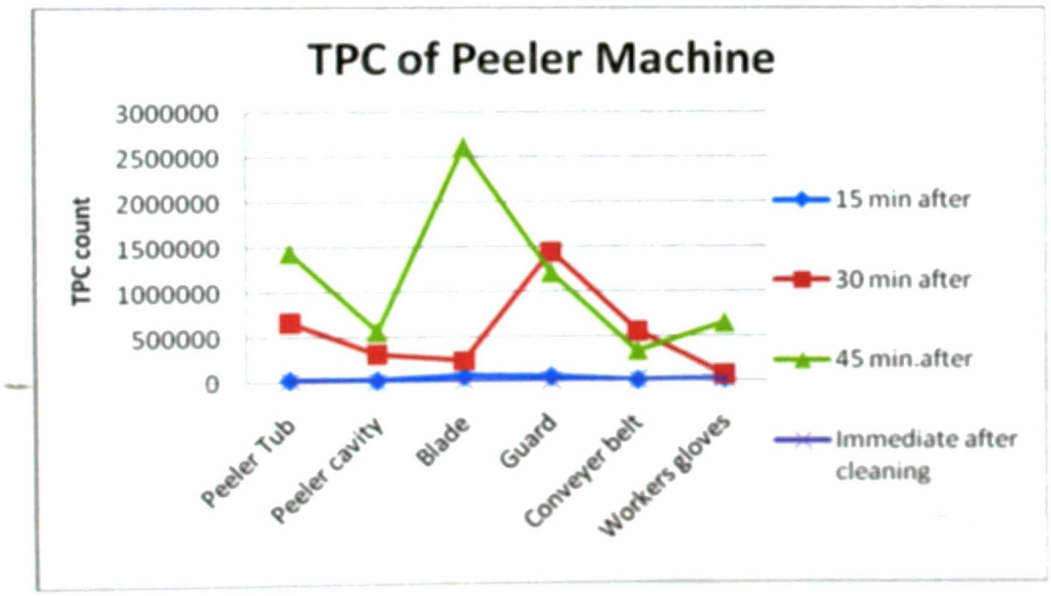


Figure 4.8: Validation of peeler machine

Aerobic plate count was less than 10^6 colony forming unit (CFU) after 30 minutes of cleaning in all areas except peeler guard. According to results survival of bacteria due to improper cleaning & sanitary practice of peeler machine and can control by increasing the cleaning frequency.

Inadequate time/temperature could result pathogenic bacteria to remain in product during cooking. It is expected to that comprehensive validation of the current existing chamber cooking procedure (core temp to be remaining at least 72^0C, 15 sec).

Samples were taken from each chamber from before cooking, immediate after cooking and after showering and tested for Aerobic plate count, *E-coli* and *Staphylococcus aureus*

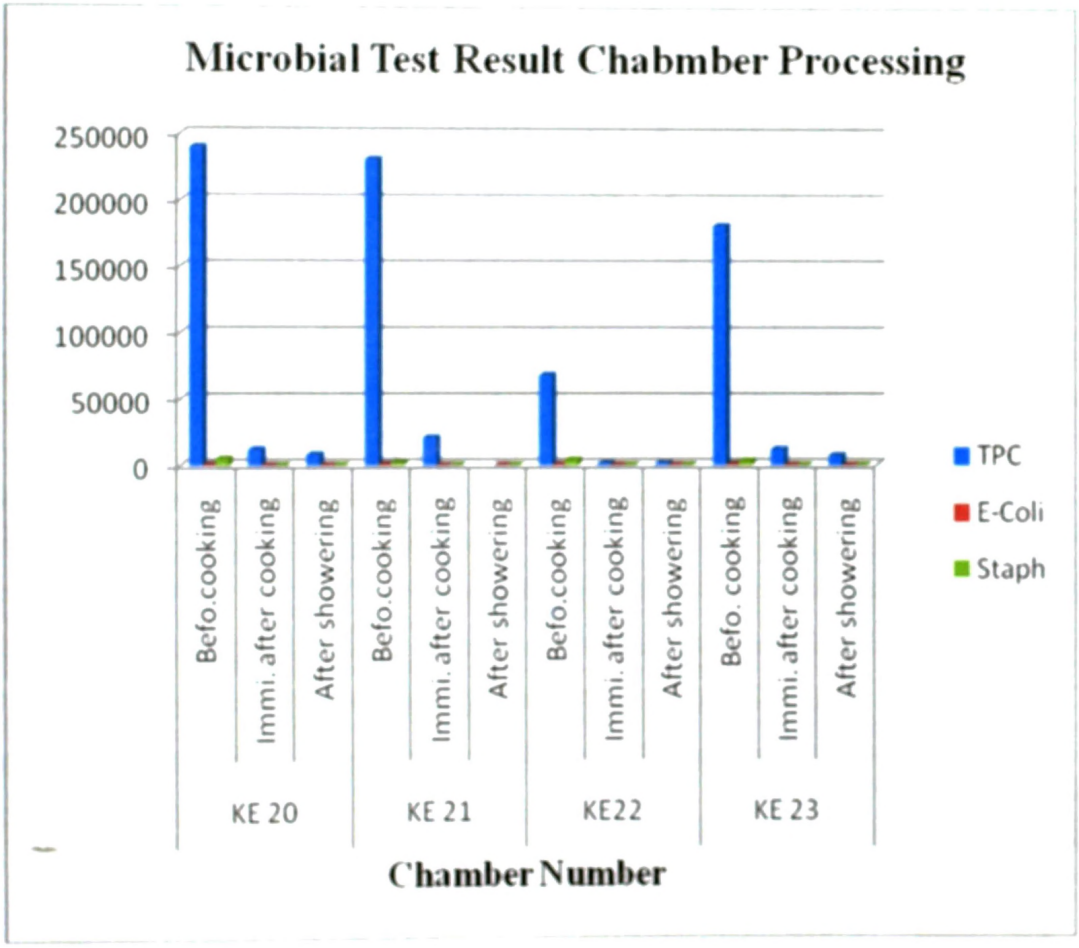


Figure 4.9: Microbial Test Result of Chamber Processing

According to result 72^{0}C core temperature of the products (specially sausage) adequate for the chamber cooking process and above time temperature combination of each chamber should maintained.

Control chart were drawn for Cut meat chill, Raw cut product chill, cooked product chill and the tunnel freezer temperature to evaluate the chill temperatures.

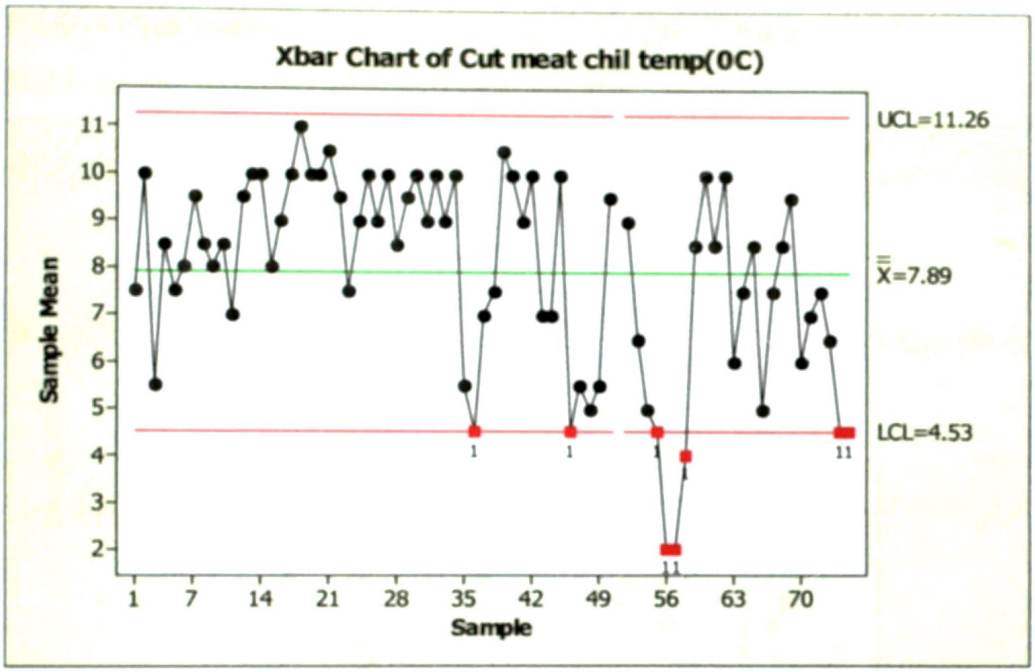


Figure 4.10: Control Chart of Cut meat chill Temperature Results

According to graph the cut meat chill temperature lower limit and the upper limit within rage of 4.55^{0}C- 11.26 ^{0}C. That is not within the specified range of 4^{0}C -10^{0}C and which is deviate from the specify limit of SLS specified limit of 0^{0}C -4^{0}C. Chill temperature maintains should be modify or take precautions to develop to get specified limit.

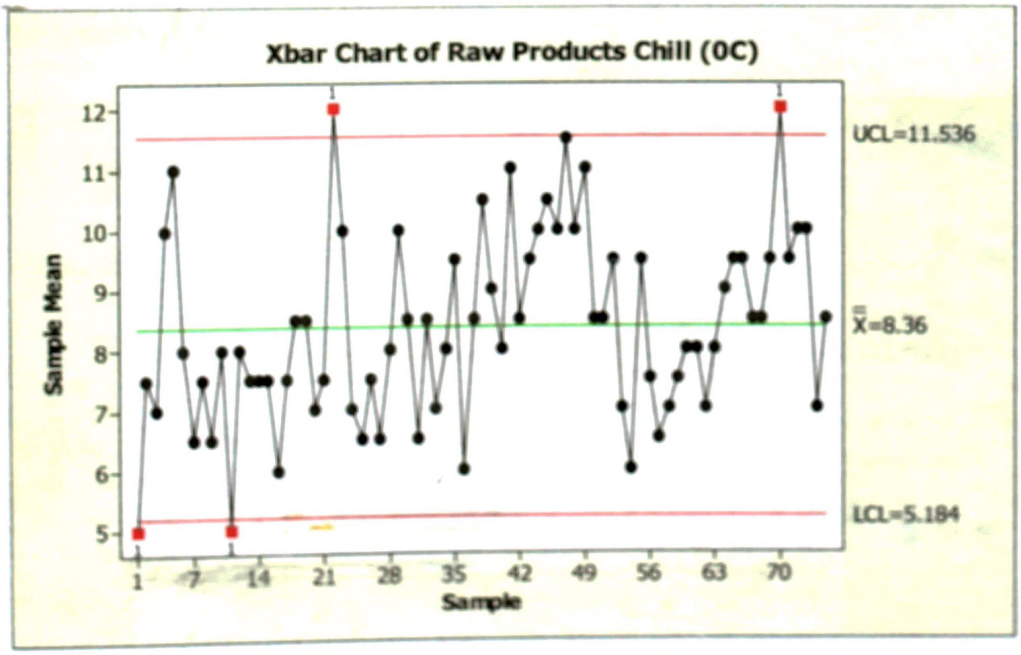


Figure 4.11: Control Chart of Raw Product chill Temperature Results

Raw Product chill Temperature also lower and the upper limit deviate from the specified limit due to improper practices of worker.

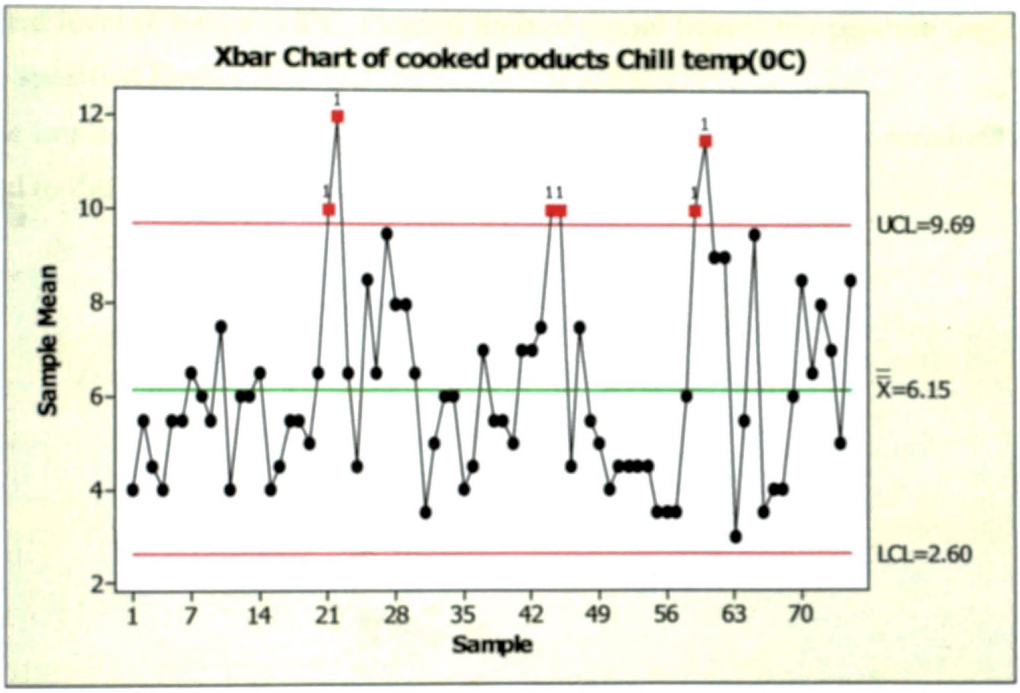


Figure 4.12: Control Chart of Cooked Product chill Temperature Results

Cooked product chill temperature lower limit 2.60 and which is below the 4^0C and which is better for the chill condition. Upper limit below 9.69^{0}C and which is deviate from the specify limit of 4^0C.

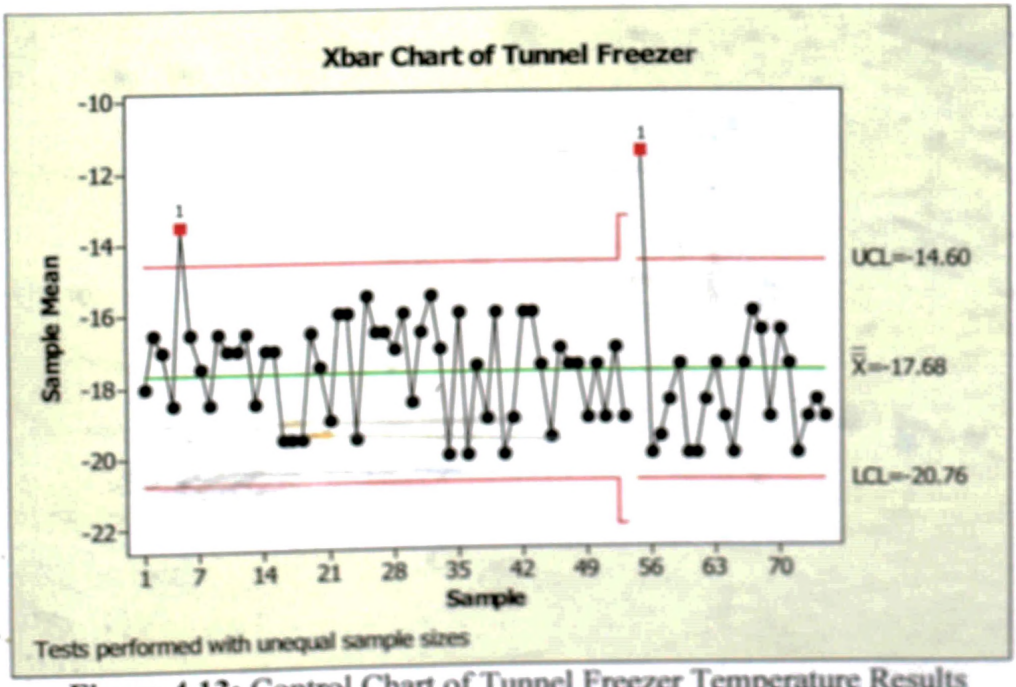


Figure 4.13: Control Chart of Tunnel Freezer Temperature Results

According to the graph tunnel freezer temperature within the range of -20^{0}C and -14^{0}C and that should be maintain within the range of -22^{0}C and -15^{0}C or SLS standard level of below -18^{0}C. Control limit of tunnel freezer temperature limits close to the specified limit.

By the implementation of proper cold room storage practices, these operations can be shifted to the specified temperature limits.

CHAPTER 05

CONCLUSIONS AND RECOMMENDATIONS

5.1. Conclusions

The evaluation performed for the PRP serves as a universal procedure to control the conditions of the factory environment with particular reference to processing and handling of food items. Hence it could be considered as the major contributor to overall safety of production of KFPL as well. There is a possibility of contamination of products through workers hand and the inadequate cleaning Practices. Improper accommodation of equipment in places cause cross contamination in factory floor. External communication, hazard analysis of cut meat range products, validation plan and the procedure and internal audit plan were identified as documentation gap.

Lack of training and awareness of workers about emergency procedure (fire drill & training) and implementation gap with fire evacuation plan has lead to the gap in emergency preparedness of KFPL.

Steps such as raw Meat receiving, frozen storage, Packaging/Labeling and transporting were identified as the OPRPs of raw cut range product hazard analysis and no CCPs were detected in this process steps.

Establishment of proper validation procedure causes to modification and maintain of control measures accurately. Achieving 72^0C and maintain 72^0C for 1 minute was identified as adequate core temperatures for chamber cooking process and therefore after cooking *E.coli* and *Staphylococcus aureus* counts were potential zero.

Maintaining an effective cold temperature in chills and freezers cause reduction of biological hazards in foods.

5.2. Recommendations

- Modification of factory lay out and the accommodation of equipment in suitable places cause reduction of the cross contamination.
- An effective implementation and maintaining of PRPs of personal hygiene, lighting levels of factory and cleaning procedure and the cleaning frequency of deboning section need to be conducted as further improvements measures
- Special care & attention should be taken for cleanliness of packaging section in the Keells.

- Workers should pay attention to cleanliness of their gloves and should increase the glove changing frequency.
- Establishment of fire team, fire training and maintain fire evacuation plan cause an effective implementation of emergency preparedness procedure in order to fill the emergency gap.
- Raw meat chills and other cold storage conditions indicated needed for maintaining temperature at 0^0C - 4^0C and freezers below -18^0C.
- It is expected that developed internal audit plan of ISO 22000 be carried out in every six months.

REFERENCES

Codex Alimentarius commission (1997) Recommended International code of practices. General Principal of Food hygiene (CAS/RCp-1969, Rev.3 1997) 33p.

Codex Alimentarius commission (Available from http// www.fao.org/WAICENT/faoinfo/economic/Esn/codex/default.html accessed on; 2008)

Devid, H. (1994), ISO 9000 Quality system Hand Book, 2nd edition, Butterworth Heinemann, 498p.

Marriott, G.N. (1999), Principle of Food Sanitation, 4th edition, Aspen Publishers, Galithersbug, Maryland, 364p.

Maclandsborough, L., (1995), Food Microbilogy Laboratory, CRC Press, 179p.

Pearson, A.M. and Gillet, T.A. (1997), Processed Meat, 3rd edition, CBS Publishers and Distributors, 445p.

Praxiom Reserch Group Limited (2008), ISO-22000-Definitions (Available from: http://www.praxiom.com/iso-22000-definitions.html accessed on; November 12, 2008)

Praxiom Reserch Group Limited (2008), ISO-22000-Gap Analysis (Available From: http://www.praxiom http: www.praxiom.com/ iso-22000-gap analysis.htm accessed on; November 10, 2008)

Praxiom Reserch Group Limited (2008), ISO-22000-Audit (Available From: http: www.praxiom http www.praxiom.com iso-22000-audit.htm accessed on; December 13, 2008)

Savic, I.V. (2008) Food and Agriculture Organization:Small-scale sausage production (Available From: http://www.fao.org/docrep/003/x6556e/X6556E00.htm#TOC accessed on: November5,2008)

Specification for Ham (First Revision), Sri Lankan Standard Institute, SLS 1146:2001

Specification for Bacon (Second Revision), Sri Lankan Standard Institute, SLS 342:2001

Specification for Communicated Meat Products, Sri Lankan Standard Institute, SLS 1218:2001

Specification for Potable Water, Part 2: Bacteriological Requirements, Sri Lankan Standard Institute, SLS 616: Part 2: 1983

Sri Lankan Standard SLS 1045:1995, Code of Hygienic Practices for Processed Meat Products, Sri Lankan Standard Institute

Sri Lankan Standard SLS 143:1999 (Second Revision), Code of Hygienic Practices for General Principle of Food Hygienic

Sri Lankan Standard SLS ISO 22000:2005, Food Safety Management Systems-Requirements for Any Organization in the food chain

Sri Lankan Standard 516: 1982, Microbial testing for Food Products, Sri Lankan Standard Institute

Sri Lankan Standard SLS 1173:1998, Guidance for the Application of the Hazard Analysis Critical Control Point (HACCP) System, Sri Lankan Standard Institute

Technical Specification ISO TS 22004, Food Safety Management Systems- Guidance on the application of ISO 22000:2005, First edition, Sri Lankan Standard Institute

Wikipedia Organization (2008). International Organization for Standardization (Available From: http://en.wikipedia. org/wiki/International Organization for _Standardization accessed on: December 13, 2008)

Wikipedia Organization (2008). (Available From: http://en.wikipedia.org/wiki/ /ISO 22000 accessed on: 2008)

Montana Educations. (Available From http:// animal range.montana.edu/course/meat/Ingredients.pdf accessed on: 2008)

APPENDIX I

Compliance assessment of the existing documentation of Keells Factory

ISO Clause No:	ISO 22000 Requirements	KFPL manual clause no.	Availability (yes(√)), Not Availability No(×)	Deficiency (if any)
4	Food safety management system			
4.1	General requirement	QM-00	√	Addressed in ISO
4.2	Documentation Requirement	QM-00	√	9001 manual (has been
4.2.1.	General	QM-00	√	Integrated to FSMS)
4.2.2.	Control of Documents	QM-00	√	
4.2.3	Control of Records		√	
5.	Management Responsibility			
5.1.	Management commitment	QM-05	√	
5.2.	Food safety policy	FSP-00	√	
5.3.	Food safety management system planning		√	
5.4.	Responsibility & authority	QM-05	√	
5.5 –	Food safety team leader	FST-00	√	
5.6.	Communication			
5.6.1.	External communication	QM-05	√	Addressed in ISO9001 manual (has been Integrated to FSMS)
5.6.1	Internal Communication	QM-05	√	
5.7.	Emergency Preparedness & response	IPM-00	√	
5.8	Management review			
5.8.1.	General	QM-05	√	
5.8.2.	Review input	QM-05	√	
5.8.3	Review out put	QM-05	√	
6	Resource Management			
6.1.	Provision of resource	QM-06	√	
6.2.	Human resource	QM-06		
6.2.1.	General		√	
6.2.2	Competence, awareness & training	QM-06	√	
6.3	Infrastructure	QM-06	√	
6.4	Work environment	QM-06	√	

7	Planning & Realization of safe product			
7.1.	General		√	
7.2.	Pre Requisite Programmes (PRP)	PRP-00	√	
7.3	Preliminary steps to enable hazard analysis			
7.3.1	General	FST-00	√	
7.3.2	Food safety team	FST-00	√	
7.3.3	Product Characteristics	PD-SL-00	√	
7.3.3.1	Raw materials, ingredients & product contact materials	PD-SL-00	√	
7.3.4.	Intended use	PD-SL-00	√	
7.3.5.	Flow diagrams, Process steps & control measures	FD-SL-00	√	
7.4	Hazard analysis	HA-00		
7.4.1.	General	HA-BR-00	√	*Not address in cut meat
7.4.2	Hazard identification & determination of acceptable level	ID-00	√	range of products
7.4.3.	Hazard assessment	HA-SL-00	√	
7.4.4_	Selection & assessment of control measure	HA-00	√	
7.5	Establishment of Operational PRP	OP-SL-00	√	
7.6	Establishing the HACP plan	HP-00(HP-BR-00/HP-SL-00)	√	
7.6.1	Identification of CCP	CD-SL-00	√	
7.6.2	Determination of Critical limits	CD-SL-00	√	
7.6.4	System for monitoring results		√	
7.6.5	Action when monitoring results exceed critical limits	CD-SL-00	√	
7.7	Updating of preliminary information &documents specifying the PRP &HACCP plan			

7.8	Verification planning	VP-00	√	
7.9	Traceability system		√	
7.10	Control of nonconformity	QM-08		
7.10.1	Corrections	QM-08	√	
7.10.2	Corrective action	QIP-00	√	
7.10.3	Handling of potentially unsafe products			
7.10.3.1	General	QM-08	√	
7.10.3.2	Evaluation for release	QIP-05	√	
7.10.3.3.	Disposition of non conformity products	QIP-05	√	
7.10.4	withdrawals	RC-00	√	
8	Validation, Verification & improvements of the FSMS			
8.1	General			
8.2	Validation of control measures combinations	VP-00	√	Not complete the validation procedure
8.3	Control of monitoring & measuring	QM-08	√	
8.4	Food safety management system verification	QM-08	√	
8.4.1	Internal Audit	QM-08	√	Addressed in ISO9001 manual (has been Integrated to FSMS)
8.4.2	Evaluation of individual verification results		×	
8.4.3	Analysis results of verification activities		×	
8.5	Improvements			
8.5.1	Continual improvements	QM-08	√	
8.5.2.	Update the Food safety management system		√	

APPENDIX II
PRP'S - DESIGN, LAYOUT AND FACILITIES

PRP's requirements		ISO22000/SLS Clause(Requirement)	Observations	Analyzed gap	Recommendation	References
Location	Establishment	SLS 1065:1995 4.3 Should be located in areas not subject to regular and frequent flooding and free from objectionable odours....	Established according to SLS requirements	No Gap	-	Existing documentation of in Keells (PRP-DL)
	Equipment	SLS 143:1999 5.1.2. Should be located adequate maintenance and cleaning	Frozen cutting machine, ham preparation done in common areas	Gap in implementation	Modify the design lay out and accommodate of equipment in suitable place	-
Premises and rooms	Floor plan	SLS 143:1999 5.2. Establishment should permit good food hygiene practices, protection against cross-contamination	In processing area work space not sufficient, Receive chill meat transport through the slaughter area to storage, Cooked product can be contaminated during, transport to cooked product chill	No Gap	Modify the design lay out to reduce cross contamination and according to SLS requirement	Floor plan-Keells factory
Internal Structure and Fittings	Floor	SLS 1065:1995 4.4.8 Floor should be water proof, non absorbent, washable and non slip material, ... Floor	Tile damage in side cooked product chill, processing area and corridors.	No gap with Existing documentation of ISO22000 but there	Repair the tile in factory	-

		should be easy to clean and disinfect		is gap in implementation		
		SLS 1065:1995 4.4.8 Floors should slope sufficiently for liquid drains to trapped outlets	In processing area front of stuffing machine edible casing machine & thawing chill and in front of cooked product chill water accumulation on the floor.	No Gap	Repair the floor according to SLS requirements	Internal cleaning checklist
	Walls	SLS 1065:1995 4.4.8 Should be of water-proof, non absorbent and washable material and be light colored.... Height, angle between walls	Established according to SLS requirements	No Gap	-	-
	Ceilings	SLS 1065:1995 4.4.8 Should be so designed, constructed and finished as to prevent the accumulation of dirt.....	Packaging area top of the metal detector, water leakages of the ceiling	Existing documentation of ISO22000 documentation supports all the SLS requirements but there is gap in implementation	Repair the ceiling	-
	Windows	SLS 1065:1995 4.4.8 Should be so constructed as to avoid accumulation of dirt...	Established according to SLS requirements	No Gap	-	-
	Doors	SLS 1065:1995 4.4.8 Should have smooth, non absorbent surfaces and be self-closing and close fitting	Established according to SLS requirements	No Gap	-	-

Facilities	Changing facilities and toilets	SLS 1065:1995 4.5.4 Should adequate, suitable and conveniently located changing facilities and toilets(one toilet per ten worker) should be provided in all establishments.	Ladies changing room, which has not enough space (Space is not sufficient)	Ladies changing room provided but space not sufficient	Ladies changing room should expand and should make coverage for the way from changing room to production factory	Floor plan-Keells factory
	Hand washing facilities	SLS 1065:1995 4.5.5 Hygienically washing and drying hands, including wash basins Taps of a non-operational type.	Number of wash basins in slaughterhouse area inadequate.	Gap in implementation	Establish new wash basins in slaughterhouse area	Internal cleaning checklist
	Lighting	SLS 1065:1995 4.5.7 Adequate natural or artificial lighting should be provided. Lighting should not alter colors and intensity should be not less than 540 Lux at all inspection points 220 Lux in work rooms 110 Lux in other areas	Lux levels in hand washing area, peeling area, production freezer, raw meat cutting section and spice room ..etc were not up to standard level.	Gap in implementation of lighting facility	Establish new lighting facilities for above mentioned areas.	Lighting level measurement report
	Ventilation	SLS 1065:1995 4.5.8 Adequate ventilation, the direction of air flow should never be from a dirty area to a clean area.	Duct lines at processing area (front of stuffing machine) was not properly work	Gap in implementation	Repair the duck lines and maintained these things according to SLS standard	

APPENDIX III

PRP'S - PERSONNEL HYGIENE

PRP's requirements		ISO22000/SLS Clause(Requirement)	Observations	Analyzed gap	Recommendation	References
Hygiene training		SLS 1065:1999 5.1 Should arrange for adequate and continuing training of every handler of meat and meat product	Should done and maintain according to the SLS standard	No Gap	-	Work Instructions for Maintaining Personnel Hygiene
Medical examination		SLS 1065:1999 5.2 Person should have medical examination prior to their employment	Should done and maintain according to the SLS standard	No Gap Existing documentation of ISO22000 documentation supports all the SLS requirements	-	Annual Medical Report file
Communicable diseases	Disease control	SLS 1065:1999 5.3 Should take care to insure that no person, while known or suspected to be suffering from, or to be a carrier of disease likely to be transmitted through meat and meat product.	Should done and maintain according to the SLS standard	No Gap	-	Work Instructions for Maintaining Personnel Hygiene
	Illness and	SLS 1065:1999 5.4 Worker should suitability	Workers may not maintain instruction for illness and	Document support guidance but	Workers Hygiene Maintenance	Workers Hygiene Maintenance

	Injuries	bandaged, should not engage in preparation, handling, packing or transportation area.	injuries in proper manner.	Workers Hygiene Maintenance Check list not yet maintained	Check list should be maintain in proper manner	Check list
Washing hands		SLS 1065:1999 5.4 Every person engaged in a meat and meat products handling area wash hands frequently and thoroughly	processing area workers hand washing habits not sufficient	Existing documentation of ISO22000 documentation supports all the SLS requirements but there is gap in implementation	New hand washing facilities should be provided for slaughter & deboning area.	Work Instructions for Maintaining Personnel Hygiene
Personal Cleanliness		SLS 1065:1995 6.6 Every person engaged in a meat and meat products handling area should maintain a high degree of personal cleanliness	Uniforms and other things should maintain in proper manner	Existing documentation of ISO22000 documentation supports all the SLS requirements	-	Work Instructions for Maintaining Personnel Hygiene
Personal behavior		SLS 1065:1995 6.6 Eating, use of tobacco, chewing, spitting, should be prohibited	Done according to SLS requirements	No Gap	-	"
Gloves / Masks/ Boots		SLS 1065:1995 6.8 Should be so maintained in a sound and clean condition and disposed at least every break	Mask not uses workers in processing areas.	Gap with implementation	Should improve usage of mask in processing workers	Swab sampling scheme
Visitors		SLS 1065:1995 6.9 Should wear clean protective clothing	done and maintain according to the SLS standard	No Gap	-	Work Instructions for Maintaining Personnel Hygiene

APPENDIX IV

PRP'S - CLEANING & SANITATION

PRP's requirements		ISO22000/SLS Clause(Requirement)	Observations	Analyzed gap	Recommendation	References
Cleaning of Machinery	Method of cleaning machinery	SLS 143:1999 Appendix A Physical method and use of detergents	Done and maintain according to the SLS standard.	No Gap	-	Swab sampling scheme Cleaning, sanitation verification plan
	Cleaning Frequency	SLS 1065:1999 5.2 Should carried out every time there is such a change use and clean at least after every shift	Done and maintain according to the SLS standard.	No Gap Existing documentation of ISO22000 supports all the SLS requirements	-	Cleaning, sanitation and verification plan
		SLS 1065:1999 5.2.4 Deboning area equipment and utensils cleaning practices should carried out at least every four hours if not temperature of these areas should maintain below 10^0C	Not maintain cleaning practices every four hours and not maintained temperature below 10^0C in deboning area	Cleanliness of the machine done at the end of the shift only.	Should modify cleaning procedure for deboning area if not maintain required temperature in this area.	Work Instructions for Cleaning and Sanitation
	Type of Detergents and cleaning facility	SLS 143:1999 Appendix A 2.3. Detergent and chemicals have good wetting capacity and ability to remove soil from	Done and maintain according to the SLS standard (Use Iso propyl alcohol and hot water.)	No Gap	-	Work Instructions for Maintaining Personnel Hygiene

		surfaces				
	Disinfecting fitted with suitable supplying hot water	SLS 1065:1999 4.5.1.2. Adequate hot potable water should be available at all times during workers hours(80^0C for not less than)	Done and maintain according to the SLS standard	**No Gap**	-	Work Instructions for Cleaning and Sanitation
	Meat and meat product Contaminati on with cleaning chemicals	SLS 1065:1999 5.2.9 Adequate precautions should be taken to prevent contamination Meat and meat product with cleaning chemicals	Water splash could occur during cleaning of chills. Disinfection & detergent material place in corridor of the nearest slicer machine (Frozen meat machine) also ham preparation done nearest wash room	Existing documentation of ISO22000 documentation supports all the SLS requirements but there is gap in implementation	Cleaning procedure should modify in chill cleaning and design and lay out should modify to reduce cross contaminations	Work Instructions for Cleaning and Sanitation
General Factory Cleaning (Walls, Chills, Drain)		SLS 1065:1999 5.2.6 Floor drains should kept in good condition and repair with strainers in place	Filling machine area walls cleaning frequency inadequate.	Gap in cleaning frequency for walls	Cleaning frequency of wall should modify	Internal and External cleaning check lists Cleaning, verification plan swab sampling scheme
External cleaning		SLS 1065:1999 5.2.8 Roadways and yards in immediate vicinity of and serving the establishment should kept clean	External cleaning maintain in adequate level.	**No Gap**	-	Internal and External cleaning check lists

APPENDIX V

PRP'S - HYGEINIC PROCESSING

PRP's requirements		ISO22000/SLS Clause(Requirement)	Observations	Analyzed gap	Recommendation	References
Control of hazards	Food Control and Monitoring equipment	SLS 143:1999 6.1. describe as follow Control procedure may be simple, such as checking stock rotation calibrating equipment, or correctly loading refrigeration display units.	maintain according to the SLS standard	Existing documentation of ISO22000 documentation supports all the SLS requirements	-	ISO manual (TM-00).
	Temperature Control	SLS 143:1999 6.2. describe as follow Temperature recording devices should be checked at regular intervals and tested for accuracy	Done and maintain according to the SLS standard	No Gap Existing documentation of ISO22000 documentation supports all the SLS requirements	-	Temperature monitoring records Temperature monitoring records – Finlays Temperature verification records
	Process and Packing room	SLS 143:1999 6.2. describe as follow System should specify	Not maintain temperature between 22-24 °C (In packing area) and not	Existing documentation of ISO22000	Should maintain temperature between 22-24 °C	Temperature monitoring records

	temperature control	tolerable limits for time and temperature variations	maintain monitoring procedure.	documentation supports all the SLS requirements but there is gap in implementation.	In packing area	
	Storage Temperature control	SLS 143:1999 6.2. describe as follow System should specify tolerable limits for time and temperature variations	Chills temperature may vary due to improper workers habits	Same	Chills temperature Should maintain between 4-10° C	Temperature monitoring records Finlays
Prevention of cross contamination	Microbial cross contaminations	SLS 143:1999 6.2.4. describe as follow Raw product should be effectively separate either physically or by time from ready-to-eat food.	Cooked product can be contaminated during, transport to cooked product chill due to transport way across the processing area.		Modify the design lay out to reduce cross contamination and according to SLS requirement	Floor plan-Keells factory
	Physical and chemical contamination	SLS 143:1999 6.2.5. describe as follow Should be prevent contamination of foods by foreign bodies and harmful fumes and unwanted chemicals	Water split could occur during washing of chill.	Existing documentation of ISO22000 documentation supports all the SLS requirements but there is gap in implementation	Cleaning procedure should modify in chill cleaning and design and lay out should modify to reduce cross contaminations	Work Instructions for Cleaning and Sanitation

APPENDIX VI

PRP'S - PEST CONTROL

PRP		ISO22000/SLS Clause(Requirement)	Observations	Analyzed gap	Recommendation	References
Pest control	Preventive access	SLS 1065:1995 5.6. & SLS 143:1999 7.3. describe as follow Should be effective and continuous programme for the control of insects, birds, rodents or other vermin.	There is gap in dry stores door, could lead to enter rats.	No gap with existing documentation of ISO22000 but there is gap in implementation	Holes, drains & other places where pests are likely to gain access should be kept seal	Pest Control (external) Record File
	Harbourage and infestation	SLS 1065:1995 5.6. describe as follow Control measures involving treatment with chemical, physical or biological agents	Established according to SLS requirements	No gap	-	Electric Fly Catchers Placement Plan & monitoring records
	Monitoring and detection	SLS 143:1999 7.3.4. describe as follow Establishment and surrounding area should be regularly examined for evidence.	Boundary walls, breeding grounds, access points and fly catchers establishments according to SLS requirements	No gap	-	GPC checklists
	Eradication	SLS 143:1999 7.3.4. describe as follow Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety	Pest Controlling party is provided required treatment & prove that the chemicals they use are harmless to the products	No gap		Pest Control (external) Record File

APPENDIX VII

PRP'S - WASTE MANAGEMENT

PRP		ISO22000/SLS Clause(Requirement)	Observations	Analyzed gap	Recommendation	References
Waste management	Procedure	SLS 143:1999 7.4. describe as follow, Suitable provision must be made for the removal and storage of waste.	Waste removing pathway across the slaughtering area.	Establishment not according to the SLS requirements	Waste removing pathway should be change.	Internal cleaning schedule
	Solid waste (Waste bins)	Same	Should done and maintain according to the SLS standard	No Gap Existing documentation of ISO22000 documentation supports all the SLS requirements	-	visual observation and monitoring records
	Animal waste Removal	SLS 143:1999 7.4. describe as follow, Waste must not be allowed to accumulate in food handling, food storage, and other working areas.	Should done and maintain according to the SLS standard	No Gap	-	Internal cleaning schedule
	Waste - water	Same	Should done and maintain according to the SLS	No Gap	-	Waste water analysis reports file

APPENDIX VIII

PRP'S -POTABLE WATER QUALITY

PRP's requirements		ISO22000/SLS Clause(Requirement)	Observations	Analyzed gap	Recommendation	References
Water quality evaluation	Water physical requirements	SLS 614. describe as follow, Colour Colorimetry-Spectophotometer method,max: 5units Odour-Unobjectionable-sensory evaluation Taste- Turbidity-visual method- Candle turbiditymeter	Maintain according to the SLS standard	No Gap	-	visual observation ITI test reports
	Water Microbiology requirements	SLS 614. describe as follow, E-coli zero in sample Coliform count should be <10 in sample	Maintain according to the SLS standard	No Gap Existing documentation of ISO22000 supports all the SLS requirements	-	Microbiology test reports ITI test reports
Storage and Distribution		SLS 143:1999. 5.4.1.describe as follow, Adequate supply of potable water, with appropriate facilities for its storage, distribution and available	Done and maintain according to the SLS standard(Present the plant utilized	No Gap	-	Procedure Mannual

			30,000gallons per day)			
Water purification system		SLS 614. describe as follow, Examine daily and cleaned properly and satitized by spraying 100ppm chlorine	Done and maintain according to the SLS	No Gap Adequate purification plant consists of square shaped tanks	-	
	Tank cleaning procedure and frequency		Done and maintain according to the SLS standard	No Gap	-	External cleaning checklist
	The tank chlorination procedure		Done twice a day. standard chlorine levels maintained	No Gap	-	Daily chlorine check list-
Water circulated		SLS 143:1999. 6.5 describe as follow, Re-use within an establishment should be treated and maintained	Recycled water is not used within the plant	No Gap	-	-

APPENDIX IX

Light level Measurements

Measurement of light -- Digital illuminance meter

Location	Lighting level (Lux)
Hand washing area	191
Bag making section	175
Thermoforming area	268
Packing table	269
Slice area	498
Peeling area	185
Production freezer	16
Cooked product chill	138
Raw meat cutting section	231
Processing area	289
Spice room	211
Cut meat chill	373
Thawing chill	366
Corridor	202
Boning section	417
Meat bowl filling area	111
Raw product chill	201
Cooking area	135
Slaughter chill	142
Washing room	348
Slaughter house	266
Receiving bay	412
Tunnel freezer	72
Box freezer	75
Production office	110

Table: Light level – Inside the Factory

APPENDIX X

Microbial test result of Chamber processing (before cooking and after cooking)

Chamber No.	Time tepm. Combination	Time sample collected	E. Coli	Staph.	TPC
KE 20	72°C-1hour & 35 min	Before cooking	600	5000	240000
		Immediate after cooking	0	0	12000
		After showering	0	0	8000
KE 21	72°C- 1hour & 45 min	Before cooking	500	2000	231000
		Immediate after cooking	0	0	21000
		After showering	0	0	1500
KE 22	72°C-1hour & 40 min.	Before cooking	300	4000	68000
		Immediate after cooking	0	0	1000
		After showering	0	0	900
KE 23	72°C-1hour & 40 min	Before cooking	400	3000	181000
		Immediate after cooking	0	0	12000
		After showering	0	0	7200

Microbial counts of different parts in Peeler machine (while working and after cleaning)

Area	Time sample collected	E. Coli	Staphylococcus
Peeler Tub	While working	80	0
	After cleaning	0	0
Peeler cavity	While working	100	0
	After cleaning	0	0
Blade	While working	500	0
	After cleaning	0	0
Guard	While working	10	0
	After cleaning	0	0
Conveyer belt	While working	120	0
	After cleaning	0	0
Workers gloves	While working	90	0
	After cleaning	0	0

Microbial counts of different parts in Peeler machine (Cleaning after every 15 minutes within one hour)

Area	Time sample collected	TPC	E. Coli	Staphylococcus
Peeler Tub	Immediate after cleaning	8000	0	0
	15 min. after cleaning	31400	0	0
	30 min. after cleaning	670000	50	0
	45 min. after cleaning	1440000	120	0
Peeler cavity	Immediate after cleaning	600	0	0
	15 min. after cleaning	24000	0	0
	30 min. after cleaning	314000	40	0
	45 min. after cleaning	570000	100	0
Blade	Immediate after cleaning	450	0	0
	15 min. after cleaning	61000	10	0
	30 min. after cleaning	239000	120	0
	45 min. after cleaning	2610000	160	0
Guard	Immediate after cleaning	680	0	0
	15 min. after cleaning	54800	0	0
	30 min. after cleaning	1446000	40	0
	45 min. after cleaning	1210000	120	0
Conveyer belt	Immediate after cleaning	1800	0	0
	15 min. after cleaning	14000	0	0
	30 min. after cleaning	560000	10	0
	45 min. after cleaning	340000	40	0
Workers gloves	Immediate after cleaning	8500	0	0
	15 min. after cleaning	28000	0	0
	30 min. after cleaning	70000	30	0
	45 min. after cleaning	654000	40	0

APPENDIX XI

Date	Time	Raw Products Chill (^{0}C)	Cut meat chil temp(^{0}C)	cooked products Chill temp(^{0}C)	Tunnel Freezer
1/11/2008	8.00am	4	7	3	19
	10.00am	6	8	3	17
	12.00pm	8	10	6	16
	2.00pm	7	10	5	17
	4.00pm	7	6	6	18
2/11/2008	8.00am	7	5	3	16
	10.00am	11	7	4	18
	12.00pm	9	10	2	19
	2.00pm	10	8	6	12
	4.00pm	12	7	5	15
3/11/2008	8.00am	7	6	2	16
	10.00am	9	10	7	17
	12.00pm	6	9	5	17
	2.00pm	7	12	8	18
	4.00pm	8	12	7	18
4/11/2008	8.00am	7	7	5	19
	10.00am	7	8	6	18
	12.00pm	6	8	5	15
	2.00pm	8	9	7	16
	4.00pm	8	8	8	18
5/11/2008	8.00am	5	7	4	18
	10.00am	5	7	2	16
	12.00pm	7	9	5	17
	2.00pm	9	10	7	16
	4.00pm	8	10	6	17
6/11/2008	8.00am	7	10	6	20
	10.00am	7	10	7	18
	12.00pm	8	10	6	16
	2.00pm	8	8	3	18
	4.00pm	7	8	3	16
7/11/2008	8.00am	6	8	5	19
	10.00am	6	10	4	20
	12.00pm	7	10	5	20
	2.00pm	8	12	6	19
	4.00pm	9	11	6	20
8/11/2008	8.00am	8	11	5	19
	10.00am	9	10	6	18
	12.00pm	8	10	4	15
	2.00pm	8	10	7	17
	4.00pm	6	10	6	18

9/11/2008	8.00am	8	12	10	20
	10.00am	7	11	12	18
	12.00pm	10	12	11	17
	2.00pm	14	9	13	15
	4.00pm	15	7	9	16
10/11/2008	8.00am	5	8	2	16
	10.00am	6	9	3	19
	12.00pm	8	9	5	20
	2.00pm	7	10	8	15
	4.00pm	6	10	9	16
11/11/2008	8.00am	7	8	5	18
	10.00am	8	10	8	15
	12.00pm	7	10	9	17
	2.00pm	6	14	10	16
	4.00pm	6	15	12	18
12/11/2008	8.00am	10	8	4	16
	10.00am	9	8	6	18
	12.00pm	11	11	10	14
	2.00pm	9	10	8	19
	4.00pm	8	10	5	18
13/11/2008	8.00am	7	9	2	17
	10.00am	6	9	3	16
	12.00pm	8	10	3	15
	2.00pm	9	10	6	16
	4.00pm	7	10	7	16
14/11/2008	8.00am	7	8	5	18
	10.00am	8	10	6	20
	12.00pm	8	10	6	20
	2.00pm	9	5	3	14
	4.00pm	10	6	3	18
15/11/2008	8.00am	6	5	5	20
	10.00am	6	4	4	20
	12.00pm	7	8	6	8
	2.00pm	10	6	8	17
	4.00pm	11	5	6	18
16/11/2008	8.00am	10	10	5	20
	10.00am	10	11	5	15
	12.00pm	8	10	6	17
	2.00pm	8	10	5	20
	4.00pm	8	10	5	20
17/11/2008	8.00am	10	7	4	20
	10.00am	12	11	10	18
	12.00pm	10	10	13	14
	2.00pm	7	10	10	18
	4.00pm	8	8	10	16

18/11/2008	8.00am	11	6	5	16
	10.00am	9	7	10	17
	12.00pm	11	7	10	18
	2.00pm	11	10	10	19
	4.00pm	10	10	10	20
19/11/2008	8.00am	9	4	4	16
	10.00am	11	5	5	18
	12.00pm	12	7	8	17
	2.00pm	11	4	7	18
	4.00pm	10	5	6	18
20/11/2008	8.00am	10	5	5	17
	10.00am	11	5	3	19
	12.00pm	11	6	6	19
	2.00pm	9	9	4	18
	4.00pm	8	10	3	17
21/11/2008	8.00am	8		3	20
	10.00am	9		5	18
	12.00pm	10	8	4	17
	2.00pm	9	10	5	17
	4.00pm	9	9	4	19
22/11/2008	8.00am	5	4	5	*
	10.00am	6	5	5	*
	12.00pm	6	5	4	*
	2.00pm	10	5	4	10
	4.00pm	9	4	3	13
23/11/2008	8.00am	7	2	4	20
	10.00am	8	2	3	20
	12.00pm	6	2	4	20
	2.00pm	7	2	3	19
	4.00pm	7	2	2	17
24/11/2008	8.00am	7	6	8	20
	10.00am	8	5	10	18
	12.00pm	7	12	12	17
	2.00pm	8	10	10	20
	4.00pm	8	10	13	20
25/11/2008	8.00am	8	7	8	20
	10.00am	8	10	10	20
	12.00pm	7	10	10	18
	2.00pm	7	10	8	19
	4.00pm	8	8	3	17
26/11/2008	8.00am	8	4	3	18
	10.00am	8	7	3	20
	12.00pm	10	8	8	18
	2.00pm	9	8	9	20
	4.00pm	10	9	10	20

27/11/2008	8.00am	8	4	3	16
	10.00am	11	6	2	19
	12.00pm	10	5	4	18
	2.00pm	7	10	2	14
	4.00pm	8	10	3	13
28/11/2008	8.00am	9	7	4	20
	10.00am	9	9	6	18
	12.00pm	10	10	6	20
	2.00pm	11	10	8	16
	4.00pm	13	2	9	17
29/11/2008	8.00am	10	6	6	16
	10.00am	9	8	7	19
	12.00pm	9	8	7	20
	2.00pm	11	7	9	20
	4.00pm	13	8	10	18
30/11/2008	8.00am	7	5	3	20
	10.00am	6	4	5	17
	12.00pm	8	5	5	20
	2.00pm	7	5	10	18
	4.00pm	10	4	7	20

National Digitization Project

National Science Foundation

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