



Food Safety Toolkit

In partnership with



IFC, a member of the World Bank Group, creates opportunity for people to escape poverty and improve their lives. We foster sustainable economic growth in developing countries by supporting private sector development, mobilizing private capital, and providing advisory and risk mitigation services to businesses and governments.

IFC Food Safety Toolkit has been produced by IFC through its Global Food Safety Advisory Program.

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Introduction and Overview

MODULE 1

Basic Facts About IFC

We work with the private sector in developing countries to help create opportunity for all.

IFC, a member of the World Bank Group, is the largest global development institution focused exclusively on the private sector in developing countries.

We utilize and leverage our products and services — as well as products and services of other institutions in the World Bank Group — to provide development solutions customized to meet clients' needs. We apply our financial resources, technical expertise, global experience, and innovative thinking to help our partners overcome financial, operational, and political challenges.

Clients view IFC as a provider and mobilizer of scarce capital, knowledge, and long-term partnerships that can help address critical constraints in areas such as finance, infrastructure, employee skills, and the regulatory environment.

IFC is also a leading mobilizer of third-party resources for its projects. Our willingness to engage in difficult environments and our leadership in crowding — in private finance enable us to extend our footprint and have a development impact well beyond our direct resources. For more information, visit www.ifc.org.

Developing Agribusiness

IFC has made agribusiness a priority because of its potential for broad development impact and especially strong role in poverty reduction. We combine investments and advisory services to help the sector address higher demand and escalating food prices in an environmentally sustainable and socially inclusive way.

In the fiscal year ended in June 2015, we invested \$3.2 billion across the agribusiness supply chain — from farm to retail — to help boost production, increase liquidity, improve logistics and distribution, and expand access to credit for small farmers. At the end of the fiscal year, IFC's committed portfolio for our own account stood at \$3.4 billion.

About IFC Global Food Safety Program

IFC's activities comprise advisory support to companies that promote good agricultural practices that benefit small-scale farmers, and value chain solutions involving small and medium size enterprises. IFC has launched an advisory platform (the Program) to help agribusiness companies build capacity in food safety globally. The goal of the Program is to reduce food safety risk for IFC clients in agribusiness while contributing to industry sector capacity in select markets. Within the scope of this project, IFC will be working with agribusiness and retail clients ("the Clients") in all food industry sectors on efforts to increase their competitiveness. Specifically, IFC will be providing advisory services that will facilitate the upgrading of food safety management systems in keeping with changing global requirements that will lead to improvement of their performance and efficiency and ultimately to sales increase, costs and risk profile reduction.

Contact: Sarah Ockman, Program Lead, sockam@ifc.org

Donor partners

Austrian Ministry of Finance (MOF)

External Economic Program

MOF's external economic program supports the development and transition process in Southeast and East Europe. The program aims at promoting sustainable investments to support economic growth, create jobs and improve the business environment. Supporting local and foreign investments helps to improve the livelihood of people and the progress towards a stable and prospering region. Our goal is to contribute to private sector growth through capacity building, SME support, facilitation of investments, and building business partnerships between Austrian and local investors.



The Norwegian Ministry of Foreign Affairs

The Royal Norwegian Ministry of Foreign Affairs (MFA) has the overall responsibility for foreign policy, trade policy and aid-related relations between Norway and developing countries and between Norway and international organizations.

The main goal of Norwegian development cooperation is to contribute towards lasting improvements in economic, social and political conditions for the populations of developing countries. The Norwegian government aid policy aims at strengthening developing countries' ability to solve their poverty problems and promote economically and environmentally sustainable development.

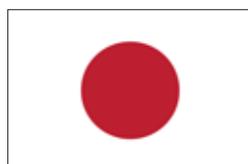
The scope for the assistance to the countries in Southeast Europe is to support the government's decision of integration with European and North Atlantic structures. Euro-Atlantic integration to promote stability and democratization in the countries of the region and in the region as a whole are central to Norway's efforts in the Western Balkans. High priority is being given to the implementation of the EU Stabilization and Association process which has given the Western Balkan countries the prospect not only of closer cooperation with the EU, but also of possible future membership.

The priorities are to strengthen the democratic institutions, support economic and political reforms, support business development, enhance respect of the human rights, fight against corruption and crime and improve the regional cooperation.



Japan's Ministry of Finance

Japan is committed to contributing to global development with a particular focus on Africa. To further deepen partnerships with developing countries and contribute to international stability, Japan provides official development assistance both bilaterally and through multilateral institutions such as IFC. Japan's Ministry of Finance has been a major donor to the Japan Comprehensive Trust Fund (CJTF), which has been an important vehicle for supporting IFC Advisory globally since 1995. In 2014, Japan added a dedicated Tokyo International Conference on African Development (TICAD) window under CJTF to support projects in Sub-Saharan Africa and North Africa.



Foreword

The latest estimates predict a global population of nine billion by the year 2050. This substantial increase in the number of people will require a sustainable and safe food supply, which unfortunately has not yet been secured. Investments in food safety management systems are a key prerequisite in assuring a reliable and constant supply of safe food as well as increased cross border trade.

The agribusiness industry is a vital engine in the economies of many countries around the globe. However, inadequate food safety standards and poor food safety practices inhibit agribusiness growth potential and shut domestic companies out of global value chains.

The corporate world recognizes the risks: according to a 2015 survey by KPMG of senior executives from global manufacturing and retail, food and product safety ranks as the top priority for sustainability and corporate responsibility, and the top priority for investment.

Internationally recognized standards have a proven track record of delivering results that include better risk management, increased access to new markets and major retailers, better operational efficiency (due to reduced costs and higher productivity) and enhanced reputations. Therefore, addressing food safety in a systemic and sustainable way will contribute toward increasing sales, exports and profits, reducing costs, minimizing risks and attracting investors.

IFC, a global leader in providing the private sector with a full range of investment and advisory services to boost sustainable development in emerging markets, has developed a unique product calibrated to help food producers to access and implement an effective food safety management system.

Designed to be a self-guided instructional manual, the Food Safety Toolkit is ideal for businesses that have not yet developed their own system or wish to improve their existing one. The Toolkit has already been successfully tested with food companies in Europe and Central Asia as well as in selected countries of Asia and Africa.

Companies which have already improved their food safety systems with the help of the Toolkit have entered new markets, increased profitability, and improved customer trust and confidence.

We are convinced that the IFC Food Safety Toolkit will help companies implement better food safety systems improve their competitiveness and facilitate entry into global value chains.

Tania Lozansky

Head of Advisory, IFC Manufacturing, Agribusiness and Services

The Food Safety Toolkit

The IFC Food Safety Toolkit is designed to enable companies in developing markets reduce a key risk in growing a sustainable food business: meeting the ever-increasing demands, needs, expectations and trust of customers, wholesalers, retailers, government food safety regulators, and ultimately, consumers.

The Toolkit was developed by IFC with food industry help and expertise. It is based on HACCP principles of foodstuff hygiene (European Union food hygiene legislation: Regulations (EC) No 852/2004, 853/2004 and 854/2004), and best industry practices and standards.

The Toolkit provides companies with the know-how to develop, implement and maintain a modern food safety management system based on the principles of the Hazard Analysis Critical Control Points system (HACCP). HACCP is a systematic approach to identifying and controlling hazards (whether microbiological, chemical or physical) which pose potential hazards in the preparation of safe food. HACCP aims to proactively identify and prevent potential problems that could put food safety at risk. In simple terms, that means controlling the safety of ingredients and supplies coming into a food business and correctly handling them thereafter.

The Toolkit helps companies to identify gaps in their existing practices and develop more efficient food safety system. Specifically companies can:

- Apply the Toolkit in any process regardless of production facility size, location and food safety sophistication;
- Develop systemic science-based approaches to food safety management;
- Benchmark their own food safety system against the best international practices;
- Use the Toolkit as simple and practical self-service tool, replicating it to all production lines as necessary;
- Tailor the templates in accordance with their needs.

The Toolkit consists of seven modules. It serves as a 'roadmap' to help companies manage their food safety systems in a clear, informative manner. The following summarizes the purpose of each module:

Module 1 introduces the Food Safety Toolkit and provides an overview of the contents. It identifies the target audience and describes the benefits of using it. This section also references an awareness presentation for companies planning to launch a food safety management system to more effectively engage employees and stakeholders. Associated with Module 1 are two executive management tools: (i) a document highlighting the benefits, challenges and lessons to be learned from other FBOs that have adopted a FSMS using the IFC FSTK; and (ii) a self-assessment tool that enables the FBO executive management team to quickly establish the maturity of their FSMS compared to the preferred GFSI or other food safety Scheme. See Module 7 – Executive Management Module and specifically the resource section for additional details.

Module 2 consists of an overview of GFSI and other FSMS schemes and standards that a producer may choose in managing food safety. The schemes and standards selected are based on international best practices.

Module 3 provides an overview of the primary food safety legislation now in place, including the role and responsibilities of the various enforcement agencies; the role and responsibility of the company; recommended sources of food safety legislation; a process through which a company can demonstrate its legal compliance with these food safety requirements; and useful links to enable the FBO become aware of new of amendments in food safety regulations, GFSI and other FSMS schemes.

Module 4 consists of two elements:

- (1) An overview of Pre-Requisite Programs [PRPs] based on the requirements of ISO/TS 22002-1. Six examples of PRPs associated with Milk Processing based upon ISO/TS 22002-1 is included in the IFC FSTK version 3.0 with a PRP document template that may be used by FBOs when developing their PRPs. Also included is general information on planning and development of PRPs;
- (2) General information about HACCP, including its history, underlying principles, benefits, and the preliminary steps in developing a HACCP system. IFC has also developed a comprehensive cost-benefit analysis tool to enable the FBO establish the benefits of adopting HACCP or a FSMS (see Module 7 of the IFC FSTK). Included in the IFC FSTK Version 3 is a partial example of a milk processing HACCP plan. In the partial milk processing example, two Critical Control Points [CCPs] and one O-PRP example are provided.

A HACCP plan document template is provided and it may be used by the FBO when developing its HACCP plan[s]. The IFC FSTK also contains a CD with a MS Word document version of the PRP and the HACCP plan document template.

Module 5 provides details on establishing and developing FSMS procedures and documentation. Specifically, this module provides an overview of the typical documentation structure or hierarchy in a FSMS; an explanation of the purpose and benefits of a documented FSMS; a description of the different documents in a FSMS [namely policy, objectives, procedures, work instructions, food safety plans, specifications, forms and records]; and the control of FSMS documents and general information on record management and retention. Finally, this module provides completed examples of the primary documented procedures an FBO is likely to need as defined by the various GFSI and other FSMS schemes. Also included is a basic example of a food defense plan enabling the FBO meet its food security requirements.

Module 6 consists of general information on training and development and provides sample documents, including a training and development procedure, an example of a FSMS responsibility, a training needs analysis and training plan, an FSMS training and development matrix, a new section on evaluation of training effectiveness, and methods of evaluating training. The FBO may adapt these documents to include in its FSMS.

Module 7 provides an overview on how to establish and develop a food safety policy, describes the need for top management commitment, and explains what resources are required to establish, develop, implement and maintain an effective FSMS. This module also includes an example of a FSMS management review procedure and a MS PowerPoint document template that the FBO may consider when documenting and recording the actions and decisions arising from a FSMS management review, including evaluation of related follow-up activities.



Food Safety Standards and Schemes

MODULE 2

Introduction

This module provides an overview of primary and voluntary food safety schemes, and the standards applicable for Food Business Operators (FBOs). The module includes the International Food Safety Management System Standard FSSC 22000 and a variety of private label and Government managed FSMS Schemes or standards known collectively as the Global Food Safety Initiative (GFSI) standards plus GMP+.

In fact, the knowledge food businesses have about these different schemes and standards is limited. Partly that is due to the number of FSMS schemes and standards already existing in the market. In this module, we offer overview-level detail on the FSMS Schemes and Standard as an aid in helping FBOs consider which FSMS Scheme(s) may be most relevant to them, their customers and consumers.

No opinion is offered or given on which FSMS Scheme or standard a particular FBO should select.

British Retail Consortium (BRC)

What is the British Retail Consortium?

BRC Global Standards is a leading safety and quality certification program, used by over 23,000 certificated suppliers in 123 countries, with certification issued through a worldwide network of accredited certification bodies.

Which standards does the BRC operate?

The BRC Global Standards consists of a list of standards, namely:

BRC Global Standard	GFSI Scheme	GFSI Scope
BRC Global Standard for Food Safety Issue 7	Yes	D, EI, EII, EIII, EIV
BRC Global Standard for Packaging and Packaging Materials Issue 4	Yes	M
BRC Global Standard for Storage and Distribution Issue 2	Yes	J
BRC Global Standard for Consumer Products Issue 3	No	
BRC Global Standard for Agents and Brokers issue 1	No	

BRC Global Standard for Food Safety (Issue Seven)

The BRC Global Standard for Food Safety (Issue Seven) is a standard developed by the British Retail Consortium for companies providing retailer-branded food products. The BRC Global Standard for Food Safety Issue 7 was published in January 2015.

This standard covers food safety and product quality management and operational criteria in a food manufacturing organization to fulfil obligations with regard to legal compliance and protection of the consumer.

The standard is owned by the BRC (United Kingdom) and written and managed with input from an international multi-stakeholder group made up of food manufacturers, retailers, and food service and certification body representatives.

BRC/IoP Global Standard for Packaging and Packaging Materials (Issue Five)

This is one of the main global standards for the manufacture and conversion of packaging materials for both food and non-food use. The BRC Global Standard for Packaging and Packaging Materials Issue 5 was published in July 2015.

The standard covers the hygienic production of packaging materials and the management of quality and functional properties of the packaging to provide assurance to customers. The standard includes optional modules to cover logistics operations such as wholesale, contract packing, product inspection and waste recovery.

Certification to this standard requires strict control of comprehensive technical and sanitary characteristics of production in order to assess the possibility of the supplier to produce and deliver consistently safe products for consumers in accordance with its specifications.

The standard is operated by the BRC in conjunction with the Packaging Society and an advisory committee of stakeholders.

Background

In 1998 the British Retail Consortium generated its first BRC food technical standard in order to address the growing demand to ensure safe and quality food production within the industry. After its initial success, it evolved into a global standard used, not just to assess retail suppliers, but as the foundation upon which companies have based their supplier assessment programs.

On April 24, 2014, the BRC Global Standard for Food Safety (Issue 6) and BRC/IoP Global Standard for Packaging and Packaging Materials (Issue 4) were successfully benchmarked by the Global Food Safety Initiative and have achieved recognition in the GFSI Guidance Document Sixth Edition.

Who is it relevant to?

The BRC Global Standards [GFSI approved schemes] are relevant to food and ingredient manufacturers, wholesalers and distributors. The BRC Global Standard deals with food, packaging, storage and distribution.

Fundamental Standard Requirements:

- Top management and continual Improvement
- The Food Safety Plan [HACCP]
- Food Safety and Quality Management System
- Site standards
- Product control
- Process control
- Personnel

For additional details see: www.brc.org.uk.

International Featured Standard (IFS) Food

What is IFS Food?

IFS Food is a standard for auditing food safety and the quality of food manufacturers' processes and products. First introduced in 2003, it is now operating in its sixth version. In 2011, it issued more than 11,000 certificates in 90 different countries.

IFS Management has five regional offices worldwide, tasked with coordinating technical working groups in different languages (German, French, North American, Spanish and Italian) for various stakeholders, including retailers, industry players, certification bodies and food services entities. It relies on a continuous improvement process regarding IFS standards, database and integrity program among other aspects of its mandate.

Which standards does the IFS operate?

The IFS operates the following standards:

IFS Standard	GFSI Scheme	GFSI Scope
IFS Food, version 6	Yes	C, D, EI, EII, EIII, EIV, L, J
IFS Logistics, version 2.1	Yes	J
IFS Broker	No	
IFC HPC	No	
IFC Cash & Carry	No	
IFS PACsecure, version 1	Yes	M
IFS Food Store	No	

Background

IFS Food Standard (version 6) was developed with the full and active involvement of certification bodies, retailers, industry and food service companies from all over the world.

On September 21, 2012 it was successfully re-benchmarked by GFSI and has achieved recognition against the GFSI Guidance Document Sixth Edition.

The standard is owned by IFS Management GmbH, Germany.

Who is it relevant to?

The IFS Standards (GFSI approved schemes) are relevant to food and ingredient manufacturers, wholesalers and distributors. The IFS Standards deals with food, packaging, storage and distribution.

Fundamental Standard Requirements:

- Top management responsibility
- A quality food safety management system
- Resource management
- Planning and production process
- Measurement, analysis, improvements
- Food defense

For additional details see: www.ifs-certification.com.

Food Safety System Certification (FSSC) 22000

What is FSSC 22000

The Food Safety System Certification 22000 (FSSC 22000) is a robust, ISO-based, internationally accepted certification scheme for the assessment and certification of food safety management systems throughout the entire supply chain.

The FSSC 22000 certification scheme is supported by the European Food and Drink Association (CIAA) and the American Groceries Manufacturing Association (GMA). The certification is accredited under ISO guide 17021.

Background

The FSSC 22000 certification scheme complies with ISO 22000 and the technical specifications for PRPs. These requirements are based on the ISO Standard developed by the International Organization for Standardization (ISO) and Publicly Available Specification (PAS) prepared by the British Standards Institution (BSI).

On February 22, 2013, FSSC 22000, version 3 (October 2011 issue) was successfully re-benchmarked by GFSI and has achieved recognition against the GFSI Guidance Document Sixth Edition.

FSSC 22000 has been recognized against the following scopes:

- C** Animal Conversion;
- D** Pre Processing Handling of Plant Products;
- EI** Processing of Animal Perishable Products;
- EII** Processing of Plant Perishable Products;
- EIII** Processing of Animal and Plant Perishable Products (Mixed Products);
- EIV** Processing of Ambient Stable Products;
- L** Production of (Bio) Chemicals;
- M** Production of Food Packaging.

Which standards does FSSC 22000 operate?

The version 3 of FSSC 22000 was published on April 10, 2013.

FSSC 22000 = ISO 22000 + ISO/TS 22002-1 + additional requirements (applicable to food manufacturing)

Two of the previous additional FSSC requirements remain unchanged:

1. Specifications for services
2. Supervision of personnel in application of food safety principles

One of the previous additional FSSC requirements was modified:

3. Specific regulatory requirements

Organizations seeking certification shall assure that specifications for ingredients and materials take account of any applicable regulatory requirements [e.g. control of prohibited substances]. The requirement for Inventory of applicable regulations is still required under Part 1 Section 3 point 4 (on page 7 of 14). This additional requirement is specific to ingredients and materials and is aimed at ensuring that specifications detail specific legislative standards such as mycotoxin levels, prohibited colors, or pesticides.

Two additional FSSC requirements were added:

There are now five additional requirements that need to be complied with and audited (compared to three in the previous FSSC 22000 version 3). The two new requirements are:

4. Announced, but unscheduled audits of certified organizations

The Certification Body will participate in a risk based program of office audits and announced, but unscheduled, audits of certified organizations. In July 2014 Walt Mart asked all GFSI schemes to introduce unannounced audits by June 2015 as a condition of doing business with them. Today all GFSI schemes have introduced unannounced audits into their schemes. The goal of the unannounced audits is to assure day-to-day compliance of the FBO's products and FSMS and to ensure the FBO is 'audit ready'. What does an unannounced audit mean? Generally it means there will be no prior notification for any unannounced audit conducted. That said most Certification Bodies [CBs] do announce the start of the unannounced audit to the client, e.g. the unannounced audit will occur anytime following the beginning of Q3 2016. The CB also requires the FBO to provide access to details of their operations or processing schedule to enable the CB audit team plan the unannounced audit. Turning up from an unannounced GFSI audit where the FBO operations is not operating adds no value to any interested party. GFSI has yet to announce the frequency of unannounced audits. The most likely option being considered is one unannounced audit every three years. Unannounced audits differ significantly from surveillance audits. Unannounced audits are much shorter and tend to focus on the FBO product and preventive controls. Surveillance audits are focused on the FSMS. Finally the introduction of the unannounced audit does impact the cost of the conformity assessment procedure, and the FBO needs to budget for the additional costs associated with the unannounced audit.

5. Management of inputs

The organization shall implement a system to assure that analysis of inputs critical to the confirmation of product safety is undertaken. The analyses shall be performed to standards equivalent to those described in ISO 17025.

Inputs are referring to analyses of incoming raw and packaging materials that are used to produce the finished product.

Who is it relevant to?

FSSC 22000 is used to audit and certify the food safety systems of food chain organizations which process or manufacture:

- Perishable animal products (such as meat, poultry, eggs, dairy and fish products);
- Perishable vegetable products (such as fresh fruits and fresh juices, preserved fruits, fresh vegetables, and preserved vegetables);
- Products with a long shelf life at an ambient temperature (such as canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, and salt);
- (Bio)chemical manufacturers (of food ingredients such as vitamins, additives and bio-cultures), although excluding technical and technological aids;
- Food packaging (with both direct and indirect contact with the food).

FSSC 22000 includes transportation and on-site storage if the latter is part of the operation (for example, with cheese ripening). It is applicable to all organizations in the food chain, regardless of size and complexity, profit making or not, public or private.

Fundamental Standard Requirements:

FSSC 22000 uses the existing standards ISO 22000, plus technical specifications for sector PRPs. It is owned by FSSC 22000 in the Netherlands.

The ISO 22000 international standard specifies the requirements for a food safety management system, including the following four elements:

- Interactive communication
- System management
- Prerequisite programs
- HACCP principles

ISO 22000 integrates HACCP system principles with the application steps developed by the Codex Alimentarius Commission. Using auditable requirements, it combines the HACCP plan with PRPs. Hazard analysis is the key to an effective FSMS, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures.

ISO 22000 requires that all hazards that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified and assessed. Thus it provides the means to determine and document why certain identified hazards need to be controlled by a particular organization and others do not.

During hazard analysis, the organization determines the strategy to be used to realize hazard control by combining the prerequisite programs with the HACCP plan. The standard contains the specific requirements needing to be addressed by the FSMS.

Generally, the **ISO 22000** requirements are:

- Having an overall food safety policy for a particular organization developed by top management;
- Setting objectives to drive that company's efforts to conform with this policy;
- Planning, designing and documenting a management system;
- Maintaining records of the system's performance;
- Establishing a group of qualified individuals to make up a food safety team;
- Defining procedures needed to ensure effective communication with important contacts outside the company (such as regulators, customers, suppliers, and others) as well as effective internal communication;
- Having an emergency plan;
- Holding management review meetings to evaluate FSMS performance;
- Providing adequate resources for effective FSMS operation including appropriately trained and qualified personnel, sufficient infrastructure and an appropriate work environment to ensure food safety;
- Following HACCP principles;
- Establishing a traceability system for product identification;
- Establishing a corrective action system and control of nonconforming product;
- Maintaining a documented procedure for handling product withdrawal;
- Controlling monitoring and measuring devices;
- Establishing and maintaining an internal audit program;
- Continual improvement and updating the FSMS.

FSCC 22000 contains Standard ISO/TS 22002-1:2009 Part 1: Food manufacturing which serves as a technical specification for prerequisite programs for food manufacturers.

This technical specification does not duplicate the requirements cited in ISO 22000:2005. It is intended to be used in conjunction with ISO 22000:2005.

ISO/TS 22002-4:2013 is intended to be used by food packaging manufacturing organizations that wish to implement PRPs in such a way as to address the requirements specified in ISO 22000:2005.

ISO/TS 22003:2007 defines the rules applicable for the audit and certification of an FSMS complying with the requirements given in ISO 22000:2005 (or other sets of specified FSMS requirements). It provides the necessary information, and so bolsters customer confidence around the way their suppliers' certification has been granted.

For further details see www.fssc22000.com.

PrimusGFS

What is PrimusGFS?

PrimusGFS is a GFSI recognized audit scheme for the certification of produce sector products — from growing operations to minimally-processed (fresh-cut) produce products.

Depending on the operation being audited, PrimusGFS audits include Food Safety Management Systems (FSMS), Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs) and Hazard Analysis Critical Control Points (HACCP).

Which standards does the PrimusGFS operate?

The PrimusGFS operates the following standards:

PrimusGFS Standard	GFSI Scheme	GFSI Scope
Primus GFS, version 2.1	Yes	BI, BII, D, EII, EIII, EIV

Background

The GFSI, managed by CIES (the food business forum), was set up in 2000 to pursue continuous improvement in food safety management systems, cost efficiency in the supply chain and safe food for consumers worldwide. In February 2010 the Global Food Safety Initiative (GFSI) announced full recognition of the PrimusGFS scheme.

PrimusGFS is a Global Food Safety Initiative (GFSI) benchmarked and fully recognized audit scheme covering both Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) scopes, as well as Food Safety Management Systems (FSMS).

Who is it relevant to?

PrimusGFS is focused on food safety of agricultural products designated for human consumption, both fresh or minimumly processed. PrimusGFS establishes a series of requirements for managing the production, handling, processing and storage operations which should be met for consumer safety.

On February 20th the PrimusGFS Standard (v2.1 – December 2011) has been successfully re-benchmarked by GFSI and has achieved recognition against the GFSI Guidance Document Sixth Edition.

Fundamental Standard Requirements:

PrimusGFS audits are composed of several modules and their applicability depends on the type of operation being audited:

Module 1	FSMS	Applicable to all operations types
Module 2	GAP	Applicable to growing areas (fields, ranches, greenhouses); harvest crew section is optional
Module 2	GMP	Applicable to facilities (coolers, packinghouses, processors and storage)
Module 3	HACCP	Applicable to all facilities; not applicable to growing areas/harvest crews

Module 1 Food Safety Management System:

- 1.1 Management System
- 1.2 Control of Documents and Records
- 1.3 Procedures and Corrective Actions
- 1.4 Internal and External Inspections
- 1.5 Rejection and Release of Product
- 1.6 Supplier Control
- 1.7 Traceability and Recall
- 1.8 Food Defense

Module 2 GAP and GMP Options:

- 2.1 General GAP
- 2.2 Site Identification
- 2.3 Ground History
- 2.4 Adjacent Land Use
- 2.5 Pest and Foreign Material Controls – Applicable for greenhouses only
- 2.6 Growing Media (Substrate) Use – Applicable for greenhouses only
- 2.7 Fertilizer/Crop Nutrition
- 2.8 Irrigation / Water Use
- 2.9 Crop Protection
- 2.10 Field Worker Hygiene (Applies to on-the-farm workers not the harvesting workers)
- 2.11 Harvesting Inspections, Policies and Training
- 2.12 Harvesting Worker Activities & Sanitary Facilities (Applies to harvesting workers)
- 2.13 Harvest Practices
- 2.14 Transportation and Tracking
- 2.15 On-site Storage
- 2.16 General GMP
- 2.17 Pest Control
- 2.18 Storage Areas & Packaging Materials
- 2.19 Operational Practices
- 2.20 Worker Practices
- 2.21 Equipment
- 2.22 Equipment Cleaning
- 2.23 General Cleaning
- 2.24 Buildings and Grounds
- 2.25 Chemicals Files
- 2.26 Pest Control Documentation
- 2.27 Operation Monitoring Records
- 2.28 Maintenance & Sanitation Files
- 2.29 Worker Documentation
- 2.30 Testing/ Analysis Records
- 2.31 Temperature Controlled Storage & Distribution Logs
- 2.32 Allergen Control

Module 3 HACCP:

- 3.1 Preliminary Steps
- 3.2 Development of the Written HACCP Plan
- 3.3 Execution of the HACCP Plan on the Plant Floor

Global red Meat Standard (GRMS)

What is the GRMS?

The Global Red Meat Standard (GRMS) is a scheme specifically developed for the red meat industry. The GRMS sets out the requirements for all processes relating to the production of meat and meat products and focuses on areas critical to achieving the highest safety and quality standards. It was launched in 2006.

Which standards does the GRMS operate?

The GRMS operates the following standards:

GRMS Standard	GFSI Scheme	GFSI Scope
GRMS, version 2.1	Yes	C, EI, EIII

Background

The GRMS is a standard specifically developed for the processes of slaughtering, cutting, deboning and sales of red meat and meat products. It encompasses the entire production chain and is, therefore, applicable to all aspects of the transport, lairage, stunning, slaughtering, deboning, cutting and handling of meat and meat products.

On February 7, 2013, the GRMS (fourth edition version 4.1) was re-benchmarked and recognized by the Global Food Safety Initiative (GFSI) against its revised Guidance Document Sixth Edition.

The Global Red Meat Standard Scheme is owned by the Danish Agricultural & Food Council, Denmark.

Who is it relevant to?

The standard sets out the requirements for all processes related to the production of meat and meat products.

Process: Transport, lairage, slaughtering, evisceration, chilling, cutting, deboning, curing, marinating, mincing, mixing, fermentation, smoking, cooking, packing, chilling, freezing, and storage.

Product: Fresh meat, meat products, meat preparations, mixed products and edible by-products.

Fundamental Standard Requirements:

- Audit protocol;
- Requirements with respect to audit qualification, training and experience;
- Good Manufacturing Practice (GMP);
- HACCP system;
- Quality Management System;
- Non-conformance procedures;
- Traceability.

For additional details see: www.grms.org.

CanadaGAP

What is CanadaGAP?

CanadaGAP® is a food safety program for companies that produce and handle fruits and vegetables. It is designed to help implement and maintain effective food safety procedures within fresh produce operations.

Which standards does the CanadaGAP operate?

The CanadaGAP operates the following standards:

CanadaGAP Standard	GFSI Scheme	GFSI Scope
GLOBALG.A.P. Integrated Farm Assurance, version 4	Yes	All, BI, D

Background

The CanadaGAP® certification program was launched by the Canadian Horticulture Council (CHC), covering eight crop groupings.

The standards program was developed by the Canadian Horticultural Council (CHC), the national industry association for fruit and vegetable producers in Canada, as a means of standardizing and updating on-farm food safety programs, and covers the safe production, storage and packing of fresh produce. The CHC participates in the federal On-Farm Food Safety Recognition Program, which involves comprehensive reviews by federal and provincial governments to ensure the technical soundness of the CanadaGAP standard.

On April 24 2013, CanadaGAP was re-benchmarked and recognized by the Global Food Safety Initiative (GFSI) against its revised Guidance Document Sixth Edition.

The owner of the Scheme is CanAgPlus, Canada.

Who is it relevant to?

CanadaGAP (Good Agricultural Practices) is an on-farm food safety program for companies that grow, pack and store fresh produce.

Fundamental Standard Requirements:

Two manuals, one specific to Greenhouse operations, the second for other fruit and vegetable operations, have been developed by the horticultural industry and reviewed for technical soundness by Canadian government officials. The manuals are designed for companies implementing Good Agricultural Practices (GAPs) in their production, packing and storage operations, and for re-packers and wholesalers implementing Good Manufacturing Practices (GMPs) and HACCP programs. The program is also designed for fresh produce brokers implementing best practices in supplier management and product traceability.

Fruit and Vegetables and Greenhouse Manuals:

- Commodity Starter Products
- Premises
- Commercial Fertilizers, Pulp Sludge and Soil Amendments
- Manure, Compost/Compost Tea and other Products
- Mulch and Row Cover Materials
- Agriculture Chemicals
- Agriculture Water
- Equipment
- Cleaning and Maintenance Materials
- Waste Management
- Personnel Hygiene Facilities
- Employee Training
- Visitor Policy
- Pest Program for Buildings
- Water (for Fluming and Cleaning)
- Ice
- Packaging Materials
- Growing and Harvesting
- Sorting, Grading, Packing, Repacking, Storing and Brokerage
- Storage of Product
- Transportation
- Identification and Traceability
- Deviations and Crisis Management
- HACCP Plan and Food Safety Program Maintenance and Review

The manuals are based on a rigorous hazard analysis applying the seven principles of the internationally-recognized HACCP (Hazard Analysis and Critical Control Point) approach.

For additional details: see www.canadagap.ca.

GLOBALG.A.P.

What is GLOBALG.A.P.?

GlobalG.A.P. is a private sector body that sets voluntary standards for agricultural product certification around the world. The GLOBALG.A.P. standard is designed to reassure consumers about how their food is produced on the farm. Focal points include minimizing detrimental environmental impacts of farming operations, reducing the use of chemical inputs and ensuring a responsible approach to worker health and safety as well as animal welfare.

The organization aims to establish one standard for Good Agricultural Practice (G.A.P.), with varied product applications capable of interfacing seamlessly with the whole pattern of global agriculture.

Which standards does the GLOBALG.A.P. operate?

The GLOBALG.A.P. operates the following standards:

GLOBALG.A.P. Standard	GFSI Scheme	GFSI Scope
GLOBALG.A.P. Integrated Farm Assurance, version 4	Yes	BI, D

Background

GLOBALG.A.P. was formerly known as EurepG.A.P. This organization was launched in 1997 as a retailers' initiative rooted in the Euro-Retailer Produce Working Group (EUREP). Its starting point was an effort to develop standards and procedures for the development of Good Agricultural Practice (G.A.P.) in conventional agriculture, specifically in highlighting the importance of integrated crop management and a responsible approach to worker welfare.

On April 24 2013, GLOBALG.A.P. was re-benchmarked and recognized by the Global Food Safety Initiative (GFSI) against its revised Guidance Document Sixth Edition.

The owner of GLOBALG.A.P. is c/o FoodPLUS GmbH, Germany.

Who is it relevant to?

Global G.A.P. is a pre-farm gate standard. The certificate covers the process of taking certified product from farm inputs, like feed or seedlings, and all the farming activities until the product leaves the farm.

The Standard Documents

Global G.A.P. is a single integrated standard with modular applications for different product groups (see below), ranging from plant and livestock production to plant propagation materials and compound feed manufacturing.

Fundamental Standard Requirements:

The requirements for each standard can be found in a document called *Controlled Points and Compliance Criteria*.

Integrated Farm Assurance Standard

For additional details: see www.globalgap.org.

GlobalG.A.P. risk assesment on social practice (GRASP)	All farm base AF	Plant Propagation Material		Transport Chaîne of Custody		
		CB Crops Base	FV Fruit&Vegetables			
			CC Combinable Crops			
			CO Green Cofee			
			TE Tea			
			FO Flowers&Ornamentals			
		LB Livestock Base	RB Ruminant Base		DY Dairy	
					CS Carttle&Sheep	
					CYB Calf/Young Beef	
			PG Pigs			
			PY Poultry			
			TY Turkey			
		AB Aquacultural module				
Compaund feed manufacturing						

Global Aquaculture Alliance (GAA) Seafood Standard

What is the GAA Seafood Processing Standard?

The Global Aquaculture Alliance (GAA) is an international, non-profit trade association dedicated to advancing environmentally and socially responsible aquaculture. The Alliance develops Best Aquaculture Practices (BAP) certification standards. These cover aquaculture facilities (hatchery and feed mill to farm and processing plant) producing shrimp, salmon, tilapia, channel catfish and pangasius. A specific standard is available for each facility type and category. Additional standards have recently been developed.

Which standards does the GAA operate?

The GAA operates the following standards:

GAA Standard	GFSI Scheme	GFSI Scope
BAP Seafood Processing Standard, Issue 3, Rev 1, 2014	Yes	EI

Background

The Alliance was established in 1997 and consisted of 59 members from America, Europe and Asia. That has grown to 1,100 members from 70 countries today, making it the highest profile industrial organization in the global aquaculture business.

The guiding principles underlying Best Aquaculture Practices aim to assure the environmental, economic and social sustainability of aquaculture operations by minimizing the environmental effects, promoting the rational use of fresh water, avoiding disease outbreaks and minimizing risks related to the introduction of exotic species, for the benefit of local economies and communities.

On May 16, 2013, GAA was re-benchmarked and recognized by the Global Food Safety Initiative (GFSI) against its revised Guidance Document Sixth Edition.

The BAP Seafood Processing Standard is owned by Global Aquaculture Alliance (GAA), in the United States.

Who is it relevant to?

A full range of aquaculture facilities (from farms to processing plants).

Fundamental Standard Requirements:

- Regulatory management
- A Quality Management System
- Personnel management
- Environment and waste management
- Food Safety Management
- Verification
- Traceability

For additional details see: www.gaalliance.org.

Safe Quality Food Institute (SQF)

What is the Safe Quality Food Institute?

The SQF Code (seventh edition level two) was redesigned for use by all sectors of the food industry, from primary production to transport and distribution. Edition seven applies to all industry sectors and replaces the SQF 2000 Code (edition six) and the SQF 1000 Code (edition five).

The SQF Code is a process and product certification standard. It is an HACCP-based food safety and Quality Management System that utilizes the National Advisory Committee on Microbiological Criteria for Food and the Codex Alimentarius Commission HACCP principles and guidelines.

The SQF Code is intended to support industry- or company-branded products and offers benefits to suppliers and their customers. With consistent application of the SQF program by certification bodies that have been accredited according to ISO/IEC guide 65: 1996, products produced and manufactured under SQF Code certification have a high degree of acceptance in global markets.

Which standards does the SQF operate?

The SQF operates the following standards:

SQF Standard	GFSI Scheme	GFSI Scope
SQF Code, 7 th Edition, Level 2	Yes	AI, BI, C, D, EI, EII, EIII, EIV, F, L, M
Safe Feed/Safe Food	No	
Ethical Sourcing, 2nd Edition	No	

Background

The code was developed and pilot programs implemented in 1994 to ensure its applicability to the food industry. *On October 15, 2012 the SQF Code (seventh edition level two) was successfully re-benchmarked by GFSI and has achieved recognition against the GFSI Guidance Document Sixth Edition.*

The scheme is owned by the Safe Quality Food Institute, United States.

Who is it relevant to?

The SQF 2000 code is relevant for the manufacturing, processing and distribution sectors.

Fundamental Standard Requirements:

- Food Safety Management System and Quality Management System
- Document controls and records
- Specification and product development
- Food safety attained
- Verification
- Product identification, trace, withdrawal and recall
- Site security
- Identity of preserved foods

For further details see www.sqfi.com.

China HACCP

What is the China HACCP?

In addition to the benchmarking and recognition of private schemes, GFSI introduced a new category for government-owned schemes entitled *Technical Equivalence*.

Taking into account the differently structure of government-owned schemes, this new category acknowledges their equivalence to the relevant technical requirements of the GFSI Guidance Document. *Technical Equivalence* is distinguished from GFSI recognition of private schemes the scheme's governance and operational management components.

The China HACCP scheme has been assessed within this Technical Equivalence category and is acknowledged as equivalent to the GFSI technical requirements.

For details of the China HACCP Scheme contact:

China HACCP

9 Madian East Road, Tower B
Haidian District, Beijing 100088
P.R.China
Tel: 86-10-82262765
Email: chinahaccp@cnca.gov.cn
www.cnca.gov.cn/bmzz/zcglb/



GMP+ Feed Certification Scheme

What is GMP+?

GMP stands for Good Manufacturing Practices. In 1992 the current GMP+ Feed Certification scheme started out with these, but later developed into a full-fledged certification scheme by integrating ISO Quality Management requirements, HACCP and other elements.

The '+' stands for the integration of Hazards Analysis and Critical Control Points (HAACP). The foundation of the GMP+ systematic is partly determined by continuous improvement according to the principle of the Deming cycle *Plan, Do, Check, Act: write down what I'm doing, do what I've written down and provide proof that I effectively did it.*

The GMP+ Feed Certification scheme defines conditions relating to production facilities of feed, storage, transport, staff, procedures, documentation and more. With its partners, GMP+ International transparently defines conditions to guarantee feed safety and sustainability so that certification bodies can conduct independent audits.

With over 14,600 participating companies in more than 70 countries, GMP+ International is a leading global player in the market of feed safety assurance certification. A GMP+ certificate provides an additional qualitative guarantee for every entrepreneur dealing with the international feed industry.

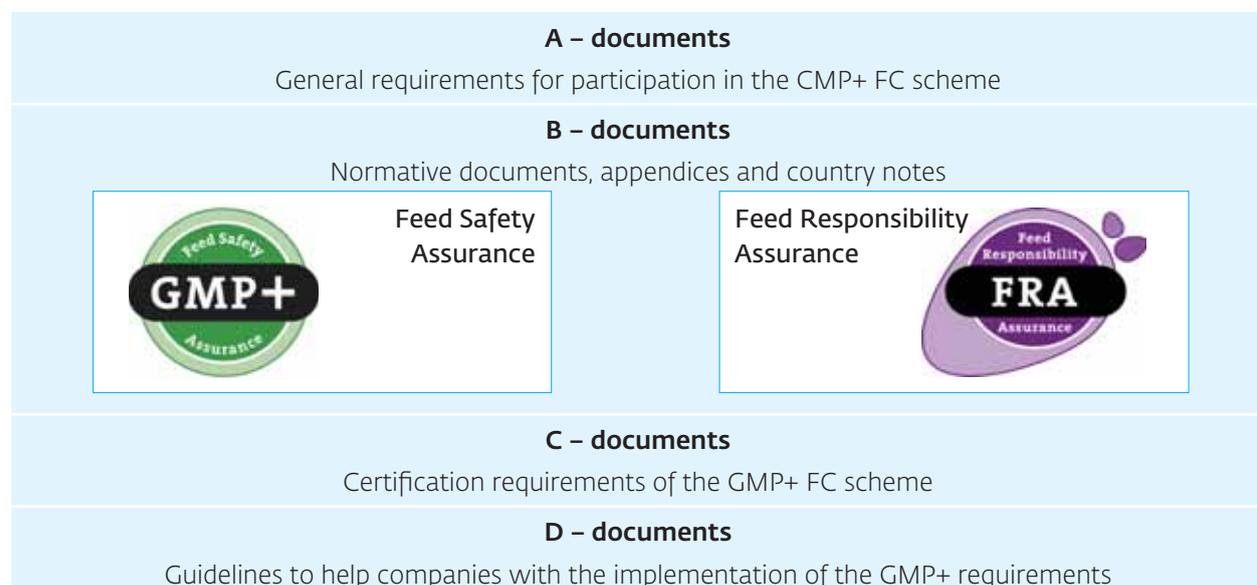
Which standards does GMP+ operate?

The GMP+ Feed Certification scheme originated from a feed safety perspective, and in 2013 the first feed responsibility standard was published. It includes two modules: GMP+ Feed Safety Assurance, focusing on feed safety, and GMP+ Feed Responsibility Assurance focusing on responsible feed.

GMP+ Feed Safety Assurance is a complete module to ensure feed safety in all links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets. Based on needs in practice, multiple components have been integrated into the GMP+ FSA module such as requirements for the Quality Management System (ISO 9001), HACCP, Product Standards, Traceability, Monitoring, Pre-Requisites Programs, Chain approach and the Early Warning System.

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next schematic representation shows the content of the GMP+ Feed Certification scheme.

GMP+ Feed Certification Scheme



Background

The GMP+ Feed Safety Assurance Scheme is currently not a GFSI-approved FSMS Scheme.

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) was developed in 1992 managed by the Product Board Animal Feed in The Hague until 2009. Since 2010, it has been managed by GMP+ International.

Who is it relevant to?

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) is a scheme for assuring feed safety in all the links in the feed chain. It is also an international scheme applied globally.



Food Safety Legislation

MODULE 3

Introduction

The issue of food safety has been addressed by different international institutions. One of the most important is the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures, commonly referred to as the “SPS Agreement.”

WTO members are encouraged to base their SPS measures on international standards, guidelines and recommendations where these exist. WTO rules are also applicable to non-members who are trading with WTO member countries. The standard specifically mentioned in the SPS for food safety is the Codex Alimentarius Commission (CAC).

The CAC implements the Joint Food Agriculture Organization (FAO) / World Health Organization (WHO) Food Standards Program. The Codex Alimentarius is a collection of internationally-adopted food standards presented in a uniform manner. Their joint purpose is:

- To protect the health of consumers;
- To ensure fair practices in food trade;
- To promote the harmonization of standards.

This section provides an overview of food safety legislation for food business operators. Complementing provisions of CAC, it addresses relevant legislation from the European Union and the United States. This legislation was selected for review because of the global importance of these two markets for FBOs. Additionally, the European Union and the United States are leaders in developing food product regulations that ensure both a high level of safety and consumer confidence.

This module also provides information on production and marketing of food products in the Eurasian Economic Union (EEU). Information was drawn from *Comparative Analysis of EEU and EC* by The Investment Climate for Agribusiness Project In Ukraine.

Main Food Safety Regulations: List of Regulations, Summary of Scope, Links with Codex Alimentarius, EU and US

Codex Alimentarius

The Codex Alimentarius is a collection of international food standards adopted by the Codex Alimentarius Commission (CAC). Along with standards for separate types of products, the Codex contains general standards for regulating issues of labeling, food hygiene, food additives, contaminants, pesticide residues, food safety research procedures and biotechnology. The CAC enables countries to develop their food safety regulations in line with international standards.

European Union (EU) Regulations

The European Union joined the Codex Alimentarius in 2003 and accepted the obligations established under the Codex statutes. The main EU food safety directives and regulations refer to CAC as the basis for their requirements.

Below is a list of important EU food legislation:

Regulation (EC) No 178/2002¹ – the General Food Law – establishes the general principles and requirements of food law, the general concepts of food legislation within the EU, and ensures a consistent approach to the development of national food law in EU countries. It sets out the general principles of EU food law for member states to follow. The main objective is to ensure the free circulation of safe food and feed in the EU, for the health and well-being of its citizens.

In addition to Regulation (EC) No 178/2002, a “Hygiene Package” group of regulations was adopted to deliver consistency in the food chain. These include:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs (general hygiene requirements for food production);
- Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin (basic hygiene principles for businesses at all stages of the food chain of animal products);
- Regulation (EC) No 854/2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption;
- Regulation (EC) No 882/2004 on official controls to be invoked in verifying compliance with feed and food law, animal health and animal welfare rules, thereby establishing control principles for EU and third-countries.

¹ Full latest consolidated text of all mentioned EU legislation is available at: <http://eur-lex.europa.eu>.

Additionally, there are number of supportive regulations that deal with specific food safety topics:

- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;²
- Regulation (EC) No 1881/2006 on maximum permitted levels for certain contaminants in foodstuffs;
- Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulations.

(EC) No 853/2004 for conducting official control according to Regulations (EC) No 854/2004, 882/2004 and partially cancelling measures requirements of Regulation (EC) No 852/2004 [addressing the registration and approval of facilities producing food of animal origin] and supplementing Regulations (EC) No 853/2004 [addressing the requirements for approval of facilities producing food of animal origin and feed], 854/2004;

- Regulation (EC) No 1162/2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, 854/2004 and 882/2004.

The General Food Law

Food safety general principles, rules,
definitions Harmonization of EU legislation

	Food hygiene		Control system	
EU regulation	Regulation (EC) No 852/2004	Regulation (EC) No 853/2004	Regulation (EC) No 882/2004	Regulation (EC) No 854/2004
Aims	General rules about food hygiene, FBO responsibility	Specific rules on the hygiene of food of animal origin	Basis for national monitoring and control	Specific rules for the organization of official controls on products of animal origin
Scope	All stages of production, processing, marketing and export	Applies to raw and processed foods of animal origin; does not apply to retailers	All stages of production, processing, and sale	Only applies in respect to activities and persons to which Regulation (EC) No 853/2004 applies
General principles	Responsibility of FBOs; transparency of the food chain; flexibility; introduction of HACCP	Specific requirements for companies to marketing products of animal origin; special guarantees for certain types of meat products	Mandatory official control; regularity and proportionality of inspections; inspections as precautions, not punishment	Cooperation with regulatory authorities; risk analysis; specific periods of control depending on the type of product

²The latest consolidated text of this regulation is available at: <http://eur-lex.europa.eu>.

United States Regulations

As the U.S. has been a member of CAC since 1963, legislators and responsible agencies there tend to harmonize US food safety laws and regulations with Codex requirements. The United States Food Regulatory System consists of numerous statutes, rules and regulations. This overview focuses on federal regulation of food safety. However, state regulatory agencies also play an important role, especially in enforcement. In particular, state regulatory agencies are primarily responsible for food sanitation and safe food handling by food retailers, foodservice providers, and food-vending operations.

The main U.S. food safety statutes are:

- *Food Safety Modernization Act (FSMA)*³ of January 4, 2011: empowers the Food and Drug Administration (FDA) to implement a science-based system to address food safety hazards, shifting the focus from responding to contamination to preventing it. The act covers FDA-regulated foods, including all domestic and imported food products except for meat, poultry, and egg products, which are regulated by the U.S. Department of Agriculture (USDA);
- *Federal Food, Drug, and Cosmetic Act* of 1938 with amendments (FDCA)⁴ is a set of laws giving authority to the FDA to oversee the safety and efficacy of FDA-regulated food, drugs, and cosmetics;
- *Federal Meat Inspection Act* of 1906 with amendments⁵ passed to prevent adulterated or misbranded meat and meat products from being sold as food. It also ensures that meat and meat products are slaughtered and processed under sanitary conditions. This bedrock legislation also regulates inspections of imported meat products to ensure that they meet U.S. food safety standards;
- *Poultry Products Inspection Act* of 1957, as amended⁶ regulates the processing and distribution of poultry products and requires certain sanitary standards and practices, as well as labeling and container standards, to prevent the sale of adulterated or misbranded poultry products. The USDA is also responsible for the enforcement of this act. It provides inspection for all poultry products sold in interstate commerce, and re-inspects imported products;
- *Egg Products Inspection Act* of 1970, as amended.⁷ The FDA shares responsibility for egg safety with the USDA. The latter is responsible for the safety of liquid, frozen, and dried egg products, domestic and imported, and for the safe use or disposition of damaged and dirty eggs under this act;
- *Federal Insecticide, Fungicide, and Rodenticide Act* of 1947, as amended⁸ provides for federal regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in the U.S. must be registered (licensed) by the U.S. Environmental Protection Agency;
- *Public Health Security and Bioterrorism Preparedness and Response Act* of 2002 (Bioterrorism Act) requires registration of food facilities, the establishment and maintenance of records, and prior notice of importation of food. The Bioterrorism Act also grants FDA additional enforcement authority. To enforce the statutes related to food safety, regulatory authorities (USDA, FDA, and others) enact rules and regulations which are referred to as administrative law (as an example, the Poultry Products Inspection Regulations.)⁹ The Code of Federal Regulations (CFR) is the codification of the general and permanent rules and regulations published in the Federal Register by the executive departments and agencies of the Government of the United States of America.

³ Available at: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm>.

⁴ Available at: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm>.

⁵ Available at: http://www.fsis.usda.gov/regulations/federal_meat_inspection_act/index.asp.

⁶ Available at: http://www.fsis.usda.gov/regulations/Poultry_Products_Inspection_Act/index.asp.

⁷ Available at: http://www.fsis.usda.gov/regulations/Egg_Products_Inspection_Act/index.asp.

⁸ Available at: <http://www.epa.gov/oecaagct/lfra.html>.

⁹ Available at: <http://www.gpo.gov/fdsys/pkg/CFR-2010-title9-vol2/pdf/CFR-2010-title9-vol2-part381.pdf>.

Additionally, regulatory authorities publish guidance documents and recommendations for both the food industry and consumers. They do not create or confer any rights for or on any person and do not operate to bind the FDA or the public, but reflect the vision of the FDA on certain issues. For instance, the FDA publishes the Food Code,¹⁰ a model set of guidelines and procedures that assists food control jurisdictions by providing a technical and legal basis for regulating the retail and food service industries, including restaurants and grocery stores.

Importantly, case law is also one of the sources of the U.S. food safety law system. Precedents are rules established in previous legal cases that are either binding on, or persuasive for, a court when deciding subsequent cases with similar issues or facts. The National Agricultural Law Center has made a compilation of reported and unreported federal and state court decisions involving food safety decided on or after January 1, 1995.¹¹

¹⁰ Available at <http://www.fda.gov/food/foodsafety/retailfoodprotection/foodcode/default.htm>.

¹¹ A compilation of decisions available at: <http://www.nationalaglawcenter.org>.

Requirements for FBOs

1. General Principles Including FBO Responsibilities

Codex Alimentarius

To protect consumers from unsafe food and ensure that consumer health is protected throughout the food life cycle, Codex Alimentarius developed the General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4-2003).¹² The document follows the food chain from primary production to final consumption, highlighting the key hygiene controls at each stage and offering recommendations regarding establishments, personal hygiene, transportation and application of the HACCP-based approach.

European Union

A. General principles of EU food legislation

The common basis for European food legislation is an integrated “farm-to-fork” approach combined with risk analysis in relation to food, precautionary principles, protection of consumer interests, principles of transparency, and the primary legal responsibility of the food business operator to ensure food safety.¹³

- **The “farm to fork” approach** is the general principle driving European food safety legislation. It aims to cover all potential hazards along the food chain, whether from primary production, processing, and transportation/distribution; or retail, catering, food service and home use of food.¹⁴
- **The “equivalency” principle** states that food and feed imported into EU markets from third countries must have food safety characteristics equivalent to food produced in EU member states. Or, in cases where there may be a specific agreement between a third country and an EU member state, that food must comply with provisions stated in that agreement.
- **Risk analysis** assumes that all measures relating to food safety will be underpinned by strong science.
- **The “precautionary” principle** is relevant in circumstances where health risks are at an unacceptable level, yet supporting data and information is too sparse to make comprehensive risk assessment possible. In such situations, measures necessary to ensure high standards of health protection, as chosen by the community, may be adopted pending further scientific information for a more comprehensive risk assessment.
- **The “early warning” principle states that** food operators must immediately withdraw unsafe food from the market and inform the authorities and consumers.
- Implementation of a **protection of consumers’ interest principle** means creating a status quo in which consumers will be able to make informed choices in relation to the foods they consume.
- EU food business operators at all stages of production, processing and distribution bear the prime responsibility for ensuring that the food under their control satisfies food law requirements.

¹² Full text of CAC/RCP 1-1969 is available at: <http://www.codexalimentarius.org/standards/list-of-standards/en/>.

¹³ General Principles of European food legislation came into force in 2002 with adoption of EU Food Law (Regulation (EC) No 178/2002 of the European Parliament and of the Council of January 28, 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety).

¹⁴ More about from “farm to fork” approach can be found in “From farm to fork: Safe food for Europe’s consumers”, available at: http://ec.europa.eu/dgs/health_consumer/information_sources/docs/from_farm_to_fork_2004_en.pdf.

B. General principles introducing general rules for FBOs on hygienic foodstuffs

In addition to general principles adopted in EU Food Law,¹⁵ a list of principles amplifying the general rules for food business operators regarding hygienic foodstuffs have been developed. These are:

- Food that cannot be stored safely at ambient temperatures, particularly frozen food, should be held in an unbroken cold chain;
- The general implementation of procedures based on HACCP principles and the application of good hygienic practice should reinforce FBO responsibility;
- Guides to best practices are valuable instruments for aiding FBOs at all levels of the food chain to comply with food hygiene rules and apply HACCP principles;
- Microbiological criteria and temperature control requirements should be established based on scientific risk assessment;
- Imported foods should be held to the same hygienic standards as food produced in the community.

United States

The U.S. food safety system is based on strong, flexible, and science-based federal and state laws and industry's legal responsibility to produce safe foods.

The system is guided by the following principles:

1. Only safe and wholesome foods may be marketed;
2. Regulatory decision-making in food safety is science-based;
3. The government has enforcement responsibility;
4. Manufacturers, distributors, importers and others are expected to comply and are liable if they do not; and
5. The regulatory process is transparent and accessible to the public.¹⁶

Science and risk analysis are fundamental to U.S. food safety policymaking. Regulatory decisions regarding food safety standards and requirements rely on risk analysis performed by competent authorities qualified to make scientifically-sound decisions. U.S. food safety statutes, regulations, and policies have *precautionary approaches* embedded in them. One example is the pre-market approval requirements established for food additives, animal drugs, and pesticides. These products are not allowed on the market unless, and until, they are shown by producers to be safe.

2. Hazard Analysis and Critical Control Points (HACCP) & Traceability Requirement

HACCP

HACCP is a globally-recognized Food Safety Management System built on a risk-based approach with potential hazards analysis and prevention established throughout the production process.

HACCP can be applied throughout the food chain, from primary production to final consumption. However, beyond enhancing food safety, HACCP implementation provides other significant benefits. Practice has shown that Food Safety Management System based on HACCP open up new international markets for high value-added food products. They also increase the efficiency of domestic markets. Most private standards, including IFS, BRC, ISO 22 000, developed and recognized by big retailers, are based on HACCP. Compliance with

¹⁵ EU Regulation 852/2002 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

¹⁶ FDA, USDA. A description of the U.S. Food Safety System is available at: <http://www.fsis.usda.gov/oa/codex/system.htm>.

HACCP principles has become obligatory for food business operators who work, or plan to work, with large global or regional retailers.

Codex Alimentarius

The recommendation to implement an HACCP-based approach wherever possible in enhancing food safety is fixed in the General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4-2003).¹⁷ Codex defines HACCP as “a system which identifies, evaluates, and controls hazards which are significant for food safety” and says that “food business operators should control food hazards through the use of systems such as HACCP.”

The annex to CAC/RCP 1-1969 (Rev. 4 - 2003) consists of seven HACCP principles with general guidance in applying the system. The principles are:

1. Conduct a hazard analysis (*identifying all hazards – and their degree of severity – that can occur, and consider the control measures best applied to each hazard*);
2. Determine the Critical Control Points. CCPs are the steps through which controls can be applied and are essential in preventing or eliminating a food safety hazard, or at minimum, reducing these to an acceptable level;
3. Establish critical limits. Critical limits are the boundaries of safety for each CCP and may be set according to specific preventive measures such as temperature, time, physical dimensions, water activity (aw), pH, and available chlorine;
4. Establish a system to monitor CCP control. Monitoring is the measurement or observation of a CCP relative to its critical limit; this helps detect loss of control at the CCP;
5. Establish the corrective action to be taken; such monitoring indicates that a particular CCP is not under control. These actions must ensure that the CCP has been brought under control, and include proper disposition of the affected product;
6. Establish verification procedures to confirm that the HACCP system is working effectively. Such procedures may include random sampling and analysis, often performed on behalf of the business by external experts;
7. Establish documentation concerning all procedures and records relevant to these principles and their application. Documentation examples include: hazard analysis, CCP determination, and critical limit determination, among others.

¹⁷ In the situation described above, the document *FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses* could be relevant. Available at <http://www.who.int/foodsafety/publications/food-businesses/en/>.

General guidance is offered recognizing that there are limitations in fully applying HACCP principles at the primary production level. Where HACCP cannot be implemented at the farm level, for instance, fastidious hygienic, agricultural and veterinary practices, good agricultural practices and good veterinary practices should be followed.

Following CAC/RCP 1-1969 (Rev. 4 - 2003), a number of industry-specific codes of practices in line with the peculiarities of implementing a HACCP-based approach have been developed and recommended by Codex. They are:

- Code of Practice for Fish and Fishery Products (CAC/ RCP 52-2003);
- Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 52-2003);
- Code of Hygienic Practice for Meat (CAC/RCP 58- 2005).

Useful to know: often, small and/or less-developed businesses face problems in developing and implementing an effective HACCP plan because they lack on-site expertise. In such situations Codex recommends using expert advice from trade and industry associations, independent experts and regulatory authorities. Even when using expertly developed HACCP guidance, substantial attention needs to be paid to the specifics of the foods and/or processes under consideration.¹⁸

European Union

EU Regulation 852/2002 requires FBOs to establish and maintain a permanent procedure or procedures based on HACCP principles. This requirement does not apply to primary production, however.

FBOs must be able to provide the competent authority with evidence of their compliance with the official norms regarding this obligatory HACCP implementation.

The regulation provides the possibility of so-called “flexible” or simplified HACCP implementation, particularly in the case of small food businesses. This approach enables HACCP application in all circumstances, regardless of the size and type of activities undertaken by a specific food business.

Useful to know: in another effort to clarify all aspects of HACCP Principles Implementation, DG-SANCO¹⁹ has developed *Guidance Document on the Implementation of Procedures Based on the HACCP Principles, and Facilitation of the Implementation of the HACCP Principles in Certain Food Businesses*.²⁰

United States

In the United States, HACCP adherence is mandatory for manufacturers of:

- Meat and poultry;²¹
- Seafood,²² and
- Juice products.²³

¹⁸ Ibid.

¹⁹ Health and Consumer Protection Directorate General of the European Commission: http://ec.europa.eu/dgs/health_food-safety/index_en.htm.

²⁰ Full text available at: http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf.

²¹ 9 CFR Parts 304, et al., <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf>.

²² 21 CFR Part 123, <http://www.gpo.gov/fdsys/pkg/CFR-2010-title21-vol2/pdf/CFR-2010-title21-vol2-part123-subpartA.pdf>.

²³ 21 CFR part 120, <http://www.gpo.gov/fdsys/pkg/CFR-2010-title21-vol2/pdf/CFR-2010-title21-vol2-part120-subpartA.pdf>.

Meat and poultry HACCP is regulated by the U.S. Department of Agriculture, while seafood and juice HACCP is covered by the U.S. Food and Drug Administration. These agencies publish guidance documents explaining the HACCP system in specific areas along with support documents for HACCP implementation and information on HACCP training activity. The use of HACCP in other food industries is not mandatory. However, according to the FSMA, food plants must have a written preventive controls plan implemented if they do not use the HACCP system voluntarily. The federal agencies responsible for food safety encourage the food industry across-the-board to implement the HACCP system, even if this is not required.

For instance, the FDA's website includes the *Manual for Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments*²⁴ and *Dairy Grade A Voluntary HACCP guidance and forms*.²⁵

Under FSMA, certain qualified facilities²⁶ are exempt from the preventive control/HACCP provisions. However, they must either identify potential hazards and implement preventive controls to address them or demonstrate to the FDA that they are in compliance with state or local food safety laws.

Traceability

Food traceability is a record-keeping instrument that follows food through all processes, from business to business/consumers. It has become a legal requirement in some parts of the world. Food traceability does not improve food safety by itself, but contributes considerably to food safety management system efficiency when combined with food safety measures such as those implicit in the HACCP-based approach.

Codex Alimentarius

Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System (CAC/GL 60-2006) declare traceability a tool that "should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system."

There are also numbers of Codex documents which consider traceability a requirement for the food business:

- *Codex Code on Prevention and Reduction of Aflatoxin Contamination in Tree Nuts* (CAC/RCP 59-2005);
- *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts* (CAC/RCP 55-2004);
- *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM) (CAC/GL 63-2007).

²⁴ *HACCP Principles for Operators of Food Service and Retail Establishments*, available at: <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControl-Points/HACCP/RetailFoodServiceHACCP/default.htm>.

²⁵ *Dairy Grade A Voluntary HACCP guidance and forms*, available at: [http://www.fda.gov/Food/FoodSafety/Product-Specific Information/MilkSafety/DairyGradeAVoluntaryHACCP/default.htm](http://www.fda.gov/Food/FoodSafety/Product-Specific%20Information/MilkSafety/DairyGradeAVoluntaryHACCP/default.htm).

²⁶ These are either (1) a "very small business" as defined by FDA rules; or (2) the average annual monetary value of all food sold by the facility during the previous three year period was less than \$500,000; but only so long as the majority of food sold by that facility was sold directly to consumers, restaurants, or grocery stores (as opposed to third party food brokers), and were in the same state where the facility sold the food, or within 275 miles of the facility.

European Union

EU food law defines traceability as “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.”

Thus, an implemented traceability system should be constructed so that it ensures the ability to identify any person supplying food, business operators with a product, as well as identify other businesses similarly supplied. It follows, therefore, that labeling/identification of products through relevant documentation is an integral component of the traceability system. In addition to EU food law, specific traceability norms are cited in legislation as they apply to certain categories of food (beef, fish, GMO):

- Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97;
- Regulation (EC) No 2065/2001 of 22 October 2001 laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards to informing consumers about fishery and aquaculture products;
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Useful to know: in order to clarify issues on traceability and ease of implementation, the EU has published Guidelines on the Implementation of Traceability. These guidelines provide details on scope of the traceability requirement and its implementations.²⁷

United States

In the U.S., many producers, manufacturers and retailers have product tracing systems in place, although currently such systems are not required by law.

The FSMA has directed the FDA to build a system that will enhance its ability to track and trace both domestic and imported foods. In particular, the FDA, along with the USDA and state agencies, has been directed to establish pilot projects to explore and evaluate methods to identify recipients of food as a means of preventing or controlling a food-borne illness outbreak. The FSMA also requires the FDA to establish record-keeping requirements for high-risk foods delivered to FBOs as an aid in tracing products.

Where this concerns a USDA-regulated area, USDA has issued a proposed rule to establish general regulations for improving traceability when animal diseases occur.

Species covered in the proposed rule include cattle and bison, sheep and goats, swine, horses and other equines, captive cervids (for example, deer and elk), and poultry. Covered animals moved interstate, unless otherwise exempt, will have to be officially identified and accompanied by an interstate certificate of veterinary inspection (ICVI) or another valid movement document.²⁸

²⁷ Full version of the guidance is available at: http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance_rev_8_en.pdf.

²⁸ USDA. Animal Disease Traceability, available at: <http://www.aphis.usda.gov/traceability/>.

3. Food Labeling

Food labelling is the primary means of communication linking the producer and seller of food on one hand, and the purchaser and consumer on the other. The most important rule of labelling is that the consumer should not be misled.

Codex Alimentarius

The Codex Alimentarius standards and guidelines on food labelling enable their wide use and understanding by governments, regulatory authorities, food industries and retailers, and consumers.

The Codex Alimentarius Commission has developed different standards and guidelines related to food labeling (specifically, on labeling of prepackaged food, food additives, and food for special dietary uses; and guidelines on claims, nutrition labeling, and the like).²⁹

The core standard is the General Standard for the Labeling of Prepackaged Food,³⁰ which applies to the labeling of all prepackaged foods to be offered as such to the consumer, or for catering purposes, and to certain aspects related to its presentation. It sets out mandatory information which must appear on the label of prepackaged food, such as the name of the food, list of ingredients, net contents and drained weight, name and address, country of origin, lot identification, date marking and storage instructions, and instructions for use. There may be additional requirements for quantitative ingredient declarations and irradiated food.

Codex Alimentarius has also developed guidelines for dealing with, among other things, the labelling aspects of organically produced food³¹ and separate guidelines for labeling genetically modified food.³²

European Union

EU labeling legislation requires that the following appear on the label:³³

- Name under which the product is sold;
- List of ingredients;
- Quantity of certain ingredients;
- Net quantity;
- Date of minimum durability;
- Any special storage instructions or conditions of use;
- Name or business name and address of the manufacturer/packager/ a seller within the European Union;
- Place of origin of the foodstuff if its absence might mislead the consumer to a material degree;
- Instructions for use where necessary;
- Beverages with more than 1.2 percent alcohol by volume must declare their actual alcoholic strength.

²⁹Codex Alimentarius labeling standards, available at: www.fao.org/docrep/010/a1390e/a1390e00.htm.

³⁰*General Standard for the Labeling of Prepackaged Food* available at: www.codexalimentarius.org/input/download/standards/32/CXS_001e.pdf.

³¹*Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Food*, available at: www.codexalimentarius.net/input/download/standards/360/cxg_032e.pdf.

³²*Compilation of Codex Texts Relevant to Labeling of Foods Derived from Modern Biotechnology*, available at: www.codexalimentarius.net/input/download/report/765/REP11_FLe.pdf.

³³Directive 2000/13/ EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of member states relating to labeling, presentation and advertising of foodstuffs.

Useful to know: As of December 13, 2014, EU Regulation (EU) 1169/2011³⁴ replaced Directive 2000/13/ EC. Beside these general labeling requirements, there are special requirements for different products. For instance, specific legislation has been set down with regard to the labeling of beef products.³⁵

Regulation (EC) No 1760/2000 requires that the beef label shall contain:

- A reference number or reference code ensuring the link between the meat and the animal or animals;
- The approval number of the slaughterhouse at which the animal or group of animals was slaughtered, and the member state or third country in which the slaughterhouse is established;
- The approval number of the cutting hall which performed the cutting operation on the carcass or group of carcasses and the member state or other country in which the hall is established Regulation (EC) No 1829/2003³⁶ sets out specific labeling requirements for foods which are to be delivered as such to the final consumer or mass caterers; and which
 - a) contain or consist of GMOs; or
 - b) are produced from or contain ingredients produced from GMOs.

United States

Under the FDCA, food labeling is required for most prepared food. The act specifies that food labels must include five types of information:

1. The name of the food;
2. The name and place of business of the manufacturer;
3. A statement of ingredients;
4. The net quantity of the contents;³⁷ and
5. Nutritional content.

Nutrition labeling for raw produce (fruits and vegetables) and fish is voluntary.

*The Food Allergen Labeling and Consumer Protection Act of 2004*³⁸ also requires food labels to indicate the presence of eight major food allergens, such as: milk, eggs, fish (for example, bass, flounder, or cod), crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

³⁴ Regulation (EU) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>.

³⁵ Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, available at: http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CLELEXnumdoc&lg=EN&numdoc=32000R1760&model=guichett.

³⁶ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, available at: http://ec.europa.eu/food/food/animalnutrition/labelling/Reg_1829_2003_en.pdf.

³⁷ Weight is expressed in pounds, with any remainder in terms of ounces or common or decimal fractions of the pound; or in the case of liquid measure, in the largest whole unit (quarts, quarts and pints, or pints, as appropriate).

³⁸ The Food Allergen Labeling and Consumer Protection Act, available at: <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106187.htm>.

To assist food producers, the FDA has developed *Guidance for Industry: A Food Labeling Guide* which contains non-binding recommendations on labeling food products.³⁹

Labeling of bio-engineered foods: The FDA also requires labeling of GE foods if the food has a significantly different nutritional property; if a new food includes an allergen that consumers would not expect to be present (for example, a peanut protein in a soybean product); or if a food contains a toxin beyond acceptable limits.⁴⁰

Country of Origin Labeling (COOL) requires retailers to notify their customers regarding the source of certain foods (namely, muscle cut and ground meats: beef, veal, pork, lamb, goat, and chicken; wild and farm-raised fish and shellfish; fresh and frozen fruits and vegetables; peanuts, pecans, and macadamia nuts; and ginseng).⁴¹ However, WTO ruled that COOL is a technical barrier to free trade and violates trade agreements the United States has with other countries.⁴²

4. Withdrawal/Recall

The withdrawal or recall of food is one of the core responsibilities of FBOs aiming to protect customers from unsafe food. There is a slight difference between recall and withdrawal, but mostly these terms are used in one context as they serve the same goal, namely to protect the public from unsafe food.

Along with the obligation to withdraw or recall unsafe food, the FBO is also responsible for cooperating with the relevant regulatory authorities.

Codex Alimentarius

Provisions on food recall can be found in the *Recommended International Code of Practice General Principles of Food Hygiene*.⁴³ paragraph 5.8 of Section 5 "Control of Operation" cites requirements for recall procedures that require having effective measures in place to assure the complete, rapid recall of any implicated lot of the finished food from the market.

In addition, where a product has been withdrawn because of an immediate health hazard, other products produced under similar conditions, and which may present a similar hazard to public health, should be evaluated for safety and may ultimately need to be withdrawn.

These principles also state the requirement to notify the public regarding existing hazards. Finally, recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

³⁹ Available at: <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabeling-Guide/UCM265446.pdf>.

⁴⁰ See *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bio-engineering / Draft Guidance*, available at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm>.

⁴¹ For more information, please see: <http://www.ams.usda.gov/AMSV1.o/cool>.

⁴² On August 21, 2012, the United States informed the WTO that it intended to implement these recommendations on removal of this barrier. See details of this case at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds384_e.htm.

⁴³ *Codex Alimentarius Recommended International Code of Practice General Principles of Food Hygiene*, available at: www.fao.org/docrep/012/a1552e/a1552e00.htm.

European Union

Withdrawal and recall provisions in EU food safety legislation are set out in the EU Food Safety Law.⁴⁴ The obligation to withdraw the food from the market applies when the following two cumulative criteria are met:

- The food in question is considered not in compliance with the food safety requirements by the operator;
- The food is in the market and has left the immediate control of the initial food business.

Withdrawal means removing the food from the market that has gone to market but has not yet reached the public; whereas recall must be implemented when the product has reached the customers and other measures undertaken have not been sufficient to achieve a high level of health protection.⁴⁵

Withdrawal/recall procedures are to be buttressed by informing the relevant regulatory authorities and collaborating with them.⁴⁶

United States

Before the FSMA, FDA-regulated food recalls were *voluntary* for the industry (except for infant formula). With the FSMA, FDA was authorized to issue *mandatory recalls* of any FDA-regulated food (including all domestic and imported food products except meat, poultry, and egg products). Nevertheless, the FDA has to follow a three-step process prior to ordering such recalls (again, apart from infant formula):

1. Determining that there is evidence of a threat that meets a certain “standard of proof;”
2. Offering the company the opportunity to voluntarily recall the product before a mandatory recall is ordered;
3. Providing the company with the opportunity to challenge a recall decision.

In 2003, FDA issued recall guidance to companies – *Guidance for Industry: Product Recalls, Including Removals and Corrections*⁴⁷ that addresses both voluntary and mandatory recalls. In summary, recall procedure consists of the following steps: recall submission to FDA, public notification, and evaluation of the recall.

Meat and poultry recalls are *voluntary* and they are initiated by the manufacturer or distributor, sometimes at the request of FSIS. If a company refuses to recall its products; however, FSIS has the legal authority to detain and seize those products that are on the market.

When FSIS learns that a potentially unsafe or mislabeled meat or poultry product is in commerce (through inspections, sampling programs, and/or other activity), it investigates the need for a recall. In case of an actual recall, FSIS notifies the public. The recall information is issued to media outlets in the areas where the product has been distributed and this information is likewise posted on the FSIS website.⁴⁸

⁴⁴ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>.

⁴⁵ More detailed information on the practical application of relevant provisions on withdrawal and recall can be found in the EU guidance document on the implementation of particular articles of Regulation (EC) No 178/2002. available at: http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf.

⁴⁶ Article 19 of the Regulation (EC) No 178/2002 deals with withdrawal/recall of unsafe food and Article 20 sets out relevant obligations of the FBO's in respect of Feed.

⁴⁷ *Guidance for Industry: Product Recalls, Including Removals and Corrections*, available at: <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.

⁴⁸ FSIS food recalls, see at http://www.fsis.usda.gov/Fact_Sheets/FSIS_Food_Recalls/index.asp.

Useful to know: Unlike food recalls, market withdrawals occur when a product reveals a minor violation that would not be subject to FDA or FSIS legal action (for example, when a product is removed from the market due to tampering, but without evidence of manufacturing or distribution problems, such a case would be considered a market withdrawal).

5. Microbiological Criteria for Food and Residues Control

Microbiological Criteria

Microbiological criteria play an important role in the validation and verification of HACCP procedures and other hygiene control measures. This is why it is necessary to set microbiological criteria to define the acceptability of processes, along with food safety microbiological criteria to establish the limits above which a foodstuff should be considered unacceptably contaminated by the microorganisms for which the criteria are set.

Codex Alimentarius

Codex Alimentarius has addressed the issue of microbiological criteria for food in a few of its publications. According to these, the microbiological criteria for food define the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area, or lot.

In general, microbiological criteria may be used to define the distinction between acceptable and unacceptable raw materials, ingredients, products, lots, by regulatory authorities and/or food business operators. Codex Alimentarius also emphasizes importance of microbiological criteria for verification and/or validation of the efficacy of the HACCP plan.

European Union

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs establishes the food safety criteria for certain important foodborne bacteria, including their toxins and metabolites. These include *Salmonella*, *Listeria monocytogenes*, *Enterobacter sakazakii*, Staphylococcal enterotoxins and Histamine in specific foodstuffs. These microbiological criteria have been developed in accordance with Codex Alimentarius. The FBO is required to ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I of the Regulation.

The Regulation requires the FBO to perform tests as appropriate against these microbiological criteria when validating or verifying whether their procedures are functioning correctly based on HACCP principles and best hygienic practices.

United States

By contrast with the EU, there is no uniform microbiological standard in the U.S. food safety system. Such a standard has not been adopted because of a wide variation in products and processing procedures that are constantly changing. Instead, FDA and FSIS simply state microbiological criteria for certain foods that are in use.

For instance, within FSIS microbiological testing programs, the agency conducts microbiological tests for *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes*.

FSIS also has performance standards for Salmonella, and a pathogen reduction regulation that requires some plants to conduct E. coli generic testing.⁴⁹ Furthermore, on June 4, 2012, FSIS began verification testing for non-O157 Shiga toxin-producing *E. coli* (STEC)⁵⁰ in domestic and imported beef manufacturing trimmings from cattle slaughtered on or after June 4, 2012.⁵¹

FDA has developed Compliance Policy Guides⁵² that describe its policy on compliance matters, setting forth specific criteria that must be met by producers. Contaminants covered by these guides include foodborne pathogens, bacterial toxins, mycotoxins, and bacterial indicators (for example E. coli). Some states also have their own microbiological standards for foods.

Residues Control

Residues control aims to protect public safety by setting maximum residue levels in accordance with generally recognized principles of safety assessment, taking into account any other scientific assessment of the safety of the substances concerned which may have been undertaken by international organizations, and in particular the Codex Alimentarius.

Codex Alimentarius

CAC has addressed the residues control issue through work done by its relevant committees – the Committee of Pesticides Residues (CCPR) and the Committee on Residues of Veterinary Drugs in Food (CCRVDF).

CCPR is responsible for establishing MRLs for pesticide in specific food items or in groups of food; CCRVDF determines priorities for the consideration of residues of veterinary drugs in foods, and recommends MRLs for veterinary drugs. Limits of MRLs for pesticides and veterinary drugs are constantly being developed and updated.⁵³

European Union

Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin⁵⁴ sets out MRLs for the 315 fresh products listed. However, these MRLs also apply to the same products after processing, albeit adjusted to take account of dilution or concentration as a result of the process.

⁴⁹ Codex Alimentarius relevant texts: *Principles for Establishment and Application of Microbiological Criteria for Foods*, *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* and *Principles and Guidelines for the Conduct of Microbiological Risk Management*, available at: www.fao.org/docrep/012/a1552e/a1552e00.htm.

⁵⁰ These six non-O157 STECs are O26, O45, O103, O111, O121, and O145.

⁵¹ For more information, see: http://www.fsis.usda.gov/science/Ground_Beef_E.Coli_Testing_Results/index.asp#14.

⁵² For more information, see: <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm>.

⁵³ List of MRLs for pesticides and veterinary drugs is available at: <http://www.codexalimentarius.org/standards/pesticide-mrls/en/> and at: <http://www.codexalimentarius.org/standards/veterinary-drugs-mrls/en/>.

⁵⁴ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R0396:EN:NOT>.

Regulation (EC) No 396/2005 covers pesticides now or previously used in agriculture in or outside the EU (totaling around 1,100). According to the Regulation, no pesticide shall be authorized without an established MRL. As for the MRLs for food of animal origin, Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin⁵⁵ (and its subsequent amendments⁵⁶) established MRLs of pharmacologically active substances relevant to different species of animals. Provisions requiring assurances from the FBO that some prohibitive substances have not been used, and that the MRLs fixed have been complied with, can be also found in the Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.⁵⁷

United States

The Environmental Protection Agency (EPA)⁵⁸ sets maximum residue limits (MRLs) on how much of a pesticide residue can remain on food and feed products, or commodities.

These pesticide residue limits are known as “tolerances” in the U.S. USDA enforces the tolerances established for meat, poultry and some egg products, while the FDA enforces tolerances established for other foods. FDA and USDA inspectors monitor food in interstate commerce to ensure that these limits are not exceeded.

These tolerances are listed in the:

- Federal Register, which publishes new tolerances and changes to tolerances;
- Code of Federal Regulations (CFR).

Importantly, the names of agricultural food and feed products, and commodities, are being standardized. The tolerance information provided in the CFR and Federal Register uses these standardized commodity names. Standardized commodity names are found in the Food and Feed Commodity Vocabulary.

These commodity terms are the only terms accepted in establishing pesticide tolerances.

⁵⁵Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, available at: http://ec.europa.eu/health/files/eudralex/vol-5/reg_2010_37/reg_2010_37_en.pdf.

⁵⁶Updates to the Commission Regulation (EU) No 37/2010 can be found at: http://ec.europa.eu/health/veterinary-use/maximum-residue-limits/regulations_en.htm.

⁵⁷Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC, available at: <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0023:EN:HTML>.

⁵⁸The EPA website contains detailed instruction on how to use Electronic Code of Federal Regulations (e-CFR) recourses to find tolerances on a specific food or commodities. See at: <http://www.epa.gov/pesticides/food/viewtols.htm>.

Import/Export

Each country has its own body of import/export legislation, which must be followed by both domestic and foreign FBOs. As a result, common principles for import/export trade which provide the possibility of both developing an efficient system of state control while avoiding deceptive marketing practices have been developed by the world food community.

Codex Alimentarius

Recognizing that quality and safety can be assured through the application of well-designed food control systems (for exports and imports), principles for food import and export inspection and certification have been developed by the Codex Committee on Food Import and Export Inspection and Certification Systems.⁵⁹

European Union

The main rule for food products slated as EU imports is that they should meet the same hygiene and safety standards as food produced in EU. However, the import system for food of animal origin differs from what is required for food of non-animal origin, or for food containing both animal-and plant-origin ingredients.

Food of Animal Origin and Live Animals:

1. Can be imported to the EU only from third countries included in the list compiled by the community, and only from establishments approved by the community;⁶⁰
2. Will be subject to compulsory veterinary border control at veterinary border inspection posts (BIPs). BIPs are under the authority of official veterinarians, who are responsible for the health checks required on incoming consignments.
3. Consignments with food of animal origin:
 - Are subject to official veterinary checks in the border inspection. Official border control is conducted on fee basis. Minimum rates were adopted by EU Regulation 882/2004 although these may vary in each member state;
 - Prior notification of consignment arrival is required;
 - Should be accompanied by required documents (certificate issued by competent authority of third country);
 - Special import conditions might be imposed on the consignment if imported products are listed in List of Special Import Conditions. This list shows which product from which county is to be checked as well as any control actions that may be taken.⁶¹

Only after these checks prove successful, and after receiving all necessary information cited in the Common Entry Veterinary Document (CEVD), will the consignment be allowed to enter the EU.

Consignments which are found not to be compliant with EU legislation will either be destroyed or, under certain conditions, re-dispatched within 60 days. If any one of the checks indicates that a consignment of animals or products is likely to constitute a danger to animal or human health; however, the consignment in question will immediately be seized and destroyed by the competent authorities.

⁵⁹The latest compilation of Codex documents related to import/export control is available at: ftp://ftp.fao.org/codex/Publications/Booklets/Inspection/CCFICS_2012_EN.pdf.

⁶⁰Updated Third Country Establishments List is available at: http://ec.europa.eu/food/international/trade/third_en.htm.

⁶¹Updated List of special import conditions is available at: http://ec.europa.eu/food/animal/bips/special_imports_en.htm.

Food of Non-Animal Origin:

1. Can be imported from any third country (no special approval of the country or establishment in third country is required);
2. Import controls of food of non-animal origin take place in accordance with national law in the different member states. This may be at the point of entry, the point of release for free circulation, the importer's premises, and retail outlets. Certain food of non-animal origin is to be imported to EU through a designated point of entry;
3. Is not subjected to a pre-notification procedure on arrival, except for certain foods of non-animal origin;
4. Can enter the EU without certification by the competent authorities of the third country of dispatch. Only certain plants and plant products must be accompanied by a phytosanitary certificate, issued by the National Plant Protection Organization of the exporting country. Upon entry into the community, the phytosanitary certificate may be replaced by a plant passport.⁶²

United States

Food imported to the U.S. must meet the same legal standards as food produced domestically. To assure this, the FSMA contains significant requirements for importers. In particular, importers must verify the safety of the food offered for import using the new *Foreign Supplier Verification Program (FSVP)*. This program requires importers to conduct risk-based verification activities to assure that imported food is not adulterated or misbranded and is produced in compliance with the FDA's preventive controls requirements and produce safety standards.

Verification activities may include monitoring records for shipments, lot-by-lot certification compliance, and annual on-site inspections, checking the hazard analysis and risk-based preventative control plan of the foreign supplier and periodically testing and sampling shipments.⁶³

The FSVP program is *mandatory*, unlike the Voluntary Qualified Importer Program (VQIP),⁶⁴ which is entirely voluntary and gives importers a green light for imported foods from trusted suppliers. Non-compliance with the FSVP is a basis for refusal of an imported article. The FSMA authorizes the FDA to require that high-risk imported foods, based on health consequences, be accompanied by a credible third-party certification or other assurance of compliance as a condition of entry into the U.S.

Before importing products to the U.S., FDA also requires that:

- Food facilities (both domestic and foreign) are registered with the FDA; and that
- The FDA be given advance notice on shipments of imported food.

Foreign facilities that manufacture/process, pack, or hold food are required to register with the FDA unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the U.S. Food facilities may be registered and prior notice may be submitted online. Food facilities are required to renew this registration every two years.

Imported food products are subject to FDA inspection when offered for import at U.S. ports of entry. The FDA may detain shipments of products offered for import if the shipments are found not to be in compliance with U.S. requirements.

Unlike the FDA, for which inspection requirements are company-specific, FSIS coordinates with the government of the country-in-question before accepting meat, poultry or egg products for sale in the U.S. In particular, to import meat, poultry or eggs into the U.S., these products must originate from certified countries and establishments eligible to export to the United States.

Remarkably, Canada is currently the only country eligible to export egg products to the U.S.

⁶² Mentioned plants and plant documents are listed in Part B of Annex V to Directive 2000/29/EC available at: <http://eur-lex.europa.eu>.

⁶³ However, importers are not required to conduct verification activity pertaining to products from foreign suppliers which are subject to low-acid canned food regulations, and seafood or juice HACCP.

⁶⁴ Available at <http://www.access.fda.gov/>.

Regulatory Authority

The issue of food safety regulation is one of the most important both in terms of assuring customer health and effective FBO operations.

In fact, the ability to produce safe food and be trusted by potential customers is crucial for food producers aiming to integrate their businesses into the international food trade – meaning that Food Safety Management Systems are a key issue for the private sector. At the same time, however, food safety regulations can also impose a heavy administrative burden on businesses.

Codex Alimentarius

CAC has addressed issues related to food safety regulation in several of its texts. For example, *Principles for Food Import and Export Inspection and Certification* sets out the basic principles that inspection and certification systems should meet. It also emphasizes the importance of having adequate means to perform such inspection and certification procedures.⁶⁵

Furthermore, the *Guidelines for Food Import Control Systems* provide a framework for the development and operation of an import control system aiming to protect consumers and facilitate fair practices in food trade.

Finally, the *Guidelines for the Validation of Food Safety Control Measures* provides practical guidance for industry and governments on the validation of individual control measures, a limited combination of control measures, or sets of control measure combinations forming a food safety control system (for example HACCP, GHP).⁶⁶

European Union

The European Food Safety Authority is an independent European agency funded by the EU budget that operates separately from the European Commission, European Parliament and EU member states. EFSA's role is to assess and communicate all risks associated with the food chain.

Through its risk communication activities, EFSA seeks to raise awareness and further explain the implications of its scientific work. EFSA aims to provide appropriate, consistent, accurate and timely communications on food safety issues to all stakeholders and the public at large, based on the authority's risk assessments and scientific expertise.⁶⁷

In the EU, the Member State Regulatory Authority has national responsibility for coordinating the enforcement of food safety legislation in a member state.⁶⁸

⁶⁵ *Codex Alimentarius Principles for Food Import and Export Inspection and Certification*, available at: <http://www.fao.org/docrep/009/y6396e/y6396e00.htm>.

⁶⁶ *Codex Alimentarius Guidelines for the Validation of Food Safety Control Measures*, available at: www.codexalimentarius.org/input/download/standards/.../cxg_o69e.pdf.

⁶⁷ More information on EFSA can be found in Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, available at: http://europa.eu/legislation_summaries/consumers/consumer_information/f80501_en.htm.

⁶⁸ References to web-pages of member states regulatory authorities can be found below in Useful Links Table.

Finally, the Rapid Alert System for Food and Feed (RASFF) needs to be mentioned. This body was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken in response to serious risks detected in relation to food or feed. This information exchange helps member states act more rapidly, and in a coordinated manner, in response to a health threat rooted in food or feed. When a RASFF member has any information about a serious health risk linked to food or feed, it must immediately notify the European Commission using RASFF.⁶⁹

United States

Numerous federal, state and local agencies regulate the American Food Safety Management System. At the federal level, 15 agencies collectively administer at least 30 laws related to food safety.⁷⁰ Two federal agencies, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) are primarily responsible for safety of the U.S. food system.

The USDA⁷¹ is responsible for the regulation of meat, poultry, and processed egg products. Within the USDA, the Food Safety and Inspection Service (FSIS)⁷² inspects and regulates meat, poultry and processed egg products produced in federally inspected plants. FSIS is responsible for ensuring that these products are safe, wholesome, correctly labeled, and packaged.

The FDA⁷³ is responsible for regulation of virtually all other foods. In particular, the Center for Food Safety and Applied Nutrition (CFSAN) works to assure that the food supply is safe, sanitary, wholesome, and honestly labeled.

Other agencies responsible for food system-related issues include:

- *The US Department of Homeland Security (DHS)*,⁷⁴ which is responsible for coordinating agencies' food security activities, including at U.S. borders;
- *The National Marine Fisheries Service (NMFS)*⁷⁵ in the U.S. Department of Commerce, which conducts voluntary, fee-for-service inspections of seafood safety and quality;
- *The Environmental Protection Agency (EPA)*,⁷⁶ which regulates the use of pesticides and maximum allowable residue levels on food commodities and in animal feed;
- *The Centers for Disease Control and Prevention (CDC)*⁷⁷ under the U.S. Department of Health and Human Services.

Tracking single cases of foodborne illness and investigating outbreaks are some of the public health functions that closely involve CDC.

At the state level, food safety regulatory functions may be carried out by departments of health, agriculture, or environment, or some combination of these. State-level agencies perform a wide range of food safety functions addressing both prevention and response to food safety problems, including outbreak response and recalls, laboratory testing, retail, food service, processing and farm inspection, among many others. At the local level, public health departments normally carry out restaurant inspections and other local food safety activities.⁷⁸

⁶⁹ More information on RASFF can be found in Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, available at: http://europa.eu/legislation_summaries/consumers/consumer_information/f80501_en.htm and at: http://ec.europa.eu/food/food/rapidalert/index_en.htm.

⁷⁰ GAO Federal Oversight of Food Safety, 2007, <http://www.gao.gov/new.items/do7449t.pdf>.

⁷¹ <http://usda.gov/wps/portal/usda/usdahome>.

⁷² <http://www.fsis.usda.gov>.

⁷³ <http://www.fda.gov>.

⁷⁴ <http://www.dhs.gov/>.

⁷⁵ <http://www.nmfs.noaa.gov/>.

⁷⁶ <http://www.epa.gov/>.

⁷⁷ <http://www.cdc.gov/>.

⁷⁸ The Essential Role of State and Local Agencies in Food Safety and Food Safety Reform, by Stephanie David etc., available

Other Relevant Regulations

European Union

The new **EU Regulation 1169/2011** on the provision of food information to consumers introduced significant changes to existing legislation on food labelling. This regulation came into force on December 13, 2014, obliging the FBO to provide nutrition information to consumers.

Regulation (EU) No 872/2012 provides a new and widened list of flavoring substances acceptable for use in food.⁷⁹ This regulation came into force April 22, 2013.

United States

The main significant changes in U.S. food safety legislation are related to the FSMA.

The Food Safety and Modernization Act (FSMA) was passed by Congress in 2011. It was the first major reform by the FDA in over 70 years. FSMA expands the regulation of produce from farm to sale and other FDA-regulated foods from processing to sale and introduces additional food safety requirements. Key changes are:

1. A shift of focus from reaction to prevention, including preventing intentional contamination;
2. More authority to inspect and assure compliance with inspection frequencies based on risk;
3. Mandatory recall authority;
4. Authorities to strengthen import safety to assure that U.S. food safety standards are met; and
5. Stronger partnerships with other government agencies and private entities.

Preventive Controls:

FSMA requires preventive controls for food consumed by humans. The rule is now final; compliance dates for some businesses begin in September 2016.

Key Requirements:

- Requires FBO facilities to have a written food safety plan that includes a hazard analysis and preventive controls;
- Hazard analysis, which must consider known or reasonably foreseeable biological, chemical and physical hazards. These include hazards that occur naturally, are intentionally introduced, or are intentionally introduced for economic gain (if they affect food safety);
- Preventive controls required to ensure that hazards will be minimized or prevented, including process, food allergen and sanitation controls, as well as supply chain controls and a recall plan. Oversight and management of preventive controls include:
 - Monitoring: procedures ensuring that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control;
 - Corrective actions and corrections taken to identify and correct a minor, isolated problem that occurs during food production. These include actions to identify a problem with preventive control implementation; reduce the likelihood the problem will recur; and evaluate affected food for safety and prevent it from entering commerce. Corrective actions must be documented;
 - Verification is required to ensure that preventive controls are consistently implemented and effective. This includes validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification of instruments such as thermometers and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

at http://www.thefsrc.org/State_Local/StateLocal_June17_background.pdf.

⁷⁹The list of permitted flavoring substances (Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012), available on <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0001:0161:EN:PDF>.

- Supply chain is more flexible, with separate compliance dates:
 - The rule mandates that a manufacturing/processing facility has a risk-based supply chain program for raw materials and other ingredients for which it has identified a hazard requiring a supply chain applied control;
 - Manufacturing/processing facilities that control a hazard using preventive controls, or that follow requirements applicable when relying on a customer to control hazards, do not need to have a supply chain program for that hazard;
 - Covered food facilities are responsible for ensuring that these foods are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use.
- Current Good Manufacturing Practices (CGMPs) are updated and clarified:
 - Education and training are not binding;
 - FBO management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties;
 - FBO employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack or hold clean and safe food;
 - FBO employees must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.

Foreign Supplier Verification Programs (FSVP)

FSMA requires that importers of food for humans and animals be subject to Foreign Supplier Verification Programs (FSVP). The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards:

- Importers covered by the rule must have a system in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations, as appropriate to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labelling;
- Importers are responsible for actions that include:
 - Determining known or reasonably foreseeable hazards with each food;
 - Evaluating the risk posed by a food, based on the hazard analysis, and for foreign supplier's food safety performance, e.g. complaints, withdrawals, or recalls;
 - Using that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities;
 - Conducting supplier verification activities;
 - Conducting corrective actions.

Third Party Certification

This rule establishes a voluntary program for the accreditation of third party certification bodies, also known as auditors, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. These requirements cover legal authority, competency, capacity, conflict of interest safeguards, quality assurance and record procedures. Certificates can be used for two purposes:

- For importers to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers expedited review and entry of food;
- To prevent potentially harmful food from reaching U.S. consumers, the FDA can also require in specific circumstances that a food offered for import be accompanied by a certification from an accredited third party certification body.

Produce Safety

This rule establishes for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

Key Requirements:

- Water quality: no detectable generic E. Coli are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. The second set of criteria of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV). The GM of samples is 126 or less CFU [colony forming unit] of generic E. Coli per 100 mL of water and the STV of samples is 410 CFU or less of generic E. coli in 100 mL of water;
- Testing: required for untreated water used for certain purposes, based on testing frequency on the type of water source (i.e. surface or ground water);
- Biological soil amendments (materials intentionally added to soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water):
 - Untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application;
 - FDA does not object to farmers complying with the USDA's National Organic Program standards, which calls for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.
- Standardized compost: microbial standards that set limits on detectable amounts of bacteria (including *Listeria Monocytogenes*, *Salmonella* spp., fecal coliforms, and E. Coli O157:H7) have been established for processes used to treat biological soil amendments, including manure.

Sprouts: new requirements help prevent the contamination of sprouts, which have been frequently associated with foodborne illness outbreaks. Sprouts are especially vulnerable to dangerous microbes because of the warm, moist and nutrient rich conditions needed to grow them.

Food Defense

Food defense is the effort to protect the food supply against intentional contamination due to sabotage, terrorism, counterfeiting, or other illegal, intentionally harmful means. Potential contaminants include biological, chemical and radiological hazards that are generally not found in foods or their production environment. FDA's proposed rule on food defense would require domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm. The proposed rule, which is required by FSMA, would require the largest food businesses to have a written food defense plan that addresses significant vulnerabilities in a food operation.

Sanitary Transportation of Human and Animal Food

This proposed rule establishes requirements for vehicles and transportation equipment, transportation operations, training, and recordkeeping. Operators of motor vehicles, railcars, and other equipment used in food transportation would be required to establish written procedures, subject to record keeping requirements, for cleaning their vehicles and transportation equipment.

Administrative Detention

FSMA enhances FDA's administrative detention authority by authorizing FDA to administratively detain articles of food that FDA has a reason to believe may adulterated or misbranded.⁸⁰

USA Fruit and Vegetable Regulations

The primary regulation relating to the importation of fruit and vegetables in the USA is 7 CFR 19.56-3. All fruits and vegetables that are imported, must be:

- Free from plant litter or debris and free of any portions of plants that are specifically prohibited in the regulations;
- Imported under permit issued by APHIS [Animal and Plant Health and Inspection Service], whether commercial or noncommercial.

Port of Entry

- Fruits and vegetables must be imported into specific ports if so required or they may be imported into any port listed in 19 CFR 101.3(b)1. Fruits and vegetables that are to be cold treated at ports in the United States may only be imported into specific ports.

Inspection, Treatment and other Requirements

- All imported fruits or vegetables are subject to inspection, and disinfection at the port of first arrival as may be required by a Border Control Protection [BCP] inspector, and are subject to re-inspection at other locations at the option of an inspector. If an inspector finds plants or portions of plants, or a plant pest or noxious weed, or evidence of a plant pest or noxious weed on or in any fruit or vegetable or its container, or finds that the fruit or vegetable may have been associated with other articles infested with plant pests or noxious weeds, the owner or agent of the owner of the fruit or vegetable must clean or treat the fruit or vegetable and its container as required by an inspector, and the fruit or vegetable is also subject to re-inspection, cleaning, and treatment at the option of an inspector at any time and place until all applicable requirements of this subpart have been accomplished.
- **Notice of arrival; assembly for inspection.** Any person importing fruits and vegetables into the United States must offer those agricultural products for inspection and entry at the port of first arrival. The owner or agent must assemble the fruits and vegetables for inspection at the port of first arrival, or at any other place designated by an inspector, and in a manner designated by the inspector. All fruits and vegetables must be accurately disclosed and made available to an inspector for examination. The owner or the agent must provide an inspector with the name and address of the consignee and must make full disclosure of the type, quantity, and country and locality of origin of all fruits and vegetables in the consignment, either orally for noncommercial consignments or on an invoice or similar document for commercial consignments.
- **Refusal of entry.** If an inspector finds that an imported fruit or vegetable is prohibited, or is not accompanied by required documentation, or is so infested with a plant pest or noxious weed that, in the judgment of the inspector, it cannot be cleaned or treated, or contains soil or other prohibited contaminants, the entire lot or consignment may be refused entry into the United States.

⁸⁰ Bibliography

Food and Drug Administration, FSMA Final Rule for Preventive Controls for Human Food
Food and Drug Administration, FSMA Final Rule on Foreign Supplier Verifications Programs (FSVP) for Importers of Food for Humans and Animals
Food and Drug Administration, FSMA Final Rule on Accredited Third Party Certification
Food and Drug Administration, FSMA Final Rule on Produce Safety
Food and Drug Administration, FSMA Proposed Rule for Focused Mitigation Strategies to Protect Food Against Intentional Adulteration
Food and Drug Administration, FSMA Frequently Asked Questions

- **Release for movement.** No person may move a fruit or vegetable from the port of first arrival unless an inspector has either:
 - (i) Released it;
 - (ii) Ordered treatment at the port of first arrival and, after treatment, released the fruit or vegetable;
 - (iii) Authorized movement of the fruit or vegetable to another location for treatment, further inspection, or destruction; or
 - (iv) Ordered the fruit or vegetable to be re-exported.
- **Notice to owner of actions ordered by inspector.** If an inspector orders any disinfection, cleaning, treatment, re-exportation, recall, destruction, or other action with regard to imported fruits or vegetables while the consignment is in foreign commerce, the inspector will issue an emergency action notification (PPQ Form 523) to the owner of the fruits or vegetables or to the owner's agent. The owner must, within the time and in the manner specified in the PPQ Form 523, destroy the fruits and vegetables, ship them to a point outside the United States, move them to an authorized site, and/or apply treatments or other safeguards to the fruits and vegetables as prescribed to prevent the introduction of plant pests or noxious weeds into the United States.
- **Costs and charges.** APHIS will be responsible only for the costs of providing the services of an inspector during regularly assigned hours of duty and at the usual places of duty. The owner of imported fruits or vegetables is responsible for all additional costs of inspection, treatment, movement, storage, destruction, or other measures ordered by an inspector under this subpart, including any labor, chemicals, packing materials, or other supplies required. APHIS will not be responsible for any costs or charges, other than those identified in this section.

The Eurasian Economic Union (EEU)

This section provides information on production and marketing of food products in the Eurasian Economic Union (EEU). The section is based on *Comparative Analysis of Certain Requirements of Food Legislation in the European Union and the Customs Union of Russia, Belarus, and Kazakhstan*.⁸¹

The Eurasian Economic Union is an international organization for regional economic integration; it has international legal personality and is established by the Treaty on the Eurasian Economic Union (EEU) dated May 29, 2014. The EEU ensures free circulation of goods, services, capital and labor force as well as coordinated, coherent or unified policy in the economy sectors. The member states of the EEU are the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic and the Russian Federation.⁸²

The EEU has been established for comprehensive modernization, cooperation, and competitiveness improvement of the national economies and to create environment for sustainable development to the benefit of improving the living standards of the citizens of the member states.

Legal Instruments

The EEU system of normative regulation consists of number of general and product-specific technical regulations that provide a framework for food control within the EEU; the common framework is then supported by member states national laws, regulations, and standards.

Within the EEU the main legal instruments used are technical regulations. There are also voluntary standards. However, products must comply with the technical regulatory act in the field of standardization, such as state standards:

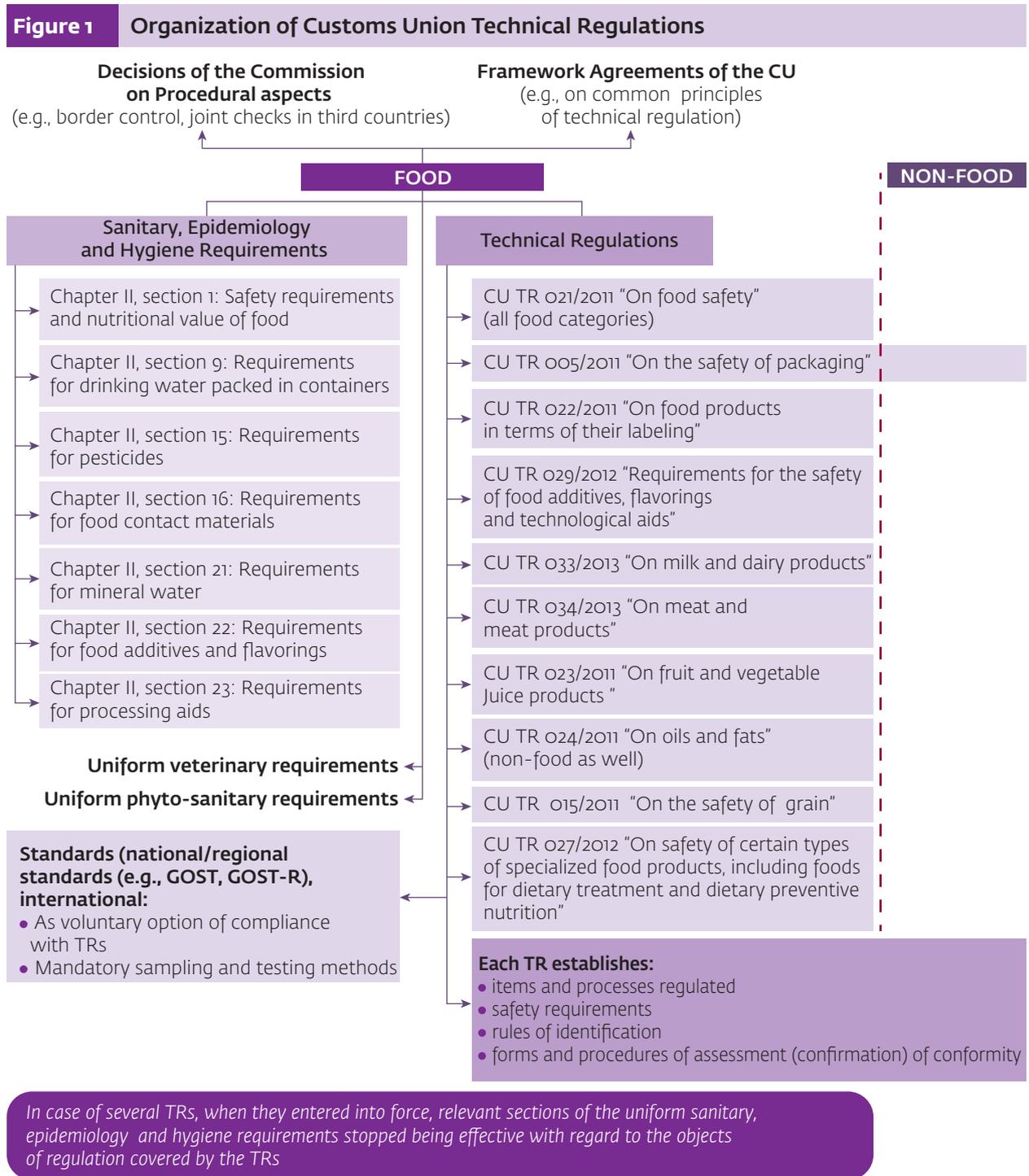
- National/regional;
- Standards (e.g., GOST, GOST-R,) or technical regulations (TR) that have been applied by a manufacturer. The regulations and standars are directly applicable within the member states (activities in the area of technical regulation and conformity assessment), but with some exceptions, they do not incorporate implementation mechanisms – these can only be found in the EEU member-states' national laws and regulations. Technical regulations, while directly applicable, focus mostly on technical aspects of products and establish specifications, not policies.

For food categories where product-specific technical regulations have not been developed, the national law of the EEU member states applies.

⁸¹<http://documents.worldbank.org/curated/en/2015/07/24794014/comparative-analysis-certain-requirements-food-legislation-european-union-customs-union-russia-belarus-kazakhstan>.

⁸² <http://www.eaeunion.org/#about>.

Figure 1 provides a graphical representation of the EEU food-related legal instruments:



Both EEU technical regulations and the laws and standards of the member states must be considered to be compliant with the EEU. Furthermore, the EEU system does not address enforcement, fines, penalties, incident management, recalls and withdrawals, and authorization/approval of new substances (for example, pesticides or veterinary medicines). These issues are addressed within the framework of the national legislation of member states. This increases the complexity of the regulatory environment and compliance for industry wishing to export to the EEU and for governments wishing to model or harmonize with the EEU.

Organizational Arrangements

The legal framework of the EEU combines horizontal and vertical legal acts. Horizontal regulations include technical regulations on general food safety, labeling, packaging, food additives and flavorings that cover cross-cutting aspects for all food products (note that technical regulations on packaging also cover packaging for non-food items). Currently, there is a technical regulation being drafted for materials contacting food that also has a horizontal nature. There are also vertical technical regulations specific to certain product groups, in particular grain, oils and fats, fruit and vegetable juices, meat and meat products, milk and dairy products. Additional vertical technical regulations are being drafted for alcohol products, poultry and poultry products, fish and fish products, bottled potable water and mineral waters.

The EEU technical regulations include a number of requirements that relate to their circulation on the market. The most important requirement is that food must pass conformity assessment procedures and bear a special EEU mark as a proof of conformity.



A single mark of circulation proves that products have passed all evaluation (conformity) procedures stipulated in technical regulations and that they comply with the requirements of all technical regulations. Furthermore, since the EEU is based on conformity assessments, many food products have to meet compositional standards, as well as requirements for chemical and physical properties, nutritional properties, organoleptic (appearance, taste, odor) and, in some cases, size.

Food Control System

In the EEU the food control system incorporates two levels: food control through all-Union conformity assessment and individual member state controls (supervision) of sanitary, veterinary, phytosanitary aspects. The EEU institutional framework and the scope of the official food control system are represented in Figure 2:

Enforcement is carried out by national bodies designated as competent authorities for specific areas of state control (supervision), and in technical regulation. Conformity assessments are carried out by authorized certification (conformity assessment) bodies. Testing needed for the purposes of enforcement is carried out by authorized testing laboratories.

Specially designated state bodies are responsible for assessing or confirming conformity for several groups of products (e.g., specialized products, GMOs). As previously mentioned, foodstuffs are subject to conformity assessment within the EEU. Evaluation (proof) of food conformity is conducted in the following forms:

1. Confirmation (declaration) of compliance of food products;
2. State registration of specialized food products;
3. State registration of new types of food products;
4. Veterinary-sanitary expertise.

In addition to conformity assessment, food products are subject to state control (supervision).⁸³ This combines border controls (people, vehicles, goods) and internal controls within the member states.

⁸³State sanitary control (supervision) is carried out against requirements to products and processes outlined in the Uniform Sanitary, Epidemiological and Hygiene Requirements over Products Subject to State Control (Supervision); State veterinary control is carried out according to Uniform Veterinary (Veterinary and Sanitary) Requirements for Goods Subject to Veterinary Inspection (Supervision).

Figure 2 Food Control System of the Customs Union

Food products are divided into three groups that subject to respectively sanitary (epidemiological, hygiene), veterinary, and phytosanitary control (supervision). The purpose of, for instance, state sanitary (epidemiological, hygiene) control (supervision) is to prevent the introduction and spread of, and to ensure the elimination of infectious and massive poisonings that are hazardous to human health. Moreover, the objects of state control are prevention of emergencies acts of terrorism with the use of biological agents, chemical and radioactive substances.⁸⁴

All food with ingredients of animal origin are subject to veterinary checks.⁸⁵

Certain products, when first imported or produced in the EEU, are subject to state registration including: mineral, therapeutic, and bottled water; beverages such as tonics and beer; food for special purposes, including food for babies and older children, food for pregnant and nursing women; food additives, foodstuffs derived

⁸⁴ Based on item 2-1 of Decision of the Customs Union Commission No. 299 of May 28, 2010 (with amendments to item 2-1 introduced by Decision No. 101 of the Eurasian Economic Council of July 7, 2014, the food products and items that are covered by the scope of certain technical regulations are exempt from the scope of Uniform Sanitary, Epidemiological and Hygiene Requirements. These include, for example, materials and articles produced of polymer and other materials intended for contact with food and food media, labeling requirements, food additives and flavorings, and technological aids, as well as meat and meat products, and milk and dairy products.

⁸⁵ The Common List of Goods Subject to Veterinary Control (Supervision). Approved by the Decision of the Customs Union Commission No. 317 dated June 18, 2010.

from genetically engineered or modified (transgenic) organisms, and some food contact materials.⁸⁶ Registration of these products is verified through state supervision.

Certain production and processing facilities also require registration. This requirement extends to facilities engaged in production and processing products containing meat, dairy, poultry and fish. State registration of production/processing facilities is conducted by the agencies authorized for this purpose by EEU member states. This procedure begins with the application by the processor and is followed by an inspection of the facility to determine its conformity to the requirements on processes (production, processing, storage, transportation, sale, disposal) established by relevant technical regulations.

Details of the procedure are established by the legislation of the EEU member states.

Upon satisfactory completion of the inspection and review of the findings, the designated agency assigns an identification number to the facility and adds it to the Registry of Food Facilities Subject to State Registration. The state registration of a production/processing facility has no expiration date; however, it can be suspended or cancelled in case of serious breach of the requirements of technical regulations.

Table 1 below provides a summary of the state control (supervision) framework within the EEU.

Regulation of Food Quality issues

Specifics of EEU quality are usually included in minimum composition requirements in product definitions. These requirements can be found in under product-specific technical regulations (e.g., Article 5, "Safety requirements for fruit and/or vegetable juice products" of CU TR 023/2011 *On Fruit and Vegetable Juice Products*), and in annexes on microbiology, physical and chemical properties and organoleptic characteristics. The intent is to ensure that products entering the market conform to the specific technical regulations in all attributes. Quality characteristics outlined in the technical regulations are used to ensure uniformity of food products offered to consumers, satisfy the needs of vulnerable groups of consumers, and for the purposes of product identification to establish whether they are subject to conformity assessment under the relevant technical regulation.

A general rule applies to compliance with EEU technical regulations: a manufacturer may choose whether to comply with the technical regulation itself, or with a set of regional standards (GOSTs), a list of which supports each technical regulation. Compliance with these standards is voluntary but meets the requirements for compliance with the technical regulation. Furthermore, in cases where norms are absent in the EEU technical regulations, national norms of the member states apply.

Food Labeling

In the EEU labeling requirements are focused on consumer and transport packaging. An information carrier must be attached, affixed or enclosed to the product packaging. The EEU established that packaged food product labeling may include additional information.

Importantly, in the EEU, labeling is one of the requirements that comprise a set of specifications for mandatory conformity assessment (in the form of declaration of conformity). Non-compliance may result in no access to the EEU market.

⁸⁶The goods from the list, manufactured for the first time on the EAEU customs territory, as well as imported for the first time to EAEU customs territory, are subject to state registration (Part II, Single List of Goods Subject to Sanitary-and-Epidemiologic Supervision (control) at the Customs Border and on the Customs Territory of EAEU, as amended by Decision of the Customs Union Commission No 341 of 17.08.2010).

Table 1 General Framework of the State Control (Supervision) in the Customs Union

State Control (Supervision) ⁸⁷			
	Sanitary	Veterinary	Phyto-sanitary
Key legal act	Customs Union Agreement on Sanitary Measures ⁸⁸	Agreement of the Customs Union on Veterinary and Sanitary Measures ⁸⁹	Customs Union Agreement on Plant Quarantine ⁹⁰
Competent authority	Competent authorities in the area of state sanitary control (supervision) in member states		
Scope	Common list of goods subject to sanitary and epidemiological control (supervision)	Common list of goods subject to veterinary control	List of goods subject to quarantine and phytosanitary control (supervision)
	<ul style="list-style-type: none"> Foodstuffs (products in natural or processed form used for human food) including those derived from genetically engineered or modified (transgenic) organisms Materials, products and equipment contacting with foodstuffs Pesticides and agrochemicals 	<ul style="list-style-type: none"> Live animals All food of animal origin, fresh and processed Food that has ingredients of animal origin Yeasts, enzymes, starter cultures Grains and other plant origin items when they are intended for manufacture of feed 	<ul style="list-style-type: none"> Vegetables, fresh or chilled Dried leguminous vegetables; Fruits, fresh, dried Nuts, fresh or dried, whether or not shelled or peeled Coffee, not roasted, whether or not decaffeinated Cocoa beans Grains Cereal flours Seeds, whether or not broken
Point of control	At the border and within the customs territory of the Customs Union		
Documents that establish compliance criteria	Uniform sanitary, epidemiology and hygiene requirements for goods subject to veterinary control (supervision)	Uniform veterinary requirements for goods subject to veterinary control (supervision)	—
Procedural documents	Procedure of state sanitary and epidemiological control (supervision) over persons crossing the CU customs border, goods subject to control that are being moved through the customs border and customs territory of the CU Common templates of product (goods) safety documentation	Procedure of carrying out veterinary control at the customs border and on the customs territory of the CU Procedure of carrying out joint inspections and sampling of goods (products) subject to veterinary control (supervision) on the territory of the CU member states and third countries Consolidated list of highly dangerous and quarantine diseases of animals Common templates of veterinary certificates (movement, import)	List of Quarantine Products subject to quarantine and phytosanitary control (supervision) while being imported to the common customs territory of the CU Procedure of carrying out the quarantine and phytosanitary control (supervision) at the external border of the CU Procedure of carrying out the quarantine and phytosanitary control in respect of quarantine products that are moved within the common customs territory of the CU
Registers	Common register of state registration certificates for certain products	Register of food production objects (facilities) that are subject to state registration	—

⁸⁷ English translations as well as links to the specific documents referenced in the table can be found at http://ec.europa.eu/food/international/trade/sps_requirements_en.print.htm.

⁸⁸ Decision No. 28 of 11 December 2009 of the Customs Union Commission, Decision No. 299 of 28 May 2010 of the Customs Union Commission.

⁸⁹ Customs Union Agreement on veterinary and sanitary measures, Decision No. 317 of 18 June 2010 of the Customs Union Commission, as amended by Decision No. 342 of 17 August 2010, No. 455 of 18 November 2010, No. 569 and No. 570 of 2 March 2011, No. 623 of 7 April 2011, No. 724 of 22 June 2011 and No. 726 of 15 July 2011.

⁹⁰ Decision of the Interstate Council of the Eurasian Economic Community No. 30 of 11 December 2009.

Food and Food-related Articles and Materials that Require Special Authorization

The EEU has established that there are types of food and classes of substances and/or materials, that, when either added to or come into contact with food, require special authorization before they can enter the market. These must meet special requirements to ensure food safety. They include novel food, food supplements, food additives and packaging and articles and materials in contact with food.

These are broad groups of substances, materials and articles that require authorizations; each group has its own laws and technical regulations, scopes of the regulations, definitions, authorization procedures, and specific requirements. This makes each area unique and requires a separate discussion for each general topic.⁹¹

Materials and Items Contacting Food

Currently, in the EEU, only packing and bottling materials have to be regulated as materials and items contacting food (CU TR 005/2011). Work is underway to draft technical regulation on the safety of materials contacting food; however, at the time of this analysis, drafting was not finalized and introduced for public discussion.⁹²

The EEU approach to conformity assessment based on testing to define the safety of packaging and bottling materials is efficient; however, this approach assumes that before releasing the product on the market, technical requirements on this product shall have been set. This means that the EEU regulatory framework on the subject basically comprises technical specifications to the existing and approved packaging and bottling materials.

⁹¹ Details on each of groups of substances, materials and articles that require authorizations could be find in Chapter *Food and Food-related Articles and Materials that Require Special Authorization* of the Comparative Analysis of Certain Requirements of Food Legislation in the European Union and the Customs Union of Russia, Belarus, and Kazakhstan. See <http://documents.worldbank.org/curated/en/2015/07/24794014/comparative-analysis-certain-requirements-food-legislation-european-union-customs-union-russia-belarus-kazakhstan>.

⁹² The Technical Regulations of the Customs Union 005/2011 *On Safety of Packaging*, which sets requirements for packaging and bottling materials both for food and non-food products. The Common Sanitary-Epidemiological and Hygienic Requirements to goods subject to sanitary-epidemiological supervision (control), Chapter II, Section 16 *Requirements to materials and items made of polymer and other materials designed for contacting food and food manufacturing environments*. The Uniform Sanitary, Epidemiology and Hygiene Requirements to Products Subject to Sanitary Epidemiology Supervision (Control) apply a different approach to defining the scope of the materials contacting food and that are subject to these requirements. The EAEU TARIC codes are applied to describe these materials. These codes are based on two criteria: the type of material, and the type of equipment. In most cases, the code specifies the type of material used to manufacture items, and within the limits of a certain category, there is classification of specific products (for example, name of equipment or utensils).

Microbiological Criteria for Food Safety

The EEU has a combination of vertical and horizontal legal acts that are used for establishing microbiological requirements to foodstuffs: they combine general requirements set for all foodstuffs in a horizontal CU TR 021/2011 *On Food Safety* with additional requirements established in vertical product-specific technical regulations for certain types of food. In a combined form, they can be found in the Uniform Sanitary, Epidemiology and Hygiene Requirements for Products Subject to State Control (Supervision).⁹³ As a general rule, when a product-specific technical regulation is adopted, the relevant section(s) of the Uniform Sanitary, Epidemiology and Hygiene Requirements loses its validity for products covered by the scope of the new technical regulation.

Microbiological requirements of the EEU focus on a combination of pathogens as well as indicative and spoilage microorganisms in finished products. This is due to the intent and regulatory framework of the EEU based on the finished product conformity assessment as a mechanism to control food safety and quality as well as food identification.

Approaches to Laboratory Control, Sampling and Testing

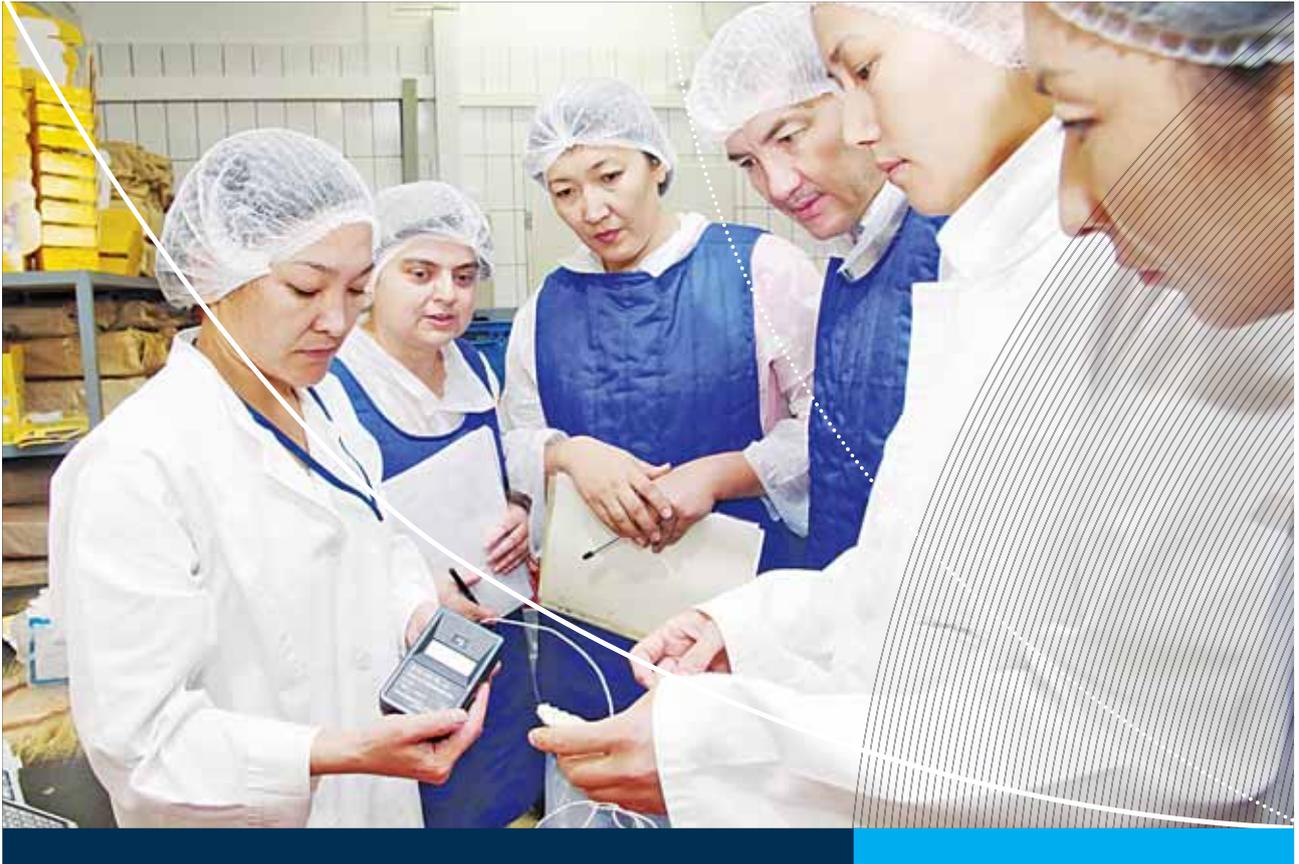
Within the EEU testing, sampling and laboratories are a part of the overall conformity assessment process whose end-product is ensuring food safety through documents establishing conformity to the technical regulations, i.e. to the safety regulations.

Within the legal framework of the EEU, sampling is a part of the conformity assessment process.

Sampling ensures the product meets the requisite technical regulations. As such, samples are used to validate a variety of parameters including pathogens, residues of pesticides, veterinary medicines, heavy metals, radio-nuclides, and mycotoxins.

Within the EEU, test methods and specific requirements to testing are codified in the approved lists to support each technical regulation and are established in GOST standards (or other national standards that are approved regionally within the EEU). This establishes a certain degree of uniformity.

⁹³ Customs Union Technical Regulation 021/2011 *On Food Safety*; Customs Union Technical Regulation 005/2011 *On Fat and Oil Products*; Customs Union Technical Regulation 023/2011 *On Fruit and Vegetable Juice Products*; Customs Union Technical Regulation 027/2012 *On Safety of Certain Types of Specialized Food Products Including Therapeutic and Preventive Dietary Food*; Customs Union Technical Regulation TR CU 033/2013 "On Safety of Milk and Dairy Products;" Customs Union Technical Regulation TR CU 034/2013 *On Safety of Meat and Meat Products*. Importantly, microbiological criteria are also set by the Uniform Sanitary and Epidemiological and Hygienic Requirements for Products Subject to Sanitary and Epidemiological Supervision (Control), Chapter II, Part 1, *Requirements for Safety and Nutrition Value of Food Products*. Per the Explanatory Note to the Technical Regulation CU TR 021/2011, the requirements, including those on microbiological safety, are based on national laws of the EAEU member states and on international requirements.



Food Safety Tools and Techniques

MODULE 4



Introduction

This section consists of two workbooks (Microsoft Excel files can be found on the enclosed CD). Their purpose is to advise and assist the implementation, development, and maintenance of a food safety management system.

The first workbook provides food business operators with tools to establish, develop, implement and maintain a prerequisites program (PRP) based on the Codex Alimentarius and ISO 22002-1 requirements.

The second workbook enables the FBO to do the same pertaining to an HACCP Plan, including an O-PRP Plan, based upon the Codex Alimentarius HACCP Principles and Steps and ISO 22000 requirements.

Both workbooks include detailed instructions.

FSTK PRP Workbook

The first workbook cites all prerequisites program details the FBO needs based on Codex Alimentarius and IS/TS 22002-1 requirements. It comprises six worksheets which should be completed by the FBO Food Safety team.

- **PRP Scope Worksheet [WS 1]** defines and documents the scope of the PRP study, including the relevant study history along with that of the members of the food safety team conducting the study.
- **PRP Management Worksheet [WS 2]** defines and documents these relevant hazards and proposes measures for controlling them.
- **PRP Verification Action Plan Worksheet [WS 3]** defines a verification plan for a particular PRP.
- **PRP Meeting Summary Worksheet [WS 4]** defines and documents all Food Safety Team meetings linked to the corresponding PRP.
- **PRP Gap Registration and Resolution Worksheet [WS 5]** defines and documents the gaps within the FBO's PRP program and advances a plan outline to address this gap.
- **PRP Hazardous Agents Worksheet (reference only) [WS 6]** defines and documents a list of hazards relevant to food products and the hazard classification acronyms used in this workbook.

FSTK PRP Workbook Instruction Guide

Step-by-step guidance in completing the FSTK PRP Workbook

An Overview of PRPs

The World Health Organization defines a prerequisite program as the “practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety.” Prerequisite programs provide a foundation for an effective HACCP system. They are often facility-wide programs rather than process or product-specific, and aim to prevent or reduce the likelihood of food safety hazards. Prerequisite programs are outside the HACCP plan but still within the HACCP system.

ISO 22000 defines a PRP as the basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption.

FBOs can meet their food safety responsibilities by implementing food safety management systems along the food production chain. The initial set of controls to be established by the FBO are called prerequisite programs (PRPs). PRPs needed by an FBO depend on the segment of the production food chain in which the organization operates and the types of organization. Examples include: Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Warehouse Practices (GWP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP).

ISO, the world’s largest publisher of international standards, and which most GFSI Private standards are benchmarked against, has published the following PRP Standards. The PRP Standards and specific guidelines to be used together with ISO 22000 ISO/TS 22002 are:

Prerequisite programs on food safety:

Part 1: Food manufacturing (2009)

Part 2: Catering (2013)

Part 3: Farming (2011)

Part 4: Food packaging manufacturing (2013)

Small-scale producers and traders in developing countries need support in planning and implementing food safety management programs in line with international requirements and in line with Codex guidelines and recommendations.

As ISO/TS 22002 specific guideline standards are aligned with the Codex, we provide a high-level overview of the PRP programs and requirements in the following sections. We specifically focus on the ISO/TS 22002-1 Food Manufacturing Specification Standard.

ISO/TS 22002-1:2009 specifies requirements for establishing, implementing and maintaining PRPs to assist in controlling food safety hazards.

ISO/TS 22002-1:2009 is applicable to all organizations, regardless of size or complexity, which are involved in the manufacturing step of the food chain and wish to implement PRPs in such a way as to address the requirements specified in ISO 22000:2005, Clause 7.

ISO/TS 22002-1:2009 is neither designed nor intended for use in other parts of the food supply chain.

Food manufacturing operations are diverse in nature and not all requirements specified in ISO/TS 22002-1:2009 apply to an individual establishment or process.

Exclusions or alternative measures implemented need to be justified and documented in a hazard analysis as described in ISO 22000:2005, 7.4. Any exclusions or alternative measures adopted should not affect the ability of the FBO to comply with these requirements. Examples of such exclusions include the following aspects of technical specifications relevant to manufacturing operations:

1. Rework;
2. Product recall procedures;
3. Warehousing;
4. Product information and consumer awareness;
5. Food defense, bio-vigilance and bioterrorism.

This technical specification details requirements to be considered in relation to ISO 22000:2005, 7.2.3:

- a) Construction and layout of buildings and associated utilities;
- b) Layout of premises, including workspace and employee facilities;
- c) Supplies of air, water, energy and other utilities;
- d) Supporting services, including waste and sewage disposal;
- e) Suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance;
- f) Management of purchased materials;
- g) Measures for the prevention of cross-contamination;
- h) Cleaning and sanitizing;
- i) Pest control;
- j) Personnel hygiene.

Included in this FSTK are six examples of PRPs based on ISO/TS 22002-1:2009 for raw milk processing, namely:

- Utilities, supply of air, water and energy;
- Management of purchased materials;
- Rework;
- Pest control;
- Equipment suitability, cleaning and maintenance;
- Product recall.

All PRP examples are for illustrative purposes only; variations may exist from one dairy plant to another. In some countries, for example, a dairy plant may own and control the dairy farms where the raw milk is collected, hence the relevant PRPs need to reflect the specific dairy plant supply chain activities.

Planning and Development of PRPs

Prerequisite Programs Support the HACCP Plan

Prerequisite programs deal with the “good housekeeping” concerns of the establishment, whereas HACCP manages specific process hazards. The FBO must provide all documentation, including the written program, records and results for all prerequisite programs which support its HACCP system. For example, an establishment may conclude that *E. coli* O157:H7 is a hazard not reasonably likely to occur in the establishment’s processing because the establishment has a prerequisite program with purchase specifications addressing *E. coli* O157:H7.

The information regarding this prerequisite program is supporting documentation which must be maintained. Without this documentation, the GFSI auditor would question the adequacy of the establishment’s HACCP system and hazard analysis. GFSI auditors expect supporting documentation concerning prerequisite programs to include the program’s procedures and operational controls in writing. In addition, GFSI auditors expect documentation to include records that show the program is effective and that *E. coli* O157:H7 is not reasonably likely to occur. Generally, the FBO’s own food safety inspectors are required to review testing and prerequisite program records at least once per week.

How a CCP in the HACCP Plan Differs from a Prerequisite Program

Prerequisite programs are not part of the HACCP plan but lie within the overall HACCP system. The FBO auditor cannot apply the same criteria to PRPs as they would to verify regulatory requirements of the HACCP plan. Inspection program personnel evaluating PRPs will determine if they support the decisions in the hazard analysis. What exactly is the difference between a CCP in the establishment’s HACCP plan and a prerequisite program? A CCP is designed to control a food safety hazard that has been determined to be reasonably likely to occur. A PRP is designed to prevent a food safety hazard from occurring.

PRPs set the stage for a HACCP system and provide on-going support for the FBO’s food safety management system. They keep potential hazards from becoming serious enough to adversely impact the safety of foods produced. If an establishment fails to follow their prerequisite program related to the production of *E. coli* O157:H7, there is a significant food safety concern.

Role of Pre-Requisite Programs

FBOs should revise their prerequisite programs as necessary to ensure their effectiveness and take appropriate corrective actions when they determine that their PRPs have failed to prevent contamination and/or adulteration of product.

Suppose, for example, that an establishment addresses *E. coli* O157:H7 in its prerequisite program but not in its HACCP plan. If it produces a product that is *E. coli* O157:H7-positive, this would be considered a “deviation not covered by a specific corrective action” or an “unforeseen hazard.” Therefore, the establishment would be required to take the corrective actions, including reassessment. The prerequisite program was not effective in reducing the likely risk in the processing environment.

Records Generated by Pre-requisite Programs Should be Reviewed

Prerequisite programs must be implemented and include documentation to verify implementation if referenced in the hazard analysis, HACCP plan, or SSOP. Records associated with monitoring and testing may include instances of less-than-perfect control without resulting in a threat to food or product safety. However, records generated from these programs must continue to support the decisions made in the establishment's hazard analysis. When GFSI auditors are reviewing PRP records, they should review the records, results, and supporting documentation for the FBO's HACCP plan. Hence, if the FBO is reviewing results and records on a weekly basis, it could identify trends or missing records that negate the decisions made in the hazard analysis, resulting in noncompliance.

Planning and Developing Prerequisite Programs

When choosing and developing prerequisite programs it is essential to consider information from the following sources:

- Statutory and regulatory requirements;
- Industry standards and codes of practices;
- Codex Alimentarius Commission principles and codes of practices;
- International food safety standards e.g. FSSC 22000, BRC, SQF, GLOBALG.A.P.;
- Customer requirements;
- Historic data such as audit reports, customer/consumer complaints, non-conforming product data, process data etc.

All prerequisite programs should be documented, regularly audited, periodically reviewed and modified when necessary. As a general rule, prerequisite programs are managed separately from HACCP plans; however, there may be certain parts of prerequisite programs that are integrated into a HACCP plan.

FSTK PRP Workbook: Examples and Instructions (WS1- WS6)

Examples of PRPs based on ISO/TS 22002-1 for raw milk processing

Prerequisite Program

PRP 6: Utilities, Supply of Air, Water and Energy

PRP 9: Management of Purchased Material

PRP 11: Cleaning and Sanitizing

PRP 12: Pest Control

PRP 13: Employee Hygiene and Employee Facilities

PRP 14: Rework



Prerequisite Programs

PRP 6: Utilities, supply of air, water and energy

[WS 1] PRP Scope Worksheet

This worksheet defines the scope of the FBO PRP. The information needs to be clear, especially in detailing the product(s), including production lines for which the study was conducted. It should also provide information about the individuals making up the study team along with any revision history of the PRP programs.

The PRP scope worksheet has five sections with instructions for their completion as outlined below. These are followed by a sample completed worksheet.

A blank [WS 1] PRP scope worksheet blank can be found on the enclosed CD.

Instructions:

PRP Study Scope			
Facility	Joe Bloggs Dairy Plant	Start Date:	20th April 2015
Product category	Grade A IMS registered whole milk	Status:	Draft
Processes	HSTS pasteurizer, aseptic filling, retort	End date:	Ongoing
Products	Grade "A" aseptically processed and packaged milk		

Provide PRP title from standard/ scheme (e.g. "Pest Control") and standard/scheme chapter number (e.g."6- Utilities, supply of air, water and energy").

Provide the facility name, product category, product, processes, PRP status, document status (e.g. draft, approved), PRP start and end dates.

PRP Review History			
PRP type	Tick as appropriate	Notes/reason for unscheduled review	Dates of last 3 reviews
New PRP Study	✓	Current PRPs underwent a comprehensive review for compliance to ISO/TS 22002-1 and ISO 22000:2005 starting in April of 2015 and completed 20th April 2015. These management sheets describe each PRP in place at the dairy plant facility.	
Scheduled Review	20th March 2016		
Unscheduled Review			

This section records information about history of PRP revisions, with explanation of reason why this update is done: 'according to plan' or 'unscheduled.' For unscheduled revisions, explain why this revision is unscheduled (what reason?)

PRP Team Members			
Name	Position	Department	Responsibility/Role
G Moran	Food Safety Manager	Food Safety	Food Safety/QA
O Brown	Hygienist/Microbiologist	Food Safety	Hygienist/Microbiologist
M Rodrigues	Milk Processing Manager	Milk Processing	Milk Processing
B Jackson	Laboratory Manager	QA	Laboratory
D Smith	Warehouse Manager	Warehousing	Warehousing
O Murphy	Engineering Manager	Engineering	Engineering
C Flack	Factory Manager	Management	Management

For every PRP study, the organization needs to establish an HACCP team with specific responsibilities and roles. Include names within the company, department name, and responsibilities. The core area of competence of each team member should also be documented in this section

Specialist Input		
Name	Location/Job Title	Input/Specialist Advice
Angela Yard	Consultant	PRP Team Facilitator

To establish PRP studies, companies may need advice from an outsourced expert. (Consultant/ Subject matter expert). Explanation of expert's role should be explained in this section: Input/Specialist advice

Authorization		
Food Safety Team Leader/Quality Assurance Manager	Signature: G Moran	Date 20th April 2015
Management Team Member:	Signature: C Flack	Date 20th April 2015

Team members must indicate their approval of the document by providing their names, positions, and responsibilities held, signature. The authorized team member should provide his/her signature and the date signed.



[WS 2] PRP Management Worksheet

This worksheet identifies hazards and the PRP necessary to manage them. It also identifies corrective actions to be taken should hazard levels rise above acceptable limits. The worksheet identifies records that FBOs should keep and the verification procedures required for each PRP.

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
6.1 General Requirements	B, C, P [See below]	Contamination	Contamination by pathogens.	Utilities specifications, e.g. air, water, gas etc. Hygienic design of the dairy plant Pathogen monitoring procedure Supplier management procedure Product inspection procedure Cleaning/sanitizing awareness/training Audits/inspections.	Audits/inspection, hygiene, cleaning, sanitization, segregation/physical breaks between circuits containing cleaning solutions; temperature and pathogen monitoring program. Each batch, daily, weekly	
6.2 Water Supply	B	Contamination	Contamination by pathogens may be introduced from the supplier of water [ground, surface].	Water supply specification Supplier CoA Supplier management program Incoming, in-process and waste water treatment laboratory testing.	Audits/inspections, Temperature and pathogen monitoring Each batch	
	C	Contamination	Cleaning and sanitizing solution residues, i.e. without proper separation between cleaning and sanitizing solutions, the product could become contaminated.	Maintain proper separation or physical break between circuits containing cleaning solutions, containers and pipelines used to contain product. Particular attention is needed to ensure that the required separation remains in place during partial/short/inter washes completed during an operating day.	Audits/inspection, segregation or physical break between circuits containing cleaning solutions and containers and pipelines used to contain product. Solution temperature, concentration, duration of application, cleaning sequence, flow rates etc. Daily	
	P	None	None	Not applicable	Not applicable	
6.3 Boiler Chemicals	B	None	None	Not applicable	Not applicable	
	C	Contamination	Boiler additives. Some boiler water compounds used in the production of steam to be used in contact with food or food contact surfaces may contain toxic substances.	Boiler additives specification Supplier management program	Boiler water additives Daily/weekly	
	P	None	None	Not applicable	Not applicable	
6.4 Air Quality and Ventilation	B	Contamination	Contamination by pathogens may be introduced into the air supply and may come in contact with the product or food contact surface if a negative air pressure in the dairy plant is allowed to occur.	Hygienic dairy plant design incorporating HVAC system [creation of positive air pressure zones], air ducts, air filtration, exhaust stacks, intake ducts Cleaning of air ducts Air filtration Environmental pathogen monitoring Air testing [past the filtration].	Environment pathogen monitoring Air filtration Air quality Air turns Cleaning of air ducts Daily/weekly	
	C	None	Not applicable	Not applicable	Not applicable	
	P	None	Not applicable	Not applicable	Not applicable	

A blank [WS 2] PRP management worksheet is available on the enclosed CD.

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Dairy plant QA/ Laboratory Dairy plant engineering Dairy plant maintenance Dairy plant hygienist/hygiene Team Cleaning/sanitization operatives	Awareness/Training, Ongoing product inspection Product disposal, where relevant	Product inspection Audits GHP inspections Pathogen monitoring Awareness/training Waste water treatment Product spoilage/disposal	Product [Water Supply] Inspection Supplier Management Program Pathogen Monitoring Chemical Residue Product Spoilage/Disposal	Dairy plant Layout of Premise and Workspace PRP Dairy plant Waste Disposal PRP Product Inspection Procedure Dairy plant Audit Procedure Dairy plant GHP Inspection Procedure Dairy plant Awareness/Training Procedure Dairy plant Waste Water Treatment Monitoring Procedure Dairy plant Pathogen Monitoring Procedure
	Dairy plant QA/Laboratory	Re-sterilization of piping, equipment and containers	Audits GHP inspections Awareness/training Pathogen monitoring	Water supply inspection Product disposal	Dairy Plant Cleaning and Sanitizing PRP Dairy Plant Product Inspection Procedure Dairy Plant Pathogen Monitoring Procedure
	Dairy plant Hygienist/Hygiene Team Cleaning/Sanitization Operatives	Awareness/Training, Product disposal, where relevant	Audits GHP inspections Awareness/training Product spoilage/disposal	Product inspection Product disposal	Dairy Plant Cleaning and Sanitizing PRP Dairy Plant Waste Disposal PRP Dairy Plant Awareness/Training Procedure
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	QA	Return product not to specification to supplier	Incoming product	Incoming product Supplier management program	Management of Purchased Material PRP Dairy Plant Product Inspection Procedure Dairy Plant Supplier Management Procedure
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	Dairy plant QA/Laboratory [Environment Pathogen Monitoring/Air Testing] Dairy plant Engineering [Dairy plant Hygienic Design HVAC System] Dairy plant Maintenance [Preventive Maintenance of Filters/Cleaning or Air Ducts etc.]	Product Hold/withdrawal/ recall Testing of all production lots Implementation of intensive cleaning/sanitization Review/revisions of process controls	Environment pathogen monitoring HVAC design/drawings Air Testing Preventive Maintenance [Filter/Cleaning]	Environment Pathogen Monitoring	Dairy plant Layout of Premise and Workspace PRP Dairy plant Cleaning and Sanitizing PRP Dairy plant Environment Pathogen Monitoring Program Dairy plant Product Inspection Procedure
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
6.5 Compressed Air and Gases	B	Contamination	Contamination by pathogens may be introduced into the air supply and may come in contact with the product or food contact surface.	Specification for the supply of compressed air. Air is drawn from a clean area, if filtered at the intake as needed, and is provided to the point of use oil free and with free of excess moisture. A final filter is provided as near as possible to the point of use to verify.	Environment pathogen monitoring Daily/weekly	
	C	Contamination	Toxic substances, i.e. air compressor lubricants may be carried over into the air and may be toxic.	Specification for the supply of compressor lubricants [food grade]. Air is drawn from a clean area; if filtered, at the intake as needed, and is provided to the point of use oil-free and free of excess moisture. A final filter is provided as near as possible to the point of use to verify.	Environment pathogen monitoring Daily/weekly	
	P	None	Not applicable	Not applicable	Not applicable	
6.6 Lighting	B	Contamination	Poor or inadequate lighting [intensity] may contribute to personnel applying poor hygienic standards, and as a result material, product or equipment may become contaminated.	Hygienic design of the dairy plant. Throughout the dairy plant storage, preparation, processing areas are provided with natural or artificial lighting (or both). A minimum light intensity of 200 lux is recommended. Reference the relevant national lighting standard for recommended lighting standards. All lights are fitted with light diffusers/ covers or shatterproof tubes to facilitate cleaning and to prevent contamination of food.	Hygienic design, light intensity, dirt, spills, pest Daily/weekly	
	C	None	Not applicable	Not applicable	Not applicable	
	P	Contamination	Poor or inadequate lighting [intensity] may contribute to personnel applying poor hygienic standards and as a result material, product or equipment may become contaminated, e.g. breakages and or dirt.	Hygienic design of the dairy plant, e.g. all lights are fitted with light diffusers/ covers or shatterproof tubes to facilitate cleaning and to prevent contamination of food and the premises should breakage occur. Hygiene inspections to detect breakages and/or dirt.	Hygienic design, breakages and dirt Daily/weekly	
A	B	C	D	E	F	

Instructions:

Prerequisite Program	Hazard Agent	Hazard presence, growth, survival, increase, re(contamination)	Hazard origin, cause, source, vector, condition	Control Measure	What is monitored and when	
Describes the ISO/TS 22002-1 requirement.	Describes the hazard agent, e.g. biological, chemical, physical or combination thereof.	Describes how the hazard manifests as a threat, i.e. presence, growth or survival.	Describes the cause, origin, condition or source of a hazard.	Describes the control measures the FBO has in place to control relevant hazards.	Describes the hazard measurement parameters and the frequency of monitoring required.	

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Dairy QA Laboratory	Replace compressed air/filter	Environment pathogen monitoring Preventive maintenance [filter]	Environment pathogen monitoring	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Pathogen Monitoring Program
	Dairy QA Laboratory	Replace compressed Air/filter	Environment pathogen monitoring Preventive maintenance [filter]	Environment pathogen monitoring	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Environment Pathogen Monitoring Program Dairy Plant Preventive Maintenance Procedure
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	Dairy plant Engineering/ Food Safety [Dairy plant Hygienic design] Dairy plant Maintenance [Lighting Maintenance, Cleaning/Sanitization Program including Spills] Dairy plant Hygienist and Hygiene Team	CapEx projects [hygiene related] Preventive maintenance Cleaning/sanitization Program	CapEx projects Preventive maintenance Cleaning GHP inspection	Cleaning/sanitizing GHP inspections Audits	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant Layout of Premises and Workspace PRP Dairy Plant Internal Structure PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Preventive Maintenance Procedure Hygiene Procedures Cleaning/Sanitization Procedures
	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
	Dairy plant Engineering/ Food Safety [Dairy plant Hygienic design] Dairy plant Maintenance [Lighting Maintenance] Dairy plant Hygienist and Hygiene Team	CapEx projects [hygiene related] Preventive maintenance Cleaning/sanitization program	CapEx projects Preventive maintenance Cleaning/sanitizing GHP inspection	Cleaning/sanitizing GHP Inspections Audits	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant Layout of Premises and Workspace PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Internal Structure PRP Preventive Maintenance Procedure Hygiene Procedures Cleaning/Sanitization Procedures
	G	H	I	J	K

Who is responsible Describes the job role or title of the department/function within the FBO responsible for monitoring the relevant hazard measurement parameters.	Correction / Corrective action Describes the correction and corrective action aimed at preventing reoccurrence of exceeding the allowable or permitted hazard measurement parameters.	Records Indicates the monitoring and hazard measurement parameter records to be maintained.	Verification activities Describes the verification activities necessary to confirm the accuracy of the monitoring and hazard measurement parameters.	Reference Documents Describes the FBO documents and, where necessary, the relevant external documents, e.g. statutory and regulatory requirements.
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[WS 3] PRP Verification Action Plan Worksheet

This worksheet aids in planning PRP verification.

Verification is confirmation, supported by objective evidence, specifying that requirements have been fulfilled.

Original prerequisite program verification is carried out after the program has been implemented and developed. Further planned verifications should take place at least once a year. Unscheduled verifications are required when PRP changes take place.

The FBO should also have a verification plan. Verification may only be carried out by an authorized person. The FBO must document all verification activities for each PRP.

A blank [WS 3] PRP verification action plan worksheet is available on the enclosed CD.

Prerequisite Program	Verification Action
Team #6 Utilities	Reviewed by Utilities RPP Team
	Review of referenced documents, e.g. PRPS, related procedures and utility specifications
	Review of pathogen monitoring records
	Review of product inspection records
	Review of cleaning/sanitizing records
	Review of preventive maintenance records
	Review of product spoilage/disposal records
	Review of rework records
	Review of awareness/training records
	Review of consumer complaints
	Food Safety Management System audits
	Internal cGMP audits / GHP inspections
	Frequency and criticality review
A	B

Instructions:

Prerequisite program	Verification Action
Organization to provide details of PRP Team Number and PRP Title. We suggest the PRP Team # should match the relevant chapter in the relevant FSMS Scheme Standard, e.g. ISO/TS 22002-1 Chapter 6 - Utilities, supply of air, water and energy	Organization to provide details of PRP verification actions associated with the PRP and who is responsible for the review of the verification action

[WS 4] PRP Meeting Summary Worksheet

This worksheet is used to document PRP meetings and any resulting decisions.

A blank [WS 4] PRP meeting summary worksheet is available on the enclosed CD.

Date	Participants	Purpose	Outcome (decisions/actions)	Responsibility	Deadline	Performed
20-Apr-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Initial review of PRP	Update PRP management worksheet review related PRPs	G Moran to complete verification sheet	15-May-15	15-May-15
28/4/2015	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Complete GAP sheet Review PRP management worksheet	Completed and approved Reviewed and approved	G Moran to update PRP worksheets	15-May-15	15-May-15
12-Oct-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Review and update utility specifications	Complete update of water supply specification	PRP team to complete	17-Dec-15	17-Dec-15
A	B	C	D	E	F	G

Instructions:

Date	Participants	Purpose	Outcome(decisions/action)	Responsibility	Deadline	Performed
List meeting dates	List attendees, including both team members and invitees	Provide the reason for the meeting	Record decisions made and next steps	Identify those responsible to execute decisions	Record deadlines	Provide action dates



[WS 5] PRP GAP Registration and Resolution Worksheet

This worksheet defines and eliminates gaps between PRP requirements of a certain standard (s), for example, ISO/TS 22002-1, and other documents that must comply with FSMS.

When completing this worksheet, the FBO may use different standards and / or documents to fulfill PRP requirements, for example, for an ISO / TS 22002-1 requirement. These should correspond to the FSMS of that particular FBO.

A blank [WS 5] PRP GAP registration and resolution worksheet is available on the enclosed CD.

Fill in only if gaps have been identified

ISO/TS 22002-1	Description [of the requirement of the Standard]	Specific requirement	Associated Dairy Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
A	B	C	D	E	F	G	H
6.3 Boiler Chemicals	The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination. Quality of utilities shall be monitored to minimize product contamination risk.	Boiler chemicals, if used, shall be approved food additives which meet relevant additive specifications.	Dairy Plant Food Safety Policy	PRP management worksheet incomplete, related PRPs and procedures to be reviewed and updated.	All documents to be reviewed and updated prior to next PRP team meeting 28-Apr-2015.	All documented reviewed and updated, see PRP team meeting.	None
6.4 Air quality and ventilation	The organization shall establish requirements for filtration, humidity (RH%) and microbiology of air used as an ingredient or for direct product contact.	Specification for pressurized air.	Dairy Plant Food Safety Policy	Utility specifications to be created.	Create pressurized air specification 12-Oct-2015.	Air specification completed, see PRP team meeting.	None
A	B	C	D	E	F	G	H

Instructions:

Standard/ Scheme name, PRP name and clause number	Description [of the requirement of the Standard]	Specific requirement	Associated Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
Provide a description of the FSMS Scheme Requirement.	Provide a description of the requirement arising from the FSMS scheme where the gap exists.	Provide a short description of the specific requirement where the gap exists within the FBO.	Detail the relevant FSMS Policy.	Describe the gap.	Provide details of the action to be taken to address the specific requirement identified as not having been fulfilled.	Provide details of the actions taken to address the gap and the date of completion.	Add any additional relevant comments, if required.

[WS 6] Hazard Agent Worksheet

The PRP Hazardous Agents Worksheet provides a standard classification system for recording hazardous agents in the FSTK PRP workbook. The hazardous agents classification system is based on the food and beverage industry hazardous agent classification system.

The hazardous agent worksheet is for reference or guidance purpose only; no template is provided.

Hazardous Agents	Hazard Class Abbreviation
Microbiological (vegetative or spores, depending on circumstances)	B
Chemical (such as cleaning chemicals, non-food grade lubricants, oils and greases, and chemical residues)	C
Physical (such as various types of foreign material including metal, wood, plastic, or other foreign bodies)	P
Allergens (milk, soy, wheat, egg, fish, shellfish, tree nut, peanut)	A
A	B

Instructions:

Hazardous agent Classify food safety hazard agents, e.g. biological, chemical, or physical.	Hazard Class Indicate the food safety hazard agent code, e.g. biological – B; chemical – C; physical – P; allergen – A
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Prerequisite Program

PRP 9: Management of Purchased Material

[WS 1] PRP Scope Worksheet

This worksheet defines the scope of the FBO PRP. The information needs to be clear, especially in detailing the product(s), including production lines for which the study was conducted. It should also provide information about the individuals making up the study team along with any revision history of the PRP programs.

The PRP scope worksheet has five sections with instructions for their completion as outlined below. These are followed by a sample completed worksheet.

A blank [WS 1] PRP scope worksheet blank can be found on the enclosed CD.

Instructions:

PRP Study Scope			
Facility	Joe Bloggs Dairy Plant	Start Date:	20th April 2015
Product category	Grade A IMS registered whole milk	Status:	Draft
Proessess	HSTS pasteurizer, aseptic filling, retort	End date:	Ongoing
Products	Grade A aseptically processed and packaged milk		

Provide PRP title from standard/ scheme (e.g. "Pest Control") and standard/scheme chapter number (e.g." 9 – Management of purchased materials").

Provide the facility name, product category, product, processes, PRP status, document status (e.g. draft, approved), PRP start and end dates.

PRP Review History			
PRP type	Tick as appropriate	Notes/reason for unscheduled review	Dates of last 3 reviews
New PRP Study	✓	Current PRPs underwent a comprehensive review for compliance to ISO/TS 22002-1 and ISO 22000:2005 starting in April of 2015 and completed 20th April 2015. These management sheets describe each PRP in place at the Dairy Plant facility.	
Scheduled Review	20th March 2016		
Unscheduled Review			

This section records information about history of PRP revisions, with explanation of reason why this update is done: 'according to plan' or 'unscheduled.' For unscheduled revision explain why this revision is unscheduled (what reason?)

PRP Team Members			
Name	Position	Department	Responsibility/Role
G Moran	Food Safety Manager	Food Safety	Food Safety/QA
O Brown	Hygienist/Microbiologist	Food Safety	Hygienist/Microbiologist
M Rodrigues	Milk Processing Manager	Milk Processing	Milk Processing
B Jackson	Laboratory Manager	QA	Laboratory
D Smith	Warehouse Manager	Warehousing	Warehousing
O Murphy	Engineering Manager	Engineering	Engineering
C Flack	Factory Manager	Management	Management

For every PRP study, the organization needs to establish an HACCP team with specific responsibilities and roles. Include names within the company, department name, and responsibilities. The core area of competence of each team member should also be documented in this section

Specialist Input		
Name	Location/Job Title	Input/Specialist Advice
Angela Yard	Consultant	PRP Team Facilitator

To establish PRP studies, companies may need advice from an outsourced expert (Consultant/ Subject matter expert). Explanation of expert's role should be explained in this section: Input/ Specialist advice.

Authorization		
Food Safety Team Leader/Quality Assurance Manager	Signature: G Moran	Date 20th April 2015
Management Team Member:	Signature: C Flack	Date 20th April 2015

Team members must indicate their approval of the document by providing their names, positions, and responsibilities held, signature. The authorized team member should provide his/her signature and the date signed.



[WS 2] PRP Management Worksheet

This worksheet identifies hazards and the PRP necessary to manage them. It also identifies corrective actions to be taken should hazard levels rise above acceptable limits. The worksheet identifies records that FBOs should keep and the verification procedures required for each PRP.

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
9.1 General Requirements	B, C, P [See below]	Presence, Contamination	Supplier Management, Hygiene, Cleaning, Sanitization and Incoming Material Inspection in place as well as pathogen, environmental and extraneous material monitoring	Supplier management program/ procedure Audits/inspection, hygiene, cleaning, sanitization and raw material monitored Pathogen, mycotoxin and extraneous material monitoring program in place	Audits/inspection, hygiene, cleaning, sanitization and raw material monitored Pathogen, mycotoxin and extraneous material monitoring program in place	
9.2 Selection and Management of Suppliers	B, C, P [See below]	Presence, Contamination	Supplier Management, Hygiene, Cleaning, Sanitization and Incoming Material Inspection in place as well as pathogen, environmental and extraneous material monitoring	Supplier management program/ procedures Audits/inspection, hygiene, cleaning, sanitization and raw material monitored Pathogen, mycotoxin and extraneous material monitoring program in place	Audits/inspection, hygiene, cleaning, sanitization and raw material monitored Pathogen, mycotoxin and extraneous material monitoring program in place	
9.3 Incoming Material Requirements	B	Presence	Based upon scientific studies vegetative pathogens [Brucella abortus; Campylobacter jejuni; Campylobacter coli; Coxiella burnetii; Pathogenic Escherichia coli (O157:H7); Listeria monocytogenes; Mycobacterium tuberculosis; Mycobacterium bovis; Salmonella enterica serotypes; Streptococcus pyogenes; and Yersinia enterocolitica] may be present in raw milk.	Supplier management program Minimize the incoming bacterial load by purchasing Grade A listed raw milk and testing incoming product Verify the tank trucks were cleaned and sanitized prior to picking up the milk being unloaded Milk temperature records from the dairy farm to the dairy plant	Incoming product Tank Trucks Cleaning and Sanitizing Records Milk Temperature Records Each Batch	
	C	Presence	Presence of therapeutic drugs.	Supplier management program Screen all tankers for animal drug residues In addition, the dairy plant should also screen for other residues	Therapeutic drugs/ [antibiotics] and other residues Each batch	
	C	Presence of Mycotoxins	Based upon historical data, mold growth in animal feed can contaminate milk with aflatoxin M ₁ . This is dependent upon geographic location, growing season conditions, etc.	Supplier management program Supplier supplied certificates of analysis Periodic QA/laboratory testing by the dairy plant [ELISA screening]	AFM ₁ [Aflatoxin hydroxymetabolites], daily analysis	

A blank [WS 2] PRP management worksheet is available on the enclosed CD.

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Dairy plant [see below for details]	Awareness/training, cleaning of area where deviation was found Raw material is sent back to supplier or discarded if not compliant	Various, see below for details	Supplier management program Tank truck cleaning and sanitization records Raw milk temperature records Raw milk in-take records	Dairy Plant Supplier Management Procedure Dairy Plant Audit Procedure Dairy Plant Awareness/Training Procedure Dairy Plant GHP Inspection Procedure Dairy Plant Mycotixin Analysis Testing Dairy Plant Raw Material Handling Procedure Dairy Plant Tank Truck Cleaning and Sanitizing Procedure Dairy Plant Record Control Procedure [Manifest] Dairy Plant Product Inspection Procedure
	Dairy plant [see below for details]	Awareness/training, cleaning of area where deviation was found Raw material is sent back to supplier or discarded if not compliant	Supplier inspections/audits, CoA requirements On-site [dairy farm] incoming product specification	Supplier management program Tank truck cleaning and sanitization records Raw milk temperature records Raw milk in-take records	Dairy Plant Supplier Management Procedure Dairy Plant Audit Procedure Dairy Plant Awareness/Training Procedure Dairy Plant GHP Inspection Procedure Dairy Plant Mycotixin Analysis Testing Dairy Plant Raw Material Handling Procedure Dairy Plant Record Control Procedure [Manifest] Dairy Plant Product Inspection Procedure
	Dairy plant QA/laboratory Dairy plant truck driver [cleaning/sanitization/ milk temperature]	Pasteurization/ Sterilization Investigation	Wash tags Plant cleaning Manifest QA/ laboratory incoming product	Supplier management program Tank truck cleaning and sanitization records Raw milk temperature records Raw milk in-take records	Dairy Plant Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Supplier Management Procedure Dairy Plant Raw Material Handling Procedure Dairy Plant Tank Truck Cleaning and Sanitizing Procedure Dairy Plant Record Control Procedure [Manifest] Dairy Plant Product Inspection Procedure Dairy Farm Hygiene Inspection/Audit Procedure
	Dairy plant QA/laboratory Dairy plant truck driver [raw milk samples at the dairy farm]	Awareness/training, return raw milk to dairy farm or environmental disposal/ investigation at dairy farm	Delvo test QA/ laboratory incoming product	Milk samples at the dairy farm Laboratory incoming product records	Dairy Plant Supplier Management Procedure Dairy Plant Awareness/Training Procedure Dairy Plant Raw Milk Sample Procedure Dairy Plant Raw Material Handling Procedure Dairy Plant Record Control Procedure [Manifest] Dairy Plant Product Inspection Procedure
	Dairy plant QA/laboratory	Awaress/training, product withdrawal by dairy farm/ Suspend delivery of raw milk from dairy farm	ELISA [Enzyme-Linked ImmunoSorbent Assay]/ HPLC [High-Performance Liquid Chromatography] screening	Screening records	Dairy Plant Mycotixin Analysis Testing Dairy Plant Product Inspection Procedure

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
	C	Presence	Milk protein is considered an allergen.	Labelling verification procedure	Statutory and regulatory requirements regarding labelling, as changes occur	
	P	Contamination	If dairy cattle are not kept clean or if milk is drawn in an unclean environment and is not properly protected, physical objects from the dairy farm environment may become incorporated into the raw milk.	Dairy farm hygiene practices Supplier management program Dairy farm inspection during milk collection	Dairy farm hygiene practices, as per supplier management program Dairy farm inspections, daily	
	B	Presence	Based upon scientific studies vegetative pathogens may be present in ingredients.	Supplier management program, e.g. supplier CoAs and dairy plant periodic QA/laboratory testing	Incoming product, Each batch	
	C	Contamination	Based upon historical data adulteration with toxic or carcinogenic chemicals may contaminate raw milk.	Approved packaging suppliers Supplier CoA's Supplier management program	Product packaging specification conformity Supplier CoA [Certificate of Analysis] Period QA/laboratory packaging testing Each batch	
	P	Contamination	Based upon historical data foreign materials may constitute food safety hazards.	Approved packaging suppliers Supplier CoAs Supplier management program	Product packaging specification conformity Supplier CoA [Certificate of Analysis] Period QA/laboratory packaging testing Each batch	
A	B	C	D	E	F	

Instructions:

Prerequisite Program	Hazard Agent	Hazard presence, growth, survival, increase, re(contamination)	Hazard origin, cause, source, vector, condition	Control Measure	What is monitored and when	
Describes the ISO/TS 22002-1 requirement.	Describes the hazard agent, e.g. biological, chemical, physical or combination thereof.	Describes how the hazard manifests as a threat, i.e. presence, growth or survival.	Describes the cause, origin, condition or source of a hazard.	Describes the control measures the FBO has in place to control relevant hazards.	Describes the hazard measurement parameters and the frequency of monitoring required.	

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Dairy plant marketing, QA, food safety	Product hold/ withdrawal Product rework Investigation Consumer alert	Evaluation of compliance Labelling QA verification	Document/ record review	Dairy Plant Evaluation of Compliance Procedure Dairy Plant Labelling Verification Procedure
	Dairy farm Dairy plant QA/food safety	Consumer awareness, refusal to accept product at source Supplier management program	Manifest QA/ laboratory incoming product Supplier hygiene inspection/audit	Document/ record review	Dairy Farm Hygiene Inspection/Audit Procedure Dairy Plant Supplier Management Procedure Dairy Plant Raw Material Handling Procedure
	Dairy farm Audit plant QA/food safety	Refusal to accept product at source Supplier management program	Manifest QA/ laboratory incoming product Supplier GHP inspections audit reports	Document/ record review	Dairy Plant GHP Inspection Procedure Dairy Plant Audit Procedure Dairy Plant Supplier Management Procedure
	Dairy plant QA/food safety	Awareness/training, product hold/return material to supplier Supplier management program	QA/ laboratory incoming product Supplier CoA Supplier inspection/audit	Document/ record review	Dairy Plant Product Inspection Procedure Dairy Plant Awareness/Training Procedure Dairy Plant Supplier Management Procedure
	Dairy plant QA/food safety	Awareness/training, product hold/return material to supplier Supplier management program	QA/ laboratory incoming product Dairy farm CoAs Dairy farm/supplier audit	Document/ record review	Dairy Plant Product Specifications Dairy Plant Product Inspection Procedure Dairy Plant Supplier Management Procedure
	G	H	I	J	K

Who is responsible Describes the job role or title of the department/function within the FBO responsible for monitoring the relevant hazard measurement parameters.	Correction / Corrective action Describes the correction and corrective action aimed at preventing reoccurrence of exceeding the allowable or permitted hazard measurement parameters.	Records Indicates the monitoring and hazard measurement parameter records to be maintained.	Verification activities Describes the verification activities necessary to confirm the accuracy of the monitoring and hazard measurement parameters.	Reference Documents Describes the FBO documents and, where necessary, the relevant external documents, e.g. statutory and regulatory requirements.
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[WS 3] PRP Verification Action Plan Worksheet

This worksheet aids in planning PRP verification.

Verification is confirmation, supported by objective evidence, specifying that requirements have been fulfilled.

Original prerequisite program verification is carried out after the program has been implemented and developed. Further planned verifications should take place at least once a year. Unscheduled verifications are required when PRP changes take place.

The FBO should also have a verification plan. Verification may only be carried out by an authorized person. The FBO must document all verification activities for each PRP.

A blank [WS 3] PRP verification action plan worksheet is available on the enclosed CD.

Prerequisite Program	Verification Action
Team #9 Management of purchased materials	Review by management of purchased materials by PRP Team
	Review of tank truck cleaning and sanitizing records
	Review of raw milk temperature records
	Review of manifest records
	Review of ELISA/HPLC records
	Review of labelling verification records
	Review of product inspection records
	Review of supplier performance records
	Review of awareness/training records
	Review of consumer complaints
	Food Safety Management System audits
	Internal GMP audits / GHP inspections
	Frequency and criticality review
A	B

Instructions:

Prerequisite program	Verification Action
Organization to provide details of PRP Team Number and PRP Title. We suggest the PRP Team # should match the relevant chapter in the relevant FSMS Scheme Standard, e.g. ISO/TS 22002-1 Chapter 9 - Management of purchased materials.	Organization to provide details of PRP verification actions associated with the PRP and who is responsible for the review of the verification action.

[WS 4] PRP Meeting Summary Worksheet

This worksheet is used to document PRP meetings and any resulting decisions.

A blank [WS 4] PRP meeting summary worksheet is available on the enclosed CD.

Date	Participants	Purpose	Outcome (decisions/ actions)	Responsibility	Deadline	Performed
20-Apr-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Initial review of PRP	Update PRP Management Worksheet Review-related PRPs	G Moran to complete verification Sheet	15-May-15	15-May-15
28/4/2015	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Complete GAP sheet Review PRP management worksheet	Completed and approved Reviewed and approved	G Moran to update PRP worksheets	15-May-15	15-May-15
12-Oct-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Review and update verification of labeling procedure and introduce management of inputs [periodic testing of raw material/ingredients/ packaging]	Complete update of labeling verification procedure; Introduce management of inputs based upon risk of raw material/ ingredients/ packaging.	PRP team to complete	17-Dec-15	17-Dec-15
A	B	C	D	E	F	G

Instructions:

Date	Participants	Purpose	Outcome(decisions/ action)	Responsibility	Deadline	Performed
List meeting dates.	List attendees, including both team members and invitees.	Provide the reason for the meeting.	Record decisions made and next steps.	Identify those responsible to execute decisions.	Record deadlines.	Provide action dates.



[WS 5] PRP GAP Registration and Resolution Worksheet

This worksheet defines and eliminates gaps between PRP requirements of a certain standard (s), for example, ISO/TS 22002-1, and other documents that must comply with FSMS.

When completing this worksheet, the FBO may use different standards and / or documents to fulfill PRP requirements, for example, for an ISO / TS 22002-1 requirement. These should correspond to the FSMS of that particular FBO.

A blank [WS 5] PRP GAP registration and resolution worksheet is available on the enclosed CD.

Fill in only if gaps have been identified

ISO/TS 22002-1	Description [of the requirement of the Standard]	Specific requirement	Associated Dairy Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
A	B	C	D	E	F	G	H
9.1 In-coming Material Requirements	Materials shall be inspected, tested or covered by COA to verify conformity with specified requirements prior to acceptance or use. The method of verification shall be documented	Management of Inputs/ verification of raw materials, ingredients and packaging	Food Safety Policy	Reliance 100% of Supplier CoA	Introduce management of Inputs by Q4 2015	Critical raw materials, ingredients and packaging verified as conforming to Dairy Plan Product Specifications by Q4 2015	Closed

Instructions:

Standard/ Scheme name, PRP name and clause number	Description [of the requirement of the Standard]	Specific requirement	Associated Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
Provide a description of the FSMS Scheme Requirement.	Provide a description of the requirement arising from the FSMS scheme where the gap exists.	Provide a short description of the specific requirement where the gap exists within the FBO.	Detail the relevant FSMS Policy.	Describe the gap.	Provide details of the action to be taken to address the specific requirement identified as not having been fulfilled.	Provide details of the actions taken to address the gap and the date of completion.	Add any additional relevant comments, if required.

[WS 6] Hazard Agent Worksheet

The PRP Hazardous Agents Worksheet provides a standard classification system for recording hazardous agents in the FSTK PRP workbook. The hazardous agents classification system is based on the food and beverage industry hazardous agent classification system.

The hazardous agent worksheet is for reference or guidance purpose only; no template is provided.

Hazardous Agents	Hazard Class Abbreviation
Microbiological (vegetative or spores, depending on circumstances)	B
Chemical (such as cleaning chemicals, non-food grade lubricants, oils and greases, and chemical residues)	C
Physical (such as various types of foreign material including metal, wood, plastic, or other foreign bodies)	P
Allergens (milk, soy, wheat, egg, fish, shellfish, tree nut, peanut)	A
A	B

Instructions:

<p>Hazardous agent Classify food safety hazard agents, e.g. biological, chemical, or physical.</p>	<p>Hazard Class Indicate the food safety hazard agent code, e.g. biological – B; chemical – C; physical – P; allergen – A.</p>
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Prerequisite Program

PRP 11: Cleaning and Sanitizing

[WS 1] PRP Scope Worksheet

This worksheet defines the scope of the FBO PRP. The information needs to be clear, especially in detailing the product(s), including production lines for which the study was conducted. It should also provide information about the individuals making up the study team along with any revision history of the PRP programs.

The PRP scope worksheet has five sections with instructions for their completion as outlined below. These are followed by a sample completed worksheet.

A blank [WS 1] PRP scope worksheet blank can be found on the enclosed CD.

Instructions:

PRP Study Scope			
Facility	Joe Bloggs Dairy Plant	Start Date:	20th April 2015
Product category	Grade A IMS Registered Whole Milk	Status:	Draft
Processes	HSTS Pasteurizer, Aseptic Filling, Retort	End date:	Ongoing
Products	Grade A Aseptically processed and packaged Milk		

Provide PRP title from standard/ scheme (e.g. "Pest Control") and standard/scheme chapter number (e.g. "11-Cleaning and Sanitizing").

Provide the facility name, product category, product, processes, PRP status, document status (e.g. draft, approved), PRP start and end dates.

PRP Review History			
PRP type	Tick as appropriate	Notes/reason for unscheduled review	Dates of last 3 reviews
New PRP Study	✓	Current PRP's underwent a comprehensive review for compliance to ISO/TS 22002-1 and ISO 22000:2005 starting in April of 2015 and completed 20th April 2015. These management sheets describe each PRP in place at the Dairy Plant facility.	
Scheduled Review	20th March 2016		
Unscheduled Review			

This section records information about history of PRP revisions, with explanation of reason why this update is done: 'according to plan' or 'unscheduled.' For unscheduled revisions, explain why this revision is unscheduled (what reason?)

PRP Team Members			
Name	Position	Department	Responsibility/Role
G Moran	Food Safety Manager	Food Safety	Food Safety/QA
O Brown	Hygienist/Microbiologist	Food Safety	Hygienist/Microbiologist
M Rodrigues	Milk Processing Manager	Milk Processing	Milk Processing
B Jackson	Laboratory Manager	QA	Laboratory
D Smith	Warehouse Manager	Warehousing	Warehousing
O Murphy	Engineering Manager	Engineering	Engineering
C Flack	Factory Manager	Management	Management

For every PRP study, the organization needs to establish an HACCP team, with specific responsibilities and roles. Names within the company, department name, and responsibilities. The core area of competence of each team member should also be documented in this section.

Specialist Input		
Name	Location/Job Title	Input/Specialist Advice
Angela Yard	Consultant	PRP Team Facilitator

To establish PRP studies, companies may need advice from an outsourced expert. (Consultant/ Subject matter expert). Explanation of expert's role should be explained in this section: Input/ Specialist advice

Authorization		
Food Safety Team Leader/Quality Assurance Manager	Signature: G Moran	Date 20th April 2015
Management Team Member:	Signature: C Flack	Date 20th April 2015

Team members must indicate their approval of the document by providing their names, positions, and responsibilities held, signature. The authorized team member should provide his/her signature and the date signed.



[WS 2] PRP Management Worksheet

This worksheet identifies hazards and the PRP necessary to manage them. It also identifies corrective actions to be taken should hazard levels rise above acceptable limits. The worksheet identifies records that FBOs should keep and the verification procedures required for each PRP.

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
11.1 General Requirements	B, C, P [See below]	Presence Contamination	Contamination by pathogens Cleaning/sanitizing solution residues	Hygiene, cleaning, sanitization Separation between cleaning and sanitizing solution Master cleaning/sanitizing schedule Temperature	Pathogen monitoring, daily Separation, weekly Temperature, daily/weekly [7 days]	
11.2 Cleaning and Sanitizing Agents and Tools	B	Presence Contamination	Contamination by vegetative pathogens	Clean water Restricted use of condensing water from milk evaporators and water reclaimed from milk or milk products Training of cleaning/sanitizing operators Hygienic design/suitability of tools e.g. brushes used for manual washing is non absorbent, nylon or plastic bristled type and designed not to retain soil, quick to dry Utensils manually cleaned using a two compartment wash and rinse sink Color coding of tools 5S program including tools being protected once cleaned, e.g. stored off the contact floor, protected from splashes following cleaning, etc.	Pathogen monitoring, daily	
	C	Presence Contamination	Without proper separation between cleaning and sanitizing solutions and product there could be product contamination	MSDS sheets for [chemicals] chlorine/acids used Approved chemicals Chemical storage Maintain proper separation or physical break between circuits containing cleaning solution and vessels and lines used to contain product Manual sanitizing with chemicals to be accomplished using a third treatment vat, unless heat is used for sanitizing	Toxic residues Alkaline detergents/acid cleaner, not mixed Daily/each batch	
	P	None				

A blank [WS 2] PRP management worksheet is available on the enclosed CD.

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	QA/laboratory cleaning/sanitizing operators	Re-clean, sanitize Review/update master cleaning/sanitizing schedule or program Revalidate the effectiveness of the cleaning/sanitizing schedule/program	GHP inspections Audit Master cleaning/sanitizing Temperature	Record review Inspection Audit	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Management of Purchased Materials PRP Dairy Plant Personal Hygiene and Employee Facilities PRP Utilities PRP Dairy Plant Master Cleaning/Sanitizing Program/Schedule Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen monitoring Procedure
	QA/laboratory cleaning/sanitizing operators	Replacement tools Re-training, if required Re-clean/re-sanitize	GHP inspections Audits Milk tank truck wash tags or log book Manual cleaning log book	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Management of Purchased Materials PRP Utilities PRP Master Cleaning/Sanitizing Program/Schedule Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen monitoring Procedure
	QA/laboratory cleaning/sanitizing operators	Monitoring frequency review Re-training, if required Re-clean, re-sanitize	GHP inspections Audits cleaning/sanitizing	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Management of Purchased Materials PRP Dairy Plant Utilities PRP Master Cleaning/Sanitizing Program/Schedule Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen monitoring Procedure

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
11.3 Cleaning and Sanitizing Programs	B	Presence Contamination	Contamination by vegetative pathogens	Master cleaning/sanitizing program Master cleaning/sanitizing schedule Validated cleaning/sanitizing program/schedule [including re-validation]	Pathogen monitoring, daily Temperature, daily/weekly [7 days] for milk storage tanks	
	C	Presence Contamination	Without proper separation between cleaning and sanitizing solutions and product there could be product contamination	Master cleaning/sanitizing program Master cleaning/sanitizing schedule Validated cleaning/sanitizing program/schedule [including re-validation]	Toxic residues Alkaline detergents/acid cleaner, not mixed Daily/each batch	
	P	None				
11.4 Cleaning in Place [CIP] Systems	B	Presence Contamination	Contamination by pathogens	CIP parameters, e.g. temperature CIP venting door device associated with larger tanks and silos Water characteristics with water hardness exceed 100ppm hardness	Temperature Pathogen monitoring	
	C	Presence Contamination	Without proper separation between cleaning and sanitizing solutions and product there could be product contamination	CIP parameters, e.g. temperature, type, concentration, concentration time etc. CIP venting door device associated with larger tanks and silos Water characteristics with water hardness exceed 100ppm hardness	Chemical type, concentration, contact time and temperature	
	P	None				
11.5 Monitoring Sanitation Effectiveness	B	Presence Contamination	Contamination by pathogens	Master cleaning/sanitizing schedule GHP inspection Audit Pathogen monitoring	Pathogen monitoring frequency daily/weekly	

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Hygienist Cleaning/sanitization	Review/update master cleaning/sanitizing schedule or program Revalidate the effectiveness of the cleaning/sanitizing schedule/program	GHP inspections Audits Master cleaning/sanitizing validation/re-validation study	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Master Cleaning/Sanitizing Program/Schedule Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Hygienist Cleaning/sanitization	Review/update master cleaning/sanitizing schedule or program Revalidate the effectiveness of the cleaning/sanitizing schedule/program	GHP inspections Audits Master cleaning/sanitizing validation/re-validation study	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Master Cleaning/Sanitizing Program/Schedule Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	QA laboratory Cleaning operator	Re-clean	CIP Charts for all dairy plant processing equipment	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Master Cleaning/Sanitizing Program/Schedule Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	QA laboratory Cleaning operator	Re-clean	CIP Charts for all dairy plant processing equipment	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Master Cleaning/Sanitizing Program/Schedule Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Cleaning/sanitizing supervisor QA/laboratory	Review/update master cleaning/sanitizing schedule or program; revalidate the effectiveness of the cleaning/sanitizing schedule/program	Cleaning/sanitizing GHP inspections Audits Cleaning/sanitizing validation/re-validation	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Master Cleaning/Sanitizing Program/Schedule Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
	C	Presence Contamination	Without proper separation between cleaning and sanitizing solutions and product there could be product contamination	Master cleaning/sanitizing schedule GHP inspection Audit Pathogen monitoring	Chemical type, concentration, contact time and temperature	
	P	None				
A	B	C	D	E	F	

Instructions:

Prerequisite Program	Hazard Agent	Hazard presence, growth, survival, increase, re(contamination)	Hazard origin, cause, source, vector, condition	Control Measure	What is monitored and when	
Describes the ISO/TS 22002-1 requirement.	Describes the hazard agent, e.g. biological, chemical, physical or combination thereof.	Describes how the hazard manifests as a threat, i.e. presence, growth or survival.	Describes the cause, origin, condition or source of a hazard.	Describes the control measures the FBO has in place to control relevant hazards.	Describes the hazard measurement parameters and the frequency of monitoring required.	

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Cleaning/sanitizing supervisor QA/laboratory	Review/update master cleaning/sanitizing schedule or program; revalidate the effectiveness of the cleaning/sanitizing schedule/program	Cleaning/sanitizing GHP inspections Audits Cleaning/sanitizing validation/re-validation	GHP inspections Audit Document/record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Master Cleaning/Sanitizing Program/Schedule Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	G	H	I	J	K

	Who is responsible Describes the job role or title of the department/function within the FBO responsible for monitoring the relevant hazard measurement parameters.	Correction / Corrective action Describes the correction and corrective action aimed at preventing reoccurrence of exceeding the allowable or permitted hazard measurement parameters.	Records Indicates the monitoring and hazard measurement parameter records to be maintained.	Verification activities Describes the verification activities necessary to confirm the accuracy of the monitoring and hazard measurement parameters.	Reference Documents Describes the FBO documents and, where necessary, the relevant external documents, e.g. statutory and regulatory requirements.
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[WS 3] PRP Verification Action Plan Worksheet

This worksheet aids in planning PRP verification.

Verification is confirmation, supported by objective evidence, specifying that requirements have been fulfilled.

Original prerequisite program verification is carried out after the program has been implemented and developed. Further planned verifications should take place at least once a year. Unscheduled verifications are required when PRP changes take place.

The FBO should also have a verification plan. Verification may only be carried out by an authorized person. The FBO must document all verification activities for each PRP.

A blank [WS 3] PRP verification action plan worksheet is available on the enclosed CD.

Prerequisite Program	Verification Action
Team #11 Cleaning and Sanitizing	Reviewed by hygienist and cleaning and sanitizing PRP team
	Review of environment, pathogen and foreign objects monitoring
	Review of GHP inspections
	Food Safety Management System audits
	Internal GMP / hygiene audits
	Review of chemicals/MSDS and chemical storage
	Review of cleaning/sanitizing validation/re-validation study
	Review of traceability
	Review of training
	Frequency & criticality review
	Food Safety Management System audits
	Internal cGMP audits / GHP inspections
	Frequency and criticality review
A	B

Instructions:

Prerequisite program	Verification Action
Organization to provide details of PRP Team Number and PRP Title. We suggest the PRP Team # should match the relevant chapter in the relevant FSMS Scheme Standard, e.g. ISO/TS 22002-1 Chapter 11 – Cleaning and Sanitizing.	Organization to provide details of PRP verification actions associated with the PRP and who is responsible for the review of the verification action.

[WS 4] PRP Meeting Summary Worksheet

This worksheet is used to document PRP meetings and any resulting decisions.

A blank [WS 4] PRP meeting summary worksheet is available on the enclosed CD.

Date	Participants	Purpose	Outcome (decisions/ actions)	Responsibility	Deadline	Performed
20-Apr-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Initial review of PRP	Update PRP management worksheet review-related PRPs	G Moran to complete verification sheet	15-May-15	15-May-15
28/4/2015	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Complete GAP sheet Review PRP management worksheet Review cleaning/ sanitization re-validation study	Completed and approved Reviewed and approved Appointed designated person	G Moran to update PRP worksheets	15-May-15	15-May-15
12-Oct-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Review of cleaning tool program awareness, e.g. 5S program, storage, replacement	Reviewed/up-dated Training and improvements shown following improved coaching and supervising by supervisors	PRP team to complete	17-Dec-15	17-Dec-15
A	B	C	D	E	F	G

Instructions:

Date	Participants	Purpose	Outcome(decisions/ action)	Responsibility	Deadline	Performed
List meeting dates.	List attendees, including both team members and invitees.	Provide the reason for the meeting.	Record decisions made and next steps.	Identify those responsible to execute decisions.	Record deadlines.	Provide action dates.



[WS 5] PRP GAP Registration and Resolution Worksheet

This worksheet defines and eliminates gaps between PRP requirements of a certain standard (s), for example, ISO/TS 22002-1, and other documents that must comply with FSMS.

When completing this worksheet, the FBO may use different standards and / or documents to fulfill PRP requirements, for example, for an ISO / TS 22002-1 requirement. These should correspond to the FSMS of that particular FBO.

A blank [WS 5] PRP GAP registration and resolution worksheet is available on the enclosed CD.

Fill in only if gaps have been identified

ISO/TS 22002-1	Description [of the requirement of the Standard]	Specific requirement	Associated Dairy Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
11.2 Cleaning and Sanitizing Agents and Tools	Tools and equipment shall be of hygienic design and maintained in a condition which does not present a potential source of extraneous matter	Review effectiveness of awareness of the ISO/TS 22002-1 requirement	Food safety policy	Enhance awareness of 5S, storage, tool protection procedures	Update awareness/training and monitoring effectiveness via greater supervision of FBO supervisors	Reviewed/ updated awareness/training effectiveness, see PRP Team Meeting 28-April-2015	Need to continue to monitor for next six months to sustain improvements shown to date
11.3 Cleaning and Sanitizing Programs	Cleaning and sanitizing programmes shall be established and validated by the organization	Re-validate cleaning/sanitizing validation study	Food safety policy	Previous validation study incomplete/inadequate	Re-validation study review/ approved	Review/ approved re-validation study, see PRP Team Meeting 12-Oct-2015	Need to continue to monitor for next twelve months
A	B	C	D	E	F	G	H

Instructions:

Standard/ Scheme name, PRP name and clause number	Description [of the requirement of the Standard]	Specific requirement	Associated Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
Provide a description of the FSMS Scheme Requirement.	Provide a description of the requirement arising from the FSMS scheme where the gap exists.	Provide a short description of the specific requirement where the gap exists within the FBO.	Detail the relevant FSMS Policy.	Describe the gap.	Provide details of the action to be taken to address the specific requirement identified as not having been fulfilled.	Provide details of the actions taken to address the gap and the date of completion.	Add any additional relevant comments, if required.

[WS 6] Hazard Agent Worksheet

The PRP Hazardous Agents Worksheet provides a standard classification system for recording hazardous agents in the FSTK PRP workbook. The hazardous agents classification system is based on the food and beverage industry hazardous agent classification system.

The hazardous agent worksheet is for reference or guidance purpose only; no template is provided.

Hazardous Agents	Hazard Class Abbreviation
Microbiological (vegetative or spores, depending on circumstances)	B
Chemical (such as cleaning chemicals, non-food grade lubricants, oils and greases, and chemical residues)	C
Physical (such as various types of foreign material including metal, wood, plastic, or other foreign bodies)	P
Allergens (milk, soy, wheat, egg, fish, shellfish, tree nut, peanut)	A
A	B

Instructions:

Hazardous agent Classify food safety hazard agents, e.g. biological, chemical, or physical.	Hazard Class Indicate the food safety hazard agent code, e.g. biological – B; chemical – C; physical – P; allergen – A.
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Prerequisite Program

PRP 12: Pest Control

[WS 1] PRP Scope Worksheet

This worksheet defines the scope of the FBO PRP. The information needs to be clear, especially in detailing the product(s), including production lines for which the study was conducted. It should also provide information about the individuals making up the study team along with any revision history of the PRP programs.

The PRP scope worksheet has five sections with instructions for their completion as outlined below. These are followed by a sample completed worksheet.

A blank [WS 1] PRP scope worksheet blank can be found on the enclosed CD.

PRP Study Scope			
Facility	Joe Bloggs Dairy Plant	Start Date:	20th April 2015
Product category	Grade A IMS Registered Whole Milk	Status:	Draft
Proessess	HSTS Pasteurizer, Aseptic Filling, Retort	End date:	Ongoing
Products	Grade A Aseptically processed and packaged Milk		

Instructions:

Provide PRP title from standard/ scheme (e.g. "Pest Control") and standard/scheme chapter number (e.g., "12- Pest Control").

Provide the facility name, product category, product, processes, PRP status, document status (e.g. draft, approved), PRP start and end dates.

PRP Review History			
PRP type	Tick as appropriate	Notes/reason for unscheduled review	Dates of last 3 reviews
New PRP Study	✓	Current PRP's underwent a comprehensive review for compliance to ISO/TS 22002-1 and ISO 22000:2005 starting in April of 2015 and completed 20th April 2015. These management sheets describe each PRP in place at the Dairy Plant facility.	
Scheduled Review	20th March 2016		
Unscheduled Review			

This section records information about history of PRP revisions, with explanation of reason why this update is done: 'according to plan' or 'unscheduled.' For unscheduled revisions, explain why this revision is unscheduled (what reason?)

PRP Team Members			
Name	Position	Department	Responsibility/Role
G Moran	Food Safety Manager	Food Safety	Food Safety/QA
O Brown	Hygienist/Microbiologist	Food Safety	Hygienist/Microbiologist
M Rodrigues	Milk Processing Manager	Milk Processing	Milk Processing
B Jackson	Laboratory Manager	QA	Laboratory
D Smith	Warehouse Manager	Warehousing	Warehousing
O Murphy	Engineering Manager	Engineering	Engineering
C Flack	Factory Manager	Management	Management

For every PRP study, the organization needs to establish an HACCP team with specific responsibilities and roles. Include names within the company, department name, and responsibilities. The core area of competence of each team member should also be documented in this section.

Specialist Input		
Name	Location/Job Title	Input/Specialist Advice
Angela Yard	Consultant	PRP Team Facilitator

To establish PRP studies, companies may need advice from an outsourced expert. (Consultant/ Subject matter expert). Explanation of expert's role should be explained in this section: Input/ Specialist advice

Authorization		
Food Safety Team Leader/Quality Assurance Manager	Signature: G Moran	Date 20th April 2015
Management Team Member:	Signature: C Flack	Date 20th April 2015

Team members must indicate their approval of the document by providing their names, positions, and responsibilities held, signature. The authorized team member should provide his/her signature and the date signed.



[WS 2] PRP Management Worksheet

This worksheet identifies hazards and the PRP necessary to manage them. It also identifies corrective actions to be taken should hazard levels rise above acceptable limits. The worksheet identifies records that FBOs should keep and the verification procedures required for each PRP.

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
12.1 General Requirements	B	Contamination	Pests	Hygiene, cleaning and incoming material inspection in place as well as pathogen and environmental monitoring procedures	Hygiene, cleaning and raw material monitored through GHP Inspections and audits monthly Pathogen monitoring program in place weekly	
12.2 Pest Control Program	B,C	Contamination	Pests, chemicals used	Pest control program in place, outsourced to an external company Dairy plant designated site contact is the sanitizing supervisor. Contact person is the dairy plant sanitizing supervisor Documents and records are with the dairy plant sanitizing supervisor List of approved pesticide chemicals used is available on a USB stick that is with the Pest Management Program folder/manual. The food safety manager approves all dairy plant chemical pesticides	Pest activity, infestation, pest activity is frequently monitored according to the pest management program	
12.3. Preventing Access	B,C	Contamination	Holes, cracks, open doors, ventilation openings	Building maintenance in place Pest access points are sealed All doors to the outside have closures, windows can't be opened, ventilation openings are designed to minimize the potential entry of pests Dairy plant approved pesticides maintained Material Safety Data Sheets for dairy plant approved pesticides maintained	Pest activity, infestation, pest activity is frequently monitored according to the pest management program	
12.4. Harborage and infestations	B	Contamination	Raw material, bad housekeeping, pallets, etc	cGMP and good housekeeping in place throughout the Dairy Plant Material found to be infested is separated or discarded Outside space is not used for storage	Pest activity, infestation, pest activity is frequently monitored according to the pest management program, monthly PRP audit	

A blank [WS 2] PRP management worksheet is available on the enclosed CD.

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Dairy Plant QA Laboratory Dairy Plant Sanitization Dairy Plant Food Safety	Training, cleaning of area where deviation was found Raw Material is sent back to supplier or discarded, if not compliant	GHP inspection Audit Reports Pathogen Monitoring Raw Material monitoring	Pest control records no pest activity	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant layout of Premises and Work-space PRP Dairy Plant Internal Structure PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Raw Material Handling Procedure Dairy Plant Product Inspection Procedure Dairy Plant Cleaning and Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen monitoring Procedure Pest Control Folder/Manual [External Pest Control Company]
	Dairy Plant QA Laboratory Dairy Plant Sanitization Dairy Plant Food Safety	Containment during construction Eliminate source of pest entry	Pest management service report [external provider]	Pest control records no pest activity	Dairy Plant Pest Control Program Dairy Plant Pest Control Map Pest Control Folder/Manual [External Pest Control Company]
	Dairy Plant QA Dairy Plant Maintenance Dairy Plant Sanitization	Close entry point of pests	Pest management service report [external provider]	Pest control records no pest activity	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant layout of Premises and Work-space PRP Dairy Plant Internal Structure PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP
	Dairy Plant Sanitation	Cleaning of invested area, Route cause analysis Training	Inspection/audit report Training, Non-conforming product Destruction of non-conforming product	Pest control records no pest activity, Audit	Dairy Plant Raw material handling procedure Dairy Plant Product Inspection procedure

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
12.5. Monitoring and Detection	B	Contamination	Pests	Pest control program in place, outsourced to an external company Pest control map of detectors and traps included in the Pest Control Folder/Manual Detectors and traps are according to ISO/TS 22002-1 Detectors and traps are frequently inspected according to pest management program	Pest activity, infestation, pest activity is frequently monitored according to the pest management program	
12.6. Eradication	B, C	Contamination	Pests	Eradication measures shown in Pest Management Service Report Only authorized and trained dairy plant personnel handles pesticides Records of dairy plant approved pesticides are maintained in the Pest Control Service Report	Pest activity, infestation, pest activity is frequently monitored according to the pest management program	
A	B	C	D	E	F	

Instructions:

Prerequisite Program	Hazard Agent	Hazard presence, growth, survival, increase, re(contamination)	Hazard origin, cause, source, vector, condition	Control Measure	What is monitored and when	
Describes the ISO/TS 22002-1 requirement.	Describes the hazard agent, e.g. biological, chemical, physical or combination thereof.	Describes how the hazard manifests as a threat, i.e. presence, growth or survival.	Describes the cause, origin, condition or source of a hazard.	Describes the control measures the FBO has in place to control relevant hazards.	Describes the hazard measurement parameters and the frequency of monitoring required.	

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Dairy Plant Sanitization	Review pest management program	Pest control records No pest activity	Pest control records No pest activity Audit	Dairy Plant Pest Control Folder/Manual [External Pest Control Company] Dairy Plant Environmental and Pathogen Monitoring Procedure Dairy Plant GHP Inspection Procedure Dairy Plant Awareness/Training Procedure
	Dairy Plant Sanitization Dairy Plant Food Safety	Review pest management program	Pest management service report	Pest control records No pest activity	Dairy Plant Pest Control Folder/Manual [External Pest Control Company] Dairy Plant Awareness and Training Procedure
	G	H	I	J	K

	Who is responsible Describes the job role or title of the department/function within the FBO responsible for monitoring the relevant hazard measurement parameters.	Correction / Corrective action Describes the correction and corrective action aimed at preventing reoccurrence of exceeding the allowable or permitted hazard measurement parameters.	Records Indicates the monitoring and hazard measurement parameter records to be maintained.	Verification activities Describes the verification activities necessary to confirm the accuracy of the monitoring and hazard measurement parameters.	Reference Documents Describes the FBO documents and, where necessary, the relevant external documents, e.g. statutory and regulatory requirements.
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[WS 3] PRP Verification Action Plan Worksheet

This worksheet aids in planning PRP verification.

Verification is confirmation, supported by objective evidence, specifying that requirements have been fulfilled.

Original prerequisite program verification is carried out after the program has been implemented and developed. Further planned verifications should take place at least once a year. Unscheduled verifications are required when PRP changes take place.

The FBO should also have a verification plan. Verification may only be carried out by an authorized person. The FBO must document all verification activities for each PRP.

A blank [WS 3] PRP verification action plan worksheet is available on the enclosed CD.

Prerequisite Program	Verification Action
Team #12 Pest Control	Reviewed by Laboratory Manager and Pest Control RPP team
	Review of Pest Sighting Log
	Review of pest management service reports
	Food Safety Management System audits
	Internal GMP / hygiene audits
	Review of approved chemical pesticide
	Review of Material Safety Data Sheets [MSDS]
	Frequency & criticality review
	Review of training
	Frequency & criticality review
	Food Safety Management System audits
	Internal GMP audits / GHP inspections
	Frequency and criticality review
A	B

Instructions:

Prerequisite program	Verification Action
Organization to provide details of PRP Team Number and PRP Title. We suggest the PRP Team # should match the relevant chapter in the relevant FSMS Scheme Standard, e.g. ISO/TS 22002-1 Chapter 12 – Pest Control.	Organization to provide details of PRP verification actions associated with the PRP and who is responsible for the review of the verification action.

[WS 4] PRP Meeting Summary Worksheet

This worksheet is used to document PRP meetings and any resulting decisions.

A blank [WS 4] PRP meeting summary worksheet is available on the enclosed CD.

Date	Participants	Purpose	Outcome (decisions/ actions)	Responsibility	Deadline	Performed
20-Apr-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Initial review of PRP	Update PRP management worksheet review-related PRPs	G Moran to complete verification Sheet	15-May-15	15-May-15
28/4/2015	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Complete GAP sheet Review PRP management worksheet Appoint designated person	Completed and approved Reviewed and approved Appointed designated person	G Moran to update PRP worksheets	15-May-15	15-May-15
12-Oct-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Review and pesticide chemicals and material safety data sheets [MSDS]	Reviewed/approved pesticide chemical specification Updated MSDS Folder	PRP team to complete	17-Dec-15	17-Dec-15
A	B	C	D	E	F	G

Instructions:

Date	Participants	Purpose	Outcome(decisions/ action)	Responsibility	Deadline	Performed
List meeting dates.	List attendees, including both team members and invitees.	Provide the reason for the meeting.	Record decisions made and next steps.	Identify those responsible to execute decisions.	Record deadlines.	Provide action dates.



[WS 5] PRP GAP Registration and Resolution Worksheet

This worksheet defines and eliminates gaps between PRP requirements of a certain standard (s), for example, ISO/TS 22002-1, and other documents that must comply with FSMS.

When completing this worksheet, the FBO may use different standards and / or documents to fulfill PRP requirements, for example, for an ISO / TS 22002-1 requirement. These should correspond to the FSMS of that particular FBO.

A blank [WS 5] PRP GAP registration and resolution worksheet is available on the enclosed CD.

Fill in only if gaps have been identified

ISO/TS 22002-1	Description [of the requirement of the Standard]	Specific requirement	Associated Dairy Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
A	B	C	D	E	F	G	H
12.2 Pest control programs	The establishment shall have a nominated person to manage pest control activities and/or deal with appointed expert contractors	Nominated person to manage pest control activities	Food Safety Policy	No clear designated person	Agree nominated person by next PRP team meeting	Nominated person appointed, see PRP team meeting 28-April-2015	Dairy Plant Sanitizing Supervisor appointed designated person

Instructions:

Standard/ Scheme name, PRP name and clause number	Description [of the requirement of the Standard]	Specific requirement	Associated Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
Provide a description of the FSMS Scheme Requirement.	Provide a description of the requirement arising from the FSMS scheme where the gap exists.	Provide a short description of the specific requirement where the gap exists within the FBO.	Detail the relevant FSMS Policy.	Describe the gap.	Provide details of the action to be taken to address the specific requirement identified as not having been fulfilled.	Provide details of the actions taken to address the gap and the date of completion.	Add any additional relevant comments, if required.

[WS 6] Hazard Agent Worksheet

The PRP Hazardous Agents Worksheet provides a standard classification system for recording hazardous agents in the FSTK PRP workbook. The hazardous agents classification system is based on the food and beverage industry hazardous agent classification system.

The hazardous agent worksheet is for reference or guidance purpose only; no template is provided.

Hazardous Agents	Hazard Class Abbreviation
Microbiological (vegetative or spores, depending on circumstances)	B
Chemical (such as cleaning chemicals, non-food grade lubricants, oils and greases, and chemical residues)	C
Physical (such as various types of foreign material including metal, wood, plastic, or other foreign bodies)	P
Allergens (milk, soy, wheat, egg, fish, shellfish, tree nut, peanut)	A
A	B

Instructions:

<p>Hazardous agent Classify food safety hazard agents, e.g. biological, chemical, or physical.</p>	<p>Hazard Class Indicate the food safety hazard agent code, e.g. biological – B; chemical – C; physical – P; allergen – A.</p>
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Prerequisite Program

PRP 13: Employee Hygiene and Employee Facilities

[WS 1] PRP Scope Worksheet

This worksheet defines the scope of the FBO PRP. The information needs to be clear, especially in detailing the product(s), including production lines for which the study was conducted. It should also provide information about the individuals making up the study team along with any revision history of the PRP programs.

The PRP scope worksheet has five sections with instructions for their completion as outlined below. These are followed by a sample completed worksheet.

A blank [WS 1] PRP scope worksheet blank can be found on the enclosed CD.

Instructions:

PRP Study Scope			
Facility	Joe Bloggs Dairy Plant	Start Date:	20th April 2015
Product category	Grade A IMS Registered Whole Milk	Status:	Draft
Proessess	HSTS Pasteurizer, Aseptic Filling, Retort	End date:	Ongoing
Products	Grade A Aseptically processed and packaged Milk		

Provide PRP title from standard/ scheme (e.g. "Pest Control") and standard/scheme chapter number (e.g. "13- Employee Hygiene and Employee Facilities").

Provide the facility name, product category, product, processes, PRP status, document status (e.g. draft, approved), PRP start and end dates.

PRP Review History			
PRP type	Tick as appropriate	Notes/reason for unscheduled review	Dates of last 3 reviews
New PRP Study	✓	Current PRP's underwent a comprehensive review for compliance to ISO/TS 22002-1 and ISO 22000:2005 starting in April of 2015 and completed 20th April 2015. These management sheets describe each PRP in place at the Dairy Plant facility.	
Scheduled Review	20th March 2016		
Unscheduled Review			

This section records information about history of PRP revisions, with explanation of reason why this update is done: 'according to plan' or 'unscheduled.' For unscheduled revisions, explain why this revision is unscheduled (what reason?)

PRP Team Members			
Name	Position	Department	Responsibility/Role
G Moran	Food Safety Manager	Food Safety	Food Safety/QA
O Brown	Hygienist/Microbiologist	Food Safety	Hygienist/Microbiologist
M Rodrigues	Milk Processing Manager	Milk Processing	Milk Processing
B Jackson	Laboratory Manager	QA	Laboratory
D Smith	Warehouse Manager	Warehousing	Warehousing
O Murphy	Engineering Manager	Engineering	Engineering
C Flack	Factory Manager	Management	Management

For every PRP study, the organization needs to establish an HACCP team with specific responsibilities and roles. Include names within the company, department name, and responsibilities. The core area of competence of each team member should also be documented in this section

Specialist Input		
Name	Location/Job Title	Input/Specialist Advice
Angela Yard	Consultant	PRP Team Facilitator

To establish PRP studies, companies may need advice from an outsourced expert. (Consultant/ Subject matter expert). Explanation of expert's role should be explained in this section: Input/ Specialist advice.

Authorization		
Food Safety Team Leader/Quality Assurance Manager	Signature: G Moran	Date 20th April 2015
Management Team Member:	Signature: C Flack	Date 20th April 2015

Team members must indicate their approval of the document by providing their names, positions, and responsibilities held, signature. The authorized team member should provide his/her signature and the date signed.



[WS 2] PRP Management Worksheet

This worksheet identifies hazards and the PRP necessary to manage them. It also identifies corrective actions to be taken should hazard levels rise above acceptable limits. The worksheet identifies records that FBOs should keep and the verification procedures required for each PRP.

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
13.1 General Requirements	B, C, P [See below]	Presence Contamination	Contamination by pathogens Contamination by cleaning and sanitizing residues Contamination by extraneous material	Dairy plan hygiene policy Dairy plant hygiene awareness and training	Pathogen monitoring, daily GHP, weekly	
13.2 Personal Hygiene Facilities and Toilets	B	Presence Contamination	Contamination by vegetative pathogens	Provision of personnel hygiene facilities Hygienic design of personnel hygiene facilities Location and cleaning/maintenance of personnel hygiene facilities	Pathogen monitoring, daily Cleaning/sanitizing, daily Temperature of water Maintenance, Weekly Supply of soap and/or sanitizer	
	C	Presence Contamination	Cleaning and sanitizing solution residues	MSDS sheets for cleaning and/or sanitizing chemicals Approved cleaning and sanitizing chemicals Chemical storage	Toxic residues Daily/weekly	
	P	Presence Contamination	Extraneous material arising from poor personnel facility maintenance and/or cleaning, e.g. paint	Preventive maintenance Cleaning log	Maintenance Cleaning Daily/weekly	

A blank [WS 2] PRP management worksheet is available on the enclosed CD.

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	All personnel Hygienist QA/laboratory	Pathogen monitoring Re-training, if required Disciplinary action, if required	Personnel hygiene GHP inspections Audits Pathogen monitoring	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP Dairy Plant Hygiene Policy Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Facilities management Hygienist QA/laboratory Cleaning operators/ service providers Maintenance	Preventive maintenance Re-training, if required Re-clean/re-sanitize	GHP inspections Audits Personnel hygiene facilities cleaning log book	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP Dairy Plant Construction and layout of Building PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Management of Purchased Materials PRP Dairy Plant Utilities PRP Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	QA/laboratory Sanitizing operators Cleaning service providers	Environmental monitoring frequency review Re-training, if required Re-clean/re-sanitize	GHP inspections Audits Cleaning/sanitizing	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP Dairy Plant Construction and layout of Building PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Management of Purchased Materials PRP Dairy Plant Utilities PRP Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Maintenance Cleaning service provider	Re-training, if required Re-clean/re-sanitize	GHP inspections Audits Cleaning/sanitizing Maintenance	GHP inspections Audit Document/re-record review	Dairy Plant Construction and layout of Building PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Management of Purchased Materials PRP Dairy Plant Utilities PRP Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen monitoring Procedure

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
13.3 Staff Canteens and Designed Eating Areas	B	Presence Contamination	Contamination by vegetative pathogens	Hygienic storage of prepared food Cooking and holding temperatures	Cleaning/sanitizing, daily Pathogen monitoring, daily Temperature and time limitations, daily	
	C	Presence Contamination	Cleaning and sanitizing solution residues	MSDS sheets for cleaning and/or sanitizing chemicals Approved cleaning and sanitizing chemicals Chemical storage	Toxic residues Daily/weekly	
	P	Presence Contamination	Entraneous material arising from poor personnel facility maintenance and/or cleaning, e.g. paint	Preventive maintenance Cleaning log	Maintenance Cleaning Daily/weekly	
13.4 Workwear and Protective Clothing	B	Presence Contamination	Contamination by pathogens Glove use, where specified Improper footwear	Personal hygiene policy [hair, dirt, personnel perspiration, etc] Hair restraints/beard snoods Dedicated dairy plant footwear/properly maintained food foamers Specification for laundry of uniforms/lab coats Adequate supply of laundered uniforms/lab coats Locker provided for uniform storage Clean uniforms to be worn	Temperature Pathogen monitoring	
	C	None				
	P	Presence Contamination	Entraneous material arising from personnel jewellery, false fingernails, fingernail polish, buttons, pens etc.	Personal hygiene policy [jewellery, fingernails, pens/biro's etc]	GHP Daily	
13.5 Health Status	B	Presence Contamination	Contamination by pathogens due to personnel ill health, minor cuts or infectious disease	Dairy plant personal hygiene policy Dairy plant hygiene awareness and training Supervisor notification Glove use after minor cuts and hand washing Personnel prohibition to work handling food products	Personnel health status Pathogen monitoring Frequency Daily/weekly	
	C	None				
	P	None	Contamination from adhesive bandage/plaster	Use of adhesive bandage reported to management	Use of adhesive bandage, if allowed	

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Hygienist Canteen staff	Cleaning/sanitizing schedule/program Ingredient/product disposal	GHP inspections Audits Environmental and pathogen monitoring Cleaning/ sanitizing Cooking and holding temperature Waste disposal	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	QA/laboratory Sanitizing operators Cleaning service providers	Environmental monitoring frequency review Re-training, if required Re-clean/re-sanitize	GHP inspections Audits Cleaning/sanitizing	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plant Environmental Monitoring Procedure
	Maintenance Cleaning service provider	Re-training, if required Re-clean/re-sanitize	GHP inspections Audits Cleaning/sanitizing Maintenance	GHP inspections Audit Document/re-record review	Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure
	QA/laboratory Cleaning operator	Re-clean	CIP charts for all dairy plant processing equipment	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP PRP Dairy Plant Construction and Layout of Building PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Management of Purchased Materials PRP Dairy Plant Personal Hygiene Policy Dairy Plant Awareness and Training Procedure
	All personnel including visitors and contractors	Re-training, if required Disciplinary action, if required	GHP inspections Audits Cleaning/sanitizing Maintenance	GHP inspections Audit Document/re-record review	Dairy Plant Personal Hygiene Policy Dairy Plant Awareness and Training Procedure
	All personnel Hygienist Medical health nurse, if available	Personnel prohibition to work handling food products	Personnel hygiene /health GHP inspections Audits Pathogen monitoring	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP Dairy Plant Personal Hygiene Policy Dairy Plant Cleaning/Sanitizing Procedures Dairy Plant Awareness and Training Procedure Dairy Plan Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Food safety manager	Use of gloves	Adhesive bandage use	GHP inspections Audit Document/re-record review	Dairy Plant Personal Hygiene Policy Dairy Plant Awareness and Training Procedure

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
13.6 Illness and Injuries	B	Presence Contamination	Contamination by pathogens due to personnel injury on hands and lower portions of the arms	Dairy plant personal hygiene policy Dairy plant hygiene awareness and training Supervisor notification Glove use after minor cuts and hand washing Personnel prohibition to work handling food products	Personnel health status Pathogen monitoring Frequency Daily/weekly	
	C	None				
	P	None	Contamination from adhesive bandage/plaster	Use of adhesive bandage reported to management	Use of adhesive bandage, if allowed	
13.7 Personnel Cleanliness	B	Presence Contamination	Contamination by pathogens due to lack of personnel hygiene by personnel	Dairy plant personal hygiene policy Dairy plant hygiene awareness and training Gloves, where required	Pathogen monitoring frequency GHP inspections/observations Daily/weekly	
	C	None				
	P	None				
13.8 Personal Behaviour	B	Presence Contamination	Contamination by pathogens	Dairy plant personal hygiene policy Dairy plant hygiene awareness and training Gloves, where required	Pathogen monitoring frequency Daily/weekly	
	P	None				
	P	Presence Contamination	Entraneous material arising from personnel behaviour, e.g. smoking, chewing gum, jewelry, pens exposed, false nails, eyelashes, medicines, etc.	Dairy plant personal hygiene policy Dairy plant smoking policy Dairy plant hygiene awareness and training Designed areas for storing smoking materials, medicines Maintenance of personal lockers [cleanliness and kept free of soiled clothing, storage of religious/cultural imperatives etc.]; in summary, personal affects Hand washing signs	GHP, weekly	
A	B	C	D	E	F	

Instructions:

Prerequisite Program	Hazard Agent	Hazard presence, growth, survival, increase, re(contamination)	Hazard origin, cause, source, vector, condition	Control Measure	What is monitored and when	
Describes the ISO/TS 22002-1 requirement.	Describes the hazard agent, e.g. biological, chemical, physical or combination thereof.	Describes how the hazard manifests as a threat, i.e. presence, growth or survival.	Describes the cause, origin, condition or source of a hazard.	Describes the control measures the FBO has in place to control relevant hazards.	Describes the hazard measurement parameters and the frequency of monitoring required.	

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	All personnel Hygienist Medical health nurse, if available	Personnel prohibition to work handling food products	Personnel hygiene /health GHP inspections Audits Pathogen monitoring	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP Dairy Plant Personal Hygiene Policy Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Food safety manager	Use of gloves	Band Aid use	GHP inspections Audit Document/re-record review	Dairy Plant Personal Hygiene Policy Dairy Plant Awareness and Training Procedure
	All personnel Hygienist QA/laboratory	Pathogen monitoring Re-training, if required Disciplinary action, if required	Personnel hygiene GHP inspections Audits Pathogen monitoring	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP Dairy Plant Personal Hygiene Policy Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Cleaning/sanitizing supervisor QA/laboratory	Pathogen monitoring Re-training, if required Disciplinary action, if required	Personnel hygiene GHP inspections Audits Pathogen monitoring	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP Dairy Plant Personal Hygiene Policy Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	All personnel Hygienist QA/laboratory	Pathogen monitoring Re-training, if required Disciplinary action, if required	Personnel hygiene GHP inspections Audits Pathogen monitoring	GHP inspections Audit Document/re-record review	Dairy Plant Measures for Prevention of Cross Contamination PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Dairy Plant Personal Hygiene Policy Dairy Plant Smoking Policy Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	G	H	I	J	K

Who is responsible Describes the job role or title of the department/function within the FBO responsible for monitoring the relevant hazard measurement parameters.	Correction / Corrective action Describes the correction and corrective action aimed at preventing reoccurrence of exceeding the allowable or permitted hazard measurement parameters.	Records Indicates the monitoring and hazard measurement parameter records to be maintained.	Verification activities Describes the verification activities necessary to confirm the accuracy of the monitoring and hazard measurement parameters.	Reference Documents Describes the FBO documents and, where necessary, the relevant external documents, e.g. statutory and regulatory requirements.
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[WS 3] PRP Verification Action Plan Worksheet

This worksheet aids in planning PRP verification.

Verification is confirmation, supported by objective evidence, specifying that requirements have been fulfilled.

Original prerequisite program verification is carried out after the program has been implemented and developed. Further planned verifications should take place at least once a year. Unscheduled verifications are required when PRP changes take place.

The FBO should also have a verification plan. Verification may only be carried out by an authorized person. The FBO must document all verification activities for each PRP.

A blank [WS 3] PRP verification action plan worksheet is available on the enclosed CD.

Prerequisite Program	Verification Action
Team #13 Employee Hygiene and Employee Facilities	Reviewed by hygienist and cleaning and sanitizing PRP team
	Review of environment, pathogen and foreign objects monitoring
	Review of GHP inspections
	Food Safety Management System audits
	Internal GMP / hygiene audits
	Review of chemicals/MSDS and chemical storage
	Review of cleaning/sanitizing validation/re-validation study
	Review of traceability
	Review of training
	Frequency & criticality review
	Food Safety Management System audits
	Internal cGMP audits / GHP inspections
	Frequency and criticality review
A	B

Instructions:

Prerequisite program	Verification Action
Organization to provide details of PRP Team Number and PRP Title. We suggest the PRP Team # should match the relevant chapter in the relevant FSMS Scheme Standard, e.g. ISO/TS 22002-1 Chapter 13 – Employee Hygiene and Employee Facilities	Organization to provide details of PRP verification actions associated with the PRP and who is responsible for the review of the verification action

[WS 4] PRP Meeting Summary Worksheet

This worksheet is used to document PRP meetings and any resulting decisions.

A blank [WS 4] PRP meeting summary worksheet is available on the enclosed CD.

Date	Participants	Purpose	Outcome (decisions/ actions)	Responsibility	Deadline	Performed
20-Apr-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Initial review of PRP	Update PRP management worksheet review-related PRPs	G Moran to complete verification sheet	15-May-15	15-May-15
28/4/2015	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Complete GAP Sheet Review PRP Management Worksheet Review Health Screening Policy	Completed and approved Reviewed and approved Appointed designated person	G Moran to update PRP worksheets	15-May-15	15-May-15
12-Oct-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Review of storage of product contact tools and equipment in personal lockers	Reviewed/updated policy and communication of prohibition of storage of product contact tools and equipment in personal lockers	PRP team to continue to monitor as part of GHP inspections	17-Dec-15	17-Dec-15
A	B	C	D	E	F	G

Instructions:

Date	Participants	Purpose	Outcome(decisions/ action)	Responsibility	Deadline	Performed
List meeting dates.	List attendees, including both team members and invitees.	Provide the reason for the meeting.	Record decisions made and next steps.	Identify those responsible to execute decisions.	Record deadlines.	Provide action dates.



[WS 5] PRP GAP Registration and Resolution Worksheet

This worksheet defines and eliminates gaps between PRP requirements of a certain standard (s), for example, ISO/TS 22002-1, and other documents that must comply with FSMS.

When completing this worksheet, the FBO may use different standards and / or documents to fulfill PRP requirements, for example, for an ISO / TS 22002-1 requirement. These should correspond to the FSMS of that particular FBO.

A blank [WS 5] PRP GAP registration and resolution worksheet is available on the enclosed CD.

Fill in only if gaps have been identified

ISO/TS 22002-1	Description [of the requirement of the Standard]	Specific requirement	Associated Dairy Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
13.5 Health Status	Medical examinations, where permitted, shall be carried out at intervals defined by the organization	Health screening of personnel	Food safety policy	Health screening policy not in compliance with country regulations and not effectively communicated to personnel	Review/update health screen policy and communicate effectively within the FBO as soon as practical	Review/approved policy and re-enforced policy/practice with relevant personnel, see PRP team meeting 12-Oct-2015	Need to continue to monitor for next twelve months
13.8 Personnel Behaviour	Prohibition of storage of product contact tools and equipment in personal lockers	Product contact tools and equipment to be stored in FBO-supplied toolbox	Food safety policy	Practice does not match requirement of the Standard	Re-enforce policy/practice and include in GHP inspections	Review/ approved new health screening policy and communicated to all personnel, see PRP team meeting 28-April-2015	Need to continue to monitor for next six months to sustain improvements shown to date
A	B	C	D	E	F	G	H

Instructions:

Standard/ Scheme name, PRP name and clause number	Description [of the requirement of the Standard]	Specific requirement	Associated Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
Provide a description of the FSMS Scheme Requirement.	Provide a description of the requirement arising from the FSMS scheme where the gap exists.	Provide a short description of the specific requirement where the gap exists within the FBO.	Detail the relevant FSMS Policy.	Describe the gap.	Provide details of the action to be taken to address the specific requirement identified as not having been fulfilled.	Provide details of the actions taken to address the gap and the date of completion.	Add any additional relevant comments, if required.

[WS 6] Hazard Agent Worksheet

The PRP Hazardous Agents Worksheet provides a standard classification system for recording hazardous agents in the FSTK PRP workbook. The hazardous agents classification system is based on the food and beverage industry hazardous agent classification system.

The hazardous agent worksheet is for reference or guidance purpose only; no template is provided.

Hazardous Agents	Hazard Class Abbreviation
Microbiological (vegetative or spores, depending on circumstances)	B
Chemical (such as cleaning chemicals, non-food grade lubricants, oils and greases, and chemical residues)	C
Physical (such as various types of foreign material including metal, wood, plastic, or other foreign bodies)	P
Allergens (milk, soy, wheat, egg, fish, shellfish, tree nut, peanut)	A
A	B

Instructions:

<p>Hazardous agent Classify food safety hazard agents, e.g. biological, chemical, or physical.</p>	<p>Hazard Class Indicate the food safety hazard agent code, e.g. biological – B; chemical – C; physical – P; allergen – A.</p>
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Prerequisite Program

PRP 14: Rework

[WS 1] PRP Scope Worksheet

This worksheet defines the scope of the FBO PRP. The information needs to be clear, especially in detailing the product(s), including production lines for which the study was conducted. It should also provide information about the individuals making up the study team along with any revision history of the PRP programs.

The PRP scope worksheet has five sections with instructions for their completion as outlined below. These are followed by a sample completed worksheet.

A blank [WS 1] PRP scope worksheet blank can be found on the enclosed CD.

Instructions:

PRP Study Scope			
Facility	Joe Bloggs Dairy Plant	Start Date:	20th April 2015
Product category	Grade A IMS Registered Whole Milk	Status:	Draft
Processes	HSTS Pasteurizer, Aseptic Filling, Retort	End date:	Ongoing
Products	Grade A Aseptically processed and packaged Milk		

Provide PRP title from standard/ scheme (e.g. "Pest Control") and standard/scheme chapter number (e.g. "14 – Rework").

Provide the facility name, product category, product, processes, PRP status, document status (e.g. draft, approved), PRP start and end dates.

PRP Review History			
PRP type	Tick as appropriate	Notes/reason for unscheduled review	Dates of last 3 reviews
New PRP Study	✓	Current PRP's underwent a comprehensive review for compliance to ISO/TS 22002-1 and ISO 22000:2005 starting in April of 2015 and completed 20th April 2015. These management sheets describe each PRP in place at the Dairy Plant facility.	
Scheduled Review	20th March 2016		
Unscheduled Review			

This section records information about history of PRP revisions, with explanation of reason why this update is done: 'according to plan' or 'unscheduled.' For unscheduled revisions, explain why this revision is unscheduled (what reason?)

PRP Team Members			
Name	Position	Department	Responsibility/Role
G Moran	Food Safety Manager	Food Safety	Food Safety/QA
O Brown	Hygienist/Microbiologist	Food Safety	Hygienist/Microbiologist
M Rodrigues	Milk Processing Manager	Milk Processing	Milk Processing
B Jackson	Laboratory Manager	QA	Laboratory
D Smith	Warehouse Manager	Warehousing	Warehousing
O Murphy	Engineering Manager	Engineering	Engineering
C Flack	Factory Manager	Management	Management

For every PRP study, the organization needs to establish an HACCP team with specific responsibilities and roles. Include names within the company, department name, and responsibilities. The core area of competence of each team member should also be documented in this section.

Specialist Input		
Name	Location/Job Title	Input/Specialist Advice
Angela Yard	Consultant	PRP Team Facilitator

To establish PRP studies, companies may need advice from an outsourced expert. (Consultant/ Subject matter expert). Explanation of expert's role should be explained in this section: Input/ Specialist advice.

Authorization		
Food Safety Team Leader/Quality Assurance Manager	Signature: G Moran	Date 20th April 2015
Management Team Member:	Signature: C Flack	Date 20th April 2015

Team members must indicate their approval of the document by providing their names, positions, and responsibilities held, signature. The authorized team member should provide his/her signature and the date signed.



[WS 2] PRP Management Worksheet

This worksheet identifies hazards and the PRP necessary to manage them. It also identifies corrective actions to be taken should hazard levels rise above acceptable limits. The worksheet identifies records that FBOs should keep and the verification procedures required for each PRP.

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
14.1 General requirements	B, C, P	Contamination	Microbiological, chemical or extraneous matter contamination	Hygiene, cleaning, product inspection, pathogen, environmental monitoring, extraneous material procedures, traceability	Hygiene, cleaning, storage monitored through GHP inspections and audits monthly Pathogen monitoring program in place weekly	
14.2 Storage, Identification and Traceability	B	Contamination	Reclaimed or reworked product may have been handled, stored or used in a way to subject it to contamination with pathogens	Product that has not been continuously in control of the dairy plant to be reclaimed or reworked; is assumed to contain pathogens. When product is no longer under the control of the dairy plant, it can be not be assumed to have been held to preclude temperature abuse of adulteration. Only product that has not left the control of the dairy plant should be used, kept segregated, handled, protected and cooled as appropriate for the product with the exception for product approved by the Regulatory Agency. Reworking is done in a clean area and in a manner that will not contaminate the product being salvaged	Environmental and pathogen monitoring Good warehousing practices [GWP] Product segregation Product protection [temperature] Daily/weekly	
	C	Contamination	Allergens being mixed with products that are not labeled as containing allergens	Foods containing undeclared allergens may cause life threatening reactions in sensitive individuals	Reworked product segregation Product labelling	

A blank [WS 2] PRP management worksheet is available on the enclosed CD.

	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Dairy plant warehousing Dairy plant QA laboratory Dairy plant food safety	Training Product rework Product disposal	GHP Inspection Audit Reports Pathogen Monitoring Product Inspection Traceability	GHP inspections Audits Product Inspection Environmental/ Pathogen monitoring	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant layout of Premises and Workspace PRP Dairy Plant Internal Structure PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Warehousing PRP Rework Procedure Dairy Plant Product Inspection Procedure Dairy Plant Awareness and Training Procedure Dairy Plant Product Traceability Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure Pest Control Folder/Manual [External Pest Control Company]
	Dairy plant warehousing Dairy plant milk processing Dairy plant QA laboratory Dairy plant food safety	Training Product rework Product disposal	GHP/GWP inspection Audit reports Rework [classification] Pathogen monitoring Product inspection Traceability	GHP/GWP Inspections Audits Environmental/ Pathogen monitoring	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant Layout of Premises and Workspace PRP Dairy Plant Internal Structure PRP Warehousing PRP Rework Procedure Product Traceability Procedure Dairy Plant Product Inspection Procedure Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Dairy plant warehousing Dairy plant milk processing Dairy plant food safety	Training Product rework Product disposal	GHP/GWP inspection Audit reports Rework [classification] Traceability	GHP/GWP Inspections Audits Environmental monitoring	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant Layout of Premises and Workspace PRP Dairy Plant Internal Structure PRP Warehousing PRP Measures of Prevention of Cross Contamination PRP Rework Procedure Allergen Management Procedure Dairy Plant Product Inspection Procedure Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure

Prerequisite program (go step by step through ISO/TS 22002-1) 6 Utilities - Air, Water, Energy	Hazards			Control Measures	What is Monitored and When	
	Agent(s)	Presence, Growth, Survival, Increase, Re (Contamination)	Origin, Cause, Source, Vector, Condition			
	P	Contamination	Extraneous material may result in choking or other physical harm to consumers	Opening of products is conducted in a manner that will minimize the opportunity for bits or packaging, cutting tools, etc. from entering the product. Verification that, at some point in the process ingredient or the milk product to which the ingredient is added, will pass through a filter, screen, small orifice	Foreign objects contamination Each batch	
14.3. Rework Usage	B,C,P	Contamination	Microbiological, chemical or extraneous matter contamination	Rework Procedure and additional documentation specifying the conditions of rework, process step, acceptable quantity, type, conditions of rework, any pre-processing steps etc. Opening of products is conducted in a manner that will minimise the opportunity for bits or packaging, cutting tools, etc. from entering the product. Verification that, at some point in the process ingredient or the milk product to which the ingredient is added, will pass through a filter, screen, small orifice	Hygiene, cleaning Foreign object contamination, each batch GHP inspections Audits Environment and pathogen monitoring program in place weekly	
A	B	C	D	E	F	

Instructions:

Prerequisite Program Describes the ISO/TS 22002-1 requirement.	Hazard Agent Describes the hazard agent, e.g. biological, chemical, physical or combination thereof.	Hazard presence, growth, survival, increase, re(contamination) Describes how the hazard manifests as a threat, i.e. presence, growth or survival.	Hazard origin, cause, source, vector, condition Describes the cause, origin, condition or source of a hazard.	Control Measure Describes the control measures the FBO has in place to control relevant hazards.	What is monitored and when Describes the hazard measurement parameters and the frequency of monitoring required.	
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	Who is Responsible	Correction / Corrective Action	Records	Verification Activities	Reference Documents
	Dairy plant warehousing Dairy plant milk processing Dairy plant QA Dairy plant food safety	Training Product rework Product disposal	GHP/GWP inspection Audit report Rework [classification] Foreign objects monitoring Product inspection Traceability	GHP/GWP inspections audits Foreign objects monitoring	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant Layout of Premises and Work-space PRP Dairy Plant Internal Structure PRP Warehousing PRP Rework Procedure Dairy Plant Product Inspection Procedure Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	Dairy plant QA Dairy plant maintenance Dairy plant sanitization	Training Product rework Product disposal	GHP inspection Audit report Rework [classification] Environment, pathogen and foreign objects monitoring Product inspection Traceability Waste disposal	GHP/GWP inspections audits Environment, pathogen and foreign objects monitoring Product inspection	Dairy Plant Design and Construction of Buildings PRP Dairy Plant Site Location and Standards PRP Dairy Plant layout of Premises and Work-space PRP Dairy Plant Internal Structure PRP Dairy Plant Environment Suitability, Cleaning and Maintenance PRP Warehousing PRP Rework Procedure Dairy Plant Product Inspection Procedure Dairy Plant Awareness and Training Procedure Dairy Plant Environmental and Pathogen Monitoring Procedure
	G	H	I	J	K

	Who is responsible Describes the job role or title of the department/function within the FBO responsible for monitoring the relevant hazard measurement parameters.	Correction / Corrective action Describes the correction and corrective action aimed at preventing reoccurrence of exceeding the allowable or permitted hazard measurement parameters.	Records Indicates the monitoring and hazard measurement parameter records to be maintained.	Verification activities Describes the verification activities necessary to confirm the accuracy of the monitoring and hazard measurement parameters.	Reference Documents Describes the FBO documents and, where necessary, the relevant external documents, e.g. statutory and regulatory requirements.
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[WS 3] PRP Verification Action Plan Worksheet

This worksheet aids in planning PRP verification.

Verification is confirmation, supported by objective evidence, specifying that requirements have been fulfilled.

Original prerequisite program verification is carried out after the program has been implemented and developed. Further planned verifications should take place at least once a year. Unscheduled verifications are required when PRP changes take place.

The FBO should also have a verification plan. Verification may only be carried out by an authorized person. The FBO must document all verification activities for each PRP.

A blank [WS 3] PRP verification action plan worksheet is available on the enclosed CD.

Prerequisite Program	Verification Action
Team #14 Rework	Reviewed by laboratory manager and pest control RPP team
	Review of environment, pathogen and monitoring of foreign objects
	Review of GHP/GWP inspections
	Food Safety Management System audits
	Internal GMP / hygiene audits
	Review of product inspection
	Review of product disposal
	Review of traceability
	Review of training
	Frequency & criticality review
	Food Safety Management System audits
	Internal cGMP audits / GHP inspections
	Frequency and criticality review
A	B

Instructions:

Prerequisite program	Verification Action
Organization to provide details of PRP Team Number and PRP Title. We suggest the PRP Team # should match the relevant chapter in the relevant FSMS Scheme Standard, e.g. ISO/TS 22002-1 Chapter 14 – Rework	Organization to provide details of PRP verification actions associated with the PRP and who is responsible for the review of the verification action

[WS 4] PRP Meeting Summary Worksheet

This worksheet is used to document PRP meetings and any resulting decisions.

A blank [WS 4] PRP meeting summary worksheet is available on the enclosed CD.

Date	Participants	Purpose	Outcome (decisions/ actions)	Responsibility	Deadline	Performed
20-Apr-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Initial review of PRP	Update PRP management worksheet review-related PRPs	G Moran to complete verification sheet	15-May-15	15-May-15
28/4/2015	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Complete GAP sheet Review PRP management worksheet Appoint designated person	Completed and approved Reviewed and approved Appointed designated person	G Moran to update PRP worksheets	15-May-15	15-May-15
12-Oct-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack	Review of rework classification records, e.g. product name, production date, shift, line of origin, shelf-life	Reviewed/updated procedure	PRP team to complete	17-Dec-15	17-Dec-15
A	B	C	D	E	F	G

Instructions:

Date	Participants	Purpose	Outcome(decisions/ action)	Responsibility	Deadline	Performed
List meeting dates.	List attendees, including both team members and invitees.	Provide the reason for the meeting.	Record decisions made and next steps.	Identify those responsible to execute decisions.	Record deadlines.	Provide action dates.



[WS 5] PRP GAP Registration and Resolution Worksheet

This worksheet defines and eliminates gaps between PRP requirements of a certain standard (s), for example, ISO/TS 22002-1, and other documents that must comply with FSMS.

When completing this worksheet, the FBO may use different standards and / or documents to fulfill PRP requirements, for example, for an ISO / TS 22002-1 requirement. These should correspond to the FSMS of that particular FBO.

A blank [WS 5] PRP GAP registration and resolution worksheet is available on the enclosed CD.

Fill in only if gaps have been identified

ISO/TS 22002-1	Description [of the requirement of the Standard]	Specific requirement	Associated Dairy Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
A	B	C	D	E	F	G	H
14.2 Storage, Identification and Traceability	The rework classification or the reason for rework designation shall be recorded (e.g. product name, production date, shift, line of origin, shelf-life)	Recording of rework classification	Food safety policy	Rework procedure does not fully meet requirements of ISO/TS 22002-1	Review/update rework procedure	Rework procedure updated, see PRP team meeting 12-Oct-2015	Need to completed training and verify effectiveness of implementation

Instructions:

Standard/ Scheme name, PRP name and clause number	Description [of the requirement of the Standard]	Specific requirement	Associated Policy	Gap	Action Plan [Including timescales for completion]	Gap Resolution [Actions Completed and Date]	Comments
Provide a description of the FSMS Scheme Requirement.	Provide a description of the requirement arising from the FSMS scheme where the gap exists.	Provide a short description of the specific requirement where the gap exists within the FBO.	Detail the relevant FSMS Policy.	Describe the gap.	Provide details of the action to be taken to address the specific requirement identified as not having been fulfilled.	Provide details of the actions taken to address the gap and the date of completion.	Add any additional relevant comments, if required.

[WS 6] Hazard Agent Worksheet

The PRP Hazardous Agents Worksheet provides a standard classification system for recording hazardous agents in the FSTK PRP workbook. The hazardous agents classification system is based on the food and beverage industry hazardous agent classification system.

The hazardous agent worksheet is for reference or guidance purpose only; no template is provided.

Hazardous Agents	Hazard Class Abbreviation
Microbiological (vegetative or spores, depending on circumstances)	B
Chemical (such as cleaning chemicals, non-food grade lubricants, oils and greases, and chemical residues)	C
Physical (such as various types of foreign material including metal, wood, plastic, or other foreign bodies)	P
Allergens (milk, soy, wheat, egg, fish, shellfish, tree nut, peanut)	A
A	B

Instructions:

<p>Hazardous agent Classify food safety hazard agents, e.g. biological, chemical, or physical.</p>	<p>Hazard Class Indicate the food safety hazard agent code, e.g. biological – B; chemical – C; physical – P; allergen – A.</p>
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FSTK HACCP/O-PRP Plan Workbook

The second workbook details the FBO's HACCP/O-PRP Plan based upon Codex Alimentarius and ISO 22000 requirements.

It consists of 13 worksheets to be filled in by the designated HACCP team. Within these are ten main worksheets, WS 1 to WS 10. There are three supplementary worksheets, WS A, WS B and WS C: see the FSTK HACCP/ O-PRP Plan Workbook Overview.

The FSTK HACCP and O-PRP Plan Workbook (Excel files) can be found on the enclosed CD.

The FSTK HACCP/O-PRP Plan workbook is recommended for use in conjunction with ISO 22000:2005.

Each section of this workbook includes a worksheet stating:

- A brief description of the worksheet's specific purpose;
- Instructions for the detail to be inserted in each field;
- An example of a completed worksheet.

Main Worksheets:

- **HACCP Scope Worksheet [WS 1]:** defines and documents the scope of the HACCP study along with its revision history. It also lists the HACCP team members conducting the study.
- **Product/Ingredient Description Worksheet [WS 2]:** defines and documents the product characteristics associated with the product or product category.
- **Flow Diagram Worksheet [WS 3]:** defines and documents all production steps concerning the product and /or a group of similar products.
- **Hazard Identification and Description Worksheet [WS 4]:** defines and documents hazards noted in the food production process, as identified by the HACCP team. These are described and assessed.
- **Control Measures Selection and Categorization Worksheet [WS 5]:** defines and documents the selection and categorization of control measures related to identified hazards [WS B].
- **Validation of Control Measures Worksheet [WS 6]:** defines and documents FBO validation of the control measures identified in worksheet [WS 5] above.
- **HACCP Plan including O-PRP Worksheet [WS 7]:** defines and documents the details of all CCPs and O-PRPs, indicating control measures, critical limits, corrective actions taken, plus the verification events detailed in worksheet [WS 8].
- **Verification Plan Worksheet [WS 8]:** defines and documents verification activities intended to substantiate HACCP effectiveness in a particular case.
- **Modification and Follow-Up Worksheet [WS 9]:** defines and documents all plan modifications and follow-up steps resulting from these modifications.
- **Meeting Summary Worksheet [WS 10]:** defines and documents meetings held by the HACCP team.

Supplementary worksheets

- **Hazardous Agent Codes and Classification Worksheet [WS A]:** defines the guideline for Food Safety/HACCP team for assessing hazards controlled by HACCP system.
- **Hazard Assessment Table [WS B]:** defines and documents the hazard assessment/risk assessment.
- **HACCP List of Supporting Documents Worksheet [WS C]:** cites details of the list of reference documents (procedures/work instructions) associated with the FBO HACCP Plan and O-PRP.

History of HACCP

In the 1960s, the Pillsbury Corporation developed the HACCP control system with NASA to ensure food safety for the first manned space missions. The HACCP system and guidelines for its application were defined by the Codex Alimentarius Commission. This Commission implements the joint Food Standards Program of the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO).

Following an outbreak of E. coli O157 in Scotland in 1996, the Pennington Report recommended that HACCP be adopted by all food businesses to ensure food safety. All Global Food Safety Initiative Scheme standards, BRC, SQF, FSSC 22000 etc. have specific requirements for the incorporation of HACCP into an FBO's food safety management system.

Effective HACCP is invaluable in supporting any due diligence defense, and will enhance good manufacturing practice.

What is HACCP?

The word HACCP (Hazard Analysis & Critical Control Point) confuses many people. Simply put, it refers to a system that must be put in place to ensure that produced food is safe. This system is called a Food Safety Management System (FSMS) and must be based on the principles of HACCP.

A FSMS based on the principles of HACCP is a systematic approach to identifying and controlling hazards, whether microbiological, chemical or physical, that could pose a threat to the production of safe food – in simple terms, it involves identifying what could go wrong in a food system and planning how to prevent it.

The FBO's FSMS should allow the FBO to identify and control any hazards that could pose a danger to the preparation of safe food. It involves identifying what can go wrong, planning to prevent it and making sure the plan is being implemented. HACCP is a legal requirement but also benefits businesses.

Principles of HACCP

A Food Safety Management System based on the principles of HACCP enables the FBO to identify and control hazards before they threaten the safety of food to its consumers.

There are **seven principles of HACCP**:

1. Identify the hazards

This step requires the FBO to look at each step (e.g. purchasing, delivery, storage, preparation, cooking, chilling etc.) in its operation and identify what can go wrong e.g. salmonella in a cooked chicken product due to cross contamination with raw meat (biological hazard), contamination of uncovered food with detergent (chemical hazard) or a piece of broken glass fallen into an uncovered food (physical hazard).

2. Determine the critical control points (CCPs)

During this step the FBO needs to identify the points in its operation that ensures control of the hazards e.g. cooking raw meat thoroughly will kill pathogens such as *E. coli* O157.

3. Establish critical limit(s)

During this step the FBO sets limits to enable them to identify when a CCP is out of control, for example, when cooking beef burgers, the center of the burger must reach a minimum temperature of 75°C (or an equivalent time temperature combination, e.g. 70°C for two minutes) to ensure pathogens are destroyed.

4. Establish a system to monitor control of the CCP

During this step when identifying CCPs and critical limits it is important to have a way to monitor and record what is happening at each CCP. Typically, monitoring will involve measuring parameters such as temperature and time. However, how you monitor and how often will depend on the size and nature of your business. Monitoring should in all cases be simple, clear and easy to do. For example, measure the temperature of refrigerated food to ensure that it is being maintained below 5°C.

5. Establish the corrective action to be taken when a particular CCP is not under control

When FBO monitoring indicates that a CCP is not under control, corrective action must be taken. For example, when the temperature of the food in a refrigerator rises to 10°C due to a technical fault, discard the food and repair the refrigerator using the manufacturer's instructions to ensure the correct temperature of 5°C is achieved.

6. Establish procedures for verification to confirm the HACCP system is working effectively

The FBO should review and correct the FSMS periodically and any time they make changes to its operations. For example, when replacing an oven, verify that the time/temperature settings in the new oven achieve the minimum safe cooking temperature for a particular dish by measuring the temperature of the food.

7. Establish documentation concerning all procedures and records appropriate to these principles and their application

For the successful implementation of the FSMS based upon HACCP, appropriate documentation and records must be kept and be readily available. It is unrealistic to operate HACCP or to demonstrate compliance with current legislation without providing evidence such as written records. As with the FSMS itself, the complexity of record keeping depends on the nature and complexity of the business. The aim should be to ensure control is maintained without generating excessive paperwork.

Preliminary Steps in Developing a HACCP Plan

Introduction

To develop a HACCP plan, the FBO needs to plan and develop the processes necessary for producing safe food products. The first step is to collect important information in a fact-finding process called *Preliminary Steps*. ISO 22000:2005 requires all relevant information needed to conduct the hazard analysis to be collected, maintained, updated and documented.

The Purpose of the Preliminary Steps:

A HACCP system and/or a FSMS is a systematic, preventive approach to ensure the safe production of food products.

Prior to the application of HACCP, the FBO should operate according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation. The FBO needs to understand the food sector requirements that applies to its food products and processes.

The FBO is obliged to implement, operate and ensure the effectiveness of the planned activities and any changes to those activities.

The Five Preliminary Steps

The internationally-recognized Codex Alimentarius Commission outlines five preliminary steps that must be completed before developing a HACCP plan. The development of the plan is a logical step-by-step process. The preliminary steps necessary before implementing a HACCP plan include the following, which must be addressed in sequence:

1. Assemble the HACCP team;
2. Describe the food and its distribution;
3. Describe the intended use and consumers of the food;
4. Develop a flow diagram that describes the process;
5. Verify the flow diagram.

Preliminary Step #1 – Assemble the HACCP Team

To ensure that all likely hazards and critical control points (CCPs) are identified, a multidisciplinary team of people must be assembled to develop, implement and maintain the HACCP system.

The HACCP team should include people with operational experience, product specific knowledge and a good understanding of the production process. The HACCP team should include the following types of employees: quality assurance (QA), technical staff, production managers and supervisors, laboratory personnel, engineering and sanitation staff.

If the FBO is small, the HACCP Team may be supported by an external FSMS consultant. In such cases, there should be a written agreement or contract in place between the FBO and the FSMS Consultant clearly defining their role and responsibilities. The FBO has a duty of care to ensure the FSMS consultant is qualified and competent and can perform his or her role given the risk level of the product or commodity being processed.

A HACCP team leader should be designated to oversee the development, implementation and maintenance of the HACCP system. He or she must have a good understanding of HACCP and a working knowledge of the product and its production process. It is desirable that the HACCP team leader has proven competence in training design and delivery, i.e. attendance at a recognized Train-the-Trainer course is recommended.

Preliminary Step #2 – Describe the Food and its Distribution

A full description of the product must be prepared to provide a profile of the product and help determine food safety hazards associated with its production. A key element is the collection of food safety hazards and acceptable limits. The HACCP team needs to collect food safety hazards identification data and acceptance levels as defined and documented by:

Statutory and regulatory agencies:

- The Codex Alimentarius Commission;
- Customers;
- Scientific studies.

Product Descriptions must describe relevant food safety information, such as:

- Available water;
- Process parameters, e.g. pH, heavy metals;
- End product characteristics, e.g. shape, size, color, texture, odor;
- Method of preservation;
- Packaging;
- Storage conditions;
- Shelf life;
- Special labelling information;
- Customer preparation;
- Method of distribution.

Preliminary Step #3 – Describe the Intended Use and Consumers of the Food

It is important to identify the expected use of a product by the end user or consumer (for example, is the product cooked before consumption or ready to eat without cooking) because the intended use of a product will affect hazard analysis decisions.

Intended use information also needs to state whether the end user will be the general public or a specific consumer group, particularly vulnerable groups of the population such as infants, the elderly, pregnant women, ill people, immuno-compromised persons or cancer patients.

Preliminary Step #4 – Develop a Flow Diagram that Describes the Process

The HACCP Team must create a flow diagram that provides a clear, simple outline of all inputs, steps and outputs in the food production process. The all steps in the process must be set out, including any rework or recycling of materials.

The flow diagram will provide the basis for carrying out a systematic hazard analysis.

Preliminary Step #5 – Verify the Flow Diagram On-Site

An on-site verification of the flow diagram must be carried out to confirm that it accurately reflects the food production process. The HACCP team should follow the production process on-site and check that the flow diagram includes all steps that are carried out.

When verifying the accuracy of the flow diagram, consider different shifts and hours of operation, different batch sizes, optional ingredients and non-routine steps such as equipment maintenance.

After the five preliminary steps to developing a HACCP plan have been completed, a solid foundation will be in place to successfully apply to the seven principles of HACCP.

Benefits of HACCP

HACCP provides businesses with a cost-effective system for controlling food safety at every stage of the food production process, including production, storage, distribution, and sale to the final consumer. The preventive approach of HACCP improves food safety management and complements other quality management systems. The main benefits of HACCP are:

- **S**aves your business money in the long run;
- **A**voids you poisoning your customers;
- **F**ood safety standards increase;
- **E**nsures you are compliant with the law;
- **F**ood quality standards increase;
- **O**rganizes your process to produce safe food;
- **O**rganizes your staff promoting teamwork and efficiency;
- **D**ue diligence defense in court.

IFC has developed a comprehensive cost-benefit analysis tool that enables the FBO to establish the benefits of adopting HACCP or a FSMS. See Module 7 of the IFC FSTK.

Included in this FSTK is a partial example of a milk processing HACCP plan. In the partial milk processing example, two CCPs and one O-PRP example are provided.

HACCP Document Templates for Whole Milk

Overview & Guide Of The HACCP Worksheets

Main Worksheets [WS1-WS10] [WSA- WSC]	Supplementary Worksheets	Comments
WS 1 HACCP Scope		Registration and approval of the HACCP Study
WS 2 PRODUCT/INGREDIENT DESCRIPTIONS		Product and process description, including raw material and end product characteristics
WS 3 FLOW DIAGRAM		Simplified process flow diagram with OPRP and CCP location
	WS A HAZARDOUS AGENT CODES AND CLASSIFICATION	Guidance for Food Safety/ HACCP team for assessing hazards controlled by HACCP system
WS 4 HAZARD IDENTIFICATION AND DESCRIPTION		Each potential hazard is listed and significance is determined with help of severity of health effect and likelihood of appearance
	WS B HAZARD ASSESSMENT TABLE	Coding and classifying of the potentially hazardous agents that need to be considered during the study
WS 5 CONTROL MEASURE SELECTION AND CATEGORIZATION		With help of the decision tree the control measures are categorized to CCP, OPRP or Modification
WS 6 VALIDATION OF CONTROL MEASURES		Evidence that the control measure can achieve the targeted limits
WS 7 HACCP PLAN INCLUDING OPRPs		List and overview of all identified CCPs and OPRPs with control measures, limits, corrective actions and responsibilities
WS 8 VERIFICATION PLAN		Overview of verification activities that shows that the CCP's and OPRPs have been implemented properly
WS 9 MODIFICATION(S) AND FOLLOW-UP		List of modifications with all details
WS 10 MEETING ACTIVITY LOG		Recording meetings, attendances and decisions made by the team
	WS C (Optional) LIST OF SUPPORTING DOCUMENTS	Recording and filing supporting information



[WS1] HACCP Scope Worksheet

This worksheet defines the extent of the scope of the FBO HACCP and demonstrates its effectiveness. The worksheet is composed of two parts: the first should be completed before the start of the HACCP study and the second section after the completion of HACCP study.

The worksheet consists of eight sections. Completion instructions are outlined below. A blank [WS1] HACCP Scope Worksheet is included on the enclosed CD.

Complete the first section (below) at the start of the HACCP study

HACCP Study N°:	Version N°:
#122015	V1.0
HACCP study details	Tick as appropriate
New HACCP study	✓
Scheduled review	20-12-2015
Unscheduled review	
Study started	Date: 01-02-2015

Instructions:

HACCP Study
Provide information including the HACCP study number, version number HACCP study details, and HACCP study start date.

HACCP Study Scope	
Factory	Job Bloggs LLC
Plant/line	2211
Brand	Bloggs
Product name	Whole Milk
Product code	IMS #1
FSMS reference	ISO 22000

HACCP Study Scope
Complete HACCP study scope, including factory name, plant/line, brand, product name, product code, FSMS reference.

Description of scope of study (e.g. module (start and end point) or products included)
Grade "A" Aseptically processed and packaged Milk

Description of Scope of Study
Provide a short description about the processes and product.

Scheduled or unscheduled review: Main changes / reasons / causes
ISO 22000/FSSC 22000 Review

Scheduled or Unscheduled Review:
Provide the HACCP review history, including type (scheduled or (unscheduled)). For unscheduled reviews, indicate the reason.

HACCP Team Members		
Name	Responsibility / Role / Expertise	Department / Company
G Moran	Food Safety Manager	Food Safety/QA
O Brown	Hygienist/Microbiologist	Hygienist
M Rodrigues	Milk Processing Manager	Milk Processing
B Jackson	Laboratory Manager	Laboratory
D Smith	Warehouse Manager	Warehousing
O Murphy	Engineering Manager	Engineering
C Flack	Factory Manager	Management
N Williams	Veterinary	Food Safety/QA

HACCP Team Members
Provide details on HACCP team members.

Authorisation for new HACCP study or update to new version		
Factory Manager	C Flack	Date: 15-02-2015

Complete the section below on completion of the HACCP study

Planned Modification(s) according to HACCP study		
Modification N°	Provisional Control Measure(s) for immediate application	Dead-line
		Date:
		Date:
		Date:

HACCP study review	
Next scheduled review - Date:	20-12-2015

HACCP study issue date	
Study issued	Date: 15-02-2015

Authorisation of finished study		
Food Safety Team Leader	G Moran	Date: 12-02-2015
Hygienist/Microbiologist	O Brown	Date: 12-02-2015
Factory Manager	C Flack	Date: 12-02-2015

Instructions:

Authorization of HACCP Study
Indicate name and positions of authorized persons and date of authorization.

Planned Modification
Identify HACCP study issue, next review date, modification number, provisional control measures and deadlines.

Authorization of Completed Study
Authorized persons should sign and date the study.



[WS2] Product/Ingredient Description Worksheet

The product description worksheet provides details of products and processes, including raw material and end-product characteristics. Each product (or a group of similar products) shall be fully specified and documented, including sensitivity to and potential for safety risks. The description of product safety encompasses the food chain, ranging from raw materials used to the distribution of the finished products. The traceability of the raw materials up to and including final supply shall be described. An extensive specification of the end products is required to ensure a comprehensive assessment of the food safety procedures.

End-products specified on the worksheet must clearly reflect the following product details:

- Product name
- Type
- General product specifications, such as appearance and weight
- Specific requirements such as relevant legislation and/or customer requirements
- Raw materials and ingredients used (composition)
- Safety indicators (chemical, microbiological and physical, allergens)
- Product packaging
- Main steps and processing conditions (production method)
- Shelf life and storage conditions
- Safety-related product labeling
- Intended use by consumers / proper use
- Transportation conditions and distribution methods
- Potential for mishandling/misuse of the product
- Target consumer groups
- Other characteristics having an impact on food safety

The description of raw and auxiliary materials which have contact with the food should concisely indicate the following:

- Names of these raw materials, ingredients and auxiliary materials
- Composition
- High-risk ingredients
- Safety indicators (chemical, microbiological and physical, allergens)
- Origin or supplier
- Main stages and processing conditions (production method)
- Methods of packaging and transportation
- Storage conditions and shelf life
- Preparation or processing before use/reprocessing
- Acceptance criteria related to food safety

The column "Source of Information" refers to relevant legislative, regulatory, technological or other documents regulating the requirements specified here. All indicators in this form are provided solely for illustrative purposes. When designing its own specifications, the FBO should give consideration to all indicators relative to existing legislation and regulations and customer requirements, as well as cited features.

A blank [WS2] Product/ Ingredient Description Worksheet is included on the enclosed CD.

End- product Characteristics

Name (product(s), product group(s), line)	Grade 'A' Aseptically Processed and Packaged Milk
Composition	Cow Milk
Type (e.g. raw, cooked, ready to eat)	Ready to Eat
Key physical, biological and chemical characteristics	Chemical Parameters: Heavy metals: Lead, mg / kg, not more than 0.1 Arsenic, mg / kg, not more than 0.05 Cadmium, mg / kg, not more than 0.03 Mercury, mg/kg, not more than 0.005 Antibiotics: Chloramphenicol is not allowed Tetracycline group is not allowed Streptomycin is not allowed Penicillin is not allowed Inhibitory substances are not allowed Melamines are not allowed Radionuclides: Cs-137 Bq / kg, not more than 100 Sr-90, Bq / kg, not more than 37
	Biological Parameters: <ul style="list-style-type: none"> • Mesophilic aerobic and facultative anaerobic microorganisms - no more than -100,000 cfu / g • (coliforms) in 0.1 - are not allowed • Pathogens including Salmonella spp 25.0 g - not allowed • Staphylococcus aureus in 1.0g - not allowed • Listeria in 25.0 g - not allowed
	Physical Parameters: Group purity - not less than 1 Particles of mechanical impurities are not allowed
Key processing steps (e.g. drying, heat treatments, freezing)	Storage, Clarifier/Seperator, Normalization, Pasteurization, Filler, Storage, Distribution/Logistics
Other	

Instructions:

End-product characteristics

Complete details of product or product family name, type, physical and chemical characteristics, key processing steps and other characteristics. Indicate details of raw materials, high risk ingredients, packaging materials, rework, and other characteristics.

Specifications and Regulatory requirements (food safety related)

Product specifications	JB-0346-7654-A
Product specific regulatory requirements	PMO 2005

Specifications and regulatory requirements (food safety related)

Indicate details of product specifications and regulatory requirements.

Filling and Packing

Packaging description (e.g. size)	High density polyethylene gallon container with a polypropylene snap-on screw tamper evident cap
Packaging system (e.g. modified atmosphere)	Aseptic packaging

Filling and packaging

Complete details of packaging and packaging system requirements.

Claims and Label Information

Instruction for use by consumers (incl. use or storage after opening)	Keep refrigerated, Grade 'A' pasteurized, homogenized, vitamin A and D added, 30% less fat than regular milk
Statements for safe use (e.g. allergen info, special instruction for safe handling)	Shelf life - 7 days; storage temperature not to exceed +6 degrees C - 24 hours
Other	Date of manufacture

Claims and label information

Complete details of product claims and label information.

Distribution / Storage / Description	
Distribution instructions (e.g. ambient, chilled, frozen)	Product is cased in standard milk cases - four units per case, using refrigerated trucks from 0 degrees C to + 20 degrees C
Storage instructions (e.g. ambient, chilled, frozen)	Distributed using refrigerated trucks from 0 degrees C to + 20 degrees C in a vehicle fitted out for the shipment of food for the wholesale and retail trade
Shelf life conditions	Storage conditions at temperature from 0 degrees C to + 20 degrees C. Shelf life - 7 days
Other	Not applicable

Distribution/storage/description
 Complete details of distribution, storage, shelf-life and other conditions.

Use by Consumers	
Intended use	Ready to serve product. May also be used as an ingredient in preparing meals
Target group of users and special consumer considerations (e.g. infants, elderly)	Consumers of all ages consume this product
Reasonably expected mishandling and misuse	Not stored under proper refrigeration

Use by consumers
 Supply details of intended use, special consumer groups, and reasonably expected mishandling and misuse.

Incoming Material Characteristics

Name of raw materials, ingredients	Cow milk
Composition	Cow milk
High-risk ingredients	Cow's milk - a hospitable environment for the development of microorganisms (lactic acid bacteria, streptococci, coliforms, putrefaction bacteria, Salmonella spp among others)

Name all raw materials, ingredients, food and contact materials.

Composition
 Specify ingredients, including food additives and processing aids.

High-risk ingredients (e.g., allergens, microbiological or dangerous raw materials, sources of foreign bodies)
 Provide a list of high-risk ingredients: allergens (celery, corn, eggs, citrus, pumpkin, legumes, peanuts, soybeans, milk, seafood, sesame, tree nuts, wheat); microbiological hazards (Salmonella spp.; Clostridium botulinum; Staphylococcus aureus; Yersinia enterocolitica; Listeria monocytogenes; Vibrio spp.; Escherichia coli O157:H7; Clostridium perfringens; Bacillus cereus; Campylobacter spp.; Shigella spp.); sources of foreign bodies: packaging, material, transport, product type.



Key physical, biological and chemical characteristics	<p>Chemical Parameters:</p> <p>Toxic elements:</p> <ul style="list-style-type: none"> • Lead, mg / kg, not more than 0.1 • Arsenic, mg / kg, not more than 0.05 • Cadmium, mg / kg, not more than 0.03 • Mercury, mg / kg, not more than 0.005 <p>Pesticides:</p> <ul style="list-style-type: none"> • Hexachloran α, β, γ isomers), mg / kg, not more than 1.25 (in terms of fat) • DDT and its metabolites, mg / kg, not more than 1.0 (in terms of fat) <p>Radionuclides:</p> <ul style="list-style-type: none"> • Cs-137, Bq / kg, not more than 100 • Sr-90, Bq / kg, not more than 3.7 <p>Inhibiting substances are not allowed</p> <p>Antibiotics:</p> <ul style="list-style-type: none"> • Chloramphenicol is not allowed • Tetracycline group is not allowed • Streptomycin is not allowed • Penicillin is not allowed 	<p>Key physical, biological and chemical characteristics</p> <p>Properties or characteristics of the product are important in determining its safety. These can be physical (particle size, porosity, weight, etc.), chemical (pH, water activity, acidity, etc.) or microbiological (content CFU/g) characteristics.</p>
	<p>Biological Parameters:</p> <p>Number of somatic cells, thousand/cm³,</p> <ul style="list-style-type: none"> • Mesophilic aerobic and facultative anaerobic microorganisms - no more than 100,000 cfu / g (coliforms) in 0.1 - are not allowed • Pathogens including Salmonella spp 25.0 g - not allowed • Staphylococcus aureus in 1.0g - not allowed • Listeria in 25.0 g - not allowed 	
	<p>Physical Parameters:</p> <p>Density, kg/m³, at least 1028</p> <p>Group of purity - not less than 1</p> <p>Particle mechanical impurities not allowed</p>	
Supplier	Dairy Farm World of Milk	<p>Supplier</p> <p>Specify raw material supplier.</p>
Processing main steps and conditions (production method)	Obtained during the mechanical milking of cattle, followed by cooling to +6 °C	<p>Main stages and conditions (method of production) such as drying, heat treatment, and freezing</p> <p>Specify processes to block the occurrence, reproduction or survival of microorganisms.</p>
Packing and transportation containers	Closed tightly-sealed transportation containers (stainless steel tanks); food rubber gaskets used in sealing the lids	<p>Packaging materials in contact with food</p> <p>Specify the type of material in contact with food.</p>
Storage conditions and shelf life	Storage temperature not to exceed +6 °C. 24 hours	<p>Storage conditions and shelf life</p> <p>Specify shelf life and appropriate storage conditions for raw materials.</p>
Preparation and/or processing before use	Filtering, cooling	<p>Preparation and/or processing before use</p> <p>Specify stages of preparation or processing of raw materials prior to use to minimize food hazards.</p>
Acceptance criteria related to safety	<p>Temperature when accepted of not more +10 °C</p> <p>Availability of veterinary certificate</p> <p>Test for the absence of antibiotics (chloramphenicol, tetracycline group, streptomycin, penicillin)</p> <p>Group of purity- not less than 1</p> <p>Particles of mechanical impurities are not allowed</p>	<p>Acceptance criteria related to safety</p> <p>Specify safety criteria of raw materials checked by the company at acceptance.</p>
Other (e.g preservatives, processing aids, services)	Not applicable	<p>Other</p> <p>Specify other relevant information, if any.</p>

[WS 3] Flow Diagram Worksheet

This worksheet illustrates the product production process within an HACCP system.

The flow diagram should be constructed by the HACCP team and should cover all operational steps pertaining to a specific product. The same flow diagram may be used for any number of products manufactured by similar processing.

Prepare flow diagrams for the products or process categories covered by the HACCP system. Flow diagrams should provide a basis for evaluating the possibility of an occurrence, increase or introduction of food safety hazards.

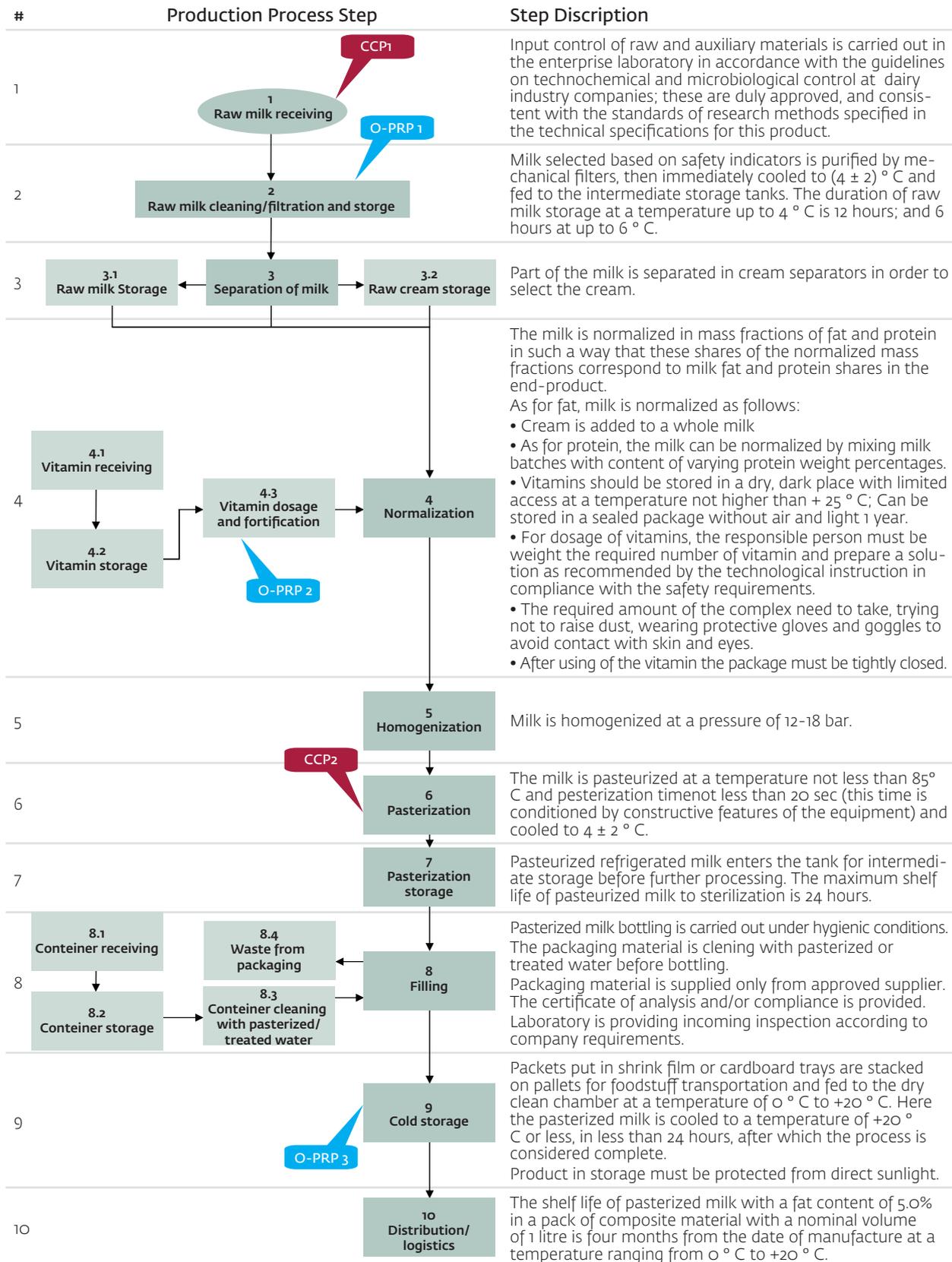
The flow diagrams need to take into account the relevant process steps, their sequence and how they relate to each other. If work is subcontracted or outsourced, it should be indicated in the flow diagram.

The flow diagram should detail the introduction of raw materials or ingredients. If rework is an option in the process or recycling, these steps need to be included. Finally, waste, by-products, intermediate and end-products should be included in the flow diagram. The accuracy of the flow diagrams and layout shall be verified by the HACCP/Food Safety Team. This verification shall be repeated periodically (at least annually) to identify and document modifications to process installation and layout. The FBO needs to make diagram for all process steps, including all control steps (CCP), with specific parameters. In parallel with the flow diagram, the document and person responsible should be identified for most flow diagram steps. It is important to include steps such as waste treatment, CIP systems, re-processing in the flow diagram:

- 1:** Construct a flow diagram of the process
- 2:** Number each step in the process
- 3:** Indicate CCP when HACCP system study is finished
- 4:** Indicate OPRP when HACCP system study is finished
- 5:** Record on-site verification of flow-diagram

To complete this Worksheet, information can be found in following system documents:

- Codex Alimentarius Standard Commission
- CAC/RCP 1-1969, Rev.4-2003 General principles of Food Hygiene
- Food Safety System based on ISO 22000



Authorization

Name	Position / responsibilities in the team	Signature	Date	The document should be approved on-site after the flow diagram check is completed
G Moran	Food Safety Manager, HACCP Team Leader	Signature	02.01.2015	This document should be verified on-site after the flow diagram check is completed

[WS 4] Hazard Identification and Description Worksheet

The hazard identification and description worksheet identifies each potential hazard and determines its significance by the severity of the potential health effect and likelihood of occurrence. Whenever the FBO changes in a manner that could adversely affect food safety, all relevant steps of the hazard analysis should be updated.

Hazard Identification

The FBO (HACCP/Food Safety Team) shall identify and document all potential biological, chemical and physical hazards that can have an adverse effect on product safety. The identification shall include all aspects of operations within the scope of the HACCP/FSMS system.

The hazard identification shall include:

- Raw materials and ingredients: specifications, process control at suppliers;
- Characteristics of interim and end products: intrinsic product specifications;
- Characteristics of used processes, including subcontracted services;
- Prerequisite program (PRP), including aspects including:
 - Layout of the facility, production lines, installations and equipment;
 - Location of rooms, routing, storage and separation of raw materials, interim products, end products, ventilation;
 - Production processes such as purchasing, cleaning and disinfection, packaging, maintenance, pest control, and waste management;
 - Personnel (including arrangements for visitors and external service providers, e.g. mechanics): hygiene, knowledge with regard to food hygiene and food safety, requirements to provide notification of diseases and infections.

Hazard Analysis (Risk)

The FBO (HACCP/Food Safety Team) shall conduct a hazard analysis to identify hazards that should be eliminated or reduced and controlled to ensure the safe production of food. The hazard analysis should include the probability of hazard occurrence and severity of adverse health effects.

A blank [WS 4] Hazard Identification and Description Worksheet is included in the enclosed CD.

Location of potential hazard		Hazard Description					
Indicate the step (e.g. raw mtrl, processing or distribution) at which the hazard may be introduced.		Describe clearly and specifically the hazards that are reasonably expected to occur at each step: class (M, P, C or A), agent, size, origin, nature, etc.					
Step No:	Step (description)	H #	Hazard	Class	Origin or source of the hazard (e.g. where and how it can be introduced into the product or its environment)	Nature of the hazard (e.g. presense, ability to grow, survive, formation of toxins or toxic chemicals, migration of chemicals)	
1	Raw Milk Receiving	C	Therapeutic drugs (antibiotics)	C1	Primary milk production [farm]	Presence	
1	Raw Milk Receiving	C	Toxic elements (heavy metals)	C3	Primary milk production [farm]	Presence, introduction	
1	Raw Milk Receiving	B	Salmonella, Staphylococcus aureus, L monocytogenes, Listeria, Shigella	B1	Primary milk production [farm], transportation	Presence, introduction	
1	Raw Milk Receiving	P	Extraneous material (stone, glass e.g.)	P1	Primary milk production [farm], transportation	Presence	
1	Raw Milk Receiving	A	Allergen	A1	Primary milk production [farm], transportation	Presence	
6	Pasteurization	B	Pathogenic microorganisms salmonella, S Aurus, L monocytogenes	B1	Primary milk production [farm], personnel, work environment	Survival	
		C	Absence	--	-----	--	
		P	Absence	--	-----	--	
A	B	C	D	E	F	G	

Instructions:

Step #	Step Description	Hazard class	Hazardous agent description	Hazard #	Origin or source of the hazard	Nature of the hazard	
Defines sequential number for each process step	Defines the title or description of the process step	Defines the hazard agent class: B - biological C - chemical P - physical A - allergen	Defines the hazard controlled by the measure	Defines the hazard agent code: B1; C1, P	Defines where and how the product or environment can be contaminated	Defines particular hazard threats (e.g., availability, capacity for growth, survival, allocation of toxins or toxic chemicals, migration of chemicals)	

		Hazard Assessment			Justification for Selection of Hazards and Assessment
		Q1: Based on the hazard description, likelihood of occurrence (before applying the control measure) and severity of health effects, does this hazard need to be controlled, i.e. is it a significant hazard?			Provide supporting data/references on likelihood of occurrence, information on severity of health effects and acceptable level in end product.
Acceptable level in end product	Likelihood of occurrence	Severity of adverse health effect	Significant hazard? (Yes/No) For significant hazard, select and categorize control measure(s) on WS 5		For each hazard, document why it is or why it is not likely to occur or causing adverse health effects. For non significant hazards document if it is managed e.g. by a PRP, through a specification or Major Allergen Declaration (MAD) Make sure that all hazards likely to occur are considered Justify why a certain hazard has been disregarded
Absence	Frequent [4]	Can cause fatality [5]	Significant [20]		Hazard likelihood is frequent, antibiotics used to treat animals.
Lead, mg / kg, not more than 0.1 Arsenic, mg / kg, not more than 0.05 Cadmium, mg / kg, not more than 0.03	Could occur [2]	Can cause illness [3]	Insignificant [6]		Last two years there were not identified heavy metals in incoming milk. This hazard is controlled by the prerequisites programs for the analysis of incoming raw materials and finished products.
Absence	Rare [1]	Can lead to serious illness [4]	Insignificant [4]		Hazard is controlled by PRP [Incoming raw material] and finished product].
Absence	Could occur [2]	Can cause illness [3]	Insignificant [6]		Taking into account a moderate level of hygiene in primary milk production on the farm, there is a remote probability of encountering foreign objects in milk.
Always presence	Rare [1]	Can lead to serious illness [4]	Insignificant [4]		This hazard is controlled by the prerequisites programs - allergen control procedure and mention in the label as cow's milk.. This hazard is not insignificant for a consumer who may suffer from the allergy.
Absence	Could occur [2]	Can lead to serious illness [4]	Significant [8]		Pasterization can be violated by the survival probability of microorganisms in the milk, creating a severe health hazard.
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H	I	G	K		L

Acceptable level in end product Defines acceptable level of hazard as required by law or customer specifications	Likelihood of occurrence Defines the likelihood of hazard occurrence	Severity of adverse health effect Defines the severity of any adverse health effect arising from the hazard	Significant hazard Defines whether the hazard is significant or not. For significant hazards, select and categorize control measure(s) on HACCP Hazard Assessment Worksheet	Justification of hazard selection and assessment Defines why it is or is not likely to occur, and cause, or not cause, adverse health effects
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[WS 5] Control Measure Selection and Categorization

The control measures selection and categorization worksheet categorizes the control measures and states whether they should be managed through operational PRPs or by the HACCP plan.

The HACCP/Food Safety Team shall identify and document the control measures to be applied or implemented when the hazard identification and hazard analysis concludes that the risk of an identified hazard is significant and needs to be eliminated or reduced and controlled at an acceptable level.

The HACCP/Food Safety Team shall conduct an assessment of every step in the process using a decision tree. The assessment shall be based on the differing expertise within the team and shall utilize external and internal information.

For each step, including all products, processes and parts of the PRP, the assessed aspects shall be identified. The reasons for deciding whether it is a CCP (critical control point) or not shall be documented and traceable.

Step and Hazard				Control Measures
Transfer hazards considered significant in the hazard assessment in WS 4 to this worksheet (WS 5).				Select and describe a control measure or combination of control measures capable of preventing, eliminating or reducing the hazard to an acceptable level. Document the rationale for the selection, e.g. effectiveness of applied control measures alone or in combination against identified hazard (refer to documents if possible)?
Step #	Step description"	H #	Hazard	Description of control measures
1	Raw Milk Receiving	C1	Therapeutic Drugs (antibiotics: chloramphenicol, tetracycline family, streptomycin, penicillin)	Control of raw milk to assure the absence of antibiotics using express method (Delvotest)
2	Raw Milk Filtration	P1	Extraneous Foreign Material- glass	PRP [Incoming Raw Material] -Filtering and purity control of raw milk
—	—	—	—	—
6	Pasteurization	B1	Pathogenic Micro Organisms	Pasteurization
—	—	—	—	—
8.3	Container cleaning with pasteurized/treated water	B1	E.coli	There are no control measures
A	B	C	D	E

Instructions:

Step #	Step description	Hazard #	Hazardous agent description	Description of control measures
Defines sequential number for each process step	Defines the title or description of the process step	Defines the hazard agent code: B1; C1, P,	Defines the hazard controlled by the measure	Describes the control measure / combination of control measures taken to prevent hazards, eliminate or reduce them to an acceptable level

More than one control measure may be required to control a hazard, and more than one hazard may be controlled by a control measure.

Classification of control measures:

- a) Prerequisites Programs (PRP)
- b) Operational Prerequisites Programs (O-PRP)
- c) HACCP plan

Each field in this worksheet contains instructions/guides as to the information or rating to be entered in the relevant fields.

The worksheet also contains a number of questions with answer options, where the significance of selecting each answer is explained.

A blank [WS 5] Control Measure Selection and Categorization Worksheet can be found on the enclosed CD.

Categorization of Control Measures in OPRPs and CCPs - answer questions Q1 to Q5 as necessary								
<p>Q1: Based on the likelihood of occurrence (before applying the control measure) and the severity of adverse health effects (WS 4), is this hazard significant (needs to be controlled)? YES: This is a significant hazard. Go to Q2. NO: This is not a significant hazard.</p> <p>Q2: Will a subsequent processing step, including expected use by consumer, guarantee the removal of this significant hazard, or its reduction to an acceptable level? YES: Identify and name subsequent step. NO: Go to Q3.</p> <p>Q3: Are control measures or practices in place at this step, and do they exclude, reduce or maintain this significant hazard to/at an acceptable level? YES: Go to Q4. NO: Modify the process or product and go to Q1.</p> <p>Q4: Is it possible to establish critical limits for the control measure at this step? YES: Go to Q5. NO: This hazard is managed by an OPRP.</p> <p>Q5: Is it possible to monitor the control measure in such a way that corrective actions can be taken immediately when there is a loss of control? YES: This hazard is managed by the HACCP-plan (CCP). NO: This hazard is managed by an OPRP.</p>								
Q1	Q2	Q3	Q4	Q5	CCP / OPRP / MOD	Justification Provide supporting evidence that that selected control measure(s) and target/critical limits will adequately control the hazard.		
Yes	No	Yes	Yes	Yes	CCP 1	Express method allows testing for each batch of raw materials and detection of antibiotics in dairy raw materials		
Yes	No	Yes	Yes	No	O-PRP 1	Filtration of milk by filter with a cell diameter of 0.01mm enables prevention of impurities in milk		
—	—	—	—	—	—	—		
Yes	No	Yes	Yes	Yes	CCP 2	Pasteurization destroys some pathogenic micro organisms in milk, or at a minimum reduces their number to an acceptable level - absence in 25 mg		
—	—	—	—	—	—	—		
Yes	No	No	—	—	Process modification	Process change needed; use pasteurized or additionally purified water		
F					G		H	

Categorization of control measures in OPRPs and CCPs. Answer questions Q1 to Q5 as necessary Provides questions the HACCP team should answer, giving a range of possible responses	CCP/O-PRP/process modification Identifies the category of control measure selected	Decision justification Notes the rationale behind the choice of a measure / combination of control measures
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[WS 6] Validation of Control Measures Worksheet

The purpose of the validation of control measures worksheet is to provide the evidence that the control measure can achieve the targeted limits. It questions the organization as to the effectiveness of the controls that has in place to address each hazardous agent.

Each field in this worksheet contains instructions/guides as to the information or rating to be entered in the relevant fields.

The worksheet contains a number of questions that prompt for the type of information required.

A blank [WS 6] Validation of Control Measures Worksheet can be found on the enclosed CD.

CCP N° OPRP N°	Step	Hazardous agent	Control measure	Justification for the Selection of Control Measures	
CCP 1	1	Therapeutic Drugs: antibiotics: tetracycline group, penicillin, streptomycin, chloramphenicol	Control of raw milk for the absence of antibiotics using the Delvo test	Rapid test allows quick determination of the presence of antibiotics in raw materials. This methodology is approved and ensures test accuracy and reliability	
O-PRP 1	2	Extraneous foreign material	Filtration and purity control of raw milk	Filtration of milk on a filter cell with a diameter of 0.01 mm enables the prevention of impurities in the finished product	
CCP 2	6	Pathogenic microorganisms, including Salmonella S. aureus, L. monocytogenes	Pasteurization	Pasteurization destroys some pathogenic microorganisms in the milk or reduces their numbers to an acceptable level	
A	B	c	D	E	

Instructions:

CCP N° OPRP N°	Step #	Hazardous agent description	Control measure	Justification for the selection of control measures	
Defines CCP and O-PRP numbers	Defines sequential number for each process step	Defines the hazard controlled by the measure	Defines the control measures selected for this hazard	Defines whether the control measure functions in practice	

The HACCP team has to provide, or ask for, evidence that selected control measures are capable of achieving the intended control for identified hazards.

The HACCP Team Leader shall provide answers to the following questions:

- Have potential hazards been correctly identified as significant or not?
- Are applied control measures capable of reducing the significant hazards to an acceptable level?
- Are critical limits correct and appropriate?
- Will the corrections restore product’s safety control?

	Checking Control Measure Effectiveness	Critical Limits (for CCP only)	Justification for the Selection of Critical Limits	Corrections
	Monthly check using ELISA or HPLC method	Absence	Legislation for raw milk	Return to supplier or disposal of milk
	Determination of purity according to the standard	Not applicable	Not applicable	Not applicable
	Monthly microbiological analysis of the product	Pasteurization temperature not less than 85 ° C, time-not less than 20 sec	Technological instruction of pasteurized milk	Flow divert and re-pasteurization
	F	G	H	I

	Checking control measure effectiveness Defines the extent to which the control measure is effective	Critical limits (for CCP only) Defines the critical limits determined for this CCP	Justification for the selection of critical limits Defines the basis for determining the relevant critical limits	Corrections Defines the actions necessary to prevent a negative effect on food safety when critical limit is exceeded
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[WS 7] HACCP Plan Including O-PRPs Worksheet

The HACCP Plan (including the OPRP worksheet) provides an overview of all identified CCPs and OPRPs with control measures, limits, corrective actions and identifies the people responsible.

A blank [WS 7] HACCP Plan, including the O-PRPs worksheet, is included on the enclosed CD.

CCP N° OPRP N°	H#	Step #	Step description	Hazard description	Control measure(s)	Critical Limits / Targets (or Limits if applicable)	
CCP 1	C	1	Raw milk receiving	Therapeutic drugs - antibiotics: chloramphenicol, tetracycline family, streptomycin, penicillin	Control of raw milk for the absence of antibiotics using the express method (Delvotest)	100% absence	
O-PRP 1	P	2	Raw milk filtration	Extraneous foreign material - glass	Raw milk filtering and purity control	Not applicable	
CCP 2	B	6	Pasteurization	Pathogenic microorganisms, including <i>S. Aureus</i> , <i>L. monocytogenes</i>	Control of temperature and pasteurization timing	Pasteurization temperature not less than 85° C , time not less than 20 sec	
A	B	C	D	E	F	G	

Instructions:

CCP N° OPRP N°	Hazard class	Step #	Step description	Hazardous agent description	Control measure	Critical limits	
Defines CCP and O-PRP numbers	Defines the hazard agent class: B - biological C - chemical P - physical A - allergen	Defines sequential number for each process step	Defines the title or description of the process step	Defines the hazard controlled by the measure	Defines the control measures selected for this hazard	Defines the critical limits determined for this CCP	

	Monitoring How, frequency, who?	Corrections, Responsibilities	Corrective actions Responsibilities	Records	Verification (details in WS 8)
	Delvotest, each batch, by quality specialist	Return of milk to supplier or environmental disposal of product/ procurement manager	Inform dairy farm and veterinary service provider, identifying reasons for therapeutic drugs use/ quality manager	Raw milk receiving log	Control by IFA methods monthly from each supplier, laboratory technician
	Determination of purity according to standard, each batch, quality specialist	Repeated filtering by quality specialist	Unannounced audit of supplier co-ordinated by the quality manager	Filtering and cooling log	Checking of cooling log by laboratory manager
	Automatic registration of pasteurization temperature and time, visual inspection of temperature indicator, continuously, by the pasteurization operator	Stopping milk supply for filling, backflow and re-pasteurization of milk by pasteurization operator	Checking technical condition of the device; checking monitoring and metering the instrument; pasteurization training for operator / mechanical engineer, HR manager	Pasteurization log, thermogram	Parameter control of reference thermometer hourly by shift foreman and control of thermometer every shift by microbiologist
	H	I	J	K	L

	Monitoring how, frequency, who? Defines the monitoring method, its frequency and the person responsible	Corrections, responsibilities Defines the actions necessary to prevent a negative effect on food safety when critical limit is exceeded; also identifies the person responsible	Corrective actions responsibilities Defines actions necessary to eliminate reasons for exceeding critical limits to prevent their repeated occurrence	Records Defines the records to be maintained	Verification (details in WS 8) Defines the verification of conducted actions
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[WS 8] Verification Plan Worksheet

The verification plan worksheet provides an overview of verification activities showing that the CCPs and OPRPs have been implemented properly.

The FBO must establish, document and implement procedures for verification of the HACCP system. The main purpose of verification is to determine compliance with the specifications of the HACCP system and to confirm that the system is working effectively through the application of (auditing) methods, procedures, tests (including random sampling and analysis) and other evaluations, in addition to monitoring.

Verification procedures should be established, documented, and should include as a minimum:

- Purpose;
- Methods, standard operating procedures or tests applied;
- Tasks and responsibilities;
- Frequency;
- Records.

These procedures shall address, as a minimum, the following topics:

- Review of the HACCP system and its corresponding records;
- Analysis of any product recalls and product dispositions;
- Assessment of all general control measures, nonconformities and corrective actions taken to confirm effective control of CCPs;
- Assessment of all general control measures to seek confirmation of implementation and to demonstrate effective control of associated hazards;
- Conformity of the actual flow diagrams and layout with the documented situation;
- Conformity of O-PRP and CCP documents with the operational situation;
- Analysis of customer and consumer complaints related to hygiene and food safety;
- Review of analytical outcome of random sampling and analysis of products;
- Evaluation of compliance in the context of applicable legislation and regulations (as well as with foreseeable changes in legislation and regulations), and identification of changes in legislation and regulations concerning food safety;
- Review of gaps between current and target levels of knowledge, awareness and staff training with respect to hygiene and food safety, and the results in terms of effective (on the job) training sessions;
- Consistency of the current documentation.

A blank [WS 8] verification plan worksheet is included on the enclosed CD.

CCP No: or O-PRP No:	Verification Activity (e.g. of CCP monitoring or OPRP functioning, corrective actions)	Verification Procedure (e.g. methods or procedures to use, observations to be made or measurements to be taken, actions if there is a deviation or follow-up)	Frequency (how often is the task to be performed)	Responsible (who is responsible for the task)	Records (which records should be used)
CCP 1	Verify the input and efficiency control of raw milk in the absence of therapeutic drugs	Selective periodic monitoring and control of records	Monthly for each supplier and weekly	FS Manager Laboratory Manager	Register of input control Laboratory technician workbook
O-PRP 1	Monitor implementation of the raw material filtration procedure and its effectiveness	Periodic control of cleaning process and records for cleaning and cooling	Weekly	Laboratory Manager	Cleaning and cooling Register
CCP 2	Verifying milk pasteurization, its effectiveness and efficiency	Periodic control of pasteurization temperature and time Periodic control of thermograms; Peroxidaze test	Control of reference thermometer parameters - hourly Control of thermograms - every shift Peroxidaze test - every shift	Shift Supervisor Microbiologist Quality Specialist	Milk pasteurization register Thermogram Peroxidaze milk test register
A	B	C	D	E	F

Instructions:

CCP N° OPRP N°	Verification activity	Verification procedure	Frequency	Responsible	Records
Defines CCP and O-PRP numbers	Defines the purpose of the verification	Defines the methods or procedures to use, observations to be made or measurements and actions taken if there is a deviation or follow-up	Defines the frequency with which verification should be conducted	Defines individual and/or department/function responsible for conducting verification	Defines the records to be maintained



[WS 9] Modifications and Follow-Up Worksheet

The modification and follow-up worksheet details any modifications to the plan and outlines/tracks any follow-up that may be required.

This worksheet references details regarding process steps and hazards.

A blank [WS 9] modifications and follow-up worksheet blank is included in the enclosed CD.

Production Process Steps		Hazard Description		Modification			Provisional Control Measure(s)
Step #	Step Description	Hazard #	Hazardous Agent Description	Modification N°	Recommended Modification and Confirmation of Transfer for Action	Limit date	Immediate measures to be applied while modifications are not yet implemented
8	Filling	P1	Foreign Body	2	Implement control of the packaged milk with x-ray detector to reveal foreign bodies	20-2-2015	None
8,3	Handling containers with water	B1	E. Coli	1	Used for rinsing containers pasteurized or additionally purified water	20-2-2015	Increased to weekly the frequency of microbiological control of water used
A	B	C	D	E	F	G	H

Instructions:

Step #	Step description	Hazard #	Hazardous agent description	Modification #	Recommended modification and confirmation of transfer to for action	Limit date	Provisional control measure(s)
Defines sequential number for each process step	Defines the title or description of the process step	Defines the hazard agent code: B1, C1, P, A	Defines the hazard controlled by the measure	Defines the modification number	Defines the recommended modification and confirmation of information to be transferred to relevant department/group for action	Defines the planned date for corrective action	Defines the immediate provisional (containment) control measure to be applied when modifications are not yet implemented

[WS 10] Meeting Summary Worksheet

The meeting activity log worksheet records meetings, attendances and decisions made by the team.

Meetings of HACCP/Food Safety Team enable the the entire team to be informed about implementation and effectiveness of their food safety system. They are an important means of information transfer.

Every HACCP/Food Safety Team should have regularly scheduled meetings. In the case of unpredicted events, the HACCP/Food Safety Team may have unscheduled meetings.

A blank [WS 10] meeting summary worksheet is included in the enclosed CD.

Date	Participants	Purpose	Outcome (decisions/actions)	Responsibility	Performed
1-Feb-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack N Williams	Review/update the product description	Updated the product description	G Moran	5-Feb-15
12-Dec-15	G Moran O Brown M Rodrigues B Jackson D Smith O Murphy C Flack N Williams	Verify the flow-diagram, compare document versus practice	No action required	G Moran	20-Dec-15
A	B	C	D	E	F

Instructions:

Date	Participants	Purpose	Outcome	Responsibilities	Performed
Shows meeting dates	Lists those HACCP team members (and invitees) attending	Details the reasons for the meetings	Details decisions made at the meeting (for example, next steps)	Identifies the individuals responsible for executing decisions	Shows actual completion dates



[WS A] Hazard Agent Codes and Classification Worksheet

Hazard agents codes and classification worksheets enable coding and classification of potentially hazardous agents.

This is an optional activity in the implementation of the HACCP toolkit.

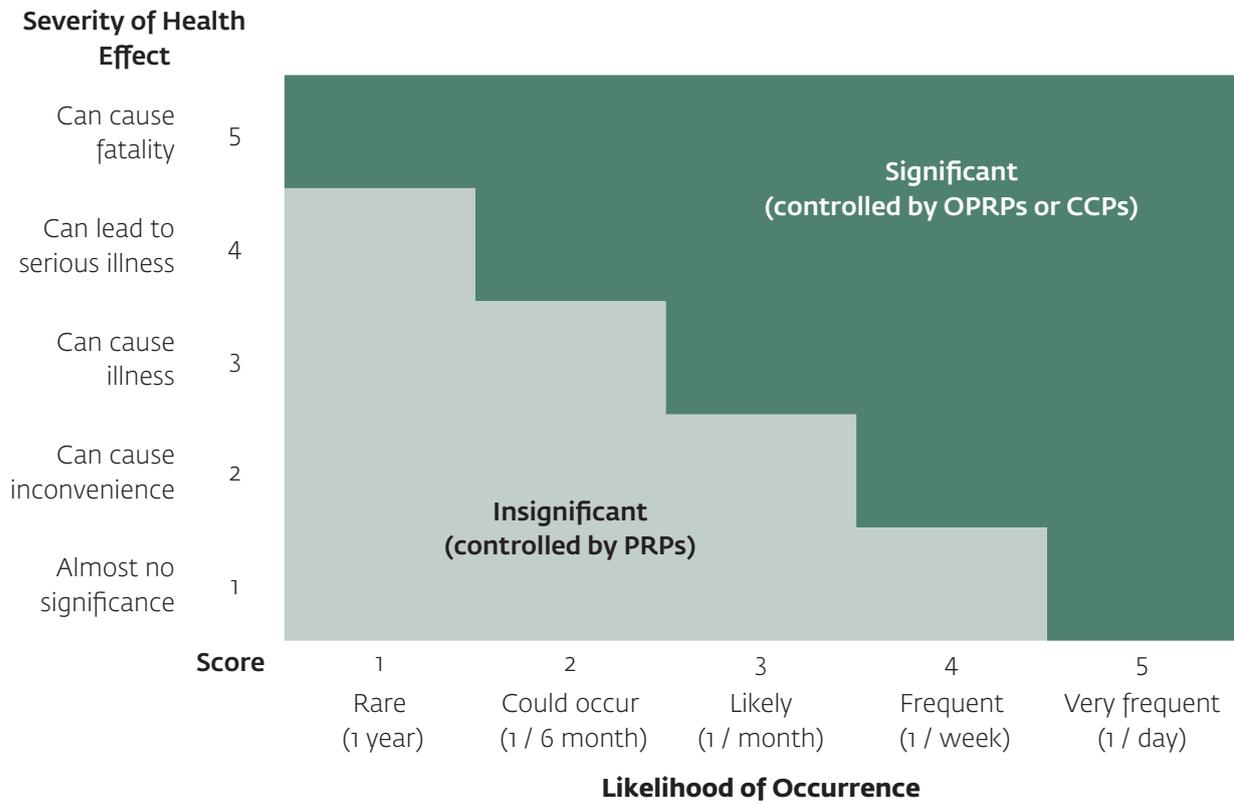
Ingredient or Process	H #	Hazard Class	Hazardous Agent Description
Raw milk	B1	Biological	Presence of vegetative pathogens (Salmonella, Staphylococcus aureus, L monocytogenes, Listeria, Shigella)
	C1	Chemical	Presence of therapeutic drugs - antibiotics: chloramphenicol, tetracycline family, streptomycin, penicillin
	C2	Chemical	Presence of mycotoxins
	C3	Chemical	Presence of toxic elements (heavy metals)
	P1	Physical	Extraneous material (not less than 2mm- glass, stone...)
Pasteurized milk	A1	Allergen	Allergy to cow milk protein
	B1	Biology	Presence of vegetative pathogens
Other ingredients/ packaging materials	B2	Biology	Contamination of vegetative pathogens
	B1	Biological	Presence of vegetative pathogens
	C1	Chemical	Presence of toxic or carcinogenic substances
Water	P1	Physical	Extraneous material
	B1	Biological	E.coli
A	B	C	D

Instructions:

Ingredient or process	H #	Hazard class	Hazardous agent description
Details of the ingredient or process	Defines the hazard agent code: B1; C1, P,	This column defines the hazard agent class: B – biological C – chemical P – physical A – allergen	Defines the hazard controlled by the measure

[WS B] Hazard Assessment Table

The guidance table for worksheets provides guidance for the FBO HACCP/Food Safety Team when assigning risk associated with each hazard type. The risk table is based on ISO 31000:2009 and ISO 2000:2005.



The Hazard Assessment Table helps to separate significant from non-significant hazards and to document the decision:

[WS C] List of Supporting Documents Worksheet

This worksheet records and files supporting information relevant to the HACCP system.

Registration must include the list of current foreign and local legal and regulatory requirements for food safety, including those relating to raw materials, services and products, and applicable codes of practice, along with customer requirements (and any additional requirements) related to food safety products.

No.	Document Title and Designation	Status and Issue of the Document	Document Developer	Filing Location
1	ISO 22000–2005	Valid from 01.09.2005, first edition	ISO	Standardization and Certification Office
2	Enterprise standard IMS 008 "Purchases of Raw and Auxiliary Materials"	Valid from 01.01.2011, first edition	Head of Procurement and Logistics	Standardization and Certification Office
3	Sanitary norms, rules and hygienic standards "Hygienic Requirements for Quality and Safety of Food Raw Materials and Food Products," approved by the Ministry of Health dated of 09.06.09 No. 63	Valid from 09.06.2009	Ministry of Health	Standardization and Certification Office
A	B	C	D	E

Instructions:

Sequential number	Document title and designation	Status and issue of document	Document developer	Filing location
Provides the sequential number assigned to each document in the register	Indicates the document number and title	Indicates the date published and, if needed, the document issue.	Identifies the document author or publisher	Records the location of the document



FSMS Procedures and Documentation

MODULE 5



Documentation Overview

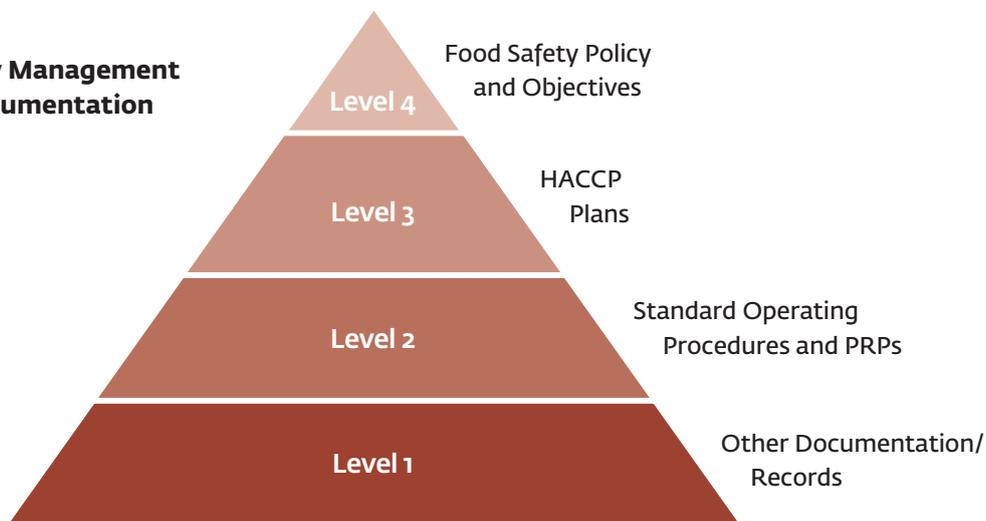
Introduction

The seventh and final principle of HACCP is to establish effective record-keeping procedures that document the food safety management system. Maintaining complete and accurate records is essential to ensure effective monitoring of the Food Safety Management System and demonstrate compliance with food safety requirements.

The structure of the documentation used in the Food Safety Management System is hierarchical, which facilitates the distribution, maintenance and understanding of the documentation.

Figure 1 illustrates a typical hierarchy of HACCP documentation. The development of a hierarchy depends on the circumstances of the organization.

Figure 1
Food Safety Management System Documentation Hierarchy



The extent of the Food Safety Management System documentation can differ from one organization to another due to the:

- a) size of the organization and type of activities;
- b) complexity of processes and their interactions; and
- c) competence of personnel.

HACCP documentation may be in any type of media, such as hard copy or electronic media.

Purpose and Benefits

The purposes and benefits of having Food Safety Management System documentation for an organization include, but are not limited to, the following:

- a) Describing the Food Safety Management System of the organization;
- b) Providing information for cross-functional groups so that they may better understand interrelationships;
- c) Communicating management's commitment to food safety to employees;
- d) Helping employees understand their role within the organization, thus giving them an increased sense of the importance and purpose of their work;
- e) Building mutual understanding between employees and management;
- f) Providing a basis for expectations of work performance;
- g) Stating how things are to be done in order to achieve specified requirements;
- h) Providing objective evidence that specified requirements have been achieved;
- i) Providing a clear, efficient framework of operation;
- j) Providing a basis for training new employees and periodic re-training of current employees;
- k) Providing a basis for order and balance within the organization;
- l) Providing consistency in operations based on documented processes;
- m) Providing a basis for continual improvement;
- n) Providing customer confidence based on documented systems;
- o) Demonstrating the capabilities within the organization to interested parties;
- p) Providing a clear framework of requirements for suppliers;
- q) Providing a basis for auditing the Food Safety Management System;
- r) Providing a basis for evaluating the effectiveness and continuing suitability of the Food Safety Management System.

Food Safety Policy and its Objectives

The Food Safety policy and its objectives should be documented either as an independent document or included in the food safety management system. The Food Safety Policy should contain the relevant defined requirements specified by the GFSI Food Safety Scheme.

Food Safety Objectives should be SMART, i.e. Specific, Measurable, Attainable, Realistic and Time bound. Food Safety Objectives should be consistent with the Food Safety Policy and should be consistent with the primary aim of the GFSI Food Safety Scheme, i.e. eliminate or reduce relevant food safety hazards.

Documented procedures

Structure and format

The structure and format of documented procedures (hard copy or electronic media) should be defined by the organization in the following ways: text, flow charts, tables, a combination of the above, or any other suitable method in accordance with the needs of the organization. The documented procedures should contain the necessary information and should contain a unique identification.

Documented procedures may make reference to work instructions that define how an activity is performed.

Documented procedures generally describe activities that cross different functions, while work instructions generally apply to tasks within one function.

Contents

Title

The title should clearly identify the documented procedure.

Purpose

The purpose of the documented procedure should be stated.

Scope

The scope of the documented procedure, including areas to be included or not included, should be described.

Responsibility and authority

The responsibility and authority of people and/or organizational functions, as well as their interrelations associated with the processes and activities described in the procedure, should be identified. These may be described in the procedure in the form of flow charts and descriptive text as appropriate for clarity.

Description of activities

The level of detail may vary depending on the complexity of the activities, the methods used, and the levels of skills and training of people that is necessary in order for them to accomplish the activities. Irrespective of the level of detail, the following aspects should be considered as applicable:

- a) Defining the needs of the organization, its customers and suppliers;
- b) Describing the process steps in terms of text and/or flow charts related to the required activities;
- c) Establishing what is to be done, by whom or by which organizational function: why, when, where and how;
- d) Describing process controls and controls of the identified activities;
- e) Defining the necessary resources for the accomplishment of the activities (in terms of personnel, training, equipment and materials);
- f) Defining the appropriate documentation related to required activities;
- g) Defining the input and output, associated with each process step;
- h) Defining the measurements to be taken.

The organization may decide that some of the above information is more appropriate in a work instruction.

Records

The records related to the activities in the documented procedure should be defined in this section of the documented procedure or in other related section(s). The forms to be used for these records should be identified as applicable. The method required to complete, file and keep the records should be stated.

Appendices

Appendices containing information supportive to the documented procedure may be included, such as tables, graphs, flow charts and forms.

Review, approval and revision

Evidence of review and approval, status and date of revision of the documented procedure should be indicated.

Identification of changes

Where practicable, the nature of the change should be identified either in the document or the appropriate attachments.

Work instructions

Structure and format

Work instructions should be developed and maintained to describe the performance of all work that would be adversely affected by lack of such instructions. There are many ways of preparing and presenting instructions.

Work instructions should contain the title and a unique identification. The structure, format and level of detail used in the work instructions should be tailored to the needs of the organization's personnel and depends on the complexity of the work, the methods used, training undertaken, and the skills and qualifications of such personnel.

The structure of the work instructions may vary from that of documented procedures.

The work instructions may be included in the documented procedures or referenced in them.

Contents

Work instructions should describe critical activities. Details which do not give more control of the activity should be avoided. Training can reduce the need for detailed instructions, provided the persons concerned have the information necessary to do their jobs correctly.

Types of work instructions

Although there is no required structure or format for work instructions, they generally should convey the purpose and scope of the work and the objectives, and make reference to the pertinent documented procedures.

Whichever format or combination is chosen, the work instructions should be in the order or sequence of the operations, accurately reflecting the requirements and relevant activities. To reduce confusion and uncertainty, a consistent format or structure should be established and maintained.

Review, approval and revision

The organization should provide clear evidence of review and approval of work instructions and their revision level and date of revision.

Records

Where applicable, the records specified in the work instruction should be defined in this section or in other related section(s). The minimum food safety records required are identified in the relevant GFSI food scheme. The method required to complete, file and keep the records should be stated. The forms to be used for these records should be identified as applicable.

Identification of changes

Where practicable, the nature of the change should be identified either in the document or the appropriate attachments.

Food Safety Plans

A food safety plan, also often referred to as a HACCP Plan (Hazard Analysis Critical Control Point) is a set of written procedures that will help eliminate, prevent or reduce food safety hazards that may cause your customer to become ill or injured. The contents of the Food Safety Plan are defined by Codex and the details can be found in detail in Module 4 of the IFC Food Safety Toolkit.

Specifications

Raw Material, Ingredient and Product-contact Materials [Packaging] Specification Contents

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis, including the following, as appropriate:

- a) Biological, chemical and physical characteristics;
- b) Composition of formulated ingredients, including additives and processing aids;
- c) Origin;
- d) Method of production;
- e) Packaging and delivery methods;
- f) Storage conditions and shelf life;
- g) Preparation and/or handling before use or processing;
- h) Food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses.

The organization shall identify statutory and regulatory food safety requirements, or the organization's food safety requirements that are more strict than statutory and regulatory food safety requirements related to the above. The descriptions shall be kept up-to-date.

Finished Product Specification Contents

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis, including information on the following, as appropriate:

- a) Product name or similar identification;
- b) Composition;
- c) Biological, chemical and physical characteristics relevant to food safety;
- d) Intended shelf life and storage conditions;
- e) Packaging;
- f) Labelling relating to food safety and/or instructions for handling, preparation and usage;
- g) Method(s) of distribution.

The organization shall identify statutory and regulatory food safety requirements related to the above.

The descriptions shall be kept up-to-date.

Forms

Forms are developed and maintained to record the data demonstrating compliance to the requirements of the Food Safety Management System.

Forms should contain a title, identification number, revision level and date of revision. Forms should be referenced in, or attached to, the quality manual, documented procedures and/or work instructions.

Records

Food Safety Management System records state results achieved or provide evidence that the activities indicated in the documented procedures and work instructions are performed. The records should indicate the compliance with the requirements of the Food Safety Management System and the specified requirements for food safety. The responsibilities for preparation of records should be addressed in the Food Safety Management System documentation.

Records are the only references available to trace the production history of a finished product.

Records can be used as a tool to alert the operator to potential problems before they lead to the violation of a critical limit.

Records can serve as evidence that proper procedures are being followed.

NOTE: Records are not generally under revision control as records are not subject to change.

Process of Approval, Issue and Control of Food Safety Management System Documents

Review and approval

Prior to issue, the documents should be reviewed by authorized individuals to ensure clarity, accuracy, adequacy and proper structure. The intended users should also have the opportunity to assess and comment on the usability of the documents and on whether the documents reflect actual practices. Release of documents should be approved by the management responsible for their implementation. Each copy should have evidence of this release authorization. Evidence of approval of documents should be retained.

Distribution

The method of distribution of the documents by authorized personnel should ensure that pertinent issues of appropriate documents are available to all personnel who will need the information included in the documents.

Proper distribution and control may be aided, for example, by using serial numbers of individual copies of the documents for recipients. Distribution of documents such as the HACCP Manual may include external parties (e.g. customers, certification bodies and regulatory authorities).

Incorporation of changes

A process for the initiation, development, review, control and incorporation of changes to the documents should be provided. The same review and approval process used in developing the original documents should apply when processing changes.

Issue and change control

Document issue and change control are essential to ensure that the contents of the documents are properly approved by the authorized personnel and that the approval is readily identifiable. Various methods may be considered for facilitating the physical process of making changes.

A process should be established to ensure that only the appropriate documents are in use. Under certain circumstances, the appropriate document to be used may not be the latest revision of the document. Revised documents should be replaced by the latest revision. A document master list with revision level may be used to assure the users that they have the correct issue of authorized documents.

The organization should consider recording the history of changes to the documents for legal and/or knowledge preservation purposes.

Uncontrolled copies

For the purpose of tenders, customer off-site usage and other special distribution of documents where change control is not intended, such distributed documents should be clearly identified as uncontrolled copies.

NOTE Failure to provide assurance of this process can cause unintended usage of obsolete documents.

Record Retention

Storing records

Records can be stored as case files, log books, softcopy databases, etc. FBOs should take reasonable steps to ensure training records are stored in a secure location and are not available to others who are not authorized to have access. FBOs also need to have a policy on backing up soft-copy data, access rights and security. Precautions should be made to protect soft copy records from electronic viruses or technical failure, and written records from damage due to fire, water, rodents or insects (e.g. termites).

Protecting records

FBOs should develop their own confidentiality policy to protect their training written and electronic records and other sensitive information, and the obligations of all employees to abide by them. FBOs should seek to balance an individual's right to confidentiality with their right to services and protection.

Access to records

When providing auditors with access to their training records, FBOs should take steps to protect the confidentiality of employees and other individuals identified or discussed in such records. Both auditor requests and the rationale for withholding records should be documented in the client's files. Sensitive and confidential information must be released only to authorized parties with employee consent, wherever applicable.

Record Maintenance and Destruction

Update of records

FBOs should develop their own internal policy on time frames for update of records.

FBOs should store training records for at least six years, where practical, as this is a general GFSI scheme requirement. FBOs need to ensure that their record-keeping practices comply with all contractual, regulatory or legal requirements. The transferring or disposing of FBO training records should be conducted in a manner that protects employee confidentiality.

Electronic or Hard Copy Records?

Electronic records

Keeping training records in soft copies allows for easy access, transfer and saves storage. However, keeping records via an electronic tool such as the Personal Digital Assistant (PDA) whilst conducting intake assessments of new clients, for example, may seem impersonal and inappropriate. If documentation and records are stored electronically, it is important for the FBO to develop its policies and procedures for information management and technology, including system maintenance, monitoring access and staff training.

Written records

Written records are common and more personable to employees and auditors. However, they are at times difficult to read due to varying and unique handwriting. In addition, duplicate copies have to be made for transmission to other parties or agencies.

FBOs could consider all factors and choose a system that meets their needs, to ultimately benefit the FBO, employees and auditors served.

Why review records?

It is good practice to review records so that improvements in training design and delivery can be made. Hence, records should be reviewed periodically to establish whether:

- Assessments conducted were thorough, complete and timely;
- Clients were actively involved in making informed choices regarding services received;
- Clients were given appropriate services to achieve client outcomes;
- The achievement of client outcomes could be improved upon.

Samples of Food Safety Management System Procedures

1. Control of Documents
2. Control of Records
3. Complaint Management
4. Control of Nonconforming Product
5. Calibration
6. Corrective and Preventive Action
7. Internal Auditing
8. Traceability
9. Product Recall and Withdrawal
10. Mock Recall
11. Food Defence
12. Allergen Control
13. Hygiene Procedure
14. Identification and Evaluation of Compliance

The standard operating procedures [SOPs] included here are for illustrative purposes only. The IFC accepts no liability for the content contained within these SOPs. The FBO may use these SOP's as a starting point or baseline for developing their own SOPs. It is expected the FBO will amend the contents of any SOP's contained within the FSTK will be amended to fit the unique needs of the FBO's organization.

Control of Documents

FBO Procedure	
Document #	SOP-001
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
<p>All documents within FBO are classified in the following way: PUBLIC documents are intended for anyone; COMMERCIAL IN CONFIDENCE documents are to be kept confidential between restricted individuals within the FBO and partner organizations; COMPANY CONFIDENTIAL documents are to be kept confidential within the FBO and used for normal business activities by the general office population; HIGHLY CONFIDENTIAL documents are to be kept confidential to restricted individuals within the FBO.</p>	
<p>© Copyright FBO. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the written permission of FBO.</p>	
Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved and released by process owner.

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Control of Documents

1 Summary

Purpose	The purpose of this procedure is to describe the: <ul style="list-style-type: none"> ● Methodology in place to control all documentation relevant to the Food Safety Management System.
Scope	This procedure applies to: <ul style="list-style-type: none"> ● The creation, review, approval, obsolescence, archival, disposal/ destruction of Food Safety Management System documentation. ● The control of documents of external original determined to be necessary for the planning and operation of the Food Safety Management System. ● The control of the company portal, website and marketing materials.
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager. They are responsible for the effective implementation and maintenance of this procedure.

2 Related documents

Policies	Food Safety Policy, POL-001
Processes	N/A
Procedures	Control of Records, SOP-002
Work Instructions	N/A
Forms	Document Request Form Disposal/Archival Request Form
Other	N/A

Control of Documents

3 Definitions

Term or Acronym	Description
FBO	Food Business Organization
FSM/MR	Food Safety Manager/Management Representative
FSMS	Food Safety Management System
HACCP	Hazard Analysis Critical Control Point – a system that identifies, evaluates, and controls hazards which are significant for food safety
HACCP Plan	A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration
Document	Information and the media on which it is contained (clause 3.7.2 of ISO 9000:2005)
Document Controller	The person responsible for the control of documentation
DMS	Document Management System
Document Template	The template used to create documentation.

4 Introduction

4.1 General

Documentation is used by an organization to ensure communication and consistency of action. The effective use of documentation enables:

- Achievement of conformity to customer requirements and quality improvement;
- Provision of appropriate training;
- Repeatability and traceability;
- Provision of objective evidence; and
- Evaluation of the effectiveness and continuing suitability of the FSMS.

In a Food Safety Management System the following documentation may typically occur:

- Documents that provide consistent information, both internally and externally, about the organization's management system; referred to as **Management System Manuals** (e.g. Food Safety/Food Safety Management System Manual);
- Documents that describe how the Food Safety Management System is applied to a specific product; referred to as **PRPs, O-PRPs, HACCP Plans, etc.**;
- Documents stating requirements; referred to as **specifications**;
- Documents stating recommendations or suggestions; referred to as **guidelines**;

Control of Documents

- Documents that provide information about how to perform activities and processes consistently; referred to as **documented procedures, work instructions and drawings, forms, document templates and other documentation**;
- Documents that provide objective evidence of activities performed or results achieved; referred to as **records**.

4.2. Document Control Policy

An electronic document management system has been implemented to control all documents falling under the scope of the Food Safety Management System. This system allows documentation, in electronic format, to be available, accessible and controlled.

The controlled master documents are held in the DMS. Any printed copies are valid only on the day of printing and are deemed 'uncontrolled' thereafter.

Employees are not permitted to hold any versions of Food Safety Management System documentation on their personal hard drives and to review/obtain all copies of required documents from the DMS.

Records are a special type of document and are controlled as per procedure SOP-002 Control of Records.

4.3 Content of Documents

As part of the standardisation process, all Food Safety Management System documentation will follow the same format. In general, all company documentation must:

- Clearly display the company logo in the header;
- Identify the number and total number of pages in the footer;
- Control number;
- Name;
- Revision number.

For **procedures and work instructions, the following numbering and sections are required:**

1. Summary, including purpose, scope and functional responsibility;
2. Related documents table, including policies, processes, procedures, work instructions, forms and others;
3. Definitions table;
4. Introduction to the procedure;
5. Procedure flowchart;
6. Procedure notes;
7. Records table.

Sub sections may be added as necessary and the layout of this procedure (document control) used as the example to follow.

The format of the header and footer in this procedure (document control) must be used and edited appropriately for all other procedures.

Classification		Company Confidential		Control of Documents	
Doc ID	SOP-001	Printed		Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner	Food Safety Manager
					Page 4 of 10

Control of Documents

4.4 Documents of External Origin

Where deemed necessary for the planning and operation of its processes and activities, the organization may obtain documents from external sources. These documents may be in any medium, e.g. DVD, CD. These documents must be controlled if a library is maintained within the FBO. Most Food Safety Schemes require access to such documents and not necessarily a physical or electronic storage of documents of external origin.

Examples of external documents include:

- Equipment manuals in hardcopy or CD/DVD;
- Building drawings;
- Customer specifications;
- Other legislative or regulatory requirements;
- International standards (e.g. ISO 22000:2005).

On receipt of or notification of an external document of relevance, the relevant department must inform the document controller so that the document can be recorded in and controlled via the DMS.

This control, through the DMS, will extend to:

- Assigning a control number (where one does not already exist);
- Assigning a receipt date (receipt by the company of the document);
- Assigning a revision number (where one does not already exist);
- Recording the distribution of the document within the company.

Documents of external origin requiring a control number and a revision number will adhere to the following format:

EXT xxx yyy Name of Document Revision zzz

Where:

- EXT = identifies the document as external in origin;
- xxx = identifies the applicable company department e.g. compliance;
- yyy = next control number available;
- zzz = revision control number.

The document controller will be responsible for the naming and numbering of all documents of external origin. The receipt date will be noted in the DMS as a note to the document.

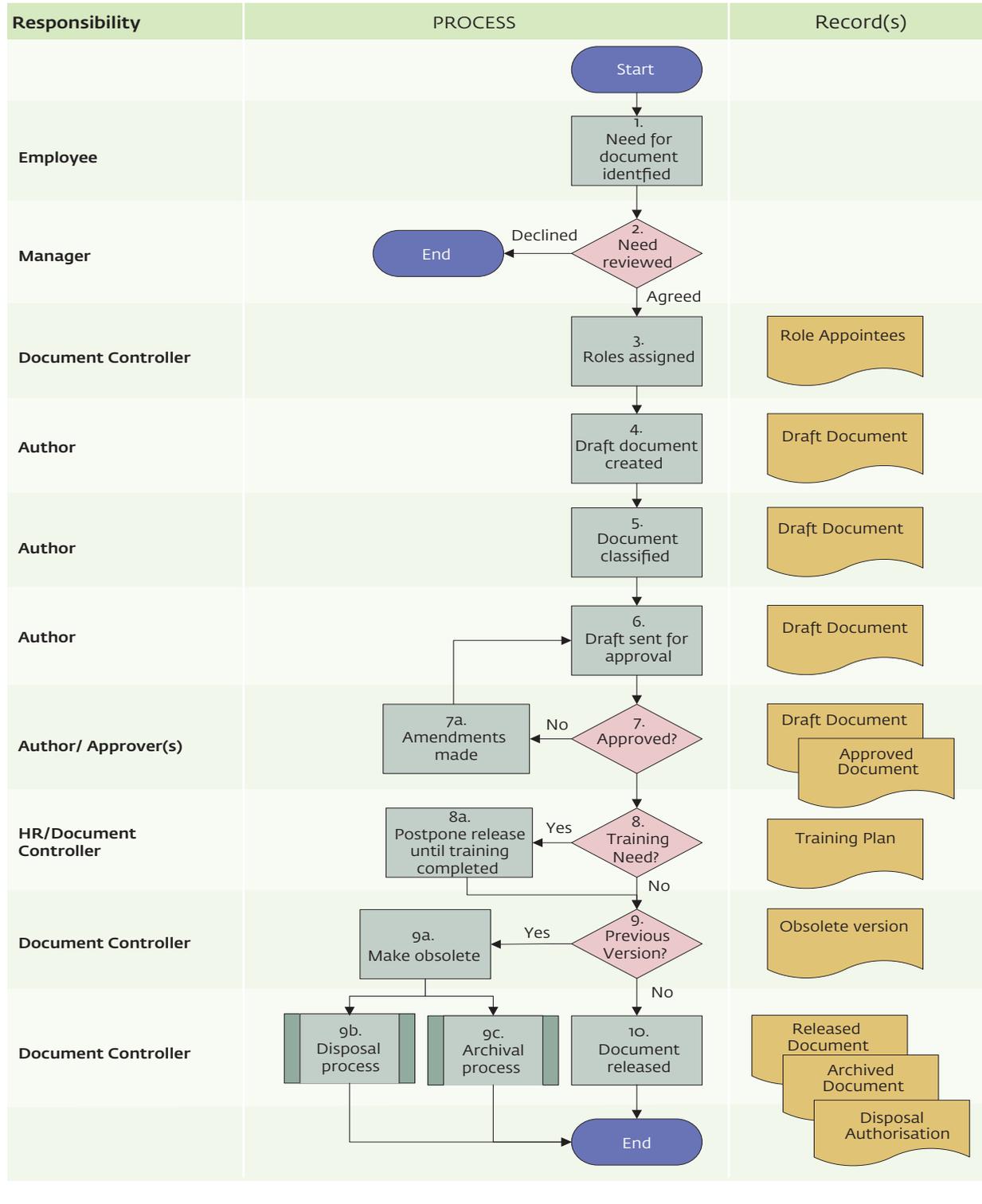
Where a document of external origin of relevance is referenced in the DMS and not stored the linkage to the online location should be recorded and maintained by the Document Controller.

Any updates to documents of external origin will be reviewed by the relevant department, an assessment of applicability made and the appropriate actions taken. The newer version of the external document will be controlled as outlined above and the previous version obsoleted.

Control of Documents

5. Procedure Flow Chart

5.1 Document Control



Control of Documents

6 Procedure Notes

Step 1

The potential need for a new document can be raised by any employee.

Step 2

This need must be reviewed by the Process Owner [or Head of Department] to ensure that it is a valid requirement and that no other document already exists that covers the identified need, or that could be amended to meet the need. Where the need is declined, the process ends at this point.

Step 3

Once the need has been accepted, the relevant documentation players are appointed, namely the document:

- **Sponsor** – the person who determined that the need was valid. Can also be the process owner;
- **Manager** – the person with responsibility and authority for the flawless implementation and management of the procedure;
- **Approver(s)** – those with review and approval responsibility and authority related to the document;
- **Author** – the person who creates/writes the document utilizing the approved document template;
- **User** – the person with the responsibility for conforming to the procedure and advising of any changes if required.

Step 4

The author will create the document, either within the DMS or external to the DMS, utilizing the approved document template. The following also need to be defined at this stage:

- The effective date of the procedure;
- The review period, e.g. 12 months or sooner;
- Any verification [testing] associated with the procedure, e.g. quiz;
- Identifying the relevant interested parties;
- Identifying other documents impacted by this procedure and notifying the relevant process owners.

This is also the point in the document control process where the control of changes to existing documents begins.

Control of Documents

Step 5

The author, in association with the sponsor and owner, will classify the document in accordance with its proposed usage and circulation. Classifications include the following:

- PUBLIC documents are intended for anyone;
- COMMERCIAL IN CONFIDENCE documents are to be kept confidential between restricted individuals within FBO and partner organizations;
- COMPANY CONFIDENTIAL documents are to be kept confidential within the FBO, and used for normal business activities by the general population;
- HIGHLY CONFIDENTIAL documents are to be kept confidential to restricted individuals within the FBO.

Step 6 & 7

Once the author is satisfied with the level of detail in the procedure, he or she will verify the procedure matches current operational practices, relevant statutory and regulatory and conformity requirements prior to submitting for approval. This can be achieved through discussions with the relevant departments.

The document is then sent for approval via the DMS (or manually) to each of the specified approvers. All approvers are required to read and evaluate the document and signify their approval or disapproval of the content. Where approved the document moves to the next stage of the process; however, if one or more approvers reject the document, it returns to the author for the appropriate amendments to be made. It will then be re-submitted for approval.

This approvals loop may go through several iterations.

Step 8 & 8a

Once the document is approved, the impact of the document will be assessed and any training needs identified. The effective date of this procedure will be postponed until any required training has been successfully completed. The DMS has the ability to test persons on their understanding of a process or procedure via a quiz.

Step 9

The DMS will automatically remove obsoleted versions of a document.

Step 9a, 9b & 9c

The DMS will automatically archive / dispose of obsoleted documents.

Step 10

The approved document is released on the DMS and the relevant personnel are informed as to its release.

Classification		Company Confidential		Control of Documents	
Doc ID	SOP-001	Printed		Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner	Food Safety Manager
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Control of Documents

7. The Document Management System

7.1 General

A DMS has been implemented within the company to ensure the necessary control of all documentation that falls under the scope of the FSMS. This DMS covers and provides evidence of the control of documentation in line with the flow chart outlined in Section 5 of this procedure and the notes outlined in Section 6 of this procedure.

7.2 Access Rights

Access rights to the DMS have been assigned as follows:

- Full access:
 - The Food Safety Manager
 - The Document Controller
- Edit / Amendments:
 - Document owners
 - Document approvers
 - Document authors
- Read Only:
 - Authorized employees

Only the Document Controller and the Food Safety Manager may release a document in the DMS, subject to a successful approvals process being completed.

7.3 Documentation Review

When placing a document within the DMS structure a review timescale is required to be defined. The Document Controller will monitor and ensure these timescales are being adhered to.

7.4 Obsolete Documents

The DMS will automatically remove obsolete documents from view. Where hard copy obsolete documents held for legal, knowledge retention or other purposes will be clearly marked as "obsolete" to prevent their unintended use. Obsolete documentation held on the DMS may only be accessed by the Document Controller and the Food Safety Manager.

7.5 Documentation Disposal

Authorisation via the DMS, must be granted for disposal of a document. Documents may be disposed of through deletion from the DMS or shredding of physical documents.

7.6. Documentation Archival

The archival of documents is managed automatically within the DMS.

Classification		Company Confidential		Control of Documents	
Doc ID	SOP-001	Printed		Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner	Food Safety Manager
					Page 9 of 10

Control of Documents

7.7 Documentation Numbering

All documents within the scope of the management system shall follow the naming structure outlined below:

Document type	Numbering structure	Example
Policy	POL. xxx yyy Name Revision number	POL FSMS 001 Food Safety Policy Rev 01
Procedure	PRD xxx yyy Name Revision number	PRD QMS 001 Document Control Rev 01
Work instruction	WI xxx yyy Name Revision number	WI QMS 001 Writing a job description Rev 01
Specification	SPEC xxx yyy Name Revision number	SPEC QMS 001 Specification Rev 01
Form/Document Template	FRM xxx yyy Name Revision number	FRM QMS 001 Master Document Register

Where:

xxx = Department identification

yyy = Document number

Document numbers will be assigned by the document controller based on the documentation master list.

Only document controller is authorised to change this naming structure.

External document naming criteria are outlined in Section 4.4 of this procedure.

8 Records

Document	Location	Duration of Record	Responsibility
Documentation Master List	DMS	Indefinitely	Document Controller
Documentation Review Report	DMS	Indefinitely	Document Controller
Disposal/Archival Request Form	DMS	Indefinitely	Document Controller

Control of Records

FBO Procedure	
Document #	SOP-002
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved for release by process owner.

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Control of Records

1 Summary

Purpose	This procedure describes the methodology employed to control records developed as part of the food safety management system.
Scope	This procedure applies to the distribution, storage, preservation, legibility, retention, disposition, access to and retrieval of records.
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager, who is responsible for the effective implementation and maintenance of this procedure. Departmental managers are responsible for ensuring records under their control are managed in accordance with this documented procedure.

2 Related documents

Policies	Food Safety Policy, POL-001
Procedures	Control of Documents, SOP-001
Work Instructions	Not Applicable
Forms	Master Document Register
Other	Document Management System

3 Definitions

Term or Acronym	Description
FSM/MR	Food Safety Manager
FSMS	Food Safety Management System
DMS	Document Management System

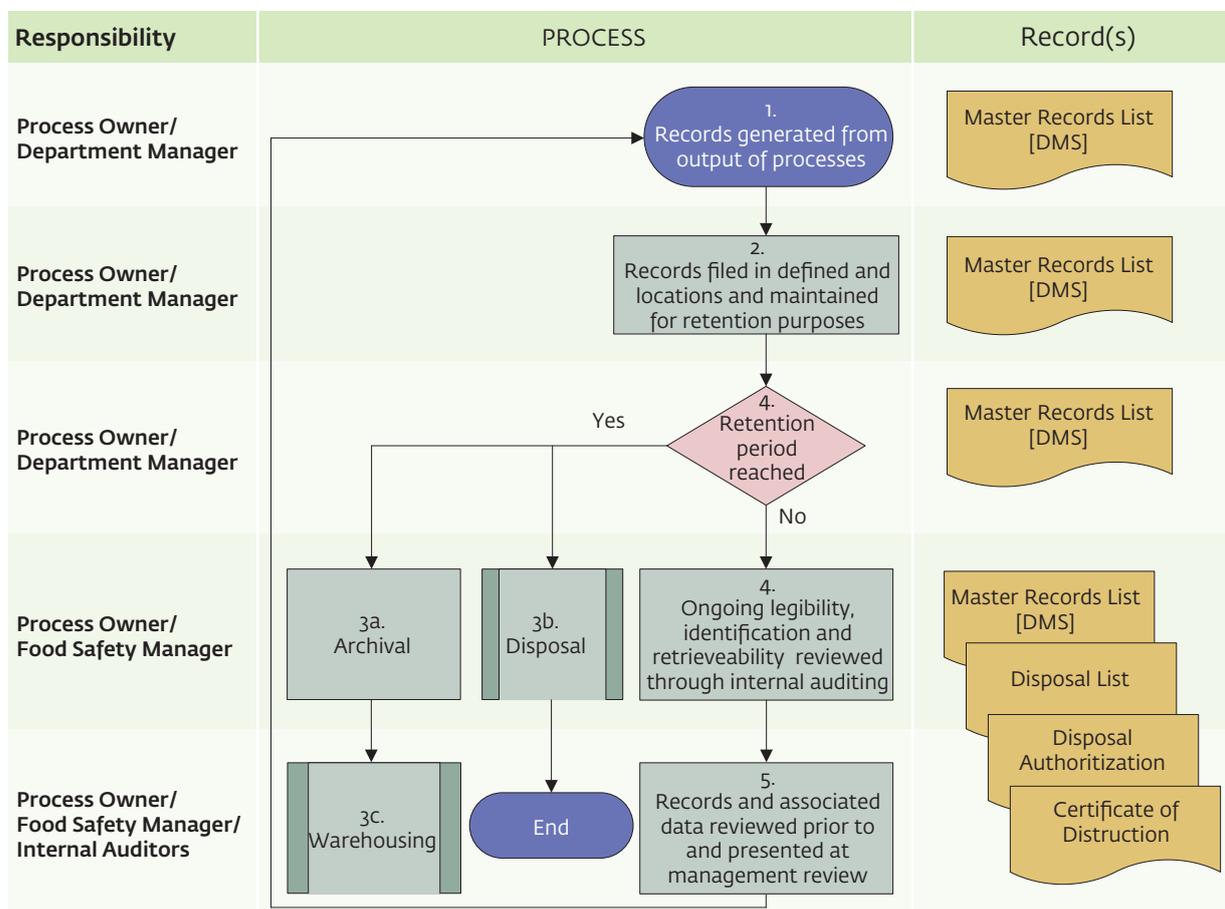
Control of Records

4 Introduction

4.1 General

Records are documents stating results achieved or providing evidence of activities performed. Records can be either hard copy or soft copy (paper or electronic) and must be managed. Management of records is a critical factor in the Food Safety Management System as without the availability of records, the company is unable to verify that required activities have taken place or that results have been achieved.

5. Procedure Flow Chart



Control of Records

6 Procedure Notes

Step 1 & 2

Through daily activities, quality records are generated that provide evidence of the completion of activities and the achievement of results. These records are held in accordance with defined retention times and to ensure preservation of their content, their identification and legibility. Storage of records will ensure that they are corrupted. These requirements are listed on the Records Master List.

Step 3

Once the retention period for the records has been reached, the Process Owner and the Food Safety Manager must decide what to do with these records. The Compliance Department will be queried to determine if any compliance issues related to the specific records exist and need to be met.

Step 3a & 3b

Where a decision to archive the records is made, these records must be suitable boxed to preserve their integrity. The box must be labelled clearly as to its contents (date, type of record, origin of records, etc.). An email is then sent by the process owner or their delegate to the warehouse informing the warehouse team to expect the delivery of the boxes. The Process Owner or their delegate will arrange for the delivery of the boxes to the warehouse.

Step 3c

Where the decision is to dispose of the records, the Process Owner and Food Safety Manager must authorize this disposal. A list of all documents to be disposed of must be created and signed off by the above to signify their approval to dispose of the records. It is the responsibility of the process owner to create the disposal list and obtain the necessary approvals to dispose. Where such records are held in the warehouse, a written instruction must be sent, following authorization, to the warehouse instructing them to dispose of the records. Records must be disposed of in a fully traceable and confidential manner using an approved disposals company. Shredding is the preferred manner for disposal of records. It is the responsibility of the Food Safety Manager to obtain a certificate of destruction from the disposal company. The certificate of destruction must be attached to the disposal list and maintained by the Food Safety Manager.

Step 4

Where the retention times are not reached, the control of records is monitored as part of the internal auditing process, the FSMS internal auditing.

Step 5

The management and control of records will be reviewed as part of the management review process, under the agenda heading of documentation.

Control of Records

7. Records

Document	Location	Duration of Record	Responsibility
Records Master List	Food Safety Manager Office	Indefinitely	Food Safety Manager
Disposal List	Food Safety Manager Office	Six years	Food Safety Manager
Disposal Authorisation	Food Safety Manager Office	Six years	Food Safety Manager
Certificate of Destruction	Food Safety Manager Office	Six years	Food Safety Manager
Warehouse Storage Location List	Warehouse Manager	Indefinitely	Warehouse Manager



Complaint Management

FBO Procedure	
Document #	SOP-015
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial draft for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Technical Review and update of correction and corrective action procedure notes.

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Complaint Management

1 Summary

Purpose	This procedure describes the methodology used by the organization to manage complaints and maintain customer (retail and commercial) and consumer satisfaction and trust.
Scope	This procedure applies to the receipt, review, investigation and resolution of complaints.
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager.

2 Related documents

Policies	Food Safety Policy, POL-001
Processes	Food Safety, PRO-001
Procedures	Control of Nonconforming Product, SOP-003 Management Review, SOP-021 Corrective Action & Preventive Action, SOP-009
Work Instructions	Not Applicable
Forms	Complaint Form
Other	Not Applicable

3 Definitions

Term or Acronym	Description
CRO	Complaint Resolution Officer
CAPA	Corrective Action & Preventive Action
Company	FBO
Root Cause	A cause that once removed from the problem fault sequence, prevents the final undesirable event from recurring
Root Cause Analysis	A method of problem solving that tries to identify the root cause of faults or problems

Complaint Management

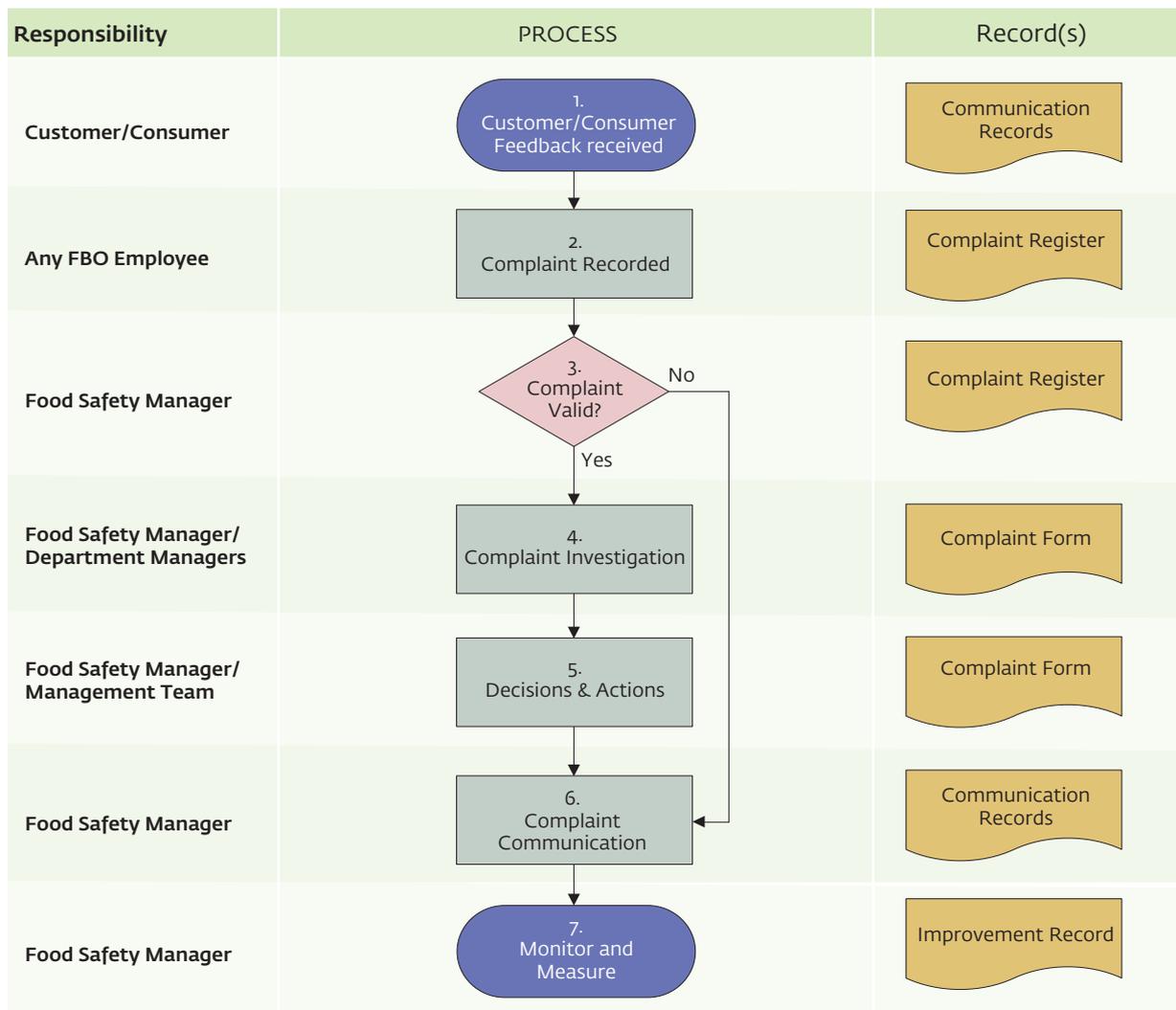
4 Introduction

4.1 Complaint Management

The FBO has implemented a set of flow chart steps for recording customer/consumer complaints, reviewing these complaints, conducting investigations, determining root cause and taking actions to resolve these complaints with a view to preventing recurrence of the complaint.

A customer/consumer complaint can be defined as any expression of dissatisfaction made by the Company's Customer or Consumer regarding any products or services provided by the Company. This policy covers all written complaints, serious or unresolved telephone complaints, complaints raised in a face to face meeting or by a third party acting for that customer such as an intermediary, legal representative or Food Safety Regulatory Body.

5 Procedure Flow Chart



Complaint Management

6 Procedure Notes

6.1 Receipt of Complaint

A complaint can be made by a customer/consumer face to face, over the phone, by email or other method. Where relevant food safety regulations also apply these must be completed in conjunction with this procedure. If food safety regulations contain requirements that are more proscriptive or demanding they should be adhered to.

When you receive a client complaint:

1. Listen to the client when the complaint is being given verbally, i.e. face-to-face;
2. Establish what the complaint is and record it on a complaint form;
3. Clarify with the client that you have understood the complaint correctly;
4. As a matter of good practice, apologize for the occurrence of the issue they have experienced;
5. Explain to the client that the company has a complaints policy and that the complaint will be investigated and a formal response will be issued. Also explain that this may take some time;
6. Correctly establish their contact details.

Retain copies of any documentation provided by the client and keep them with the complaint form.

6.2 Recording of Complaint

Formally complete the complaint form.

1. Date;
2. Reference number;
3. Customer name;
4. Customer contact number;
5. CPR number;
6. Customer complaint - description;
7. Action taken;
8. Final status.

Attached all documentation relating to the complaint. Forward the complaint details to the Food Safety Manager.

The Food Safety Manager formally completes the complaint register. The client should be contacted by phone/mail to advise that their complaint is being considered within 48 hours maximum. The complaint is forwarded to the Food Safety Manager. A deputy may also carry out this work on behalf of the Food Safety Manager.

Complaint Management

6.3 Review of Complaint - Validity

The CRO carries out an initial assessment on whether the complaint is valid or not. If it is, the complaint goes to Step 5. If not, a formal response outlining the reasons is given as per Step 7. The complaint is forwarded to the relevant Department Manager for investigation.

6.4 Investigation of Complaint

The Department Manager carries out a detailed investigation using the staff resources available, the Branch Manager, the member of staff who took the initial complaint, and other members of staff as required. The Department Manager uses the corrective action procedure to investigate the root cause, determine initial containment actions, and corrective actions.

6.5 Action and Decision

Appropriate actions and decisions are taken following the complaint investigation and documented as a correction and corrective action, referencing the corrective action procedure. The corrective actions are verified for effectiveness as per the corrective action procedure. The time needed to verify effectiveness of any corrective actions may take longer.

6.6 Closure of Complaint

The Department Manager drafts a response for the complainant. This is agreed with the Food Safety Manager if required by the circumstances and then released to the customer/consumer. The Food Safety Manager retains a copy of the formal response with the complaint form. Complaints are filed by reference number and date. This should occur within 20 working days of receiving the complaint. Where required, the complaint response is communicated to the relevant food safety regulatory body.

6.7 Monitoring and Measure

The Food Safety Manager maintains the complaint files and Complaint Register for review. The Food Safety Manager carries out analysis of complaints (specifically recurrences) and carries out trending and analysis of the effectiveness of the complaints system. The Food Safety Manager prepares trending data for the Management Review process to demonstrate that the complaints are being effectively managed to the satisfaction of the company and the client. The complaints and summaries trending are inputs into the management review procedure. All complaints are to be completed and auditable under the internal audit procedure. Finally, the Food Safety Manager will continue to monitor and measure the effectiveness of actions and decisions to ensure the effectiveness and to verify if the same problem and cause occurs in the future.

Complaint Management

7 Records

Document	Location	Duration of Record	Responsibility
Complaint Form	Food Safety Office	7 years	Food Safety Manager
Complaint Register	Food Safety Office	7 years	Food Safety Manager
Complaint Investigation Notes and Formal Responses	Food Safety Office	7 years	Food Safety Manager
Trend Analysis	Food Safety Office	Indefinitely	Food Safety Manager



Control of Nonconforming Product

FBO Procedure	
Document #	SOP-003
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved and released by process owner.

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Control of Nonconforming Product

1 Summary

Purpose	This procedure describes the methodology used by the FBO to control instances where expected outputs have not met requirements.
Scope	This procedure applies to product delivery, i.e. ingredients, raw material, intermediate or finished product at all levels in the organization.
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager. They are responsible for the effective implementation and maintenance of this procedure.

2 Related documents

Policies	Food Safety Policy, POL-001 Customer/Consumer Complaints Policy, POL-002
Processes	Departmental Process Descriptions
Procedures	Corrective and Preventive Action, SOP-009
Work Instructions	Not Applicable
Forms	Non Conformance Log (DMS)
Other	Not Applicable

3 Definitions

Term or Acronym	Description
FSM/MR	Food Safety Manager/Management Representative
FSMS	Food Safety Management System
Risk	Effect of uncertainty on an expected result
Nonconformity	Non-fulfilment of a requirement
Corrective action	Action to eliminate the cause of a nonconformity and to prevent recurrence
Correction	Action to eliminate a detected nonconformity
Customer	Person or organization that could or does not receive a product or a service is intended for or required by this person or organizations
Statutory requirement	Obligatory requirement specified by a legislative body
Regulatory requirement	Obligatory requirement specified by an authority mandated by a legislative body

Classification Company Confidential

Control of Nonconforming Product

Doc ID SOP-003
Created 20-04-2015Printed
Updated 24-04-2015Controller Document Controller
Owner Food Safety Manager

Page 2 of 6

Control of Nonconforming Product

Term or Acronym	Description
Defect	Nonconformity related to an intended or specified use
Product	Output that is a result of activities where none of them necessarily is performed at the interface between the provider and the customer. For the FBO this can be an ingredient, raw material, intermediate product or finished product supplied to a customer or consumer
Service	Intangible output that is the result of at least one activity necessarily performed at the interface between the provider and the customer
Feedback	Opinions, comments and expressions of interest in a product, a service or a complaints-handling process
Customer satisfaction	Customer's perception of the degree to which the his or her expectations have been fulfilled
Complaint	Expression of dissatisfaction made to an organization related to its product or service, or the complaints-handling process itself where a response or resolution is explicitly or implicitly expected
Concession	Permission to release a product or a service that does not conform to specified requirements
Characteristic	Distinguishing feature, inherent or assigned, qualitative or quantitative
Root cause	A cause that once removed from the problem fault sequence prevents the final undesirable event from recurring
Root cause analysis	A method of problem solving that tries to identify the root cause of the fault or problem.

4 Introduction

4.1 Nonconforming Product

Nonconforming product results from a defined requirement not being met. Examples of nonconforming product include, but are not limited to:

- Breach of statutory or regulatory compliance;
- Failure to implement and maintain a requirement of FSSC 22000/BRC/SQF;
- Failure to meet a customer requirement, both specified or implied;
- Failure to deliver a required process output.

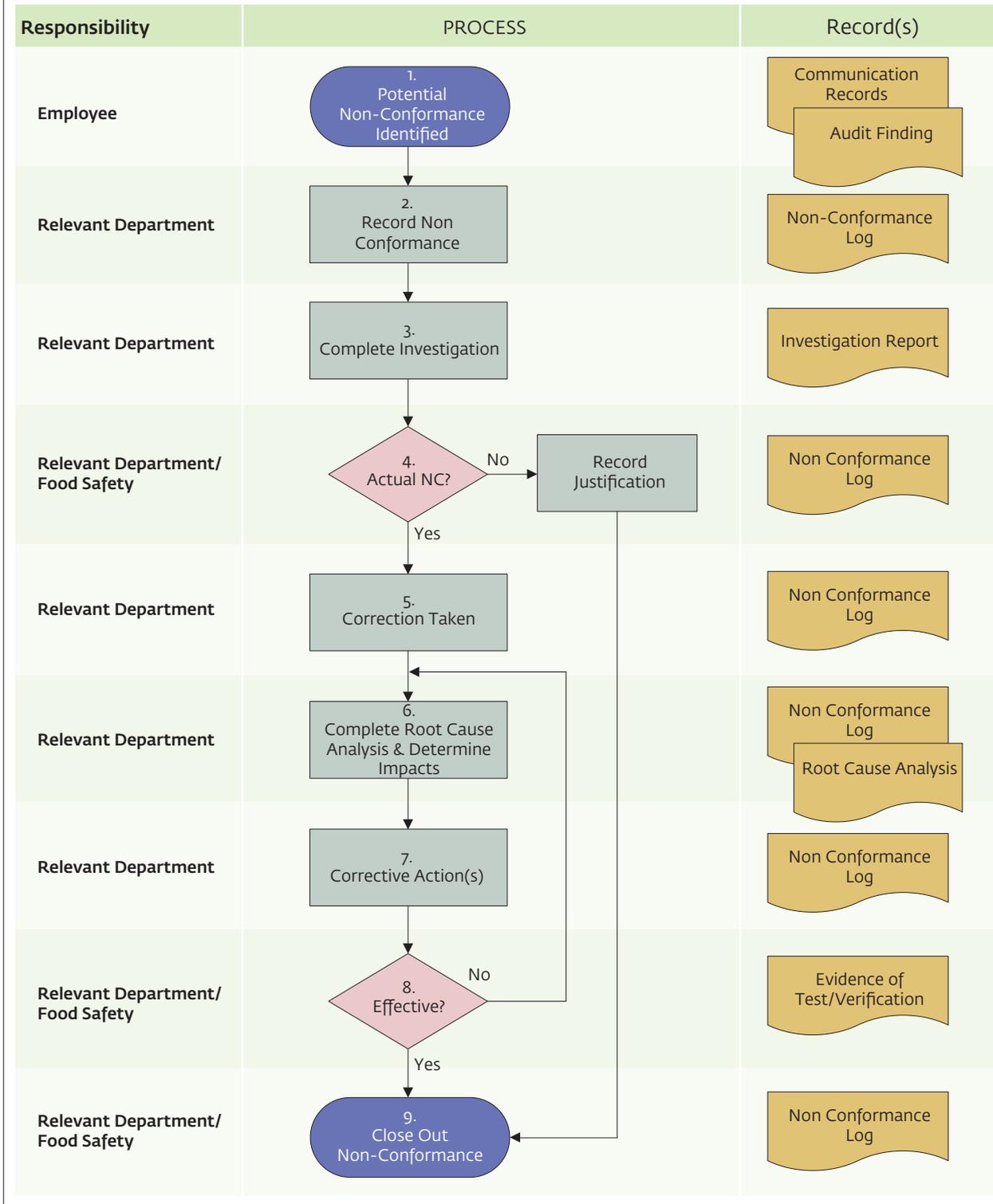
Customer complaints are handled in accordance with POL-002 Customer/Consumer Complaints Policy.

All instances of nonconforming service must be identified, investigated and resolved to ensure continual improvement of the FSMS and the service provided by the organization.

Control of Nonconforming Product

5. Procedure Flow Chart

5.1 Control of Nonconforming Product or Service



Control of Nonconforming Product

6 Procedure Notes

6.1/6.2 Identification and Recording of Non-Conformance

Any employee can identify a potential non-conformity in relation to the provision of our service or the company can be notified from an external source. Once received, the potential non-conformity must be documented in the FSMS.

6.3 Complete Investigation

An investigation will be conducted by the appropriate department to determine the validity of the potential non-conformity. This investigation will be in proportion to the potential risks that may arise based on the potential non-conformity. Where there is a risk to compliance, the FSM/MR will be notified immediately and their direction and assistance sought. The results of the investigation will be documented and forwarded to the Food Safety Department for review.

6.4 Actual Non-conformance

A decision will be made based on the outcome of the investigation as to whether or not an actual non-conformity exists. Where all parties agree (Food Safety and the relevant affected department) that no non-conformity exists, then the justification for this decision will be documented and the matter closed.

6.5 Correction

Where, based on the outcome of the investigation, it is found that a non-conformity does exist, the required correction will be taken to immediately resolve the issue.

6.6 Root Cause Analysis

A full and thorough root cause analysis will be conducted to identify the root cause of the issue. This root cause analysis will be based on a recognized methodology (e.g. 5 Whys, Cause & Effect Diagram [Fishbone], 8D, etc.) and documented. Assistance may be sought from external parties where required. The root cause arrived at cannot be simply stated as "human error;" if this occurs, the root cause analysis must be re-done. Where the root cause analysis identifies other potential risks, then the appropriate preventive action must be identified, documented and implemented.

See the Corrective and Preventive Action procedure, document ID SOP-009.

Control of Nonconforming Product

6.7 Corrective Action

Based on the root cause identified in the previous step, the required corrective actions will be identified, documented and implemented. Responsibilities and timelines will be established and documented for these corrective actions. Where corrective action is planned to occur over a long time period, appropriate monitoring and/or measurement must be put in place to track the progress and effectiveness of the corrective actions.

6.8 Verification of Effectiveness

After a suitable period of time has elapsed following the implementation of corrective action, the effectiveness of the corrective action must be determined. The corrective action is aimed at eliminating the cause of the non-conformity and also preventing recurrence, hence the verification of effectiveness must test the possibility of the non-conformity recurring. The test performed or the data reviewed as part of this process must be documented. Assistance from external sources may be utilized for the review of effectiveness. Where the test shows that the corrective action has not been effective, then the root cause analysis must be re-visited to ensure the correct cause was identified and the process repeated.

6.9 Closure

Where the verification of effectiveness of the corrective action taken is successful in determining that the non-conformity has been rectified, then the matter is closed out and recorded as closed.

7 Records

Document	Location	Duration of Record	Responsibility
Non-conformance log	DMS	Indefinitely	FSM/MR
Root cause analysis	Relevant department	Indefinitely	Process Owner/Department Manager
Investigation report	Relevant department	Indefinitely	Process Owner/Department Manager
Evidence of the verification of effectiveness	Relevant department	Indefinitely	Process Owner/Department Manager

Calibration

FBO Procedure

Document #	SOP-022
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved for release by process owner.

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Classification	Company Confidential	Calibration	
Doc ID	SOP-022	Printed	Controller
Created	20-04-2015	Updated	24-04-2015
		Owner	Document Controller Food Safety Manager
			Page 1 of 14

Calibration

1 Summary

Purpose	<p>This procedure describes the calibration program requirements for measurement and test equipment (MTE).</p>
Scope	<p>This procedure applies to measurement and test equipment, which are devices used to test, measure, evaluate, inspect, or otherwise examine materials, supplies, equipment, and systems, or to determine compliance with specifications.</p> <p>This also includes process control devices with the potential to impact food safety.</p> <p>This procedure shall provide instructions for the management of calibrations performed on measurement and test instruments by service organizations, original equipment manufacturers, contractors, or laboratories (herein referred to as Contractors) and to ensure traceability to National or International Standards.</p> <p>This procedure states the documentation requirements for equipment calibrated by in-house personnel.</p> <p>All measurement and test equipment is to be enrolled in the Calibration Program and/or the Preventative Maintenance Program. Enrollment shall include measurement and test equipment designated "Reference Only" and "No Calibration Required".</p>
Functional Responsibility	<p>The functional responsibility for this procedure lies with the Food Safety Manager. They are responsible for the effective implementation and maintenance of this procedure.</p> <p>Departmental managers are responsible for ensuring records under their control are managed in accordance with this documented procedure.</p>

Calibration

2 Related Documents

Policies	Food Safety Policy, POL-001
Processes	Food Safety, PRO-001
Procedures	Control of Documents, SOP-001 Non-Conformity Product, SOP-003 Corrective and Preventive Action, SOP-009
Work Instructions	Not Applicable
Forms	Test Equipment Installation Qualification Measurement Instrument Status Change
Other	TEM Manuals

3 Definitions

Term or Acronym	Description
Accuracy	The relative agreement of a measured value with an accepted standard
Calibration	Verification of a measurement instrument's performance against a traceable standard
Calibration Interval	The duration of time between calibrations
FSM/MR	Food Safety Manager
FSMS	Food Safety Management System
Loop Calibration	The calibration of measurement instruments "as installed" in a total system and represents calibration of the instruments "as used"
Measurement Equipment	Any instrument which monitors or controls a critical parameter of a manufacturing process, controlled environment or used to measure a product or component specification
National Standard	A reference tool utilized by an internationally recognized standards laboratory representing the country which operates that laboratory
Precision	Also known as repeatability and is the variation in readings obtained when repeating the exact same measurement(s)
Reproducibility	A measure of the ability of a measuring instrument to give the same readings when used by a different operator

Calibration

Term or Acronym	Description
Resolution	The power of discrimination of an instrument. For analogue instruments, it is limited to 1/2 of a minor scale graduation
Range	The breadth or span of an instruments capability of measurement
Standard	A defined reference tool with traceability to a national standard
Traceability	Documented reference of calibration results to a recognized standard.

4 Introduction

4.1 General

Calibration defines the accuracy and quality of measurements recorded using a piece of equipment. Over time there is a tendency for results and accuracy to drift, particularly when using particular technologies or measuring particular parameters such as temperature and humidity. To be confident in the results being measured there is an ongoing need to service and maintain the calibration of equipment throughout its lifetime for reliable, accurate and repeatable measurements.

The goal of calibration is to minimize any measurement uncertainty by ensuring the accuracy of test equipment. Calibration quantifies and controls errors or uncertainties within measurement processes to an acceptable level.

For example, if you know that a particular food product, e.g. batch, vat milk needs to be kept above 63°C or 161°F [USA PMO Standard] and the instrument system you are using displays a figure of 63°C, then provided the system is calibrated to be accurate within 0.5°C at 63°C you can be confident the food is safe; if the system has an accuracy of 1°C, however, then you cannot be certain that the food's temperature has been correctly controlled. Food is, of course, only one example of why it is essential to have a confirmed calibrated level of accuracy. Manufacturing processes that require specific controlled pasteurization temperatures are another. In fact, the list goes on.

The equivalent pasteurization temperature for batch, vat milk in the EU is >62°C [EU] or > 65°C [East African Standard].

In summary, calibration is vitally important wherever measurements are important, it enables users and businesses to have confidence in the results that they monitor record and subsequently control.

5. Procedure Flow Chart

Not applicable.

Calibration

6 Procedure Notes

6.1 Enrolment of Equipment in the Calibration Program

- 6.1.1 The Requester will notify the Calibration Department of new equipment by completing and returning the Test Equipment Installation Qualification Form to the Calibration Department.
- 6.1.2 The Requester shall deliver the following to the Calibration Department:
- 6.1.2.1 Measuring equipment (if portable);
 - 6.1.2.2 Test Equipment Installation Qualification Form;
 - 6.1.2.3 The Test Equipment Installation Qualification Form shall detail the measurement instrument's suitability for its intended use prior to enrolment. Suitability must consider accuracy, test accuracy ratio, precision, range, resolution and conditions of use (including environmental conditions). A Test Accuracy Ratio (TAR) of at least 4:1 is required; rationale for exceptions must be documented and approved;
 - 6.1.2.4 A Test Accuracy Ratio (TAR) of at least 10:1 shall be required for standards used for in-house calibration; rationale for exceptions must be documented and approved;
 - 6.1.2.5 A copy of the equipment specifications (if available from manual/catalogue), otherwise calibration requirements will be listed in the special instructions section;
 - 6.1.2.6 Operation and/or service manual(s) for equipment that is to be, or can potentially be, calibrated in-house (in some occasions where an equipment manual is missing, the FBO must be able to demonstrate suitable controls, e.g. SOP's etc.);
 - 6.1.2.7 Calibration certificate(s);
 - 6.1.2.8 Certificates for new measurement and test equipment require at a minimum a statement of traceability to national, or international, or consensus standards and conformance to published specifications.
- 6.1.3 Active measurement and test equipment that is not calibrated over the entire measurement range or capabilities shall be identified with a "Limited" label, or equivalent. Limitations of use shall be affixed on or near the measurement and test equipment. Limitations shall be listed in the "Special Instructions" section of Test Equipment Installation Qualification Form.

6.2 Calibration Intervals

- 6.2.1 Interval assignment – should be established as recommended below in descending order of preference:
- Calibration history of the equipment under evaluation, and the intended use;
 - Similar measurement and test equipment enrolled in the calibration system;
 - Documented engineering rationale based on usage;
 - Manufacturer's Recommendation.

In the event none of the above information is available the initial interval shall not be greater than six months.

Calibration

6.2.2 Interval changes – may be requested by the owning department by completing the Interval Change Form. Rationale must be documented on the form. Approvals should consider the risk of using out-of-tolerance measurement and test equipment in the production or inspection process(s). Records of the risk assessment must be maintained by the FBO.

6.2.2.1 Interval increases – greater than half (1/2) of the current calibration cycle require justification based on recommendations in section 6.2.1.

6.2.2.2 Initial introduction of new Measurement Instruments that have not been used since initial calibration performed by the OEM (Original Equipment Manufacturer), may be extended another full cycle, where permitted by the OEM as documented on the OEM Calibration Certificate.

6.2.3 Calibration intervals – shall be evaluated and documented on an annual basis by the Calibration Coordinator.

6.3 Change of Equipment Status

6.3.1 The Equipment Owner will request changes of equipment/calibration status using the measurement Instrument Status Change Form. Equipment/calibration status categories include, but are not limited to, the following:

6.3.1.1 Active – measurement and test equipment that is calibrated over the entire measurement range or capabilities. This equipment shall be labelled with a “Calibrated” label;

6.3.1.2 Inactive – measurement or test equipment that is currently not in use and consequently should not be an active part of the calibration program. This equipment shall be labelled with a “Do Not Use-Out of Service” label and made non-operational if possible;

6.3.1.3 Discontinued – measurement and test equipment that has been discontinued or destroyed;

6.3.1.4 Reference Only – measurement and test equipment that has a measurement capability but is currently not used for ANY measurement or test activities for determining conformance to any equipment, product, process, design verification/validation, or environmental specifications. This equipment shall be labelled with a “Not Calibrated – For Reference Only” label;

6.3.1.5 No Calibration Required – measurement and test equipment which by nature or application does not require periodic calibration. Equipment in this category includes intrinsic standards, and equipment used in specific applications whose output values are verified by other calibrated measurement and test equipment. This equipment shall be labelled with a “No Calibration Required” label;

6.3.1.6 Lost – Equipment that cannot be located by the owning department.

6.3.2 Discontinued / Disposed Equipment

6.3.2.1 The department owning the equipment to be disposed/discontinued will complete the Measurement Instrument Status Change Form.

6.3.2.2 The Calibration ID label will be removed from the equipment by the Owing Department and affixed to the Measurement Instrument Status Change Form.

6.3.2.3 The equipment shall be appropriately identified for disposal/destruction by the Owing Department.

6.3.2.4 The Owing Department will obtain approval for disposal of asset.

6.3.2.5 The completed Measurement Instrument Status Change Form will be forwarded to the Calibration Department.

Calibration

6.3.3 Equipment Transfers – measurement and test equipment whose primary use/ownership is being permanently transferred between departments or divisions. The original owning department is responsible for completing the Measurement Instrument Status Change Form for any Measurement and Test Equipment that is being transferred to another department or division, and obtaining the signature of the new owning department.

6.4 Calibration Database and Reporting

6.4.1 QA / Engineering / Document Control shall maintain a system for tracking and controlling measurement and test equipment which will prevent the use of expired or unfit measurement and test equipment.

6.4.2 The calibration database shall outline the calibration method in the comments section of the equipment history record. For example:

6.4.2.1 Sub-contract on-site calibration (performed on-site by approved supplier);

6.4.2.2 Sub-contractor (typically measuring and test equipment sent out to an approved supplier).

6.4.3 The calibration database shall distinguish company-owned standards from measurement instruments.

6.4.4 The Calibration Department will issue a calibration status report once every month to the Product Department Supervisors, Department Calibration Representatives, the Food Safety Manager and the Production Manager.

6.4.5 Monthly calibration status report shall consist of:

6.4.5.1 Equipment DUE for calibration in the next 30 days;

6.4.5.2 Equipment OVERDUE;

6.4.5.3 Equipment on-hand;

6.4.5.4 Remedial/Corrective Action Form status.

6.4.6 Calibration manager has two main sets of records which store all pertinent information: Equipment Master and Equipment History. Records are entered in these two corresponding screens by the Calibration Coordinator(s). The Equipment Master stores general information, such as ID description and scheduling information (called events) for each piece of equipment. The Equipment History maintains historical information for specific pieces of equipment. Events can be calibrations, repairs, operations, etc. Each time an event is performed, the result of the event, including any measurement information, is entered as a history record by the Calibration Coordinator(s).

6.4.7 All data is entered by the Calibration Coordinator(s) and Administrator; other users such as the Calibration Representatives have 'User' or 'Read Only' status. All information, whether deleted or entered, is mapped through an audit trail in the database.

Calibration

6.5 Remedial/Corrective Action Process

- 6.5.1 The Calibration Department will issue a Remedial/Corrective Action Form to the equipment's owning department Supervisor when measurement and test equipment is returned from being calibrated with an identified out-of-tolerance condition before calibration. A description of the specific out-of-tolerance parameters will be included or attached to the form.
- 6.5.2 Any equipment with out-of-tolerance occurrences "before calibration" will be issued a "Do Not Use – Out of Service" label, or quarantined in the calibration area, pending completion of the Remedial/Corrective Action Form by the Owing Department.
- 6.5.3 All Remedial/Corrective Action Forms will address:
- 6.5.3.1 The impact of the out of tolerance condition on the product(s)/process(s). A concise and detailed explanation for this decision shall be documented. The following should be addressed in the Remedial response:
 - 6.5.3.1.1 How important the affected feature is to the end user;
 - 6.5.3.1.2 How the out-of-tolerance condition relates to the product specification(s);
 - 6.5.3.1.3 Any potential product impact;
 - 6.5.3.1.4 If product impact has been identified, the product Failure Mode Effect Analysis [F]MEA and/or a Risk Analysis report shall be used to define potential patient and or user safety impact;
 - 6.5.3.1.5 This may include ancillary documents such as handwritten notes, calculations, graphs, tables, sketches, or photographs.
- 6.5.4 Remedials should also address measurement and test equipment disposition:
- 6.5.4.1 The fitness of the equipment for continued use;
 - 6.5.4.2 The calibration interval of the equipment if a change to the interval is being made as a result of the evaluation;
 - 6.5.4.3 Other changes to prevent the recurrence including: the appropriateness of the equipment for the measurement/test function and operator handling of the equipment.
- 6.5.5 Any open remedial/corrective actions open more than four (4) weeks will be reported to the Food Safety Manager and Department Supervisor by the Calibration Coordinator.

6.6 Labelling, Identification and Storage

- 6.6.1 A Calibration label must be attached to, or be posted within visual range of, the measurement and test equipment.
- 6.6.2 Calibrated measurement and test equipment shall be marked with a label to display:
- 6.6.2.1 The date of the most recent calibration;
 - 6.6.2.2 The date when the next calibration is scheduled;
 - 6.6.2.3 (Note, the aforementioned dates shall be of the format type requirements of SOP-xxx, e.g., Jan/5/2015 or 5/Jan/15 so as to avoid confusion between calibrations performed in the United States and Europe);
 - 6.6.2.4 The initials of personnel or sub-contractor who performed the calibration or the name of the sub-contractor.

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- 6.6.3 If the item is too small for this type of marking, a color code or smaller identifying mark shall be employed and cross-referenced on the Test Equipment Installation Qualification Form for that specific item.
- 6.6.4 Calibration Seals shall be affixed to measurement and test equipment where a possibility of alteration to calibrated settings could occur. A tamperproof seal is affixed to the setting adjustment area and or access screw; this acts to safeguard against any internal and or external adjustments that could invalidate the calibration settings. Acceptable methods of sealing are:
- 6.6.4.1 Tamperproof labels;
 - 6.6.4.2 Inspector's lacquer;
 - 6.6.4.3 Low-strength tread-loc.
- 6.6.5 Measurement instruments and standards, where applicable, i.e., Vernier callipers, shall be stored in suitable packaging when not in use to avoid damage.
- 6.6.6 Spare/backup measurement and test equipment (portable) shall be stored in locked cabinets.
- 6.6.7 These cabinets are identified as "Calibrated Test Equipment" that contain standards and measurement equipment that are currently suitable for use and "Test Equipment not Calibrated" that contains items due for calibration and inactive measurement and test equipment.
- 6.6.8 Only the Calibration Coordinator(s) and Administrator shall have access to these storage cabinets.

6.7 Battery Replacement

- 6.7.1 Measurement and test equipment that requires battery replacement shall be performed by the Calibration Coordinator using appropriate Electro Static Devices [ESD] practices and subsequent replacement of any tamperproof seals/labels.

6.8 Calibration Procedures

- 6.8.1 Calibration procedures must be application specific and prescribe step-by-step instructions for calibration of measurement and test equipment or categories thereof. These shall be prepared internally, by another agency, the manufacturer or a composite of any of these. Internal calibration procedure part number and current revision shall be referenced on the related Calibration Record/Form.
- 6.8.2 Calibration procedures must state: the acceptable limits of accuracy and precision; standards required; and sufficient information to enable qualified personnel to perform the calibration.
- 6.8.3 Equipment used for calibration(s) shall have a Test Accuracy Ratio (TAR) of at least 10:1, i.e. calibration equipment uncertainty will be 10 times greater than the uncertainty of the measurement and test equipment being calibrated; rationale for exceptions must be documented and approved. Rationale may include an increase to the calibration frequency to compensate for this lack of compliance.
- 6.8.4 Calibration procedures and internal calibration records must state: "Calibration performed by trained personnel only."

Calibration

6.9 Calibration – Internal

6.9.1 Requirements for calibrations performed by company personnel:

- 6.9.1.1 Calibration standards used to perform internal calibration shall be traceable to a National or International Standard(s);
- 6.9.1.2 Calibrations are to be performed per application-specific written procedures, at the most current revision level, describing the step-by-step method of calibrating specific instruments or categories of instruments;
- 6.9.1.3 For company manufactured equipment, calibrations will be performed at the revision level applicable to the equipment;
- 6.9.1.4 Calibrations performed by company personnel require a cross-check to be performed prior to commencing to ensure proper documentation / procedure(s) is/are used;
- 6.9.1.5 Company personnel performing calibrations must be trained to the proper procedure and revision level as evidenced in the individuals training record;
- 6.9.1.6 Calibration procedures shall clearly state the ranges of acceptable tolerances or limits;
- 6.9.1.7 Recorded calibration data shall be recorded to the significant digit expressed in the limits;
- 6.9.1.8 Environmental conditions for test and measurement equipment calibration such as lighting, vibration, etc., i.e. other than temperature and humidity except where defined by the manufacturer's specification or user manual, shall comply with the manufacturer's published specification;
- 6.9.1.9 Environmental conditions shall be monitored by calibration personnel to ensure requirements are met when performing calibration in-house;
- 6.9.1.10 Upon completion of calibrating an item, personnel performing the calibration will indicate environmental compliance by checking off the appropriate section on the company Calibration Report.
- 6.9.1.11 If temperature or humidity exceed the specified limits for a particular calibration type, work for that type will be suspended and a supervisor notified to assess the impact.

6.9.2 Documentation of calibration shall consist of the following:

- 6.9.2.1 Completed Internal Calibration Report, including:
 - 6.9.2.1.1 Equipment I.D. number;
 - 6.9.2.1.2 Description of equipment;
 - 6.9.2.1.3 Part number and/or manufacturer of the equipment;
 - 6.9.2.1.4 Revision of the equipment (if applicable);
 - 6.9.2.1.5 Calibration/test procedure/drawing numbers used;
 - 6.9.2.1.6 Revision of the procedure used;
 - 6.9.2.1.7 Indication of cross-check performed (if applicable);
 - 6.9.2.1.8 Identification of person performing calibration/test;
 - 6.9.2.1.9 Calibration standard(s) and/or equipment used;
 - 6.9.2.1.10 Due date(s) of the standard(s) used;
 - 6.9.2.1.11 Date the calibration was completed;

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- 6.9.2.1.12 Next calibration due date;
- 6.9.2.1.13 Indication of equipment condition (pre- and post-calibration).
- 6.9.3 Personnel training for performing calibrations must also include:
- 6.9.3.1 Their trainer signature in the section labelled "Approved by" indicating verification of:
 - 6.9.3.1.1 Training to, and use of, correct procedure;
 - 6.9.3.1.2 Cross-check (if applicable);
 - 6.9.3.1.3 Acceptability of data.
- 6.9.4 Calibration data (pre and post) including acceptable tolerances/limits. These may be recorded on the Internal Calibration Report or on a data sheet specific to the equipment's calibration procedure. Completed data sheet will be attached to Internal Calibration Report.
- 6.9.5 The Calibration Department will perform a cursory review of the completed Internal Calibration Report Form and applicable Data Sheets to:
- 6.9.5.1 Review for completeness.
 - 6.9.5.2 Review for out of tolerance conditions:
 - 6.9.5.2.1 If the results indicate that the pre-calibration condition was out-of-tolerance, issue a Remedial/Corrective Action Form.
 - 6.9.5.3 If the equipment is not fully calibrated to the manufacturer's or procedural specifications, the equipment may be used in a "Limited" status. In these circumstances:
 - 6.9.5.3.1 Equipment will be identified using the "Limited Calibration" label;
 - 6.9.5.3.2 Limitations of use will be clearly identified on or near the equipment.
- 6.9.6 If the calibration is found to be acceptable, the Calibration Department shall:
- 6.9.6.1 Sign or stamp and date the Calibration Report as evidence of completion in the section labelled "Reviewed by;"
 - 6.9.6.2 Apply, or issue, an updated calibration label;
 - 6.9.6.3 Note: if changing the equipment status, the equipment owner must complete a Measurement Instrument Status Change Form;
 - 6.9.6.4 The Calibration Department shall file the Calibration Report and relevant data sheets in the equipment's history folder.

6.10 Calibration – External

- 6.10.1 Calibration Method
- 6.10.1.1 Calibration performed by Contractors shall be conducted by approved Suppliers (registered on the Approved Supplier List, ASL);
 - 6.10.1.2 The methods and criteria used to perform calibration of Measurement and Test Equipment shall comply with the manufacturers specification and shall be traceable, through certification, to a National or International Standard, e.g., NIST, UKAS or equivalent;
 - 6.10.1.3 Method of Calibration for linear Measurement Instruments such as External Micrometers, Vernier Callipers and Dial Gauges may use the methodology outlined in the British Standards in Engineering Metrology, e.g., BS 870, BS 887, BS 907, etc.;

Calibration

- 6.10.1.4 Special instructions for calibration shall be detailed in the Test Equipment Installation Qualification Form, where applicable.
- 6.10.2 Documentation Requirements. All documentation provided by the Contractor shall include at a minimum:
- 6.10.2.1 Measurement instrument identifier;
 - 6.10.2.2 The date of calibration;
 - 6.10.2.3 Tolerances or specified accuracy;
 - 6.10.2.4 Pre-calibration data;
 - 6.10.2.5 Post-calibration data (if adjusted);
 - 6.10.2.6 Identity of standards used;
 - 6.10.2.7 Calibration due-date of standards;
 - 6.10.2.8 Ancillary measurement documentation (graphs, tables, photos, etc.), if applicable;
 - 6.10.2.9 Statement of acceptability (pass/fail):
 - 6.10.2.9.1 Signature or stamp of person performing the Calibration, or Contractor's name and address.
- 6.10.3 Repairs. For equipment identified as requiring repairs by the Contractor, the Calibration Department will:
- 6.10.3.1 Request the Contractor to provide a quote for the cost of the repair and provide an estimated time for completion of repair;
 - 6.10.3.2 Notify the owning department of the need for equipment repair and request approval for repairs.
 - 6.10.3.3 Approval of repairs:
 - 6.10.3.3.1 The owning department will provide a signed and dated purchase request for the cost of repair;
 - 6.10.3.3.2 The Calibration Department will inform the Contractor to proceed with repairs and provide an account number or purchase order number.
 - 6.10.3.4 Disapproval of repairs:
 - 6.10.3.4.1 Inform the Contractor to return the equipment, un-repaired, if offsite.
- 6.10.4 Receiving Equipment. Upon receipt of the equipment from the Contractor, the Calibration Department will:
- 6.10.4.1 Physically examine the measurement and test equipment for any damage;
 - 6.10.4.2 Review all calibration documentation for required information by checking off blocks on the Calibration Return Checklist as conformance to requirements is verified;
 - 6.10.4.3 Measurement and test equipment with documentation missing or insufficient information shall be detained in the Calibration Storage Cabinet ("Test Equipment not Calibrated"), or label "Do Not Use-Out of Service;"

Calibration

6.10.4.4 Measurement and test equipment with documentation missing or insufficient information shall require approval of Calibration Department personnel prior to releasing equipment for use. Calibration Department personnel will print name, sign or stamp, and date the Discrepancy Approval section of the Calibration Documentation Return Checklist upon acceptance or approval of documentation, as well as document rationale in the 'Remarks' section for any deficient Certificates accepted.

6.10.4.5 If Calibration Department personnel approval is denied, contact the Sub-Contractor, requesting the deficient information. Repeat section 6.10.4.4;

6.10.4.6 Compare specific values (data) to acceptance criteria (tolerances/accuracy specifications), or review statement of acceptability for out of tolerance conditions;

6.10.4.7 Owing departments of equipment having a pre-calibration condition of being out-of-tolerance shall be issued a Remedial/Corrective Action Form;

6.10.4.8 If the Calibration Certificate indicates that the equipment is not calibrated over the entire range of measurement or the "post-calibration" condition was out-of-tolerance, the equipment may be:

6.10.4.8.1 Discontinued;

6.10.4.8.2 Placed in "Not in Use" or "Inactive" status;

6.10.4.8.3 Used as "Reference Only;"

6.10.4.8.4 Used in a "Limited" status. In these circumstances equipment will be identified using a "Limited Calibration" or "Special Calibration" label. Limitations of use will be clearly identified on or near the equipment.

6.10.4.9 Verify dates on the Calibration Label and Calibration Certificate concur as well as comparing the due date to the calibration interval.

6.10.4.10 Check for calibration seals in place, where appropriate.

6.10.5 Finalizing

6.10.5.1 Print name, sign or stamp, and date the form, return checklist as evidence of review and availability for use. The form will be placed with equipment calibration certificate records in the designated cabinet;

6.10.5.2 Update the calibration database to include all newly received information, such as next calibration due date and status, etc.;

6.10.5.3 File the Certificate of Calibration and relevant documents as part of the equipment's calibration history records;

6.10.5.4 Place the equipment in the calibrated equipment storage cabinet if not required for immediate use;

6.10.5.5 Notify the owning department if applicable.

6.10.6 External calibration company supplier survey/audits

6.10.6.1 Accreditation by a recognized body may be accepted by in lieu of an audit, e.g., International Laboratory Accreditation Co-Operation [ILAC]. If an audit is not deemed necessary, a copy of the current certificate of accreditation will be maintained in the supplier audit file.

Calibration

7 Records

Document	Location	Duration of Record	Responsibility
Equipment Master and History List	Calibration Department	Indefinitely	Calibration Co-Ordinator
Calibration Program/ Schedule	Calibration Department	Six years	Calibration Co-Ordinator
Equipment calibration Report	Calibration Department	Six years	Calibration Co-Ordinator
Equipment Calibration Certificate	Calibration Department	Indefinitely	Calibration Co-Ordinator

Corrective and Preventive Action

FBO Procedure	
Document #	SOP-009
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial draft for review and discussion.
24-04-2015	V1.0	Mary Cahill	Original issue & update after technical review.

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Corrective and Preventive Action

1 Summary

Purpose	This procedure describes the methodology used within the organization to manage the corrective and preventive action process.
Scope	This procedure applies to the generation of corrective and preventive actions, associated root cause analysis and the effective closure of corrective and preventive actions.
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager/Management Representative.

2 Related documents

Policies	Food Safety Policy, POL-001
Processes	Compliance, PRO-004
Procedures	Complaint Management, SOP-014
	Management Review, SOP-021
	Strategic Planning, SOP-029
Work Instructions	N/A
Forms	CAPA Form
Other	N/A

Corrective and Preventive Action

3 Definitions

Term or Acronym	Description
CA	Corrective Action
PA	Preventive Action
DMS	Document Management System
FSM/MR	Food Safety Manager/Management Representative
FSMS	Food Safety Management System
RCA	Root Cause Analysis
Correction	Action taken to eliminate a detected nonconformity
Corrective action	Action taken to eliminate the cause of a nonconformity and prevent recurrence
Preventive action	Action taken to prevent the occurrence of nonconformity
Root cause analysis	A method of problem solving that tries to identify the root cause of faults or problems

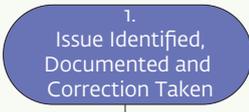
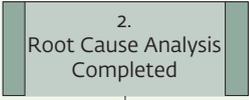
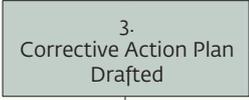
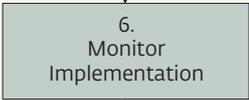
4 Introduction

The identification of issues affecting the FSMS and the implementation of corrective and preventive actions are a core requirement in the continual improvement process within a management system. In order for such corrective actions to be effective, a rigorous root cause analysis process must be followed to ensure the actual cause of the issue is identified, eliminated and recurrence prevented.

This procedure outlines the process implemented within the organization to ensure this is achieved.

Corrective and Preventive Action

5. Procedure Flow Chart

Responsibility	PROCESS	Record(s)
Employee/Auditor/ Customer		
Relevant Department		
Relevant Department		
FSM/MR/ Relevant Department/ Auditor		
Relevant Department		
FSM/MR/ Relevant Department/ Auditor		
Relevant Department		
FSM/MR/Auditor		
FSM/MR/ Relevant Department/ Auditor		

Corrective and Preventive Action

6 Procedure Notes

6.1 Step 1 Problem Definition/Record Creation

An issue can be identified from several sources including auditing (both internal and external), customer complaints or legal/regulatory issues. Once identified, **immediate correction** must be taken to resolve the issue and the issue **must** be documented within the DMS software. The appropriate resources will then be put in place to manage the investigation of the issue in line with the above flowchart.

6.2 Step 2 Root Cause Analysis

It is mandatory that all issues raised are investigated thoroughly utilizing a recognized root cause analysis methodology, e.g. 5 Whys, 8D, Go See Think Do, etc. Only when the root cause has been identified can corrective action and/or preventive action be identified. Root cause analysis may only be undertaken by trained personnel. Under no circumstances can 'human error' or a 'restatement of the issue' be described as the root cause. In the event of this being the case, the root cause **must** be rejected and redone. Root cause analysis **must** be completed by the department in which the issue arose. Where necessary, preventive actions may also be identified during the root cause analysis. Where this is the case, they must be documented as part of the corrective action plan.

6.3 Step 3 Corrective Action Plan Drafted

A corrective action plan will be created as follows:

Issue Description	Root Cause	Corrective Action(s)	Preventive Action(s)	Assigned to	Expected completion date

The corrective action plan will be created by the relevant department where the issue arose. It is fully their responsibility to generate this plan and submit it for review and approval.

6.4 Step 4 Corrective Action Plan Reviewed

The corrective action plan must be submitted to the FSM/MR/Auditor for review and approval. Where the FSM/MR/Auditor decide that the corrective action plan is not sufficient or acceptable, they will return it for rework. Corrective actions plans may be rejected on the grounds of a badly completed root cause analysis, unrealistic timeframes or no assignment of responsibilities or other grounds as deemed appropriate by the review team.

Where the corrective action plan is deemed to be approved, the review team will notify the department to proceed with the plan.

Corrective and Preventive Action

6.5 Step 5 Implement the Corrective Action

The relevant department will implement the corrective action plan as documented.

6.6 Step 6 Monitor Implementation

Implementation will be monitored in accordance with the documented plan on regular basis to ensure timely corrective action is taken and that any issues arising are dealt with.

6.7 Step 7 Verify Implementation

When the implementing department are satisfied that the corrective action taken has been completed, a test to determine the effectiveness of the corrective action must be undertaken and relevant evidence recorded. Where results show that the expected outcome has not been achieved, i.e. the elimination of the root cause, the department must redo the root cause analysis. Only when this evidence objectively shows that the root cause of the issue has been eliminated, the department may request that the issue be closed out.

6.8 Step 8 Review for Closure

The FSM/MR/Auditor, and other interested parties as necessary, will review the objective evidence related to the effectiveness of the corrective action taken. Only when they are satisfied that the root cause has been eliminated will they allow the issue to be closed. Where any doubt exists, the review team may request extra verification activities to be undertaken and results submitted again or they may request a complete re-submittance of the corrective action plan.

6.9 Step 9 Close CAPA

Where the review team is satisfied that the root cause has been eliminated, they will authorize the closure of the issue on the CAPA system.

7, Records

Document	Location	Duration of Record	Responsibility
Compliant	Food Safety Office	Indefinitely	FSM/MR
Audit finding	Food Safety Office	6 years	FSM/MR
Corrective action plan	Food Safety Office	6 years	FSM/MR
Verification evidence	Food Safety Office	6 years	FSM/MR

Internal Auditing

FBO Procedure	
Document #	SOP-006
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
<p>All documents within FBO are classified in the following way: PUBLIC documents are intended for anyone; COMMERCIAL IN CONFIDENCE documents are to be kept confidential between restricted individuals within the FBO and partner organizations; COMPANY CONFIDENTIAL documents are to be kept confidential within FBO and used for normal business activities by the general office population; HIGHLY CONFIDENTIAL documents are to be kept confidential to restricted individuals within FBO.</p> <p>© Copyright FBO. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the written permission of FBO.</p>	
Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved for release by process owner.

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Internal Auditing

1 Summary

Purpose	<p>The purpose of this procedure is to describe the:</p> <ul style="list-style-type: none"> ● Internal audit methodology employed to ensure that the Food Safety Management System remains suitable, adequate and effective in meeting business, customer, and compliance requirements, the requirements of FSSC 22000 and ensure that the FSMS is effectively implemented and maintained.
Scope	<p>This procedure applies to:</p> <ul style="list-style-type: none"> ● Audit program planning, performance and follow-up, including initiating of audit, audit preparation, conducting the audit, preparing and distributing the audit report, completing the audit and audit follow-up if required; ● Compliance and conformance auditing.
Functional Responsibility	<p>The functional responsibility for this procedure lies with the Food Safety Manager, who is responsible for the effective implementation and maintenance of this procedure.</p>

2 Related documents

Policies	Food Safety Policy, POL-001
Processes	Departmental process descriptions
Procedures	Corrective and Preventive Action, SOP-009 Management Review, SOP-021
Work Instructions	N/A
Forms	FSMS Audit Checklist
Other	Statutory and Regulatory Requirements FSSC 22000:2010

Internal Auditing

3 Definitions

Term or Acronym	Description
Audit plan	Description of the activities and arrangements for an audit
Audit conclusion	The outcome of the audit provided by the audit team after consideration of all the audit findings and audit objectives
Audit criteria	Set of policies, documented information or requirements used as a reference against which audit evidence is compared
Audit finding	Results of the evaluation of the audit evidence against the audit criteria
Audit programme	Set of one or more audits planned for a specific timeframe and directed towards a specific purpose
Audit scope	The extent and boundaries of the audit
Auditor	Person with the demonstrated personal attributes and competence to conduct an audit
Compliance auditing	Determination of compliance with defined statutory and regulatory requirements
Conformance auditing	Determination of conformance to defined International Standards e.g. FSSC 22000:2010
Correction	Action taken to eliminate a detected nonconformity
Corrective action	Action taken to eliminate the cause of a nonconformity and prevent recurrence
FSM/MR	Food Safety Manager/Management Representative
FSMS	Food Safety Management System
High risk finding	Significant weakness in the system or process – need rectification immediately
Internal audit	Systematic and independent process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled
Low risk finding	A general weakness in the system or process which if rectified immediately could improve efficiency
Major finding	A total breakdown or absence of objective evidence to satisfy one or more Quality Management System requirements, or a situation which would, on the basis of available objective evidence, raise significant doubt as to the quality of the product that the organization is supplying
Medium risk finding	A potentially significant weakness in the system or process – if not rectified immediately may lead to high risk
Minor finding	Where there is defined and documented system which generally satisfies one or more Food Safety Management System requirements, or a situation which would, on the basis of available objective evidence, raise a concern as to the potential quality of what the organization is supplying, e.g. the system and/or one or more processes have not reached an acceptable maturity level

Internal Auditing

Term or Acronym	Description
Nonconformity	The non-fulfilment of a requirement
Objective/audit evidence	Records, statements of fact or other information which are relevant to the audit criteria and verifiable
Opportunity for improvement	An issue, identified by the auditor that warrants investigation by the auditee to affect improvement
Root cause Analysis	A method of problem solving that tries to identify the root cause of faults or problems
SWOT analysis	A SWOT analysis is a section of the audit report where the audit team categorises the audit findings into Strengths, Weaknesses, Opportunities and Threats.

4 Introduction

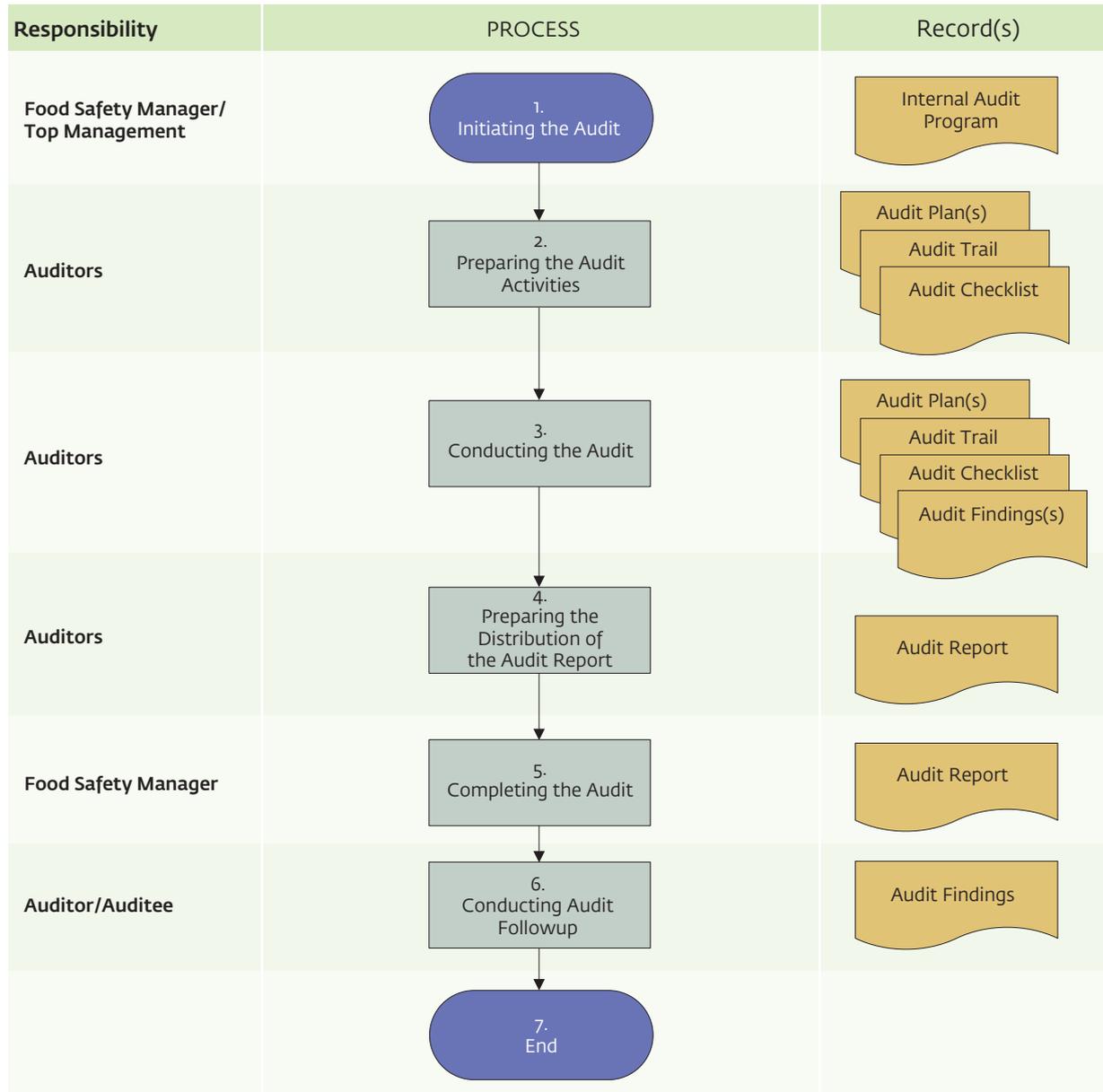
4.1 Internal Auditing

Internal auditing is completed to monitor and measure the company’s level of compliance against its statutory and regulatory requirements and its level of conformance with the requirements of the Food Safety Management System.

Internal audits will be scheduled on a planned basis, conducted by trained internal auditors and their findings reported to management for review and action. Where audit findings are raised, the auditee will be required to give a commitment to addressing and resolving these issues. The internal auditor will seek evidence of the effective implementation of these actions. The results of internal audits and the overall effectiveness of the internal audit programme will be reported at the management review meeting.

Internal Auditing

5 Procedure Flow Chart



Internal Auditing

6 Procedure Notes

Step 1

The Food Safety Manager has the responsibility to create and management the internal audit process. This involves establishing initial contact with the auditee(s) and agreeing the following:

- Audit objectives, scope and criteria;
- Agree the date for the audit to take place;
- Resources to complete the audit, including access to the required people, processes, activities and documentation;
- Statutory and regulatory requirements to be assessed during the audit;
- The need for any observers and/or guides; and
- Determine any specific areas of concern for the auditee.

The output from this phase is the development of an audit programme outlining the audits to be completed over a defined period of time. It also may identify the Internal Auditor assigned to the audit. Once completed, the programme will be published and communicated across the company.

Step 2

Each individual internal auditor is responsible to create an:

- Audit plan, including audit objectives, scope and criteria;
- Audit checklist or audit trail.

Audit plans and checklist/trails will be template based to ensure consistency. Once documented by the Internal Auditor, the audit plan will be communicated to the relevant auditee(s).

It should be noted that some audits will be conducted on an unannounced basis as directed by the Food Safety Manager. Where this is the case, no audit plan may be produced; however, the Food Safety Manager will fully brief the Internal Auditor as to the objectives, scope and criteria of the audit.

Internal Auditing

Step 3

The Internal Auditor will conduct the audit in accordance with the plan. Audit checklists or audit trails will be used by the auditor to record audit evidence. Audits will be conducted using interview, observation, review of records and documents, and analysis of data. Trend analysis and tests may also be utilized to gather evidence as required. Details to be recorded on the checklist or audit trails include the requirement being checked, the evidence gathered, the conformance indication and identification of the auditee.

In the event of an Internal Auditor identifying a non-conformity, based on objective evidence, the Internal Auditor will inform the Process Owner/Head of Department of the issue and explain what the non-conformity is, why it is a non-conformity and the requirement that has not been fulfilled. The internal auditor will document the non-conformity in their checklist or audit trail and get the auditee to sign it signifying the auditee's acceptance of the issue and their commitment to rectify the issue. The Internal Auditor will classify the audit finding as major, minor or an opportunity for improvement based upon risk. The Internal Auditor should not downgrade an audit finding to an opportunity for improvement where there is evidence of a non-conformity.

It is solely the responsibility of the Process Owner/Head of Department, where audit findings are raised, to rectify these findings. Correction must be taken, a root cause analysis using a recognised root cause analysis methodology, e.g. 5 Whys, Fishbone Diagram, etc. must be completed and corrective action identified and implemented. A response plan must be submitted to the Internal Auditor by the auditee within 10 days of the audit outlining the above correction, root cause analysis and corrective action(s). The Internal Auditor will review the response plan and approve or reject it [i.e. if there is no root cause analysis, the root cause analysis is inadequate, etc.]. If rejected, the Auditee must correct the response plan and re-submit for approval. All audit findings should be closed out within 12 weeks of the finding being made, exceptions to this may be granted subject to approval of the Internal Auditor and the FSM/MR.

The outputs from this phase is that the audit objective has been achieved, audit plan met, completed checklists/audit trails and, where applicable, identified audit findings and a response plan received from the Process Owner/Head of Department.

Step 4

The Internal Auditor will prepare an audit report outlining the audit conclusion. This conclusion is based on a comparison of all the audit findings against the audit objective. The report will be detailed and cover the following points at a minimum:

- Identification of the audit objective, scope and criteria;
- Identification of the Auditor and Process Owner(s)/Head of Department;
- The audit conclusion;
- Executive summary;
- SWOT analysis;
- Description of the process, critical process parameters and process performance;
- The number of audit findings and their classification;

Classification

Company Confidential

Internal Auditing

Doc ID **SOP-006**
Created **20-04-2015**

Printed
Updated **24-04-2015**

Controller **Document Controller**
Owner **Food Safety Manager**

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Internal Auditing

- The audit findings in detail;
- Sample/confidentiality statement;
- Audit follow up;
- Audit checklist and/or audit trail (as an attachment).

The audit report will then be released to the Food Safety Manager and the Process Owner/Head of Department.

Step 5

The audit is completed when all planned audit activities have been completed or otherwise agreed with the Process Owner, e.g. there may have been an unexpected event that prevented the audit plan from being completed.

The Food Safety Manager will technically review the audit report to ensure that all aspects of the audit plan have been covered, the evidence gathered is objective and related to the audit criteria, and the audit conclusion reached is correct. He or she will also manage any appeals raised by the Process Manager/Head of Department in relation to an audit finding, and where agreement cannot be reached between the Food Safety Manager and the Process Owner/Head of Department, the Food Safety Manager will elevate the issue to the Executive Management Team for resolution.

Step 6

Based on the response plan submitted by the Process Owner and the agreed closure timescales, the internal auditor will follow up to ensure that all audit findings have been effectively closed out. This will be achieved through the verification of the effectiveness of the corrective action(s) taken by the auditee. A test or review of evidence will be conducted by the auditor to determine if the audit finding has been closed out. Where satisfied, the internal auditor will close the audit finding.

Where the Internal Auditor does not agree to close the audit finding, agreement on the actions to be taken will be determined between the Internal Auditor and the Auditee.

7 Audit Records

The following documentation will be maintained as evidence of audits being performed:

- Audit Plan;
- Audit Checklist/Audit Trail;
- Audit Report;
- Root Cause Analysis Data/Response Plan.

Internal Auditing

8 Records

Document	Location	Duration of Record	Responsibility
Internal Audit Program	Food Safety Office	Six years	Food Safety Manager
Internal Audit Plan	Food Safety Office	Indefinitely	Food Safety Manager
Audit Checklist / Audit Trail	Food Safety Office	Indefinitely	Food Safety Manager
Audit Report	Food Safety Office	Indefinitely	Food Safety Manager
Response Plan	Food Safety Office	Indefinitely	Food Safety Manager

Traceability

FBO Procedure	
Document #	SOP-012
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved and released by process owner.

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Traceability

1 Summary

Purpose	To describe the process being able to trace each ingredient back to its source and being able to track dairy product after they leave the dairy plant.
Scope	This instruction covers all products manufactured or distributed by the FBO. <i>Note: Local regulations and laws prevail over this guideline.</i>
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager and Traceability/Recall PRP Team. They are responsible for the effective implementation and maintenance of this procedure.

2 Related documents

Policies	Food Safety Policy, POL-001 Customer/Consumer Complaints Policy, POL-002
Processes	Departmental process descriptions
Procedures	Control of Non-Conforming Product, SOP-003 Recall and Withdrawal, SOP-023 Communications, SOP-020 Crisis Management, SOP-029 Corrective and Preventive Action, SOP-009
Work Instructions	Not Applicable
Forms	Recall/Withdrawal Log Communication Log Root Cause Analysis/Corrective Action
Other	Not Applicable

Traceability

3 Definitions

Term or Acronym	Description
Complaint	Expression of dissatisfaction made to an organization related to its product or service, or the complaints-handling process itself where a response or resolution is explicitly or implicitly expected
Correction	Action to eliminate a detected nonconformity
Corrective action	Action to eliminate the cause of a nonconformity and to prevent recurrence
Critical Tracking Events [CTEs]	Events that identify those core business processes where traceability data capture is vital to a successful traceability process
Dilution	The ability to separate the products that may have a large amount of the contaminant, and those that may only have possible traces
Exclusion	Exclusion is the ability to EXCLUDE the products that do not contain any contaminant
FSM/MR	Food Safety Manager/Management Representative
FSMS	Food Safety Management System
Inclusion	Inclusion is the ability to INCLUDE any product(s) that could contain any trace of a possible contaminant.
Key Data Elements [KDEs]	The data captured during a CTE to support a successful traceability process
Nonconformity	Non-fulfilment of a requirement
Product	Output that is a result of activities where none of them necessarily is performed at the interface between the provider and the customer. For the FBO this can be an ingredient, raw material, intermediate product or finished product supplied to a customer or consumer
Recall	Recall is the process by which a product is removed from the external supply chain/distribution and where consumers are publicly advised to take specific actions with the product (e.g. "do not consume the product," or "return the product to the shop or manufacturer"). This includes the FDA class I and class II recalls
Regulatory requirement	Obligatory requirement specified by an authority mandated by a legislative body
Risk	Effect of uncertainty on an expected result
Root Cause	A cause that once removed from the problem fault sequence, prevents the final undesirable event from recurring
Root Cause Analysis	A method of problem solving that tries to identify the root cause of faults or problems

Traceability

Term or Acronym	Description
Statutory requirement	Obligatory requirement specified by a legislative body
Traceability	Traceability is the ability to track a food through all stages of production, processing and distribution (including importation and at retail). Traceability should mean that movements can be traced one step backwards and one step forward at any point in the supply chain
Tracing	The capability to identify the origin and characteristics of a product based on criteria determined at each point of the supply chain
Tracking	The capability to locate a product based on specific criteria wherever it is within the supply chain.

4 Introduction

4.1 Traceability

Traceability systems are designed to trace and track products and their components through the supply chain. Although traceability must be an end-to-end process, it is accomplished in a supply chain consisting of independent firms with different stand-alone information systems. To ensure continuity in the flow of traceability information, each partner in the food chain must pass on information about the identified lot or product group to the next partner in the food chain [traceability information chain should not be broken].

Thus, to accomplish end-to-end traceability, supply chain partners must undertake three key activities:

- 1. Data collection:** The system must be able to capture the required data. Although this may be accomplished using paper-based methods, more effective technologies like bar code scanners, radio frequency identification, handheld computers and specially engineered input devices are simplifying data collection and allowing more data to be captured.
- 2. Data storage:** Once collected, the data must be organized and stored in a database which allows different options for retrieval and search.
- 3. Data transmission and sharing:** The system is only effective if data can be exchanged between supply chain intermediaries. Thus, traceability systems must have systems integration capabilities, connecting hardware and software, which allows diverse corporate systems to communicate.

In dairy processing, traceability requires collecting, filing and sharing information about:

- Product ingredients;
- Processing;
- Packaging;
- Labelling;
- Storage;
- Distribution.

Traceability

5 Procedure Flow Chart

Not applicable.

6 Procedure Notes

6.1 Identify and Record Lot IDs or Key Data Elements [KDEs]

Identify the places in the FBO facility where bulk products, ingredients, or packaging materials are added to make your final product and identify key points in the physical process where product is transformed or lots can be discretely separated (Critical Product Flows):

- a) Create a method of recording the Lot ID's for each of these places;
- b) Decide on which identifying mark will be used for the Lot ID on the various materials;
- c) Train FBO employees to be consistent and accurate when recording Lot IDs;
- d) Keep FBO records in a way that makes the Lot IDs easy to find. Identify and record flows (Critical Tracking Events, CTEs).

The following specific areas are common in the dairy foods industry and should be considered when listing KDEs - Lot Entry Points:

Raw Milk Receiving – When receiving raw milk, the receiving facility should consider each farm on a truck as a lot of product received. The facility should have, or have access to, the farm name and address of the farmer. Model the receiving bay as a Lot Entry Point, and record each farm received and the silo that it was received into. This can be accomplished in three ways:

1. The receiver records the load information only, and turns the dairy farm tickets into the office where the individual tickets are correlated with the load information. This would be used when multiple dairy farms pickups are accumulated on a single delivered load;
2. Only the route information is recorded by the receiver because the load is co-mingled [mixed by a cooperative]. In this case, the cooperative would need to have the dairy farm information for each load, and would be involved in the tracking if a recall were required;
3. The receiver records the individual dairy farm tickets that are received with the load information.

Milk Hauler/Driver Responsibility – The records of the Milk Hauler/Driver performing the dairy farm pickups are paramount to making a recall work and are the first step in creating a successful traceability program. Accurate identification of the dairy farm, quantity, CIP records, and sample of milk is essential, reference the manifest or e-manifest

Traceability

Using Dairy Farm ID – The Dairy Farm ID is often used as the identifier for the dairy farm load. This can be helpful to trace the loads, since this number is issued by a country Department of Agriculture and is used in inspections and other records. However, many cooperatives and other dairy businesses assign their own dairy farm ID as well. It is important that your haulers'/drivers' and receivers' records are consistent and accurate.

Raw Milk Pooling – When milk is picked up from the dairy farm, loaded into silos or tanks and reshipped to dairy foods plants, it is the responsibility of the milk pooling facility to keep the records of the dairy farm loads as they relate to the tankers shipped. This facility will be modeled as any other facility.

Rework – Rework is common but complicates traceability. Consider and model rework as you would for any other ingredient or product. Rework is best handled in the following manner:

- List the points [steps in the process] where rework could be collected in the process. Identify and label the rework as a final product;
- If the rework is not a final product, create a Lot Identifying Mark on the rework. If it is a bulk rework situation, create a Lot Identifying Mark and mark or tag the tank with this identifier;
- If the rework is a final product, use that Lot Identifying Mark;
- List the points [steps in the process] where the rework is added back into the process. Record the Lot Identifying Marks as you would with any other ingredient. (KDE – Lot Entry Point);
- Take note of the Rework narrative in the following section, Critical Tracking Event;
- To reduce the co-mingling of lots, limit rework from one day added into another as much as possible.

Packaging Materials – Any packaging materials that come in contact with the product should be recorded.

Common Lot Entry Points Missed – CO₂ addition, or other gases:

- Bags and liners for product packaging;
- Vitamins and small quantity additives.

Disposed Ingredients or Products – Records should be maintained for ingredients, products, and packaging materials that are disposed. The quantity disposed, and the Lot Identifying Mark should be recorded as any final product.

6.2 Identify and Record Flows or Critical Tracking Events [CTEs]

Identify the main flow paths in the Dairy Plant that product pass through from the beginning to end:

- a. Create a method of recording each of these flows;
- b. Train FBO employees to be consistent and accurate when recording these flows;
- c. Keep GBO records in a way that makes it easy to relate the above recorded Lot IDs with the flows.
- d. Track FBO flows between the facilities within your corporation or cooperative. Keeping good records of FBO interplant transfers or a system that can link the traceability of FBO products between facilities will reduce your time to identify products or exclude the FBO from a recall.

Traceability

There are a few areas of special consideration for modeling the Critical Tracking Events in a dairy foods facility:

- *Storage that does not get CIP'd on a frequent basis.* Oils, sugars, and other bulk ingredients are stored for long periods of time without being completely emptied or CIP'd. This is common and safe, but breaks a granular model of traceability.
- *Reset the trace for this vessel on a calculated first-in, first-out method.* For example, 3,000 kg of oil were delivered, so the first 3,000 kg used exhausts that lot. On a reoccurring basis (possibly monthly) re-verify the calculated inventory to actual inventory.
- *Reset the trace based on a recurring time period.* This is a common practice for city water, since there never is really an interruption. For government-supplied water, many reset the trace every 24 hours.
- *Continuous processes.* Some processes run for longer periods of time than is practical for consideration as one lot of finished product. Spray dryers, powder silos or other processes may run for several days without stopping for a CIP. Yet the flows through these processes need to be documented either manually or automatically to provide good traceability.
- *Reset the Critical Tracking Event whenever a source or destination changes.* For instance, on a dryer, create a new flow record when the powder bin selection changes. In the case of an evaporator, change the flow record whenever the silo feeding the evaporator changes. If these two are combined, the quantity of product under one Critical Tracking Event becomes much smaller, reducing the size of the Lot that will be considered for a recall.

When the Critical Tracking Event is reset as described, the following traceability can be accomplished:

Inclusion – Depending on the risk of the contaminant, the entire list of final product Lot Identifying Marks can be held, recalled, or tested during the CIP to CIP run of the dryer.

Exclusion – Depending again on the risk of the contaminant, the final products that are within the narrowest scope of a single silo crossing to a single powder bin can be isolated. This may be the highest risk product.

Dilution – Depending once again on the risk of the contaminant, final product that contains items such as a common silo, powder bin, a common rework Lot Identifying Mark, can now be isolated to find those product lots with trace amounts of the contaminant.

This method can be used to find the source of the contaminant, especially in an automatically collected traceability solution.

Adding rework into the process. Rework addition should be handled as any other ingredient additions. However, where creation of rework is possible, the points in the process should be modeled as a Critical Tracking Event, with a final Lot Identifying Mark so when it is added it can be traced.

Traceability

6.3 Place a Standard, Human Readable Lot ID on FBO Products [Lot ID]

Label the FBO final products with a simple, human-readable Lot ID so everyone using your products in their manufacturing can also maintain consistent and accurate records:

- a. Use this Lot ID in FBO records as either a primary identity, or at least a searchable field in FBO electronic or ERP system;
- b. Use this Lot ID in every record, both manual and electronic (ERP);
- c. Add "LOT" or "Lot ID" near the human-readable Lot ID so the operators in the FBO's customers' facilities can easily record the correct identity.

6.4 Product Labelling

A simple, readable LOT ID should be accurately recorded is the key element in a successful traceability system.

To allow efficient and expedient traceability, the Lot Identifying Mark should:

- Be easily readable for your customers that use manual lot tracking records;
- Stand out on the package, pallet label, and bill of lading so that customers can clearly determine the Lot Identifying Mark they should use in their traceability records.

If you are incorporating a bar code into your records that is used by all customers, ensure that both distributors and the final customers are bar code scanning the Lot Identifying Mark, and integrating it into their traceability records.

The Lot Identity Mark should be obvious on every package, container, pallet and bill of lading that leaves the FBO.

If the product is meant for use by another manufacturer or processor, the text "LOT" or "Lot ID" should be printed boldly and visibly next to the Lot Identifying Mark.

Alternatively, for a small manufacturer, the number should be applied in human readable form. Again the text "LOT" or "Lot ID" should appear near the code.

If a customer requests or accepted more extensive Lot Identifying Marks, this is also acceptable; simply make sure the mark is clear. The Lot Identifying Marks should be used in all correspondence.

The recommended lot identifying mark content should consist of:

- The dairy plant number, the date and a process identifier. The plant numbers are typically 4-6 digits;
- The date should be in a plain format. For example, July 26, 2012 could be shown in YYYYMMDD format as 20120726, or alternatively, in YYYYDDMM format as 20122607;
- An additional identifier for the product created in a specific day. This identifier is a line identity.

Traceability

6.5 Dairy Milk Traceability Records

General Information

- Any final product, bulk or packaged, should have a listing of the Lot Numbers that it contains.
- The Lot Numbers that these records contain should match the Lot Numbers in the warehouse records.

If the FBO traceability system is stored in a database, the Lot Identifying Marks should link or associate all the records.

Traceability records should enable the FBO to find a Lot Identifying Mark and any contributing Lot Identifying Marks quickly and accurately. The traceability records need to only contain the information to accomplish this.

For internal records, it is recommended to have the basic traceability information linked with the full record of the process and the quality assurance records.

The following is the contents of the basic record content set.

KDEs - Lot Entry Points. An up-to-date listing of the KDEs - Lot Entry Points for your facility or process area. This shows that you can track where other Lot Identifying Marks enter your process. It will also correlate to the daily records you keep, either manually or electronically, of the Lot Identifying Marks that you incorporate into your final products. These records can be either textual or flow charts.

Critical Tracking Events. An up-to-date listing of the physical flows in the process, or Critical Tracking Events. This will correlate to the daily records of the flows in your facility and will be used to find the path of the Lot Identifying Marks through the process. These records can be either textual or flow charts.

Lot Identifying Mark. This record is only a short written description of how your Lot Identifying Mark is structured and what the digits represent. The following are the minimum records to be maintained by the FBO.

Farm Milk Records should minimally contain:

- Farm number;
- Carrier/hauler identification;
- Driver identification;
- List of farm identification in load;
- Time load was received;
- Therapeutic drug [antibiotic] test result;
- Receiver/tester;
- Milk temperature;
- Silo destination for load.

Traceability

Bulk Receipt Records should minimally contain:

- Bill of lading number;
- Carrier information;
- Lot identifying mark from supplier;
- Time received.

Ingredient Addition Records should minimally contain:

- Lot identifying mark from supplier;
- Carrier information;
- Manufacturer name (if manual system; if electronic, this can be joined in the database from the Lot Identifying Mark);
- Ingredient name (if manual system; if electronic, this can be joined in the database from the Lot Identifying Mark);
- Time of addition;
- Operator.

Final Product records should minimally contain:

- Lot Identifying Mark;
- Product name;
- Time of product run start;
- Time of product run end.

Peripheral Areas (Warehouse, Distribution Centers, Shipping)

Outside the physical processing environment (within the supply chain) traceability becomes discrete, meaning each product that can be contaminated is contained in one package. If an easily identifiable Lot Identifying Mark is contained in the Bill of Lading, Shipping Records, Receiving Records, Warehouse system, etc., once the suspect product(s) are traced and identified each can be quickly held, tested, removed from the food chain or destroyed.

Record Retention, Security, and Backup

Traceability records are retained for the same duration as other regulatory records, such as CIP and pasteurization records. Until regulatory documents list traceability record retention, assume the same length of time as the PMO (Pasteurized Milk Ordinance) specifies for HTST record retention.

It is important that these records are not lost, or edited. Note the following:

- If the records are manual, they should be stored in files that are either in an office that is locked when it isn't staffed or after business hours, OR are locked in a file cabinet;
- If the records are electronic, they should be backed up once every 24 hours and stored in a database or data archival system in a Write Once, Read Many (WORM) format.

Traceability

6.6 Testing and Validation of the Traceability System

The testing and validation of the FBO traceability system should at a minimum cover two scenarios via the FBO product recall procedure:

1. Get one or more final product KDEs – Lot Identification Mark(s) and identifying the contributing bulks, dairy farms, ingredients, additives or packaging materials that the product contains;
2. Getting a suspect or possible adulterated alert of a bulk, dairy farm, ingredient, additive, or packaging material and needing to find the final products(s) that contains the possible containment.

The results of the traceability system testing and validation should be confirmed via QA/Laboratory results.

6.7 Traceability System Testing and Validation Frequency

The FBO policy states that testing frequency and validation of the traceability system should be at least annual or following a serious food incident/event or a significant change to the FBO or food chain partner traceability system.

6.8 Post Review Actions

A post review action review must be conducted when the mock recall is over and potential improvements implemented. Any actions arising should be monitored and tracked via the FBO corrective and preventive action procedure.

As a minimum, an analysis of the involved quantities of materials must be made (produced, sold, returned, destroyed, authorized for release and not accounted for or consumed).

The simple goal of the Mock Recall is ideally 100 percent product [bulk, dairy farm, ingredient, additive, intermediate product or finished product] is accounted for within two hours or less.

7 Records

Document	Location	Duration of Record	Responsibility
Dairy Plant Records [Various]	Food Safety Office	Indefinitely	Food Safety Manager
Mock Recall Log	Food Safety Office	Indefinitely	Food Safety Manager
Communication Records	Food Safety Office	Indefinitely	Food Safety Manager
Root Cause Analysis	Food Safety Office	Indefinitely	Food Safety Manager
Mock Recall Report	Food Safety Office	Indefinitely	Food Safety Manager
Post Review Minutes	Food Safety Office	Indefinitely	Food Safety Manager

Product Recall and Withdrawal

FBO Procedure	
Document #	SOP-023
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved and released by process owner.

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Classification		Company Confidential		Product Recall and Withdrawal	
Doc ID	SOP-023	Printed		Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner	Food Safety Manager
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Product Recall and Withdrawal

1 Summary

Purpose	To describe the process for effectively removing a product from the external supply chain/distribution.
Scope	This instruction covers all products manufactured or distributed by the FBO. <i>Note: Local regulations and laws prevail over this guideline.</i>
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager, who is responsible for the effective implementation and maintenance of this procedure.

2 Related documents

Policies	Food Safety Policy, POL-001 Customer/Consumer Complaints Policy, POL-002
Processes	Departmental process descriptions
Procedures	Control of Non-Conforming Product, SOP-003 Mock Recall, SOP-008 Communications, SOP-020 Crisis Management, SOP-029 Corrective and Preventive Action, SOP-009
Work Instructions	Not Applicable
Forms	Recall/Withdrawal Log Communication Log Root Cause Analysis/Corrective Action
Other	Not Applicable

Product Recall and Withdrawal

3 Definitions

Term or Acronym	Description
Complaint	Expression of dissatisfaction made to an organization related to its product or service, or the complaints-handling process itself where a response or resolution is explicitly or implicitly expected
Correction	Action to eliminate a detected nonconformity
Corrective action	Action to eliminate the cause of a nonconformity and to prevent recurrence
FSM/MR	Food Safety Manager/Management Representative
FSMS	Food Safety Management System
Nonconformity	Non-fulfilment of a requirement
Product	Output that is a result of activities where none of them necessarily is performed at the interface between the provider and the customer. For the FBO this can be an ingredient, raw material, intermediate product or finished product supplied to a customer or consumer
Recall	Recall is the process by which a product is removed from the external supply chain/distribution and where consumers are publicly advised to take specific actions with the product (e.g. "do not consume the product", or "return the product to the shop or manufacturer"). This includes the FDA class I and class II recalls
Regulatory requirement	Obligatory requirement specified by an authority mandated by a legislative body
Risk	Effect of uncertainty on an expected result
Root Cause	A cause that once removed from the problem fault sequence, prevents the final undesirable event from recurring
Root Cause Analysis	A method of problem solving that tries to identify the root cause of faults or problems
Statutory requirement	Obligatory requirement specified by a legislative body
Withdrawal	Withdrawal is the process by which a product is removed from the external supply chain/distribution, but which does not require any action from the consumer.

Product Recall and Withdrawal

4 Introduction

4.1 Product Recall and Withdrawal

Even within the best managed food business, an issue involving the safety and suitability of a food may occur. This may be the result, for example, of a packaging defect, a product formulation error, a manufacturing or storage problem, a problem with the food ingredients. It is important that food business operators are aware that food safety issues can arise with their products and therefore, recognize that there is a need to plan ahead.

European Union (EU) food law requires all food business operators to be able to trace the food they receive back to the immediate supplier of that food. Then, following food handling, preparation or processing, food business operators must be able to track the distribution of food, forward from their own business to their immediate customer.

In addition, food business operators are required to withdraw unsafe food from the market where it has left their immediate control and, if it has reached the consumer, inform consumers of the reason for the food being removed from the market and if necessary, recall the affected food from them. Therefore, food business operators should develop documented food traceability and food recall/withdrawal systems and integrate them into their Food Safety Management Systems.

5 Procedure Flow Chart

Not applicable.

6 Procedure Notes

6.1 Data Collection and Management

The Food Safety Team:

- Gathers all necessary information, facts and data to enable a conscious decision to confirm the validity of the claim and proceed to a withdrawal or recall;
- Informs regulatory authorities according to crisis management rules and local regulations;
- Defines the communication with the employees, sales force, customers or consumers and other stakeholders;
- Decides the destiny of the products removed;
- Considers all other elements which might impact the FBO.

Product Recall and Withdrawal

6.2 Decision to Recall or Withdraw

The decision to withdraw or recall is taken by the Food Safety Manager.

The decision-making process follows the Crisis Management procedures and especially takes into account:

- The situation and actions to take in markets where the same material is commercialized (inter-market supply);
- Foreign markets, which must be consulted when taking decisions or to approve the decisions. Specific guidelines may apply.

6.3 Decision to Recall or Withdraw

Communications are critical for the success of a recall as well as for the image of our brands. Communications are based on:

- The position statement prepared by the Food Safety Team and FBO PR/Legal Advisor recalling a product;
- Questions and answers to be used by Consumer Services.

The media used for communications must be adequate to reach the potential consumers of the product to be recalled.

Communication must be simple and factual:

- Why do we recall?
- What do we recall?
- What do we do as a FBO to eliminate the defect and put the product back on the market?
- What is our refund policy?

The same principles must be applied for communications to other stakeholders (employees, customers, authorities, etc.).

6.4 Actions in the FBO Factory

The factory provides the traceability data necessary to define the material and quantities to be removed from the entire supply chain/distribution. All affected batches must be restricted in the FBO computer system.

The accuracy of the traceability system must be considered and a "safety margin" on either side of the concerned batch added if necessary.

The incident must be investigated, root case analysis and corrective actions taken.

Product Recall and Withdrawal

6.5 Actions in the FBO Distribution/Logistics

Upon receiving instructions to block a particular product quantity, the warehouse staff must immediately remove it from assembled loads in the warehouse. The blocked stock must be physically marked and segregated.

If advised by the Food Safety Team, distribution will co-ordinate urgent material pickup from identified warehouses and stores if necessary.

The material received back must be registered in the FBO computer system with the status "blocked" as for all returned material.

On request, warehouse personnel can check and sort the suspected stock. The Food Safety Manager provides instructions as to how to examine product and adequate resources (training, specialists, etc.).

A detailed report must be prepared on the fate of the recalled batches. Other goods must be included when relevant (e.g. "non-recalled" goods, other FBO products or even competitors' products).

6.6 Actions in Trade

The Food Safety Team establishes clear instructions for shops and retailers on how to proceed with the affected material.

Materials in the warehouses must be blocked, physically marked and a pickup schedule agreed with FBO Distribution.

Materials already in shops (supermarkets shelves or back room storage) must be removed from shelves, blocked, physically marked and placed in the back room storage awaiting pickup or destruction (as agreed between the FBO and the retailer). Sales or merchandising staff may be called to assist as needed.

Retailer will communicate actual quantities to be picked up to facilitate transport. The material must be returned as soon as possible to FBO or dedicated warehouses.

Disposal at customer sites is possible if mutually agreed on what to dispose. Method of disposal must be defined and properly documented.

6.7 Return Transport

The return transport of affected material needs special attention and a good organization. It must be done without delay.

Product Recall and Withdrawal

6.8 Handling of Returned Product

The returned product must be controlled, registered, marked and segregated from normal stocks.

Precise inventories must be kept. Regulatory authorities might have additional requirements on records and information.

Returned product must be handled as non-conforming product; the rules for responsible destruction or disposal must be followed.

In line with the FBO accounting procedure, all costs related to recalls and withdrawals must be charged to Production-Related Overheads and not to Bad Products.

6.9 Post Review Actions

Post review action review must be conducted when the incident is over and potential improvements implemented.

As a minimum, an analysis of the involved quantities of materials must be made (produced, sold, returned, destroyed and not accounted for or consumed).

6.10 Post Review Actions

Recalls and withdrawals must be practiced. An annual mock recall exercise is mandatory (see Mock Recall Procedure). A post review action of a real case cannot replace a Mock Recall. An actual recall is not the time to test the FBO recall/traceability system.

7 Records

Document	Location	Duration of Record	Responsibility
Recall/Withdrawal Log	Food Safety Office	Indefinitely	Food Safety Manager
Communication Records	Food Safety Office	Indefinitely	Food Safety Manager
Root Cause Analysis	Food Safety Office	Indefinitely	Food Safety Manager
Recall/Withdrawal Report	Food Safety Office	Indefinitely	Food Safety Manager
Post Review Minutes	Food Safety Office	Indefinitely	Food Safety Manager

Mock Recall

FBO Procedure	
Document #	SOP-008
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
<p>All documents within FBO are classified in the following way: PUBLIC documents are intended for anyone; COMMERCIAL IN CONFIDENCE documents are to be kept confidential between restricted individuals within the FBO and partner organizations; COMPANY CONFIDENTIAL documents are to be kept confidential within FBO and used for normal business activities by the general office population; HIGHLY CONFIDENTIAL documents are to be kept confidential to restricted individuals within FBO.</p> <p>© Copyright FBO. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the written permission of FBO.</p>	
Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved and released by process owner.

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Mock Recall

1 Summary

Purpose	To describe the process for effectively removing a product from the external supply chain/distribution.
Scope	This instruction covers all products manufactured or distributed by the FBO. <i>Note: Local regulations and laws prevail over this guideline.</i>
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager, who is responsible for the effective implementation and maintenance of this procedure.

2 Related documents

Policies	Food Safety Policy, POL-001 Customer/Consumer Complaints Policy, POL-002
Processes	Departmental process descriptions
Procedures	Control of Non-Conforming Product, SOP-003 Recall and Withdrawal, SOP-023 Communications, SOP-020 Crisis Management, SOP-029 Corrective and Preventive Action, SOP-009
Work Instructions	Not Applicable
Forms	Recall/Withdrawal Log Communication Log Root Cause Analysis/Corrective Action
Other	Not Applicable

Mock Recall

3 Definitions

Term or Acronym	Description
Complaint	Expression of dissatisfaction made to an organization related to its product or service, or the complaints-handling process itself where a response or resolution is explicitly or implicitly expected
Correction	Action to eliminate a detected nonconformity
Corrective action	Action to eliminate the cause of a nonconformity and to prevent recurrence
FSM/MR	Food Safety Manager/Management Representative
FSMS	Food Safety Management System
Nonconformity	Non-fulfilment of a requirement
Product	Output that is a result of activities where none of them necessarily is performed at the interface between the provider and the customer. For the FBO this can be an ingredient, raw material, intermediate product or finished product supplied to a customer or consumer
Risk	Effect of uncertainty on an expected result
Recall	Recall is the process by which a product is removed from the external supply chain/distribution and where consumers are publicly advised to take specific actions with the product. (e.g. "do not consume the product", or "return the product to the shop or manufacturer"). This includes the FDA class I and class II recalls
Regulatory requirement	Obligatory requirement specified by an authority mandated by a legislative body
Root Cause	A cause that once removed from the problem fault sequence, prevents the final undesirable event from recurring
Root Cause Analysis	Is a method of problem solving that tries to identify the root cause of faults or problems
Statutory requirement	Obligatory requirement specified by a legislative body
Traceability	Traceability is the ability to track a food through all stages of production, processing and distribution (including importation and at retail). Traceability should mean that movements can be traced one step backwards and one step forward at any point in the supply chain.

Mock Recall

4 Introduction

4.1 Mock Recall

The Food Industry Recall Protocol (Protocol) provides information on recalling food in and guidance for food businesses on developing a written food recall plan. A food recall is action taken to remove from distribution, sale and consumption, food which is unsafe. This means food that may cause illness or other physical harm to a person consuming the food.

The three primary objectives of a food recall are to:

- Stop the distribution and sale of the product as soon as possible;
- Inform the government, the food businesses that have received the recalled food and the public (consumer level recalls only) of the problem;
- Effectively and efficiently remove unsafe product from the market.

This protocol provides guidance only and is not legally binding; however it outlines legal requirements relating to mock recalls that are enforceable by the National or Federal and territory governments, where applicable. Where legal obligations are not applicable, customer or Food Safety Scheme Standards requirements should be followed.

Recall systems should be tailored to the individual needs of the FBO. A business may seek independent advice (including legal advice) about the system it develops for food mock recalls.

5 Procedure Flow Chart

Not applicable.

6 Procedure Notes

6.1 Data Collection and Management

A food business may be informed of a problem with any of its food products, raw material, ingredient, intermediate product or finished product by:

- In-house testing indicating there may be a potential problem with a particular food product or batch;
- Customer/consumer complaints/feedback (e.g. phone call or email from a customer or wholesaler informing the business about a potential problem);
- A supplier of a raw material that is used by the company in making its food products informing the business that there is a problem with an ingredient;
- Government bodies, such as health departments, local councils, or the police, indicating that there may be a problem with a particular food product.

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Doc ID	SOP-008	Printed		Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner	Food Safety Manager
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Mock Recall

Such problems may include:

- The presence of pathogenic bacteria (e.g. Salmonella);
- Chemical contamination (e.g. chemical sanitiser);
- Foreign matter contamination (e.g. pieces of glass, metal or plastic), which could cause physical harm to a person consuming the food;
- Labelling errors (e.g. incorrect/insufficient cooking instructions);
- Undeclared allergens (e.g. allergens such as peanut, milk or soy products not being declared on the label);
- Packaging defects (e.g. where the integrity of the package is compromised and a piece of the packaging results in a choking hazard);
- Under-processing resulting in potentially unsafe food;
- It is important that all necessary information about the nature of the problem/hazard is obtained so that an assessment can be made to establish whether the food product is unsafe and recall action is required. In assessing the risk the sponsor needs to:
 - Identify the hazard associated with the food, for example, is it microbiological, physical, chemical or allergen related;
 - Determine if the identified hazard poses a potential food safety risk, for example the food may contain harmful levels of pathogenic bacteria;
 - What action needs to be taken to manage the food safety risk.

The Food Safety Team

- Gathers all necessary information, facts and data to enable a conscious decision in order to proceed with a mock recall. It is important to have a clearly defined goal and objective for the mock recall being conducted, as these exercises can be done to validate specific processes and confirm suspected weaknesses;
- Defines the communication with the employees, sales force, customers or consumers and other stakeholders;
- Decides the destiny of the products removed;
- Considers all other elements which might impact the FBO.

6.2 Decision to Conduct a Mock Recall

The decision to conduct a mock recall is taken by the Food Safety Manager. The frequency of a product mock recall should be twice per annum and more frequently if requested by the primary stakeholders.

The decision-making process follows the crisis management procedures and especially takes into account:

- The situation and actions to take in markets where the same material is commercialized (inter-market supply);
- Foreign markets must be consulted when taking decisions or to approve the decisions. Specific guidelines may apply.

Mock Recall

Where a food safety issue has been identified for the mock recall, the Food Safety Manager should also consider the possibility of the same problem occurring in:

- Different package sizes of the same line;
- Different flavors or varieties of the product;
- Food products with a different batch number or date marking;
- A different food product processed on the same line or in the same plant;
- The same or similar food products packaged under a generic label.

If the food safety issue is present in other foods, batches, sizes or brands, all of these foods will need to be considered for inclusion in the mock recall.

The Food Safety Manager should also consider whether there are other products on the market or in the food supply chain that may have been affected by the same hazard as the food subjected to the mock recall. This is referred to as trace-back. For example, if the problem is found to be linked to one or more raw materials supplied to the FBO, then the FBO needs to notify the supplier of the raw materials to enable this supplier to potentially notify other customers of the raw materials. This may then result in additional mock recalls being initiated for more food products by other food businesses.

6.3 Decision to Mock Recall

Communications are critical for the success of a mock recall as well as for the image of our brands. Communications are based on:

- The position statement prepared by the Food Safety Team/Recall Team and mock recall of a product(s);
- The sensible and workable recall plan;
- Test procedures and plans with mock recalls;
- Identification of the Risks and Problem Areas;
- Statutory and Regulatory requirements related to mock recall communication, if relevant;
- Questions and answers to be used by Consumer Services.

The media used for communications must be **adequate to reach the potential consumers** of the product to be recalled.

Communication must be simple and factual:

- Why do we mock recall?
- What do we mock recall?
- What do we do as a FBO to eliminate the defect and put the product back on the market?

The same principles must be applied for communications to other stakeholders (employees, customers, authorities, etc.).

This protocol provides guidance only and is not legally binding; however it outlines legal requirements relating to product recalls/withdrawals that are enforceable by the National or Federal and territory governments, where applicable. Where legal obligations are not applicable, customer or Food Safety Scheme Standards requirements should be followed.

Classification		Company Confidential		Mock Recall	
Doc ID	SOP-008	Printed		Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner	Food Safety Manager
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Mock Recall

6.4 Actions in the FBO Factory

The factory provides the traceability data necessary to define the material and quantities to be removed from the entire supply chain/distribution. All affected batches must be restricted in the FBO computer system.

The accuracy of the traceability system must be considered and a "safety margin" on either side of the concerned batch added if necessary.

6.5 Actions in the FBO Distribution/Logistics

Upon receiving instructions to block a particular product quantity, the warehouse staff must immediately remove it from assembled loads in the warehouse. The blocked stock must be physically marked and segregated.

If advised by the Food Safety/Recall Team, Distribution will co-ordinate urgent material pickup from identified warehouses and stores, if necessary.

The material received back must be registered in the FBO computer system with the status "blocked" as for all returned material.

On request, warehouse personnel can check and sort the suspected stock or hold the affected product until the product is authorized as released. The Food Safety Manager provides instructions as to how to examine product and adequate resources (training, specialists, etc.).

A detailed report must be prepared on the fate of the mock recalled batches. Other goods must be included when relevant (e.g. "non-recalled" goods, other FBO products or even competitors' products).

6.6 Actions in Trade

The Food Safety/Recall Team establishes clear instructions for shops and retailers on how to proceed with the affected material.

Materials in the warehouses must be blocked, physically marked and traceability performed, and if required, a pickup schedule agreed with the FBO Distribution.

Materials in shops (supermarkets shelves or back room storage) must be fully traced and where required removed from the shelf, blocked, physically marked and placed in the back room storage awaiting pickup or destruction or authorized release (as agreed between the FBO and the retailer). Sales or merchandising staff may be called to assist as needed.

Retailer will communicate actual quantities to be picked up to facilitate transport, if required. The material must be returned as soon as possible to FBO or dedicated warehouses.

Mock Recall

6.7 Return Transport

The return transport of affected material needs special attention and good organization. It must be done without delay.

6.8 Handling of Returned Product

The returned product must be controlled, registered, marked and segregated from normal stocks. At a minimum, product should be obtained for laboratory analysis.

Precise inventories must be kept. Regulatory Authorities might have additional requirements on records and information.

Returned product must be handled as non-conforming product; the rules for responsible destruction or disposal must be followed.

In line with the FBO accounting procedure, all costs related to mock recalls must be charged to *Production-Related Overheads* and not to bad products.

6.9 Post Review Actions

Post review action review must be conducted when the mock recall is over and potential improvements implemented.

As a minimum, an analysis of the involved quantities of materials must be made (produced, sold, returned, destroyed, authorized for release and not accounted for or consumed).

The simple goal of the mock recall is ideally 100 percent product [raw material, ingredient, intermediate of finished product] is accounted for within two hours or less.

6.10 Mock Recall Frequency

Mock recalls must be practiced. To annual mock recall exercises are mandatory. A post-review action of a real case cannot replace a mock recall. An actual recall is not the time to test the FBO recall/traceability system.

7 Records

Document	Location	Duration of Record	Responsibility
Mock Recall Log	Food Safety Office	Indefinitely	Food Safety Manager
Communication Records	Food Safety Office	Indefinitely	Food Safety Manager
Root Cause Analysis	Food Safety Office	Indefinitely	Food Safety Manager
Mock Recall Report	Food Safety Office	Indefinitely	Food Safety Manager
Post Review Minutes	Food Safety Office	Indefinitely	Food Safety Manager

Classification Company Confidential

Mock Recall

Doc ID SOP-008
Created 20-04-2015

Printed
Updated 24-04-2015

Controller Document Controller
Owner Food Safety Manager

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Food Defence Plan

A FBO Plan	
Document #	PLAN-001
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
<p>All documents within FBO are classified in the following way: PUBLIC documents are intended for anyone; COMMERCIAL IN CONFIDENCE documents are to be kept confidential between restricted individuals within the FBO and partner organizations; COMPANY CONFIDENTIAL documents are to be kept confidential within FBO and used for normal business activities by the general office population; HIGHLY CONFIDENTIAL documents are to be kept confidential to restricted individuals within FBO.</p>	
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	V1.0	Joe Bloggs	Original Draft.
24-04-2015	V1.0	Joe Bloggs	Approved for release by Process Owner.

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Food Defence Plan

1 Summary

Purpose	To document the measures taken by the FBO to protect food and the food production processes from intentional harm.
Scope	This procedure is applicable to products, process and storage and production environments and suppliers across the food chain of the FBO and address the risks to the FBO's people, products, assets and the brand.
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager. They are responsible for the effective implementation and maintenance of this procedure.

2 Related documents

Policies	Food Safety Policy, POL-001
Processes	Food Safety, PRO-001
Procedures	Control of Documents, SOP-001 Traceability, SOP-012
Work Instructions	Not Applicable
Forms	Master Document Register
Other	Document Management System

Food Defence Plan

3 Definitions

Term or Acronym	Description
DMS	Document Management System
Electronic Security	Procedures used to protect electronic systems from sources of threat, such as malware and hackers, intent on misusing them, corrupting them or putting them out of use
FBO	Food Business Organization
Food Defence	Security of food and drink and their supply chains from all forms of malicious attack including ideologically motivated attack leading to contamination or supply failure
Food Supply	Any and all elements of what is commonly called the food supply chain, net or web with the inclusion of drink and supporting and allied services
FSMS	Food Safety Management System
Personal Security	Procedures used to confirm an individual's identity, qualifications, experience and right to work, and to monitor conduct as an employee or contractor
Product Security	Techniques used to make food products resistant to contamination or misuse including tamper-evident closures and lot marking
Protective Security	All the measures related to physical, electronic and personnel security which any organization takes to minimize the threat of malicious attack.



Food Defence Plan

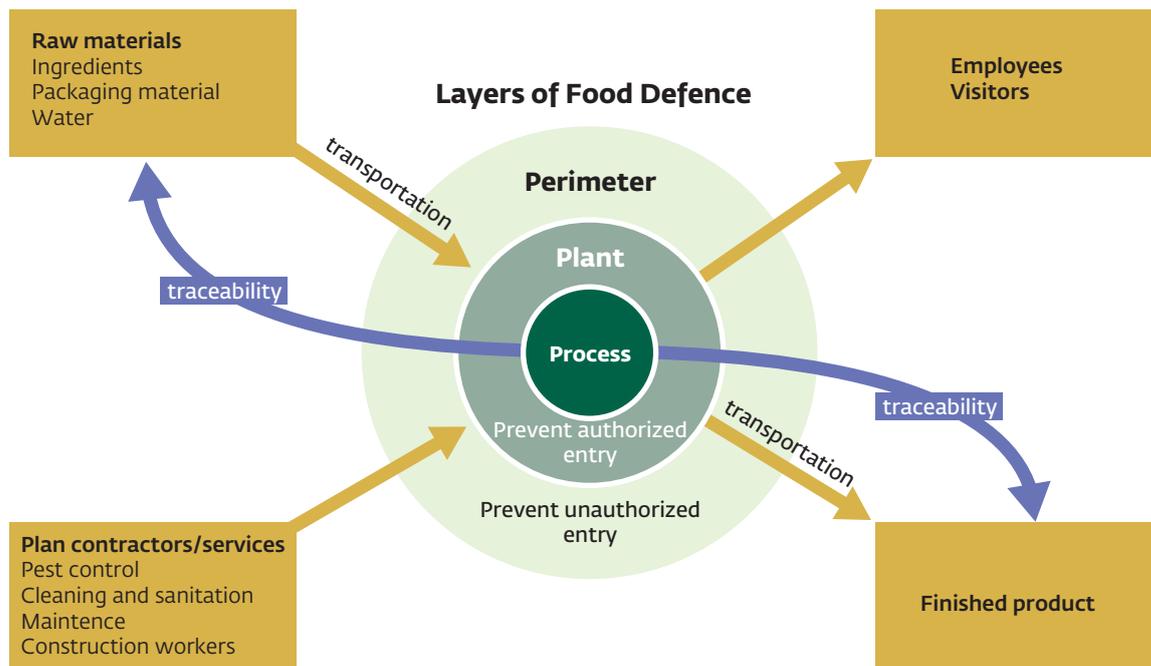
4 Introduction

4.1 General

Multinational organizations are driving the need for their suppliers globally to have robust food defence programs, thereby minimizing the risk of intentional contamination and tampering. If you work with, or want to work with, a multinational company you will probably be required to have a Food Defence Plan. The Food Defence Plan will build on your existing food safety, HACCP and crisis management plans, as well as incorporate audits of the security of premises, shipping/receiving and personnel, in order to help ensure safe and secure food supply.

Risks can originate from various sources: internal (employees, temporary workers, cleaning staff, etc.) or external (visitors, delivery personnel, suppliers, terrorist groups, activists, etc.). Malicious acts may come from outside, but the scope of identifying risks must be understood in a broader sense. Internal risks should not be overlooked: 70 to 80 percent come from the staff itself – disgruntled employees, for example. These can take many forms: fraud, damage, sabotage, terrorist acts, theft, blackmail, and more. The probability is more or less proven. Furthermore, these occurrences have a relatively strong impact on business.

The scope of Food Defence can be represented thus:



Food Defence Plan

5 Procedure Flow Chart

Not applicable.

6 Procedure Notes

This food defence plan is organized in four sections: (1) Outside Security Measures; (2) Inside Security Measures; (3) Personal Security Measures; and (4) Incident Response Security Measures.

1. Outside Security Measures (examples: door locks, lighting, monitoring loading/unloading)

GOAL: To prevent unauthorized access by people of unapproved materials to the facility.

The FBO has in place at least one of the following measures for outside security.

1.1 Physical Security

- a. Plant boundaries are clear and secured to prevent unauthorized entry (for example, fences installed, no trespassing signs posted)
- b. Entrances are secured (for example, locks and/or alarms installed and operating)
- c. Plant perimeter is periodically monitored for suspicious activity
- d. Outside lighting is present to deter unauthorized activities
- e. Other access points such as windows and vents are secured
- f. Outside storage on the premises is protected from unauthorized access
- g. Other _____

1.2 Shipping/Receiving Security

- a. Incoming shipments are examined for potential tampering
- b. Incoming and outgoing vehicles are examined for suspicious activity
- c. Loading and unloading are scheduled and monitored
- d. Loading dock access is controlled (for example, monitored or locked)
- e. Incoming shipments are secured with locks or seals
- f. Outgoing shipments are locked or sealed
- g. Other _____

1.3 Mail Handling Security

- a. Mail is handled away from food including ingredients and packaged food product
- b. Employees who handle mail are aware of proper handling of suspicious mail and U.S. Postal Service guidelines
- c. Other _____

Food Defence Plan

2. Inside Security Measures (examples: Signs, observations, restricted access)

GOAL: To protect product from intentional contamination throughout the production process.

The FBO has in place at least one of the following measures for inside security.

2.1 General Inside Security

- a. Suspicious packages are reported to appropriate personnel
- b. Restricted areas of the establishment are clearly identified
- c. Previously unattached materials are checked before used
- d. Unexpected changes in inventory (product or equipment) are reported to appropriate personnel
- e. Emergency lighting is in place
- f. An emergency alert system is identifiable, tested, and reviewed with emergency contacts (for example, police or fire personnel)
- g. Other _____

2.2 Processing Area Security

- a. Access to ingredients, and packaged product is restricted
- b. Access to process control equipment such as ovens and mixers is restricted
- c. Ingredients are examined for possible tampering
- d. Records ensure traceability for one step backward, one step forward, or both
- e. Other _____

2.3 Storage Security

- a. Access to storage areas is restricted
- b. Stock rotation (First In, First Out) is practiced
- c. Labels and packaging materials are controlled to prevent theft and misuse
- d. Periodic examinations for tampering of materials in storage are preformed
- e. Other _____

2.4 Ingredients/Water/Ice Security

- a. Restricted access to storage tanks for potable water and to water reuse system
- b. Access to lines that transfer water or ingredients are examined and restricted
- c. Access to plant ice-making equipment is controlled
- d. Restricted ingredients (for examples, nitrates) are controlled
- e. Supplier food safety/security information is requested
- f. Other _____

Food Defence Plan

2.5 Chemical/Hazardous Material Control Security

- a. Chemicals/hazardous materials, including pesticides, cleaning or laboratory materials, and sanitizers, are in a restricted area or secured by a lock
- b. Maintain an up-to-date inventory of hazardous materials and chemicals, and investigate discrepancies
- c. Potential hazardous waste (biological or chemical) is controlled and disposed of properly
- d. Other _____

2.6 Information Security

- a. Access to sensitive information such as site plans and processing details is controlled
- b. Access to computer systems is protected through firewalls and/or passwords
- c. Other _____

3. Personnel Security Measures (Examples: Check references, use visitor log or sign-in, or check IDs)

GOAL: To ensure that only authorized personnel are in the facility at any time

The FBO has in place at least one of the following measures for personnel security.

3.1 Employee Security

- a. A method to recognize or identify employees in the facility
- b. Background or reference checks are conducted for new hires
- c. Employees have restrictions on what they can bring in or take from the facility (for example, cameras)
- d. Other _____



Food Defence Plan

3.2 Non-employee Security (example: visitors, contractors, guests, customers, truck drivers)

- a. A log of non-employees and persons working for and on behalf of the FBO entering the establishment is maintained
- b. A method to recognize or identify non-employees and persons working for and on behalf of the FBO in the establishment is in place
- c. Non-employees and persons working for and on behalf of the FBO are chaperoned on-site
- d. Non-employees and persons working for and on behalf of the FBO are restricted to appropriate areas
- e. Non-employees and persons working for and on behalf of the FBO have restrictions on what they can bring in or take from the facility
- f. Other _____

3.3 Security Training

- a. Awareness training on security measures is provided to new employees and persons working for and on behalf of the FBO
- b. Refresher awareness training on security measures is offered to employees and persons working for or on behalf of the FBO on a periodic basis
- c. Employees or persons working for or on behalf of the FBO are trained to report suspicious activities or unusual observations
- d. Other _____

4. Incident Response Security Measures (examples: reference your emergency plan, security plan, or other)

GOAL: To respond quickly to a product contamination threat or event using planned measures

The FBO has in place at least one of the following measures for incident response security.

4.1 Investigating Security Concern

- a. Have procedures to ensure that adulterated or potentially harmful products are held
- b. Customer/Consumer comments are investigated
- c. Reporting unusual activities is encouragement
- d. Information is available to employees on how to respond to phone or other threats
- e. Employees have the ability to stop activities to minimize a potential food defense incident
- f. Reported security breaches (for example, alarms, suspicion of tampering) are investigated
- g. Other _____

4.2 Emergency Contact Security

- a. Plant personnel contact information is kept up to date
- b. Emergency contact information is kept up to date
- c. Other _____

Food Defence Plan

4.3 Other Plan Security

- a. A product recall plan is maintained and periodically reviewed
- b. Key personnel are trained in product recall/withdraw procedures
- c. Other _____

This attachment provides a list of tools or additional security measures. These are provided to assist in tailoring the plan to meet the FBO's specific needs.

1. Outside Security Tools

Physical Security Tools

- Ensure proper lighting to monitor the establishment outdoors at night and early morning;
- Install self-locking doors and/or alarms on emergency exits;
- Ensure the following are secured with locks, seals, or sensors when unattended (after hour/week-ends) to prevent unauthorized entry:
 - Outside doors and gates
 - Tanker truck hatches
 - Windows
 - Railcars
 - Roof openings
 - Bulk storage tanks/silos
 - Vent opening
 - Loading ports
 - Trailer (truck) bodies
 - Hose/Pump stations
- Regularly conduct and document security inspections of storage facilities, including temporary storage vehicles;
- Restrict outdoor access to water wells/sources.

Shipping/Receiving Security

- Closely monitor loading and unloading of vehicle transporting raw materials, finished products, or other materials used in food processing;
- Inspect tanker trucks and/or railcars to detect the presences of any material, solid or liquid, in tanks prior to loading liquid products. Load only when appropriate. Report/record results;
- Control access to loading docks to avoid unverified or unauthorized deliveries;
- Require advance notification from suppliers for all deliveries;
- Immediately investigate suspicious changes in shipping documents;
- Check all deliveries outside establishment premises pending verification;
- If off-hour delivery is accepted, require prior notice of the delivery and an authorized person to be present to verify and receive the delivery;
- Check less-than-truckload (LTL) or partial load shipments for content and condition;
- Require incoming shipment of raw product, ingredients, and finished products to be sealed with tamper-evident or numbered, documented seals and verify the seals prior to entry. Reject if seal is broken or missing;

Food Defence Plan

- Select transportation companies and suppliers with consideration of security measures that they use;
- Examine returned good at a separate location for evidence of tampering before salvage or use in rework;
- Maintain records of disposition of returned good;
- Require drivers or delivery personnel to provide identification, preferably with a photo ID, record names;
- Minimize the time a truck is unlocked during loading or delivery.

2. Inside Security Tools

General Inside Security

- Install and monitor security cameras;
- Increase visibility within the establishment (for example, improve lighting, openness, increase supervision, add cameras);
- Regularly take inventory of keys to secured/sensitive areas of the establishment;
- Restrict access to controls (by locked door/gate or limiting access to designated employees) for the following systems:
 - Heating, ventilation, and air conditioning (HVAC);
 - Propane, natural gas, water, electricity;
 - Disinfection systems;
 - Clean-in-place (CIP) systems or other centralized chemical systems.

Processing Area Security

- Maintain records to allow efficient trace backward or forward of materials and finish product;
- Reduce the time an area is left unmonitored;
- Reduce access to product containers or processing equipment;
- Do not allow unnecessary personal items within the production area.

Storage Security

- Maintain an access log for product and ingredient storage areas;
- Regularly check the inventory of finished products for unexplained additions and withdrawals from existing stock;
- Restrict access to external storage facilities to designated employees only.

Ingredients/Water/Ice Security

- Examine packages of ingredients before use for evidence of tampering;
- Restrict access to product, ingredient, and packaging storage areas to designated employees only (for example, by lock or gate);
- Water is from a municipally or local authority controlled source;
- Inspect water lines for possible tampering (perform visual inspection for integrity of infrastructure, proper connections);

Food Defence Plan

- Make arrangements with local health officials to ensure immediate notification to the establishment if the potability of the public water supply is compromised.

Chemical/ Hazardous Material Control

- Restrict access to the in-plant laboratory;
- Have procedures in place to control receipt of samples;
- Have a procedure in place to receive, securely store, and dispose of reagents.

Information Security

- Track customer and consumer complaints/comments for trends;
- Keep details of food defense procedures confidential as necessary;
- Have up-to-date establishment layout/blueprint/drawings for local law enforcement, including the fire department if needed.

3. Personnel Security Tools

- Authorize appropriate employees and persons working for or on behalf of the FBO to stop a process for significant concerns;
- Control access by employees, non-employees and persons working for or on behalf of the FBO entering the FBO establishment during working and non-working hours (use coded doors, receptionist on duty, swipe cards);
- Restrict temporary employees, non-employees and persons working for or on behalf of the FBO to areas relevant to their work;
- Implement systems to identify personnel with their specific functions, assignments or departments (for example, corresponding colored uniforms or hair covers);
- Prohibit employees from removing company-provided uniforms or protective gear from the premises;
- Maintain an updated shift roster for each shift.

4. Incident Response Tool

- Establish evacuation procedures and include in food defense plan;
- Establish procedures for responding to threats as well as actual product contamination events;
- Pre-establish communication with local, state, and federal incident response personnel for a more efficient response.

Food Defence Plan

**FBO
Food Defence Plan Review Form**

Complete this form to document your annual review of this Food Defence Plan
Not all measures are required or need to be reviewed each time this form is completed

Date of Annual Review	Person Who Conducted Annual Review (Name and Title)	Was the Food Defence Plan Tested?*(Yes/No)

**Testing can be done using simple measures, such as checking locked doors or making unannounced perimeter checks.*

7 Records

Document	Location	Duration of Record	Responsibility
Food Defence Plan Review Record	Food Safety Office	Indefinitely	Food Safety Manager

Allergen Control

A FBO Procedure	
Document #	SOP-007
Created	20-04-2015
Updated	28-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
<p>All documents within FBO are classified in the following way: PUBLIC documents are intended for anyone; COMMERCIAL IN CONFIDENCE documents are to be kept confidential between restricted individuals within the FBO and partner organizations; COMPANY CONFIDENTIAL documents are to be kept confidential within FBO and used for normal business activities by the general office population; HIGHLY CONFIDENTIAL documents are to be kept confidential to restricted individuals within FBO.</p>	
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved for release by process owner.

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Allergen Control

1 Summary

Purpose	To ensure the effective use, storage and labelling of allergens and food allergen management at the FBO.
Scope	This procedure is applicable to products, process and storage and production environments and suppliers of raw materials in the FBO.
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager, who is responsible for the effective implementation and maintenance of this procedure.

2 Related documents

Policies	Food Safety Policy, POL-001
Processes	Food Safety, PRO-001
Procedures	Control of Documents, SOP-001 Traceability, SOP-012
Work Instructions	Not Applicable
Forms	Master Document Register
Other	Document Management System

3 Definitions

Term or Acronym	Description
DMS	Document Management System
FBO	Food Business Organization
Food allergy	Immunological-based reaction to chemical substances, usually proteins or protein fragments, by individuals who have previously been sensitized to the same substance and have formed antibodies. Allergic reactions can be initiated by small quantities of allergens. Reactions are usually mild and transitory, but in a small percentage of the population, reactions can be severe and may in some cases lead to death
FSMS	Food Safety Management System
Major food allergens at FBOs	Milk, soy, and gluten allergens.

Allergen Control

4 Introduction

4.1 General

Under Article 9 (1)(c) of EU FIC, all FBOs should declare the presence – whether for use as an ingredient or a processing aid – of any of the 14 major allergens listed in Annex II to the Regulation. It should be noted that in accordance with Articles 12 and 13 of EU FIC, the mandatory information should be easily accessible, in a conspicuous place, easily visible and clearly legible. Information should be indelible (permanent) where appropriate, for example, on food labels where it needs to withstand handling. The information should not be hidden, obscured, detracted from or interrupted by other written or pictorial matter or any other intervening material.

The 14 allergens listed in Annex II (as amended by Commission Delegated Regulation No. 78/2014) are recognized across Europe as the most common ingredients or processing aids causing food allergies and intolerances. If there is a food product which contains or uses an ingredient or processing aid (such as wheat flour used to roll out dough made from rye flour) derived from one of the substances or products listed in the Annex II, it must be declared, by the FBO to the consumer.

The information supplied in this procedure is not exhaustive and does not cover other labelling requirements (such as other general labelling (e.g. country of origin, lactose, quantities, additives, nutrition, etc.).

5 Procedure Flow Chart

Not applicable.

Allergen Control

6 Procedure Notes

1) Storage of allergen-containing raw materials

- Allergen-containing raw materials should be stored separately from the non-allergen materials;
- Allergen-containing raw materials should not be stored over non-allergen materials;
- Milk allergen pallets should not be stored over soy allergen pallets or vice versa.

Please see Raw Material Management Procedure, SOP-010 for details.

2) Labelling

All allergen containing raw materials are initially received with orange labels from factories. Then milk and soy allergens are labelled with purple and green labels, respectively. All finished products are labelled as "Contains Allergens."

3) External panel/consumer screening

External panellists and consumers who participate in product tasting are screened for sensitivity to major allergens. Only panellists who are not allergic to foods are permitted to participate in consumer tests.

4) Internal panel screening

Internal panellists are alerted that samples consumed at the FBO may contain any one of the known allergens indicated in definition section of this document.

5) Preventing allergenic cross contamination

- Use dedicated scoop for each raw material when transferred;
- Wipe down all affected surfaces after weighing out an allergen;
- Change gloves or wash hands after an allergen is handled;
- Keep all containers with allergens sealed;
- Whenever possible, store allergens on the lower section of the storage racks.

7 Records

Document	Location	Duration of Record	Responsibility
Allergen File	Food Safety Office	Indefinitely	Food Safety Manager

Classification Company Confidential

Allergen Control

Doc ID SOP-007
Created 20-04-2015

Printed
Updated 28-04-2015

Controller Document Controller
Owner Food Safety Manager

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Hygiene Procedure

A FBO Procedure	
Document #	SOP-005
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial draft for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Reviewed and approved by Process Owner.

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Hygiene Procedure

1 Summary

Purpose	To comply with legal requirements, all workers in direct contact with food and processing lines must maintain a high standard of personal hygiene and routines, which are outlined in this procedure.
Scope	This procedure is valid for the FBO and applies to all staff working in the FBO and the visitors/contractors/ part time and temporary workers present on the premises.
Functional Responsibility	The functional responsibility for this procedure lies with the Food Safety Manager.

2 Related documents

Policies	Food Safety Policy, POL-001
Processes	Food Safety, PRO-001
Procedures	Visitor Control, SOP-004 Contractor Control, SOP-007 Change Management, SOP-011 Internal Audit, SOP-006 Corrective Action & Preventive Action, SOP-009
Work Instructions	Not Applicable
Forms	Not Applicable
Other	Not Applicable

Hygiene Procedure

3 Definitions

Term or Acronym	Description
Basic hygiene area	Basic hygiene area is defined as the areas of food tasting and handling for research and development purposes. A basic hygiene area at the FBO includes the development and sensory labs
CAPA	Corrective Action & Preventive Action
Company	FBO
High hygiene area	A critical hygienic area within the plant where products and ingredients vulnerable to contamination and/or microbial growth are processed, treated, handled or stored
Medium hygiene area	Medium hygiene area is defined as the areas of food handling, i.e. where food is produced, processed, stored and packaged. A medium hygiene area at the FBO includes the production plant only.

4 Introduction

4.1 Hygiene

The great majority of people will experience a food or water borne disease at some point in their lives. This highlights the importance of making sure the food we eat is not contaminated with potentially harmful bacteria, parasites, viruses, toxins and chemicals.

Over the past half century, the process by which food gets from the farm to the plate has changed drastically. Food contamination that occurs in one place may affect the health of consumers living on the other side of the planet. This means that everyone along the production chain, from producer to consumer, must observe safe food handling practices.

Good food hygiene is essential for the FBO to make or sell food that is safe to eat. It is very important for the FBO and staff to understand what good food hygiene is. Good food hygiene helps the FBO to:

- Obey the law;
- Reduce the risk of food poisoning among your consumers;
- Protect your business's reputation.

Hygiene Procedure

5 Procedure Flow Chart

Not applicable.

6 Procedure Notes

Hygiene Rules

1) Personal Hygiene Rules

- Nails must be clean, neatly trimmed, without nail polish or artificial nails;
- No strong perfumes or strongly scented personal care products /heavy make-up are to be worn (i.e. false eyelashes);
- Cuts and lesions must be fully covered with approved (blue), waterproof, metal-detectable adhesive bandages, which can be obtained from first aid kits. Any lost dressing must be reported to the supervisor immediately;
- All unhygienic practices such as spitting, coughing or sneezing over food, or using food dropped on the floor for consumption, is unacceptable;
- Wash hands before entering work and after handling something dirty (e.g. waste, floor, shoes, money, etc.);
- Gloves should be only worn when aesthetic appeal of products is endangered or for personal safety reasons. They never replace hand washing;
- The white lab coats must be removed before entering toilet cubicles and should not be replaced until hands have been washed;
- The FBO site is a non-smoking site and smoking is only allowed in defined areas;
- Personal safety gear must be worn when necessary;
- Personal items, such as smoking materials and medicines are allowed in designated areas only;
- Personal lockers should be maintained clean and tidy so that they are kept free from rubbish and soiled clothing.

2) Basic Hygiene Area (Development and Sensory Labs)

- Maintain a high level of personal hygiene listed under Personal Hygiene Rules above;
- Wear lab coats and hairnets while handling products that will be tasted;
- For bench tasting, only wearing a lab coat is a minimum requirement. Further hygiene rules are up to the tasting organizer to define if necessary;
- Employee's private foods [food brought to the Dairy by the FBO Employee and consumed during an official break, e.g. lunch] should be stored separately and the private foods should not be handled and consumed where the products are handled and tasted;
- Clean and sanitize after handling private foods.

Classification

Company Confidential

Hygiene Procedure

Doc ID
Created

SOP-005
20-04-2015

Printed
Updated

24-04-2015

Controller
Owner

Document Controller
Food Safety Manager

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Hygiene Procedure

3) Medium Hygiene Area (Processing Plant)

- Maintain a high level of personal hygiene listed under Personal Hygiene Rules above;
- Workwear should be changed daily;
- Wear clean garment, hairnet, and safety shoes while working;
- Wash hands before entering work;
- Eating, drinking or chewing is forbidden in the medium hygiene area;
- Remove all jewellery before entering work except solid band, plain wedding rings;
- Carrying of writing implements behind the ears is prohibited;
- Product contact tools and equipment should not be stored in personal lockers;
- Fully enclosed shoes must be worn when entering and working in the processing plant.

4) High Hygiene Area (Processing Area – Filing)

- Access only with clean protective clothing, hair covered, hand-washing (and if necessary disinfecting) upon each entry, boot dips (if necessary);
- Stringent controls of cleaning, frequent cleaning, disinfection prior to start of new process;
- Access only for specially trained personnel required for process;
- No wooden pallets, cardboard or other unhygienic material;
- Air flow out of area (i.e. higher pressure inside zone).

5) Visitors and Contractors

- It is the responsibility of FBO employees to ensure that all visitors and contractors understand the hygiene and safety rules and to check that they are following them when on site;
- When visitors and contractors arrive, the visitor control form will be given by the contact person to let them read carefully and understand it and then sign on the bottom of the form;
- The contact person should keep the signed form and has responsibility to ensure the visitors and contractors follow the stated rules in the form;
- White coats for visitors and contractors are available and they will be given by the contact person.

Cleaning and House Keeping

1) All Hygiene Areas

- Keep your working area clean and tidy at all times;
- Apply a CLEAN AS YOU GO approach of cleaning and inspect for absence of residues.

Hygiene Procedure

2) Medium/High Hygiene Areas

- Follow the cleaning procedure and schedule in the Processing Plant Master Plans. Always remember to clean equipment when you have finished using it to prevent hygiene issues as pest infestation and microbiological contaminations.

Cleaning Equipment in Medium/High Hygiene Area

- The sign below is actually posted and applied in the medium hygiene area and a colour coding indicates where tools have to be used:

White – Used on Food Contact Surfaces ONLY

Yellow – Used on Outside of Food Equipment and/or Packaging
(i.e. Drums, Boxes, Bags, etc.) Surfaces ONLY

RED – Used in Warehouse and Maintenance Shop ONLY

Black – Used on Floor, Wall, Pipe and Ceiling Surfaces ONLY

Black OVAL– Used on Drain Surfaces ONLY

Different coloured tools must be stored separately from each other.

Hygienic Maintenance in Medium/High Hygiene Area

- Equipment sent for maintenance should be cleaned before its re-installation in the processing plant. Particular attention should be given to food contact surfaces that need thorough cleaning and sanitation;
- Working tools must be stored in assigned containers and must not be placed onto food contact surfaces or above them. The tools should be removed from the processing plant immediately after work;
- The use of food grade lubricants is mandatory unless technological reasons prevent their use. All exceptions should be approved by the manager. Lubricants should be applied in appropriate quantity to avoid excess lubricant falling into products;
- Material which could taint any food product or ingredient (such as paint, glue, etc.) must not be brought on to the site (contractors need to have written permission from the FBO Food Safety Department to use such materials);
- Obsolete or unused equipment should be removed on a regular basis;
- Apply the change management procedure for any equipment change.

Hygiene Procedure

Waste in Medium/High Hygiene Area

Food contact wastes and the other garbage should be placed separately:

Orange bags: food scrap or animal feed

Hygiene Training

- New personnel will receive an initial hygiene induction training session;
- Once a year, all staff working in hygiene areas need to be retrained by the Food Safety Department;
- What about contractor staff working in medium hygiene area for a period of time or regular basis for a period of time?

Reporting of Illness and Injuries

When an employee or a member of his/her household has suffered from one of the following conditions, the employee must report it immediately when returning to work to his/her line manager. It is the manager's responsibility to discuss the symptoms with the employee:

- Jaundice;
- Diarrhoea;
- Vomiting;
- Fever;
- Sore throat with fever;
- Visibly infected skins (boils, cuts, acne, pustles);
- Discharge from ear, eye and nose.

No person with such a disease shall be permitted to work in the Medium Hygiene Areas. The advice is to avoid food handling for at least 48 hours after the last either vomiting or diarrhoea episode has occurred in order to prevent contamination of the food produced at the FBO.

If the employee contracted a disease while travelling abroad (either for business or personal reasons), it is the employee's responsibility to contact a doctor on return to get information and advice on the disease they have suffered from, and report the illness to his/her line manager on first day back to work.

How does this information get fed to the Food Safety Manager (confidential) and what about considering and activating the non-conforming procedure and corrective and preventative action procedure?

7 Records

Document	Location	Duration of Record	Responsibility
Signed Training Participant Lists (hard copies)	Food Safety Office	7 years	Food Safety Manager
Visitor Control Form	Food Safety Office	7 Years	Food Safety Manager

Identification and Evaluation of Compliance

A FBO Procedure	
Document #	SOP-013
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
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Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2014	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved for release by process owner.

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Identification and Evaluation of Compliance

1 Summary

Purpose	To outline how identification and evaluation of compliance to statutory and regulatory and other requirements (hereafter referred to as compliance) is managed within the FBO.
Scope	The procedure starts with the identification of a new or changed compliance requirement; recording; information collected; relevance impact assessed; degree of compliance established; gaps, if any identified and resolved; compliance register updated/improved and ongoing monitoring and evaluation of compliance.
Functional Responsibility	<p>The functional responsibility for this procedure lies with the Food Safety Manager. They are responsible for the effective implementation and maintenance of this procedure.</p> <p>Departmental managers are responsible for ensuring records under their control are managed in accordance with this documented procedure</p>

2 Related documents

Policies	Food Safety Policy, POL-001
Procedures	<p>Control of Documents, SOP-001</p> <p>Non-Conforming Product, SOP-003</p> <p>Corrective and Preventative Action, SOP-009</p> <p>Internal Audit, SOP-006</p> <p>Management Review, SOP-021</p> <p>Product Recall and Withdrawal, SOP-023</p> <p>Food Safety Legal Register, REG-001</p>
Work Instructions	Not Applicable
Forms	Master Document Register
Other	Document Management System

Identification and Evaluation of Compliance

3 Definitions

Term or Acronym	Description
Compliance	Statutory and regulatory including other legal obligation requirements
Compliance Register	Food Safety Legal Register
DMS	Document Management System
Enforcement Agency	Any person or organization with statutorily delegated or vested authority, capacity, or power to perform a designated function or any agency which enforces the law, e.g. FSA, FDA
FSM/MR	Food Safety Manager
FSMS	Food Safety Management System
Interested Party	External person or group (e.g. external FBO unit, consumers, regulatory agencies) having an interest in the performance or success of the organization.

4 Introduction

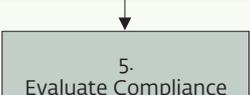
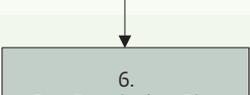
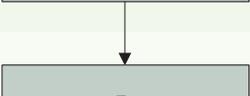
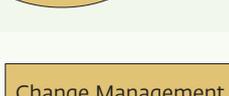
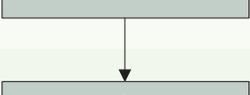
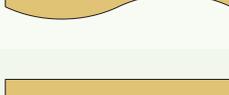
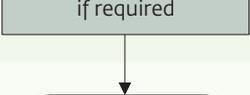
4.1 General

A corporate vision for food safety compliance is a defined and documented strategy for mapping out the business's objectives for meeting its compliance obligations now and in the future. It is focused on future-proofing the business's need to meet a dynamic compliance framework, maintain a high level of consumer protection and support business development objectives.

This procedure outlines the procedure for the identification and evaluation of a FBO's legal obligations, primarily statutory and regulatory, and to the customer.

Identification and Evaluation of Compliance

5 Procedure Flow Chart

Responsibility	PROCESS	Record(s)
Interested Party		
Food Safety Manager		
Food Safety Manager		
Food Safety Manager		
Food Safety Manager/ Internal Auditors		
Food Safety Manager/ Management Team		
Food Safety Manager/ Management Team		
Food Safety Manager/ Management Team		
Food Safety Manager		

Identification and Evaluation of Compliance

6 Procedure Notes

Step 1

Any new or changes in compliance requirements are identified via a combination of the FBO business; enforcement agency; industry representative; and a legal register subscription communication/update service.

Step 2

The Food Safety Manager shall record the information including updating of the Compliance Register (Food Safety Legal register), as required.

Step 3

The Food Safety Manager shall collect additional information on the new or changed compliance requirement where necessary for the purposes of better understanding and evaluation. The relevant legal register shall be updated and maintained, as required.

Step 4

Once the necessary information and data has been collected, the relevance and impact of the new and/or changed compliance requirement shall be identified. The relevant legal register shall be updated and maintained, if required. The Food Safety Manager shall communicate the information to the relevant internal parties via a combination of email, report or meeting. The management review meeting shall review all new or changed compliance requirements, reference the management review procedure.

Step 5

Based upon the information collected, the Food Safety Manager shall determine the best strategy for evaluating the degree of compliance, e.g. document review, monitoring and measurement data, audit or a combination of one or more etc., referencing the relevant legal register and updating it if required.

Step 6

Where the periodic evaluation results show there is a gap, a gap resolution plan shall be defined and documented. This may include a corrective and preventative action plan, if required. Reference the Non Conformity Product Procedure and Corrective and Preventative Action Procedure.

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Doc ID	SOP-013	Printed	Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner
			Food Safety Manager	Page 5 of 6

Identification and Evaluation of Compliance

Step 7

The gap analysis plan shall be implemented in a timely manner to ensure full compliance.

Step 8

The relevant compliance register including FSMS documented system shall be reviewed and updated as required.

7 Records

Document	Location	Duration of Record	Responsibility
Food Safety Legal Register	Food Safety Office	Indefinitely	Food Safety Manager
Internal Audit File	Food Safety Office	Three years	Food Safety Manager
Management Review Package	Food Safety Office	Three years	Food Safety Manager







Food Safety Training

MODULE 6



Introduction

If you have a food business, or work in the food industry, you are legally required to undertake food safety training and/or be supervised in line with the level of activity you are involved in. So, for example, managers will need different training from those serving food.

If you are responsible for the development and maintenance of your business's food safety management system, then you must undertake adequate training in the application of HACCP Principles and the Food Safety Management System.

Choosing Food Safety Trainers or Training Course

In most countries there is no national accreditation body for trainers or training courses; therefore, if you decide to take a course or employ a trainer, bear in mind the points below. Remember, it is advisable to contact a number of training providers to find the one that suits your needs, as there is no single training course that meets the needs of everyone.

Do the trainers have appropriate food safety qualifications?

- Trainers must have a background in food safety;
- They must have relevant experience in the food industry;
- They must have knowledge of how people learn and training skills.

Can they provide follow-up support?

Post-training follow-up is beneficial as it can help when putting the training theory into practice in the workplace and can help clarify issues that may have arisen since the training took place.

Is management participation encouraged?

Management involvement is crucial to the success of the training. It is important that the trainer and management work together to ensure that all food safety aspects relating to the business are addressed in the course.

What do some of their previous clients say about them?

Talking to previous clients will help determine the quality of the training provided. However, the success of the service depends on the input of the training provider and the food business.

Are the training providers interested in identifying your specific needs?

Are they willing to spend time with you, listen to you and explain the best method of meeting your requirements?

Are they willing to show you some of their training aids or previous work?

This will give you an indication of the quality of training you can expect to receive and assess whether the training is generic or tailored to suit your needs.

How often does food hygiene training have to be done?

There is no frequency set out in legislation for training. It is up to food businesses to decide when the staff require refresher training.

Where can I find a list of trainers or training courses?

As there is no accreditation body for trainers there is no centralized list. It is simply a matter of checking your local or searching online for courses or trainers in your area.

IFC has developed two FSMS training courses that you should consider, namely:

- IFC Food Safety Foundation Course. This is an entry-level, three-day, on-site course aimed at the FBO processing, catering and retail sectors. This course is recommended as a pre-requisite to attendance of the IFC Food Safety Toolkit Training Course. The course covers the basics of Food Safety Management and focuses on the prerequisites prior to establishing a HACCP based FSMS. The course can also be tailored to an industry sector.
- IFC Food Safety Toolkit Training Course. This is a self-learning based training course aimed at providing the FBO with knowledge and skills, including access to best practice HACCP tools and techniques, and useful links that enable the FBO establish and develop a HACCP based FSMS based upon the HACCP requirements of most GFSI FSMS schemes, including some other FSMS schemes.

For more information on the above courses, please contact:

Sarah Ockman at sockman@ifc.org

What does the auditor (e.g. external or internal auditor) look for when assessing food safety training?

The auditor will not necessarily want to see a certificate from a particular training course; rather, he or she will observe hygiene practices and verify the food safety knowledge of staff. The officer may ask to see food safety records or ask about the food safety training that has been provided.



Training Effectiveness and Evaluation

Key Terms

- Training effectiveness refers to the benefits that the FBO and learners receive from training
- Training outcomes or criteria refer to measures that the trainer and the FBO use to evaluate training programs
- Training evaluation refers to the process of collecting the outcomes needed to determine the effectiveness of training
- Evaluation design refers to how, from whom, what, and when information needed for determining the effectiveness of the training program will be collected

Reasons to Evaluate Training Programs

- FBOs need to make optimal use of the significant resources invested in training programs to gain the maximum competitive advantage
- Learning creates knowledge which differentiates between successful and unsuccessful FBOs and employees
- Evaluations help identify the strengths and weaknesses of training programs
- To determine whether content, organization, and administration of the program contribute to learning and the use of training content on the job
- To identify which learners benefited most or least from the training program
- To gather data to assist in marketing training programs
- Enables comparisons of costs and benefits of different training programs
- Enables comparisons of costs and benefits of different training programs, and of training versus non-training investments

Training Program Evaluation Process



Outcomes Used in Evaluating Training Programs

Cognitive Outcomes

- Determine the degree to which learners are familiar with the principles, facts, techniques, procedures, or processes emphasized in the training program
- Measure what knowledge participants learned in the program

Skill-Based Outcomes

- Assess the level of technical or motor skills
- Include acquisition or learning of skills and use of skills on the job

Affective Outcomes

- Include attitudes and motivation
- Learners' perceptions of the program including the facilities, trainers, and content

Results

- Determine the training program's payoff for the FBO

Return on Investment (ROI)

- Comparing the training program's monetary benefits with the cost of the training
 - Direct costs
 - Indirect costs
 - Benefits

Training Program Objectives and Their Implications for Evaluation

<i>Reactions:</i>	Did learners like the program?	<i>Skill-Based:</i>	Ratings by peers or managers based on observation of behavior
	Did the environment help learning?		
<i>Cognitive:</i>	Pencil-and-paper tests	<i>Affective:</i>	Trainees' motivation or job attitudes
<i>Skill-Based:</i>	Performance on a work sample	<i>Results:</i>	Did company benefit through sales, quality, productivity, reduced accidents, and complaints?
			Performance on work equipment

What Determines Good Outcomes of Training Programs?

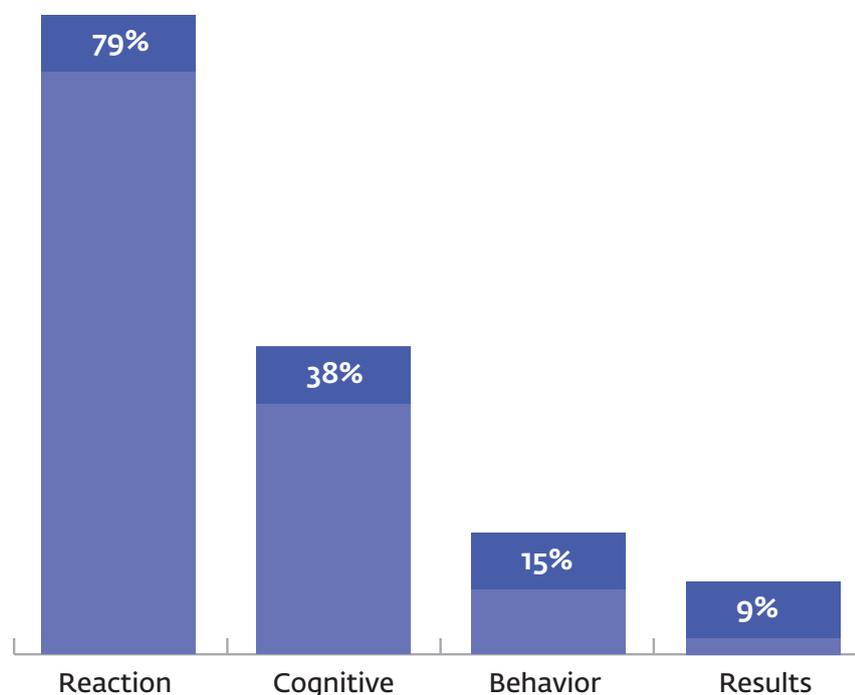
Good training outcomes need to be:

- Relevant
- Reliable
- Discriminative
- Practical

Good Outcomes Depend On...

- **Criteria relevance** – the extent to which training programs are related to learned capabilities emphasized in the training program
- **Criterion contamination** – extent that training outcomes measure inappropriate capabilities or are affected by extraneous conditions
- **Criterion deficiency** – failure to measure training outcomes that were emphasized in the training objectives
- **Reliability** – degree to which outcomes can be measured consistently over time
- **Discrimination** – degree to which Learner's performances on the outcome actually reflect true differences in performance
- **Practicality** – refers to the ease with which the outcomes measures can be collected

Industry Training Evaluation Practices



Training Outcome: Kirkpatrick's Four-Level Framework of Evaluation Criteria

Level	Criteria	Focus
1	Reactions	Learner satisfaction
2	Learning	Acquisition of knowledge, skills, attitudes, behavior
3	Behavior	Improvement of behavior on the job
4	Results	Business results achieved by trainees

Types of Evaluation Design

- **Pre-evaluation** – to quantify the FBO and learner training program needs or problems and identify specific competencies required to close gaps in FBO and learner performance
- **Continuous assessment** –training outcomes measured during training program delivery
- **Post-evaluation** –training outcomes measured after training program delivery

Pre-evaluation and post-evaluation can also be time based, i.e. a comparison of learner performance before and after the delivery of the training program.

Training and Development Procedure Template

Training and Development

FBO Procedure	
Document #	SOP-014
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	HR Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
<p>All documents within FBO are classified in the following way: PUBLIC documents are intended for anyone; COMMERCIAL IN CONFIDENCE documents are to be kept confidential between restricted individuals within the FBO and partner organizations; COMPANY CONFIDENTIAL documents are to be kept confidential within FBO and used for normal business activities by the general office population; HIGHLY CONFIDENTIAL documents are to be kept confidential to restricted individuals within FBO.</p>	
<p>© Copyright FBO. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the written permission of FBO.</p>	
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20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion
24-04-2015	V1.0	Mary Cahill	Format changes and reviewing and approval by process owner

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Doc ID	SOP-014	Printed		Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner	HR Manager
					Page 1 of 8

Training and Development

1 Summary

Purpose	The purpose of this procedure is to describe the methodology used by the company to enable individuals, business units and the company overall fulfil performance requirements through the provision of training and development.
Scope	This procedure applies to the training and development of all employees from initial onboarding to the identification of training and development needs following a performance evaluation or mandatory corporate training, and ending with the evaluation and/or confirmation of performance.
Functional Responsibility	The functional responsibility for this procedure lies with the Human Resources department, specifically the Human Resources Manager. They are responsible for the effective implementation and maintenance of this procedure.

2 Related documents

Policies	Food Safety Policy, POL-001
Processes	Human Resources Process Description, PRO-002
Procedures	Recruitment & Selection Procedure, SOP-025 Performance Appraisal Procedure, SOP-026 Disciplinary Procedure, SOP-027 Purchasing Procedure (for provision of external training), SOP-028
Work Instructions	Not Applicable
Forms	Job descriptions Training attendance form Training request Logging data from LMS
Other	'Train the trainer' training course

3 Definitions

Term or Acronym	Description
Job Description	A formal account of an employee's responsibilities
HRMS	Human Resource Management System
LMS	Learning Management System

Training and Development

4 Introduction

4.1 Training and Development Policy

The overall objective of training and development is to develop a trained workforce that can deliver superior customer service using the latest technology and expert domain knowledge. To achieve this goal, we provide several types of training, including new joiner onboarding, domain training, food safety compliance training and on-the-job training.

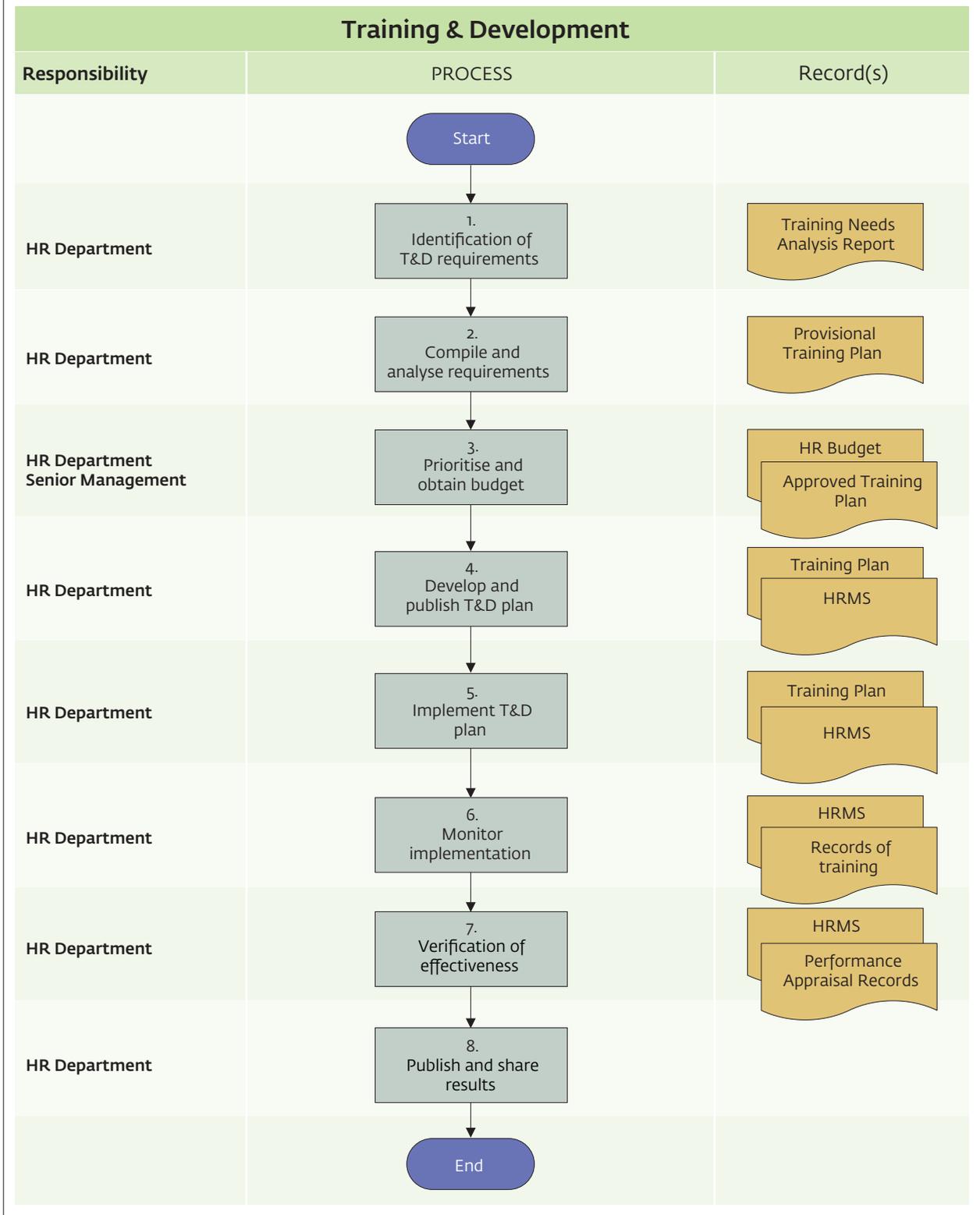
New joiner onboarding (induction) training helps new employees to integrate quickly and effectively into their new working environment.

Domain training refers to the industry specific knowledge training that is required by an individual to be successful in the role that he/she holds.

Food safety compliance training is mandatory and plays an important role in the process of educating employees on industry laws, regulations and company food safety policies and procedures. Every new employee must go through this training immediately after joining, and every employee must complete food safety compliance training on a yearly basis.

Training and Development

5 Procedure Flow Chart



Training and Development

6 Procedure Notes.

Step 1 T&D Requirements

The Human Resources department will identify the training and development needs across the company. This will be achieved through a review of corporate mandatory training requirements, training requirements identified through the recruitment and selection process and/or the outcomes of performance appraisals. Each department will be consulted during this process.

Step 2 T&D Analysis

Based on the needs identified in step one, Human Resources will compile and analyze these requirements resulting in a provisional training plan.

Step 3 T&D Prioritization/Budget

The provisional training plan, including prioritization requirements, will be submitted to top management for approval. Once approved, the necessary resources will be provided as part of the Human Resources budget.

Step 4 T&D Plan

Once budget approval has been received, the Human Resource department will develop and publish the approved training and development plan via the HRMS. This plan will outline what training and development will be provided for the coming period both mandatory and/or optional.

Step 5 & 6 T+D Plan Implementation and Monitoring

Human Resources, in association with applicable departments, will implement the training and development plan. The Human Resources department will continuously monitor the implementation of the training plan, using the HRMS and the LMS, to ensure that it is flawlessly executed. The HRMS and LMS systems will show what training has been completed on a 'per employee' basis. Training attendance sheets and training evaluation records will also be maintained. Where it becomes evident that the training and development plan is not being adhered to, Human Resources will take the necessary actions, including review with senior management, to bring the plan back on track or take other measures to ensure training is completed.

Step 7 T&D Effectiveness Verification

Human Resources will determine the effectiveness and impact of training and development courses provided on individual, business unit or company performance. Where analysis shows that training and development is not having the desired effect, a review of the training and development plan and its implementation will be held and the necessary actions identified, taken and recorded. The outputs of the performance appraisal process will be a direct input to the determination of the overall effectiveness of training and development and drive the creation of the next training and development plan.

Step 8 T&D Publish Results

Human Resources will publish and share the results achieved through the implementation of the training and development plan with all interested parties to ensure decisions related to ongoing training and development are based on factual information.

Training and Development

7 Management of Training and Development

7.1 Selection, Approval and Evaluation of Trainers

7.1.1 Internal Trainers

All employees selected to act as company trainers are required to meet the following minimum criteria:

- Be working in the area covered by the training for a significant period, two to three years minimum;
- Be a subject matter expert in the required subject/area;
- Have successfully completed a 'Train the Trainer' training course;
- Have successfully presented the training course to their peers and Human Resources.

7.1.2 External Trainers

Where it is necessary to employ the services of an external trainer to provide training, they shall be selected in accordance with a defined process. Human Resources shall ensure that this trainer is competent to complete the task. All external trainers shall meet the following criteria:

- Be a subject matter expert in the required subject/area;
- Have successfully completed a 'Train the Trainer' training course;
- Hold the necessary educational qualifications related to the training course;
- Have several years work experience related to the training course, ideally be still working in a related area;
- Provide written references and approvals with respect to the provision of training;
- Where required, hold the necessary certifications from recognized certification bodies or work on behalf of a certified/accredited training organization.

Documented evidence of meeting the above criteria must be maintained on file by Human Resources for all external training organizations and related trainers.

In the event of an approved external trainer not being able to attend scheduled training and a substitute external trainer being recommended by the supplier, the substitute external trainer must also meet the above requirements.

A panel of approved trainers and training organizations will be maintained by Human Resources.

7.2 Training Course Evaluation

All training course material and trainers will be subject to evaluation. This is required to ensure that the level of course materials and course delivery does not deteriorate, remains relevant and that the trainee is receiving a high standard of training.

Evaluations will take the form of:

- Training course evaluation forms – completed at the end of the course by the trainee, outlining their rating of course delivery, course material, trainer and other relevant criteria;
- Internal trainer presentation review – witnessed and documented evaluation of the internal trainer's presentation completed by Human Resources on a defined basis.

Training and Development

Human Resources will review the output from these evaluations and ensure that where the standards are not being met, the appropriate actions are taken to ensure no negative impact on the trainee or the company as a whole.

7.3 Trainee Evaluation

Depending on the type of training delivered, the trainee will be evaluated to ensure that they have both received and understood the information being delivered and can implement the training in their day-to-day role. This evaluation and/or assessment can take several forms including, but may not be limited to:

- Written examination on the subject matter;
- Documented continuous assessment throughout course delivery;
- Trainer assessment of trainee through role play or similar exercises;
- On the job mentoring and review;
- Performance appraisal.

Trainee evaluation must be documented and maintained on file.

7.4 Training Materials

Where training material (e.g. PowerPoint presentations, training manuals, exams, or tests) are developed in-house, it is important to assess it for quality and technical content prior to use and following any updates.

Human Resources will review the material from a quality perspective to ensure that:

- It is in a form and manner and language that is likely to be understood;
- Is grammatically correct;
- Is clear, concise and visually acceptable;
- Meets the company requirements regarding templates (e.g. for power point presentations, or notes);
- Does not contain any unauthorized language or material;
- Is revision-controlled.

The tutor, or subject matter expert, will review the material from a technical perspective to ensure that:

- The training course content is technically correct, accurate and up to date;
- The information and examples presented are compliant with all necessary rules and regulations.

Where possible, training materials provided by external providers will be reviewed prior to course delivery.

Human Resources will be responsible for the maintenance of internal course materials; however, it is the responsibility of the subject matter expert to ensure that the course is updated as necessary and in line with any changes to food safety compliance and/or regulatory requirements or other significant changes affecting the course content.

All internal training materials will be held by Human Resources and issued to the trainers as required.

Training and Development

7.5 Training Course Attendance

Once a training course has been scheduled, it is the responsibility of management to release their staff to attend the training and it is required that all trainees attend the full duration of the course. If for any reason the trainee has to leave the course, then they must re-sit the entire course again. Human Resources may amend this requirement on a case-by-case basis.

7.6 Poor Performance / Unsuccessful Completion of Training

A training matrix will be maintained by the Human Resources department identifying the both mandatory and optional training courses available. This may be used by departments and the management team to identify potential training solutions available where an employee is found not to be performing to expected levels.

In the event of an employee not successfully completing a mandatory training course, they may be offered the option to re-sit the course or course assessment. Where an employee has not successfully completed mandatory training course after numerous attempts or their performance in the job role does not improve, then both Human Resources and the departmental manager will meet to determine the best course of action to be taken with regard to that employee. A decision will be made and communicated to the employee. This decision will be documented and monitored by Human Resources.

8 Records

Document	Location	Duration of Record	Responsibility
Induction Pack Forms	Human Resources Office	Indefinitely	Human Resources Manager
Training Needs Analysis	Human Resources Office	Six years then archive	Human Resources Manager
Training Plan	Human Resources Office	Six years then archive	Human Resources Manager
Training attendance sheet	Human Resources Office	Six years then archive	Human Resources Manager
Record of training	Human Resources Office	Six years then archive	Human Resources Manager
Education records	Human Resources Office	Indefinitely	Human Resources Manager
LMS login record	LMS	Indefinitely	Human Resources Manager
LMS evaluation results	LMS	Indefinitely	Human Resources

Responsibility Matrix, Training Needs Analysis and Training Plan [Partial Sample]

Identify responsibilities of individuals for food safety pre-requisites and the food safety management system, and of individuals performing tasks that have a potential to cause a significant food safety impact, determine their competency, identify training needs, and plan for training.

Role / Position Title/ Position no.	Name	Responsibilities	Qualifications/ competency	
Managing Director	Mike Murphy	<ul style="list-style-type: none"> Participate in FSMS Management review Setting policy Reviewing objective & targets Resource allocation 	Senior Business Administrator	
Food Safety Manager (management representative)	Joe Bloggs	<ul style="list-style-type: none"> Establish, develop, implement, maintain and improve the FSMS including food defence Training the FSMS team members Implementing programs for achieving set objectives & targets Monitoring and measurement of FSMS performance including reporting to top management Awareness of FSMS compliance within the FBO Liaison with external audit/inspection organizations 	BSc Food Science Certificate of Attainment in Food Safety Management Systems (FSSC 22000)	
Internal Auditor	Mary Cahill	<ul style="list-style-type: none"> Developing internal audit program in liaison with Food Safety Manager Conducting internal audits as per schedule Training other internal auditors 	Certified (IRCA) FSSC 22000 Internal Auditor	
FSMS team members	A. Sullivan J. Wright M. Brown K. Wriggly	<ul style="list-style-type: none"> Awareness on Policy & FSMS Implementing program for achieving set objectives & targets PRP, HACCP Plan and O-PRP implementation, verification and validation Helping in monitoring and measurement Training respective staff in implementing FSMS policies and procedures 	FSMS including HACCP principles and practices	
Department managers	All	<ul style="list-style-type: none"> Context of organization planning, leadership, performance evaluation, improvement of the FSMS 	Planning, Operations Management	
Laboratory technician	R. Harley	<ul style="list-style-type: none"> Conducting analytical tests, laboratory equipment maintenance and calibration, p-test, laboratory training 	Laboratory Management [Chemistry/Biology]	
Associate	All	<ul style="list-style-type: none"> Awareness on policy & FSMS 	N/A	
Transport driver(s)	All	<ul style="list-style-type: none"> Awareness on policy & FSMS 	Drivers licence	

	Training needs	Planned dates	Training details	Remarks
	FSMS orientation (in house)	24.04.15	FSMS-1	Training completed 24.04.15
	Mandatory FSMS training, reference the training matrix (internal)	March – Oct 2016	Various	Training to be completed by October 2016
	Emergency preparedness and response/crisis management (external)	June 2016	FSMS-4	Training to be completed by June 2016
	FSMS orientation (in house)	24.04-15	FSMS-1	Training completed 24.04.15
	FSSC 22000 lead Auditor training (external)	March – April 2016	FSMS-5	Training confirmed
	Mandatory FSMS training, reference the training matrix (internal)	March – Oct 2016	Various	Training to be completed by October 2016
	Emergency preparedness and response/crisis management (external)	June 2016	FSMS-4	Training to be completed by June 2016
	FSMS orientation (in house)	24.04.14	FSMS-1	Training completed 24.04.15
	FSSC 22000 internal Auditing course	March - April	FSMS-6	Training confirmed
	FSMS orientation (in house)	19.01.16	FSMS-1	Training completed 24.04.15
	Mandatory FSMS training, reference the training matrix (internal)	March – October 2016	Various	Training to be completed by October 2016
	Emergency preparedness and response/crisis management (external)	June 2016	FSMS-4	Training to be completed by June 2016
	FSMS orientation (in house)	24.04.15	FSMS-1	Training completed 24.04.15
	Emergency preparedness and response/crisis management (in-house)		FSMS-5	Training to be completed by June 2016
	FSMS orientation (in house)	24.04.15	FSMS-1	Training completed 24.04.15
	Analytical policies and procedures	30.09.15	LAB-1	Training completed 30.09.15
	Mandatory FSMS training, reference the training matrix (internal)	March- October 2016	Various	Training to be completed by October 2016
	FSMS orientation (in house)	24.01.15	FSMS-1	Training completed 24.04.15
	Mandatory FSMS training, reference the training matrix (internal)	March- October 2016	Various	Training to be completed by October 2016
	FSMS orientation (in house)	24.04.15	FSMS-1	Training completed 24.04.15
	Tank cleaning/ sanitizing	24.05.15	FSMS-10	Training completed 24.04.15
	Dairy farm raw milk handling/testing	24.05.15	FSMS-11	Training completed 24.04.15
	Mandatory FSMS training, reference the training matrix (internal)	March- October 2016	Various	Training to be completed by October 2016

Food Safety Training Maxtrix

Job Title	Food Safety Orientation	Personal Hygiene	Pest and Waste Control	Cleaning	Allergen Management	Food Delivery	Food Processing	Food Storage	HACCP Level 1	HACCP Level 2	Maintenance	Calibration	FSMS Policies and Procedures	Analytical Policies and Procedures	HACCP Verification and Validation	Document Control	Record Control	Emergency Preparedness/ Crisis Management	Food Defense	Consumer complaint Management	Communications	Internal Auditing	FSMS Management Review
Managing Director	M	M	M	M	M	M	M	M	M	M	N/A	N/A	M	M	M	M	M	M	M	M	M	N/A	M
Food Safety Manager	M	M	M	M	M	M	M	M	M	M	N/A	M	M	O	M	M	M	M	M	M	M	M	M
Hygienist/Microbiologist	M	M	M	M	M	M	M	M	M	M	N/A	N/A	M	O	M	M	M	M	M	M	M	M	M
Milk Processing Manager	M	M	M	M	M	M	M	M	M	M	N/A	N/A	M	M	M	M	M	M	M	M	M	N/A	M
Laboratory Manager	M	M	M	M	M	M	M	M	M	M	M	M	M	N/A	M	M	M	M	M	M	M	M	M
Warehousing Manager	M	M	M	M	M	M	M	M	M	M	N/A	M	M	N/A	M	M	M	M	M	O	M	O	M
Engineering Manager	M	M	M	M	M	M	M	M	M	M	O	M	M	N/A	M	M	M	M	M	O	M	N/A	M
Maintenance Manager	M	M	M	M	M	M	M	M	M	M	M	M	M	N/A	O	M	M	M	M	O	M	N/A	M
Logistics Manager	M	M	M	M	M	M	M	M	M	M	M	O	M	N/A	O	M	M	M	M	M	M	O	M
Laboratory Technician	M	M	M	M	M	M	M	M	M	M	M	M	M	M	O	M	M	M	O	O	O	O	N/A
Food Handler	M	M	M	M	M	M	M	M	M	M	M	N/A	M	N/A	N/A	M	M	M	O	O	O	O	N/A
Transport Driver	M	M	M	M	M	M	M	M	M	M	M	O	M	N/A	N/A	M	M	M	M	O	O	O	N/A

M = Mandatory
 O = Optional
 N/A = Not applicable



Food Safety T&D Maxtrix

Job Title	Food Safety Induction	Personal Hygiene	Pest and Waste Control	Cleaning	Allergen Management	Food Delivery	Food Processing	Food Storage	HACCP Level 1	HACCP Level 2	FSMS Policies and Procedures	Analytical Policies and Procedures	HACCP Verification and Validation	Document Control	Record Control	Emergency Preparedness/Crisis Management	Food Defense	Consumer Complaint Management	Communications	Internal Auditing	FSMS Management Review	
Managing Director										N/A		N/A	N/A								N/A	
Food Safety Manager																						
Hygienist/Microbiologist																						
Milk Processing Manager												N/A									N/A	
Laboratory Manager												N/A										
Warehousing Manager										N/A		N/A										
Engineering Manager												N/A										
Maintenance Manager												N/A										N/A
Logistics Manager										N/A		N/A										N/A
Laboratory Technician													N/A									N/A
Food Handler										N/A		N/A	N/A									N/A
Transport Driver											N/A	N/A	N/A								N/A	N/A

Completed 

Planned 

Overdue 







Information for Company Management

MODULE 7



Introduction

This module provides an overview of the FBO executive management team's responsibilities and covers topics such as food safety policy, management commitment and resources, management review including, actions, decisions and follow up required to maintain an effective FSMS and improve it.

The information is also provided on two important IFC-developed management resources:

(1) An IFC publication, italicize *Wisely in Food Safety: How to Maximize the Benefits and Reduce Costs*, which outlines the benefits, challenges and lessons learned by CEOs. This is a good resource for executive management considering the adoption of a food safety management system;¹ and

(2) IFC Food Safety Self-Assessment Tool that enables the FBO executive management team to assess the maturity of their existing FSMS system within 30 minutes and use the output when identifying the gaps within the GFSI or other food safety management schemes being considered.

This resource should be reviewed by any FBO executive management team considering the adoption of a FSMS. Both executive management resources are included in the CD provided by the IFC. Training on their application is provided during the IFC Foundation and IFC FSTK training courses referenced in Module 6.

Food Safety Policy

A policy is a statement of intent and is implemented as a procedure or protocol with an FBO. The FBO's food safety policy is generally established and adopted by top management typically on the recommendation of the food safety manager.

All international food safety management system schemes require an organization to establish, and flawlessly implement their food safety policy.

Before we look at the contents of a food safety policy we will examine some key principles food safety schemes that food safety auditors would look to when examining a FBO's food safety policy:

- The policy should be established and adopted by top management;
- It should clearly set out top management's aspirations and expectations in relation to food safety;
- It should address and meet the defined requirements of the relevant food safety Scheme adopted by the FBO;
- It should be consistent with the FBO's food safety objectives, the FBO's regulatory and other legal obligations.

¹<http://www.ifc.org/wps/wcm/connect/41c7d0004c915a0faa8dabd4c83f5107/ECAAGRInvest+Wisely+ENGApril2016+%281%29.pdf?MOD=AJPERES>

Food Safety Policy Contents

The following is an example of what a food safety policy should consist of according to ISO 22000:

- Top management shall define, document and communicate its food safety policy;
- Top management shall ensure that the food safety policy:
 - a) is appropriate to the role of the organization in the food chain;
 - b) conforms with both statutory and regulatory requirements and with mutually-agreed food safety requirements of customers;
 - c) is communicated, implemented and maintained at all levels of the organization;
 - d) is reviewed for continued suitability;
 - e) adequately addresses communication; and
 - f) is supported by measurable objectives.

Top management means the top manager of the FBO and his or her direct reports.

Appropriate means that the policy is based on the scope of the FBO's food safety management system products, food chain activities and markets.

Suitability means the policy is 'fit for purpose.' Sometimes changes within the FBO makes the food safety policy not fully 'fit for purpose.' This could happen, for example, if: (i) the FBO introduces new products with new food safety hazards; (ii) the FBO markets and sells products in new markets; (iii) the FBO introduces significant changes in technology, process or equipment.

The final requirement states that the food safety policy needs to be supported by measurable objectives. Measurable means *Specific, Measurable, Attainable, Realistic and Time Bound*. In summary, *SMART*.

In keeping with the spirit of all food safety schemes, for example, BRC, SQF, or FSSC 2000, the primary objective is safe food; hence, all food safety objectives should be aimed at reducing or eliminating food safety hazards in the FBO product. The following example illustrates how to draft a food safety objective based on SMART:

By December 2015 reduce 1.14g salt per 100g in all FBO brown and white bread products, a reduction of 10 percent compared to 2015.

To organize and train all the milk processing operators with GMP by conducting two trainings per month and thereby decreasing the Out of Specification [OOS] products by 20% by the end of the year 2016.

The above food safety objective is in keeping with the WHO recommended daily intake of salt by adults to 6gm per day.

Management Commitment

Every management system, including a food safety management system, requires management commitment. What does this actually mean?

All levels of management – particularly the highest – are responsible for creating and fostering an environment that promotes food safety.

Top management should be aware of how the success of the organization depends largely on the ability to monitor and continuously improve the effectiveness of risk control measures with respect to the safety of the FBO's products across the food chain in a continuously changing internal and external environment.

If top management does not express informed, sustained commitment to food safety as one of its primary business objectives, the commitment to food safety in the food chain can easily shift towards other, sometimes conflicting, business objectives, particularly in less mature organizations.

Management commitment implies the direct participation by the highest level management in all specific and important safety aspect or programs of an organization.

The following examples demonstrate how management commitment can be delivered in practice within an FSMS:

- Showing passion for and interest in food safety;
- Formulating and establishing safety policies and objectives;
- Setting targets to improve or maintain food safety;
- Providing resources and training;
- Ensuring that all staff – including top management – are sufficiently trained and competent in their food safety responsibilities;
- Ensuring operational control at all levels of the organization, i.e. PRPs, HACCP plans, O-PRP plans;
- Receiving regularly information about food safety, e.g. performance data (consumer complaints, waste), and evaluating and reviewing the FSMS in light of results achieved;
- Being aware of what is happening on the ground; what audits or assessments are undertaken; receiving results related to the activities carried out internally or by contractors and other persons working for or on behalf of the FBO;
- Ensuring appropriate top management-level review of the FSMS;
- Ensuring that all levels of the organization, including top management, receives relevant food safety information regarding evaluation of compliance and other legal obligations;
- Being confident that persons working for or on behalf of the FBO are properly communicated to and consulted on food safety matters, and that their concerns are reaching the appropriate level;
- Ensuring that your organization's risks are assessed and that appropriate control measures are established and maintained;
- Creating an environment conducive to continuous improvement;
- Bringing to the attention of top management the changes in working arrangements that may have significant implications for food safety;
- Promoting a food safety culture throughout the FBO.

Strong and active leadership is reinforced by visible, active commitment from the top:

- Establishing effective 'downward' and 'upward' communication systems;
- Establishing effective management structures;
- Integrating food safety management with business decisions.

Resources

Resources is a term within an FSMS that refers to the four generic resources with a FBO; namely finance, human resources, infrastructure, and work environment within the scope of the FBO's FSMS. Resources within an FBO are typically controlled and managed by top management. In this chapter we will examine two of these resources, namely financial and human.

IFC has developed a useful executive management resource entitled: Investing Wisely in Food Safety: Lessons learned from IFC Clients. This resource was developed to assist the FBO CEO and the management team consider the adoption of an FSMS based on HACCP to understand the benefits and challenges. The resource also contains five key lessons covering the following topics:

- Planning;
- Financing;
- Changing Behaviour;
- Outsourcing Wisely;
- Typical Mistakes and How to Avoid Them.

It is strongly recommended that this resource be reviewed by any FBO executive management team considering the adoption of a FSMS based upon a GFSI or other relevant food safety scheme as a valuable input prior to a formal decision being made. This executive management resource is available on the IFC-supplied CD.

The second executive management resource is a self-assessment tool that enables the FBO executive management team to assess the maturity of its existing FSMS system within 30 minutes and to use the output when identifying the gaps within the GFSI or other food safety management schemes being considered.

Both executive management resources should be reviewed by any FBO executive management team considering the adoption of an FSMS. Both executive management resources are included in the CD provided by IFC and training on their application is provided during the IFC Foundation and IFC FSTK training courses referenced in Module 6.

Finance

Clearly finance is a key input or requirement for any organization. As top management controls finances within the FBO, it is responsible for ensuring that the FBO has sufficient financial resources to fulfil its food safety policy and objectives. Food safety throughout the food chain should not be endangered because of financial issues.

Typically, a food safety auditor would look for the following:

- CapEx investment in preventing and/or improving food safety risk across the FBO food chain;
- Financial investment in food safety training of persons working for or on behalf of the FBO.

Note that risk assessment finance is not a factor in ensuring food safety across the food chain.

Human Resources

The most difficult challenge facing most FBOs is engaging employees in the FSMS so that employees take personal responsibility for their food safety actions and performance.

A good place to start is for top management to communicate its belief to all employees and persons working for, and on behalf of, the FBO that they are responsible for contributing to the success of their FSMS. It is top management's responsibility to provide incentives, encourage and empower people to bring forward ideas that can improve the FBO efforts and take action when they see operational problems that could compromise food safety.

Secondly, top management should strive to ensure that every employee is provided the relevant food safety training necessary to understand the FBO's food safety policies and practices and their role in food safety.

The FBO's managers have additional responsibilities:

- Line managers are required to respond to employees' food safety concerns in a timely manner and to listen to ideas for improving our food safety management system;
- Line managers at all levels are responsible for helping create a culture of food safety across the FBO;
- Top management provides line managers with the resources required to maintain a robust FSMS and to comply fully with food safety regulations, standards and expectations set by the FBO, regulators and customers.

For most food safety auditors, the focus is training and its effectiveness. From a FBO perspective both the relevant food safety regulations and standards set out what is required and provide practical advice to the FBO.

Let us first examine the food safety regulatory perspective on food safety training. Most food safety regulatory agencies require the FBO to legally undertake food safety training and/or be supervised in line with the level of activity the FBO is involved in. For example, line managers in an FBO will need different training than employees processing or serving food.

To illustrate, the Irish Food Authority of Ireland [FSAI] has produced guides for the FBO to assist with the training of FBO employees in the workplace:

- *Guide to Food Safety Training Level 1* provides information on basic food safety skills that staff should be able to demonstrate within the first month of employment;
- *Guide to Food Safety Training Level 2* provides information on the additional food safety skills that staff should be able to demonstrate within 3-12 months of commencing employment in your food business;
- *Guide to Food Safety Training Level 3* provides information on the food safety skills that should be demonstrated by managers and supervisors in food operations.

For additional information on the FSAI guides see: https://www.fsai.ie/food_businesses/training_guides.html

Management Review Procedures Templates

Management Review

FBO Procedure	
Document #	SOP-021
Created	20-04-2015
Updated	24-04-2015
Controller	Document Controller
Owner	Food Safety Manager
Confidentiality Statement	Information in this document must be kept confidential as per its classification below and the rules of disclosure.
<p>All documents within FBO are classified in the following way: PUBLIC documents are intended for anyone; COMMERCIAL IN CONFIDENCE documents are to be kept confidential between restricted individuals within the FBO and partner organizations; COMPANY CONFIDENTIAL documents are to be kept confidential within FBO and used for normal business activities by the general office population; HIGHLY CONFIDENTIAL documents are to be kept confidential to restricted individuals within FBO.</p> <p>© Copyright FBO. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the written permission of FBO.</p>	
Classification	Company Confidential

Revision History

Date	Version	Author	Comments (including Review History)
20-04-2015	Draft 01	Joe Bloggs	Initial document for review and discussion.
24-04-2015	V1.0	Joe Bloggs	Approved for release by process owner.

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Management Review

1 Summary

Purpose	<p>The purpose of this procedure is to describe:</p> <ul style="list-style-type: none"> • The methodology employed by senior management to ensure that the Food Safety Management System [FSMS] remains suitable, adequate and effective.
Scope	<p>This procedure applies to:</p> <ul style="list-style-type: none"> • The planning, data gathering and trending, presentation to the senior management team and the follow-up of any identified action items, including the updating of the FSMS.
Functional Responsibility	<p>The functional responsibility for this procedure lies with the Food Safety Team Leader. They are responsible for the effective implementation and maintenance of this procedure.</p>

2 Related documents

Policies	Food Safety Policy, POL-001
Procedures	<p>Corrective and Preventive Action, SOP-009</p> <p>Strategic Planning, SOP-029</p> <p>Risk Management, SOP-030</p> <p>Internal Auditing, SOP-006</p>
Work Instructions	N/A
Forms	<p>Management review meeting minutes document template</p> <p>Management review meeting presentation template</p>
Other	Data reviewed as part of the management review meeting

3 Definitions

Term or Acronym	Description
FSM/MR	Food Safety Manager
FSMS	Food Safety Management System
Executive Management Team	Person or group of people who directs and controls and organization at the highest level.

Classification Company Confidential

Management Review

Doc ID SOP-021
Created 20-04-2015

Printed
Updated 24-04-2015

Controller Document Controller
Owner Food Safety Manager

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Management Review

4 Introduction

4.1 Management Review Policy

In line with good business practice and the requirements of FSSC 22000:2010, clause 5.8, top management of the company will review the Food Safety Management System [FSMS], at least annually (fixed date), to ensure it remains suitable, adequate and effective. This review will be a structured process and identify outputs and actions related to continual improvement opportunities, the need for changes to the Food Safety Management System and resource needs.

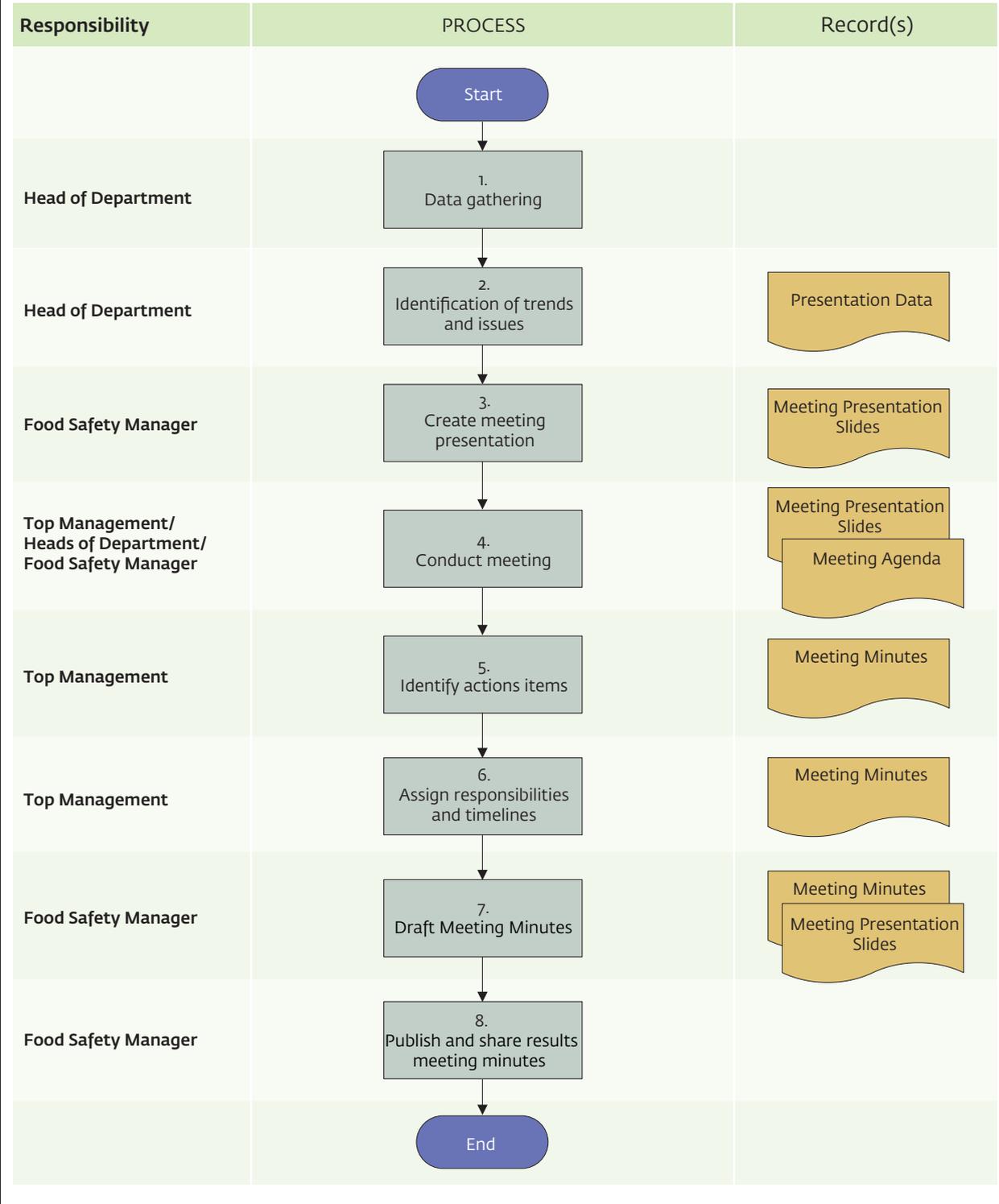
This review will be held at least annually and must be attended by the General Manager, the Heads of Department, the Food Safety Team Leader. A quorum of at least the General Manager, all Heads of Department and the Food Safety Manager is required for the meeting to proceed. Minutes must be taken, including action items arising from the meeting and held on file.



Management Review

5 Procedure Flow Chart

5.1 Management Review



Classification Company Confidential Management Review

Management Review

6 Procedure Notes

Step 1 & 2

In advance of the scheduled management review meeting, the Heads of Department will gather together data in relation to the performance of their department's processes and activities. This data will then be reviewed by them to identify trends, either positive or negative. These trends will then be presented to the management team during the review.

Step 3

Based on the data received from the Heads of Department, the Food Safety Manager will create the overall management review presentation slides, where necessary/required.

Step 4, 5 & 6

The General Manager will chair the meeting, supported by the Food Safety Manager. They will assign a person to take the minutes of the meeting on a rotational basis. The Food Safety Manager may invite other process owners to present specific agenda items of the meeting. Each attendee will be allowed to ask any questions in relation to the data to allow for a full and open discussion to take place. Where decisions are taken and/or action items identified, these must be agreed by the management team and recorded in the minutes in accordance with section 7.4 of this procedure. Where an action is agreed, the specific action, person responsible and timescale should be recorded.

Step 7 & 8

The minutes will be taken during the meeting and the:

- Food Safety Manager must review and approve the minutes prior to issuing to the General Manager;
- The General Manager or their deputy must sign and date the minutes of the meeting to signify approval of the minutes and a commitment to ensure completion and implementation of any identified decisions and/or actions.

Once approved, the minutes can be circulated to the organisation. A copy of the minutes must be held on file for record purposes.

Minutes of the meeting should be published within 5 days of completion of the meeting.

Management Review

7 The Management Review Meeting

7.1 Attendees

The following persons are required to attend the meeting:

- General Managers;
- Heads of Department;
- Food Safety Manager;
- Any other roles as required.

Where a deputy attends and represents a person, they are assumed to have the full authority of that person in relation to making decisions and accepting responsibility to carry out any decisions or actions agreed at the meeting. Deputies should only be used as an exception.

7.2 Agenda

The agenda for the management review meeting must include the following points at a minimum:

- The status of actions from the previous management reviews;
- Changes in external and internal issues [significant] that are relevant to the Food Safety Management System including its strategic direction;
- Information on the food safety performance, including trends and indicators for:
 - Nonconformities and corrective actions;
 - Analysis of results of verification activities;
 - Audit results;
 - Emergency situations, accidents and withdrawals;
 - Issues concerning external providers and other relevant interested parties;
 - Adequacy of resources required for maintaining an effective Food Safety Management System;
 - Reviewing results of system-updating activities;
 - Review of communication activities, including customer/consumer feedback.
- New or revised statutory and regulatory requirements;
- The effectiveness of actions taken to address risks and opportunities;
- New potential opportunities for continual improvement;
- Food Safety policy;
- Documentation;
- Any other business.

Management Review

7.3 Review Output

The output from the management review meeting shall include decisions and actions based on factual data presented during the review and related to:

- Assurance of Food Safety;
- Improvement of the effectiveness of the FSMS;
- Resource needs;
- Any need for changes to the Food Safety Management System, including revisions to the food safety policy and objectives.

The overall output from the meeting is a decision as to whether or not the Food Safety Management System remains suitable, adequate and effective.

7.4 Management Review Minutes

Minutes must be produced following every meeting and be created using the approved template. The minutes must be detailed and accurate, giving a clear description of the topics covered. Where any decisions and/or action(s) are identified as a result of the meeting they must:

- Clearly describe the decision made including potential implications;
- Clearly describe the required action(s) to be taken;
- Identify the role responsible for the completion of the action;
- Identify the timescale assigned for completion of the action.

Management Review records will be maintained for six years.

7.5 Approval of the Management Review Minutes

The minutes are approved as outlined in steps 7 & 8 of the above flowchart.

7.6 Communication of the Output from Management Review

An abridged version of the minutes will be communicated to the company, via the Heads of Department.

8 Records

Document	Location	Duration of Record	Responsibility
Management review presentation slides (where used)	Food Safety Office	Indefinitely	Food Safety Manager
Management review meeting minutes	Food Safety Office	Indefinitely	Food Safety Manager

Classification		Company Confidential		Management Review	
Doc ID	SOP-021	Printed		Controller	Document Controller
Created	20-04-2015	Updated	24-04-2015	Owner	Food Safety Manager
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Example of Management Review Meeting materials

Agenda

1. Previous Management Review Meeting Minutes
2. Policy and FSMS Documentation
3. Product and Process Monitoring and Measurement Data
 - a. Factory Objectives
 - b. Process KPIs
 - c. Raw Material, PRP, HACCP, Withdrawals/Recall
 - d. Inspections/Audits
 - e. Vendor / Contractor Data
 - f. Interested Party Feedback
 - g. Corrective and Preventative Actions
4. Changes affecting FSMS
6. FSMS Improvements/Preventative Actions
7. Resources Review [Resources, Infrastructure/Work Environment]
8. Updates Management Review Program
9. Miscellaneous

1. Previous Management Review Meeting

Action/Decision	Agenda Point	Who	Due Date	Status
All process owners to verify access to eDMS and be able to locate relevant controlled documents	1	All Department Manager	Immediate	In process
Establishment and confirmation of factory objectives for 2015	3	Joe	End February 2016	In process
Establish KPIs scorecard 2015 and align with factory objectives 2015 and process description KPIs	3	Joe	End February 2016	In process
Align factory objectives 2015 and KPI scorecard	3	Joe, Mary and Natia	End February 2016	In process
Industrial Performance Coordinator to publish status of factory objectives, KPI scorecard months	3	Natia to discuss and agree process with Lisa	End February 2016	In process
Factory risk register to be established to manage risks associated with attainment of factory objectives and KPIs	3	Natia to discuss and agree process with Lisa	End February 2016	In process
FSMS PRP development project plan to be created and published following completion of GAP analysis	3	Mary	End January 2016	In process
Improve quality of management review data and presentation	3	Mary/Mike	End February 2016	In process
Ownership of process for collection and analysis of management review presentation pack (this document) to be managed by Industrial Performance Coordinator	3	Natia to discuss and agree process with Lisa	End February 2016	In process
Improvement plan to be developed for downtime (total)	3	Joe/Henry	End February 2016	

1. Previous Management Review Meeting

Action/Decision	Agenda Point	Who	Due Date	Status
Improvement plan to be defined and documented to improve downtime (total)	3	Mike/Frank	End February 2016	In process
Improvement plan to be developed to reduce consumer complaints associated with packaging/maintenance	3	Joe	End February 2016	In process
Improvement plan to be developed to reduce variation in GMP inspection results	3	Joe	End February 2016	In process
Improve cycle time for closure of NC/CAPAs to under 30 days	3	Department Managers/Joe	End February 2016	In process
Manager/supervisor development program to be introduced to ensure supervisors actively coach, mentor and supervise associates with operational control FSMS	3	Jack, Sheila, Mary and Joe	End February 2016	In process
Development plan, including hiring of food safety resources to be implemented to ensure sustainability of FSMS	3	Sheila	End January 2016	In process
Implementation plan to be developed for FSMS following initial Stage I audit	3	Natia to discuss and agree process with Lisa	End February 2016	In process

1. Previous Management Review Meeting

Action/Decision	Agenda Point	Who	Due Date	Status
Implementation plan to be developed for FSMS following initial Stage I audit	6	Joe/Mary	End January 2016	In process
FSMS visualization performance to be introduced in all operational areas	6	Process owners/Joe/Mary	End February 2016	In process
Schedule February and May 2016 management review meetings in leadership team diary	7	Joe/Mary	End January 2016	In process
Micro laboratory construction/upgrade to be completed	7	Jack/Sheila	End February 2016	In process



2. Policy and FSMS Documentation

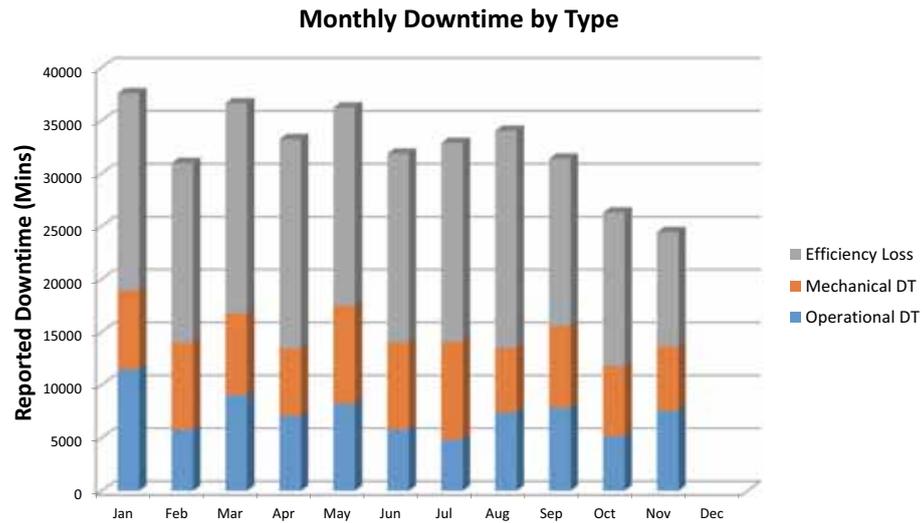
- First draft of FSMS manual based on Annex SL (ISO 2015 version) and PAS 99:2012. It covers FSMS, with option to extend to ISO/IEC 17025 [Laboratory]
- All FSMS process descriptions in the eDMS and published
- All core FSMS core procedures in eDMS
- All current job profiles in eDMS
- All process owners need to master the use of eDMS. As we roll out implementation of FSMS, awareness sessions for managers/supervisors and associates will be essential
- We also need to review and upload all other existing documentation into eDMS during Q1/Q2 2016

3. Product and Process Monitoring and Measurement Data

a. Factory Objectives 2015

FG	Indicator	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD	Budget	Base	Goal	YTD Imp.
1	Cases Produced	428,157	377,311	442,489	443,016	444,102	419,861	454,705	493,307	440,600	371,886	254,463	0	4,569,897	4,844,254			
2	Cases Produced % to Budget	121.7%	109.7%	107.2%	81.3%	88.0%	96.3%	97.0%	93.9%	100.2%	94.8%	59.9%	0.0%	94.3%				
3	Cases Produced per Employee Hour	32.82	32.86	34.70	31.14	31.81	33.07	33.37	33.01	31.65	29.24			32.36		33.99	35.00	<-4.80%>
4	Operational Downtime	18.64	21.05	20.26	20.96	19.25	19.69	19.28	20.80	17.58	19.00	20.02	20.28	19.71		19.67	15.00	<-0.20%>
5	Mechanical Downtime	7.41	10.14	7.88	6.77	9.49	9.06	9.45	6.19	8.57	8.74	11.24	9.04	8.52		5.78	5.45	<-47.40%>
6	3 L Line Efficiency	596	571	608	624	582	605	610	616	594	558			597		550	600	8.55%
7	Overhead Cost per Case	3.68	3.71	3.32	3.22	3.49	3.10	3.06	3.48	3.38	3.98	4.13		3.43	3.93	3.93	3.85	12.72%
8	Raw Material Yields	97.73	99.00	98.40	99.06	98.56	99.46	98.32	99.78	99.26	96.82			98.69	98.00	98.17	98.50	0.53%
9	Warehouse Cases Shipped /Employee Hr	127.92	152.54	157.57	170.25	154.03	152.36	164.08	138.06	138.45	136.44			148.62		143.68	158.00	3.44%
10	On Time & Complete Shipments	96.08	96.88	98.80	95.87	95.66	97.17	96.11	97.72	95.78	97.12			96.70		87.77	97.00	10.17%
11	Obsolete, Damage, Defects, Rework	(35,060)	(23,215)	(18,123)	(47,733)	(36,845)	(23,754)	(31,871)	(137,756)	(131,741)	(111,398)			\$ (59,749)		(59,545)	(53,590)	0.34%
12	Injury Frequency	3	0	0	0	0	0	0	1	0	2	0	1	0.58		0.67	0.470	12.94%
13	Sanitation Score	83.0%	85.0%	82.0%	90.0%	85.0%	90.0%	92.0%	81.0%	89.0%	86.0%	90.0%		86.64%		86.25%	90.00%	0.45%
14	Customer Complaints	2	7	3	7	24	2	11	9	3	7	4		7.18		13.50	12.15	46.80%
Performance Matrix Index		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD			Goal	
		Base	300	300	300	300	300	300	300	300	300	300	300	300			1000	
		Month Score	454	623	730	714	605	707	702	458	563	250	#VALUE!	#VALUE!	565			

3. Product and Process Monitoring and Measurement Data b. Process KPIs 2015



3. Product and Process Monitoring and Measurement Data b. Process KPIs 2015

INDICATORS	DEFINITION	RESPONSIBLE FOR MEASURING	TARGET VALUE	Nov Value	YTD Value
Master Schedule Attainment (MSA)	Planned orders vs. actual production	Planning	80%	72%	72%
Case Fill Rate	Cases delivered against cases ordered	Warehouse	99%	99%	99.61%
Stock Cover	Number of calendar days for finished goods at month end against the demand plan for the following months	Planning	3.5 weeks	3.57	4.46
Obsolescence	Material past the shelf-life date and due to be written off [plant related only]	Planning	<€31k pm	N/A	€59,749
DT Due to Out of Supplies	Unplanned stoppages due to out of supplies as % of net production hours	Production Manager	0.00%	0.00%	0.00%
Line Performance (Down Time)	Stoppage (time duration)	Production Manager	20%	20%	19.67%
Case Fill Rate	Cases shipped vs. cases ordered	Warehouse	99%	99%	99.61%
Inventory Count Accuracy	Physical count/ actual count x100	Warehouse	92%	N/A	N/A
Order fill rate		Warehouse	95%	N/A	97%

3. Product and Process Monitoring and Measurement Data

c. PRP, HACCP, O-PRP 2015

HACCP:

- Scheduled annual review performed on 10/07/15
- Unscheduled review due to O-PRP (Metal detector) failure on 9/03/15, 03/10/15
- HACCP verification:
- O-PRP (metal detector) failure on 03/09/13
- New product added:
 - Super milk and semi-skimmed milk
 - Organic milk
 - Orange juice

New projects:

- EDTA, FBO ongoing initiative to add EDTA to formulas containing sodium benzoate
- New hazards:
- FDA warning Carbendazim in orange juice, FDA release – “Based on EPA’s conclusions from its preliminary risk assessment, consumption of orange juice with Carbendazim at the low levels that have been reported does not raise safety concerns.”

PRP:

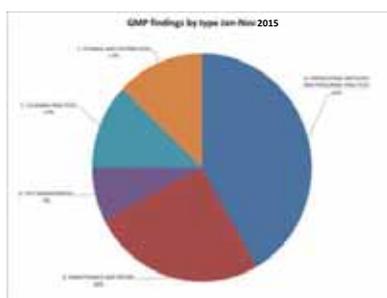
- Transfer to FBO approved format – in progress , due date 31/1/16

FSMS

- FSMS checklist – assessed, gaps closure in progress, due date TBD

3. Product and Process Monitoring Data and Measurement

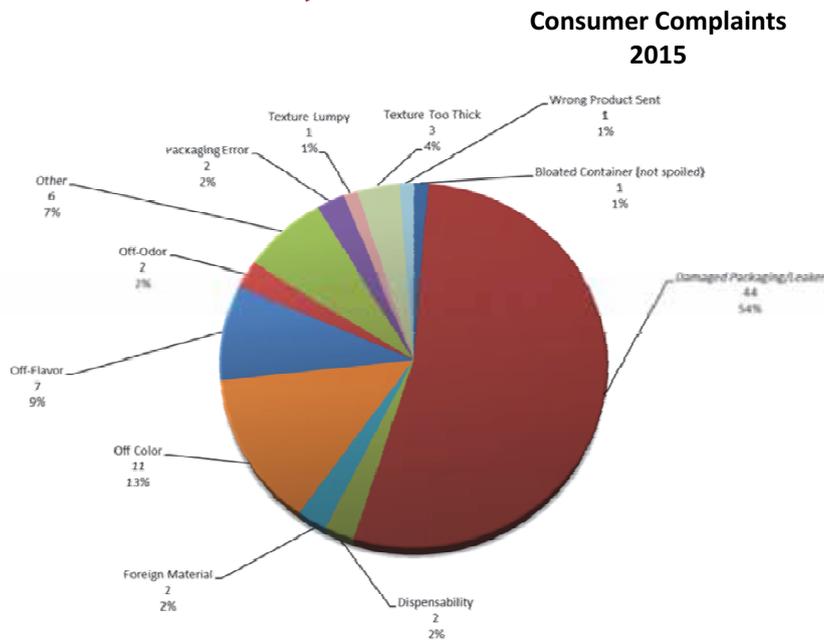
d. Inspections/Audits 2015



FSMS desktop audit results show:

- Goal alignment, factory objectives, and process KPI/PPI needs to be strengthened
- KPI data is limited for some processes
- Some process KPIs need to be reviewed
- Some process KPIs need improvement plans where targets are not being achieved
- Department managers need to gain ‘mastery’ of processes including performance

3. Product and Process Monitoring and Measurement Data f. Interested Party 2015



3. Product and Process Monitoring and Measurement Data d. CAPA 2015

- **Quality CAPA Data**
- Number of CAPA year-to-date: 17
 - 6 complaint related
 - 11 process/compliance related
- Number of open CAPAs: 5
 - 2 complaints
 - 3 micro-related issues
- Aging of CAPAs 5 months
 - Micro issues
- Average cycle time to close CAPAs – 30 to 45 days

3. Product and Process Monitoring and Measurement Data

g. CAPA 2015

- It is expected the FSMA will introduce two important rules during 2015, namely rules regarding importing of raw materials, ingredients and packaging from countries outside the USA and food defence
- Currently, the main priority within FBO is to comprehensively establish a formal and systematic system for managing compliance with client technical standards
- The plan is to introduce a new SaaS compliance tool to assist with the management of statutory and regulatory compliance

5. Changes affecting FSMS

- The core discipline standard, namely ISO/FSSC 22000 will be going through a major change in February 2017. The timetable for the changes will not occur until March 2016 when the DIS versions of the standards will be published
- Planned changes as a result of changes in the FSMA will require key changes to the FSMS documented management system

6. FSMS Improvements/Preventative Actions

- Now that the core FSMS documentation has been developed, it will now be necessary for all process owners to demonstrate mastery of goal alignment, process KPI/PPIs and performance
- As we prepare for the initial stage II audit, the active involvement, participation and communication with managers/supervisors and associates is critical
- Training will be required for internal auditors to provide feedback/input to top management/department managers. This is a key common discipline requirement that forms part of the FSMS improvement process
- Knowledge management and the use of data to drive decision making and continuous improvement will need to become the norm in FBO
- Top management/department managers focus on ensuring an effective NC/CAPA process within FBO will be required to ensure an effective FSMS deployment
- Deployment of visual PRP standards will facilitate better compliance

7. Review - Resources

- Key resources with food safety will be needed to ensure they have the resources and competency to lead, manage and sustain both food safety and FSMS within FBO
- The role of managers/supervisors and their active engagement with FSMS is arguably the biggest resource requirement to achieving a sustainable FSMS in FBO
- Given the rate of change in FSMS additional resources may be required on a temporary basis to manage specific projects, e.g. integration of IT applications/tools
- Specifically the introduction of the visual PRP standards will require particular resources, however it is expected this will greatly help develop the management of competencies and effectiveness of training within FBO

8. Update FSMS Management Review Program

- Propose two FSMS management reviews during 2016, rationale FSMS needs time to settle in
- Proposed 2016 management review program
 - February 2016 [Prior to FSSC 22000 Stage I audit]
 - May 2016 [Prior to FSMS Stage II audit]

9. Management Review Miscellaneous

- External audit stage I initial audit

Annexes

1. Useful Links

State institution	Internet address
Asia Pacific Food Industry	http://www.apfoodonline.com/
Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management – Food	http://www.lebensministerium.at/lebensmittel.html
Austrian Federal Office of Food Safety	http://www.ages.at/ages/en/federal-office-of-foodsafety/
Belgian Federal Public Service for Health, Food Chain Safety and Environment – Food Safety	http://www.health.belgium.be/eportal/foodsafety/index.htm
Belgian Federal Agency for the Safety of the Food Chain (FASFC)	http://www.favv-afsca.fgov.be/home-en/
BRC Global Standards	http://www.brcglobalstandards.com
Bulgarian Food Safety Agency	http://www.babh.government.bg/en/
Danish Ministry of Food, Agriculture and Fisheries	http://www.fvm.dk/english.aspx?id=14541
CanadaGap	http://www.canadagap.ca
CHINA HACCP	http://www.cnca.cn/bmzz/zgclb/
Croatian Food Agency	http://www.hah.hr/english/eng_index.php
Cyprus Ministry of Agriculture, Natural Resources and Environment	http://www.moa.gov.cy/moa/agriculture.nsf/All/9638239B67CB5B93C22578A200307D00?OpenDocument
Cyprus Ministry of Health	http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument
Cyprus State General Laboratory	http://www.moh.gov.cy/moh/sgl/sgl.nsf/DMLindex_en/DMLindex_en?OpenDocument#
Czech Republic Ministry of Agriculture	http://eagri.cz/public/web/en/mze/food/
Danish National Food Institute	http://www.dfvf.dk/Default.aspx?ID=21023
Danish Veterinary and Food Administration – Food	http://www.foedevarestyrelsen.dk/english/Food/Pages/default.aspx
Estonian Ministry of Agriculture	http://www.agri.ee/food-safety/
European Commission – basic food hygiene legislation page	http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide_en.htm
European Commission Directorate General for Health and Consumers (DG SANCO) – Food	http://ec.europa.eu/dgs/health_consumer/index_en.htm
European Commission Health EU Portal – Food Safety	http://ec.europa.eu/health-eu/my_environment/food_safety/index_en.htm
European Food Information Council (EUFIC) – Food Safety	http://www.eufic.org/article/en/expid/basics-foodsafety/
European Food Safety Authority (EFSA)	http://www.efsa.europa.eu/
EUR-Lex - Direct free access to European Union Law with full search facility	http://eur-lex.europa.eu/en/index.htm
EUROPA Summaries of EU legislation – Food Safety	http://europa.eu/legislation_summaries/food_safety/index_en.htm
Food Engineering	http://www.foodengineeringmag.com/
Food and Drink Technology	http://www.foodanddrinktechnology.com/
Finnish Ministry of Agriculture and Forestry – Food Safety and Consumer Information	http://www.mmm.fi/en/index/frontpage/food_safety.html

State institution	Internet address
Finnish Food Safety Authority (EVIRA)	http://www.evira.fi/portal/en/food/
French Agency for Food, Environment, and Occupational Health and Safety	http://www.anses.fr/
French Ministry of Agriculture, Food, Fisheries, Rural and Regional Development	http://agriculture.gouv.fr/
Food Processing	http://www.foodprocessing.com
Food Risk	http://foodrisk.org/rm/guidelines-and-standards/
Food and Agriculture Organisation (FAO) of the United Nations –	http://www.fao.org/food/food-safety-quality/en/
FSSC 22000	http://www.fssc2200.com
Food Safety and Quality	http://www.bfr.bund.de/en/food_safety-737.html
German Federal Institute for Risk Assessment (BfR)	http://www.bmelv.de/EN/Food/food_node.html
German Federal Ministry of Food, Agriculture and Consumer Protection – Food & Safety	http://www.ble.de/EN/oo_Home/homepage_node.html
German Federal Office for Agriculture and Food	www.foodsafetyforum.org
Global Aquaculture Alliance	http://www.gaalliance.com
Global Food Safety Initiative	http://www.mygfsi.com/
Global Forums - policy makers in the field of food safety	http://www.minagric.gr/en/index.html
GlobalG.A.P.	http://www.globalgap.com
Global Red Meat Standard	http://www.grms.com
GMP+ International	http://www.gmpplus.org/
Hellenic Ministry of Agriculture and Food	http://www.efet.gr/
Hellenic Food Safety Authority	http://www.nebih.gov.hu/en/
Hungarian National Food Safety Chain Office	http://www.agriculture.gov.ie/
IFS	http://www.ifsc-certification.com
Irish Department of Agriculture, Food & the Marine	www.ipfsaph.org
International Portal on Food Safety and Animal and Plant Health	http://www.mast.is/index.aspx?GroupId=1281
The Icelandic Food and Veterinary Authority	http://www.fsai.ie/links.html
ISO, the International Organization for Standardization	http://www.iso.org
Italian Istituto Superiore di Sanit (ISS)	http://www.iss.it/chis/?lang=2
Latvian Food and Veterinary Service	http://www.pvd.gov.lv/eng/left_menu/food_surveillance/
Lithuanian State Food and Veterinary Service	http://vmvt.lt/en/
Luxembourg Ministry of Health	http://www.ms.public.lu/fr/
Malta Competition and Consumer Affairs Authority	http://www.mccaa.org.mt/en/smi
Maltese Environment and Planning Authority	http://www.mepa.org.mt/topics
Maltese Health, the Elderly and Community Care Ministry	http://ehealth.gov.mt/HealthPortal/others/foodsafety_week/food_safety_week.aspx
Netherlands Ministry of Economic Affairs, Agriculture and Innovation – Food and Food Safety	http://www.government.nl/issues/food-and-foodsafety

State institution	Internet address
Netherlands Food and Consumer Product Safety Authority	http://www.vwa.nl/english
Norwegian Ministry of Agriculture and Food	http://www.regjeringen.no/en/dep/lmd.html?id=627
Norwegian Food Safety Authority	http://www.regjeringen.no/en/dep/hod/About-the-Ministry/Subordinate-institutions/Norwegian-Food-Safety-Authority.html?id=279765
Polish Chief Sanitary Inspectorate	http://www.gis.gov.pl/?lang=en&go=content&id=10
Portuguese Economy and Food Safety Authority	http://www.asae.pt/
PrimusGFS	http://www.primusgfs.com
Swedish Ministry of Rural Affairs – Foodstuffs	http://www.sweden.gov.se/sb/d/11310
Romanian National Sanitary Veterinary and Food Safety Authority	http://www.ansvsa.ro/
Slovak Republic Ministry of Agriculture and Rural Development	http://www.mpsr.sk/en/index.php?navID=1
Slovenian Ministry of Agriculture, Forestry and Food	http://www.arhiv.mkgp.gov.si/en/areas_of_work/food_safety/
Spanish Agency on Food Safety and Nutrition	http://www.aesan.msc.es/en/AESAN/web/home.shtml#
Standards and Trade Development Facility (STDF)	http://www.slv.se/en-gb/
SQF	http://www.sqfi.com
Swedish National Food Agency	http://www.bag.admin.ch/index.html?lang=en
Swiss Federal Office of Public Health	http://www.defra.gov.uk/
UK Department for Environment Food, and Rural Affairs	http://www.food.gov.uk/
UK Food Standards Agency	http://www.who.int/foodsafety/codex/en/
World Health Organization (WHO) – Codex Alimentarius	http://www.who.int/foodsafety/en/
World Health Organization (WHO) – Food Safety	www.wto.int
World Trade Organization (WTO)	http://www.standardsfacility.org/en/index.htm
U.S. Department of Agriculture - Food Safety	http://www.usda.gov/wps/portal/usda/usdahome?navid=FOOD_SAFETY
U.S. Department of Agriculture - Food Safety Legislation	http://fsrio.nal.usda.gov/sanitation-and-qualitystandards/legislation-and-regulations
U.S. Department of Agriculture - Food Safety and Inspection Service	http://www.fsis.usda.gov/
U.S. Food and Drug Administration – Animal & Veterinary	http://www.fda.gov/AnimalVeterinary/default.htm
U.S. Food and Drug Administration – Food	http://www.fda.gov/Food/default.htm
U.S. Food and Drug Administration – Food Safety	http://www.fda.gov/Food/FoodSafety/default.htm
U.S. Environmental Protection Agency – Food Safety	http://www.epa.gov/agriculture/tfsy.html
U.S. Meat and Poultry HACCP	http://www.fsis.usda.gov/science/hazard_analysis_&_pathogen_reduction/index.asp
U.S. Seafood HACCP	http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/SeafoodHACCP/default.htm
U.S. Juice HACCP	http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/JuiceHACCP/default.htm

2. Terms and definitions

Term	Definition
Accreditation	The independent evaluation of the Training Provider or Training Provider Product against recognised standards to ensure the organization's management system, product and competence meets defined standards
Allergy	A medical condition that causes someone to become sick after eating, touching, or breathing something that is harmless to most people
ASL	Approved Supplier List
ATD	The Association for Talent Development (ATD, formerly ASTD)
Audit criteria	Set of policies, procedures or requirements used as a reference against which audit evidence is compared
Auditor	Person with the competence to perform an audit
Audit scope	The extent and boundary of the audit
BAP	Best Aquaculture Practice
BIS	Border Inspection Post
BIS	Border Inspection Service
BPC	Border Protection Control
BRC/IoP	Global standard for packaging and packaging materials from the British Retail Consortium
BRC	British Retail Consortium
CAC	Codex Alimentarius Commission
CAC	Codex Alimentarius Commission
Calibration	Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement (IAS/CL/013 October 30, 2013, revised October 1, 2014, page 1 of 7 "uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication")
CanadaGAP	On-farm food safety program of the Canadian Horticulture Council
CAPA	Corrective Action and Preventive Action
CCPR	Commission Committee of Pesticides Residues
CCRVDF	Commission Committee on Residues of Veterinary Drugs in Food

Term	Definition
CCRVDF	Commission Committee on Residues of Veterinary Drugs in Food
CDC	Center for Disease Control and Prevention
CDC	Centre for Disease Control and Prevention
Certification Body/ Registrar	A Certification Body or Registrar is an organization accredited by an authorizing body to undertake third party assessment of management systems or management system auditor training, and to award and withdraw certificates in accordance with international or national standards
CEVD	Common Entry Veterinary Document
CEVD	Common Entry Veterinary Document
CFR	Code of Federal Regulations
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CFSAN	Centre for Food Safety and Applied Nutrition
CFU	Colony forming Unit
cGMP	Current Good Manufacture Practice
China HACCP	The China HACCP Government Owned Scheme
CIAA	European Food and Drink Association
CoA	Certificate of Analysis
Codex Alimentarius	The Food and Agriculture Organization of the United Nations that published the Codex Standards, Guidelines and Codes of Practice of 'Food Code'
Competence	A demonstrated ability to apply knowledge and/or skills and, where relevant, demonstrated personal attributes, as defined in the certification scheme
Competent Authority/ Enforcement Agency	Any person or organization with statutorily delegated or vested authority, capacity, or power to perform a designated function or any agency which enforces the law
Compliance	Fulfillment of a statutory or regulatory requirement including other legal obligations
Conformity	Fulfillment of a requirement
Contract	Binding agreement

Term	Definition	Term	Definition
Controlled Document	A controlled document is a FSMS document which, through the course of its lifecycle, may be reviewed, modified and distributed several times	End Product	Product that will undergo no further processing or transformation by the organization
Control Measure	[food safety] action or activity that can be used to prevent or eliminate a food safety hazard (3.3) or reduce it to an acceptable level	Enforcement Officer	Any officer, agent, or employee of a National/Federal/State, unit of local government, authorized by law or by a government agency to engage in or supervise the prevention, detection, or investigation of any violation of food law
COOL	Country of Origin Labeling	Environmental Health Officer	Also known as Public Health Inspectors, Environmental Health officer [EHOs] are responsible for carrying out measures for protecting public health, including administering and enforcing food hygiene legislation related to public health and providing support to minimize health and safety hazards
Correction	Action to eliminate a detected nonconformity	EPA	Environmental Protection Agency
Corrective Action	Action to eliminate the cause of a detected nonconformity or other undesirable situation	EU	European Union
Criteria	Requirement	EUREP	Euro-Retailer Produce Working Group
Critical Limit	Criterion which separates acceptability from unacceptability	FAO	Food and Agriculture Organization
Critical Control Point [CCP]	[food safety] step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level	FBO	Food Business Organization. Natural or legal persons, controlling production, processing, distribution, storage and handling of food, and responsible for ensuring that food law requirements are met within the food business under their control
CRO	Compliance Resolution Officer	FDA	Food and Drug Administration
Customer	Person or organization that could or does receive a product or a service that is intended for or required by this person or organization	FDCA	Federal Food, Drug, and Cosmetic Act
Defect	Nonconformity related to an intended or specified use	FMEA	Failure Mode Effect Analysis
Delivery	A shipment of food product from the seller to the buyer	Food Chain	Sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption
DHS	Department of Homeland Security	Food Defense Plan	A food defense plan is a written document that records the practices implemented to control/minimize the risk of an intentional contamination incident
DMS	Document Management System	Food Defense	Security of food and drink and their supply chains from all forms of malicious attack including ideologically motivated attack leading to contamination or supply failure
Document	Information and its supporting medium. It must be stressed that documents may be in any form or type of medium, for example: paper; magnetic; electronic or optical computer disc or photograph	Food Hygiene	The set of basic principles employed by the food associates at all stages of food handling to ensure that food is safe to consume and is of good keeping quality
EC	European Commission	Food Safety	Concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use
EDMS	Electronic Document Management System		
EDTA	Experimental Training and Development Alliance		
Education	Education is the process of facilitating learning, or the acquisition of knowledge, skills, values, beliefs, and habits especially delivered by or recognised by a college or university		
EFSA	European Food Safety Authority		
ELISA Method	Enzyme-Linked Immunosorbent Assay method for testing for Aflatoxins		

Term	Definition
Food Safety Policy	FBO intentions and direction of an organization related to food safety as formally expressed by its top management
Food Scheme	A recognised International [ISO 22000] or Private Label Food Safety Management System Standard or Government Owned Scheme [recognised by the GFSI]
Form	A document used to record data required by the FSMS. A form becomes a record when data are entered
FSAI	Food Safety Authority of Ireland
FSIS	Food Safety and Inspection Service
FSMA	Food Safety Moderization Act
FSMS	Food Safety Management System
FSSC 22000	Food Safety Certification Scheme 22000
FSTK	Food Safety Toolkit
FSVP	Foreign Supplier Verification Program
G.A.P.	Good Acriculture Practice
GAA	Global Aquaculture Alliance Seafood Processing Standard
GFSI	Global Food Safety Initiative
GFSI Scope of Recognition	GFSI recognised sector and sub-sector scopes for recognition against the GFSI Guidance Document Sixth Edition
GHP	Good Hygiene Practice
GlobalG.A.P.	Standards for the certification of agriculture products
GMA	American Groceries Manufacturing Association
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GRMS	Global red Meat Standard
GWP	Good Warehouse Practice
HACCP	Hazard Analysis Critical Control Point. A systematic approach taken to identify and control hazards (whether microbiological, chemical or physical) that pose a potential hazard in the preparation of safe food
HACCP Plan	A document prepared in accordance with HACCP principles to ensure control of significant food safety hazards in the segment of the food chain under consideration
Halal	Food permissible according to Islamic law

Term	Definition
Hazard	An allergen, or a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect
Hazard Analysis	A systematic process to identify any hazardous biological, chemical, or physical property in raw materials and processing steps, and to assess their likeliness of occurrence and potential to render food unsafe for consumption
HPLC	High Performance Liquid Chromatography, a test analysis method to seperate aflotoxins in food
HRMS	Human Resource Management System
HVAC	Heating, Ventilation, and Air Conditioning. HVAS Systems are used in FBO presmises to ensure positive air pressure flows and maintain ventilation
IFA	Indirect Fluorescent Antibody Test
IFC	International Finance Corporation
IFS Food	International Featured Standard for Food
Infrastructure	FBO system of facilities, equipment and services needed for the operation of an organization
Inspection	An organized examination or formal evaluation exercise to confirm food products are safe, wholesome, and correctly labeled and packaged
Interested Party	External person or group (e.g. external FBO unit, consumers, regulatory agencies) having an interest in the performance or success of the organization
Intermediate Product	Partly finished goods, used as inputs in the production of other goods including final goods
Internal Audit	Internal audits, sometimes called first party audits, conducted by the organization itself, or on its behalf, for management review and other internal purposes, e.g. confirm the conformity and compliance of the FSMS
IRCA	International Register of Certificated Auditors
ISO/TS 22002-1	ISO standatd on prerequisite programs associated with food products
ISO	International Organization for Standardization
Job Description	A detailed written account, agreed between management and employee, of all the duties and responsibilities which together make up a particular job
KPI	Key Performance Indicator

Term	Definition	Term	Definition
Legal Requirements	The obligation or duty that is enforced by a court of law	Product	Output of an organization that can be produced without any transaction taking place between the organization and the customer
LMS	Learning Management System	PRP	in the segment of the food chain under consideration
Management Commitment	Direct participation by the highest level executives in a specific and critically important aspect or program of an organization	Purchaser	Person or entity that is a recipient of a good or service provided by a seller under a purchase order or contract of sale
Management Review	Top management-led evaluation of the overall performance of an organization's food safety management system and to identify improvement opportunities	RASFF	Rapid Alert System for Food and Feed
Mock recall	Mock recalls are routine exercises conducted by manufacturers, processors, distributors and other various trading partners in the supply chain to assess their recall procedures and responsiveness	RCA- Root Cause Analysis	A collective term that describes a wide range of approaches, tools, and techniques used to uncover causes of problems
MRL	Maximum Residues Level	Recall	A food safety program that requires the FBO to recall food from the market where unsafe food may have reached the final consumer or where the FBO determines other measures are insufficient to protect consumer health
Mycotoxins	Mycotoxins are toxins produced by some species of mold or fungal infection that affects crops and may cause fatality. A most common type is AFM ₁ , an aflatoxin can contaminate maize, red chilli, black pepper or dry ginger and may result in fatality	Record	Document that provides objective evidence of activities performed, events occurred, results achieved, or statements made
NIST	National Institute of Standards and Technology	Regulatory Requirement	Obligatory requirement specified by an authority mandated by a legislative body
NMFS	National Marine Fisheries Service	Regulatory	Rule or Standard adopted by a Competent Authority/Enforcement Agency
Non-compliance	Non fulfilment of a statutory and regulatory requirement	Requirement	Need or expectation that is stated, generally implied or obligatory
Non-conformity	Non fulfilment of a requirement	Resources	Resources include people, money, information, knowledge, skill, energy, facilities, machines, tools, equipment, technologies, and techniques
O-PRP	Operational Pre-Requisitive Program	Risk Analysis	Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards
OEM	Original Equipment Manufacturer	Root Cause	A factor that caused a nonconformance and should be permanently eliminated through process improvement
OOS	Out of Specification	SAAS	Software as a Service
PPI	Process Performance Indicator	SMART	Acronym denoting Specific, Measurable, Attainable, Realistic, Time bound
Preventive Action	Preventive Action	SOP	Standard Operating Procedure
Primary Production	The growing, raising, cultivating, picking, harvesting, collecting or catching food, including the transporting or delivering food on, from or between the premises on which it was grown, raised, cultivated, picked, harvested, collected or caught; and the storing food in a silo that is not connected with a food processing operation	Specification	Document stating requirements related to raw materials, ingredients, product contact materials (packaging) and end-products
Procedure	Specified way to carry out an activity or a process	SPS	Sanitary and Phytosanitary
Process	Set of interrelated or interacting activities that use inputs to deliver an intended result		

Term	Definition
SQF	Safe Quality Food Institute
Statutory	A Law set by a Competent National/ Federal Government
Statutory Requirement	Obligatory requirement specified by a legislative body
Supplier	Organization that provides a product or a service
SWOT analysis	Strengths, Weaknesses, Opportunities and Threats Analysis
System	Set of interrelated or interacting elements
TAR	Test Accuracy Ratio
Test	Determination according to requirements for a specific intended use or application
Therapeutic Drug	Drugs provided in animal production
Traceability	A risk management tool to enable the FBO, competent authority or enforcement agency the ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all stages of production, processing and distribution
Training Aid	Training device such as a chart, flash cards, diagram, notes, etc., intended to enhance learning and retention by a learner or trainee
Training Effectiveness Methods	Methods for evaluation of the effectiveness of training
Training Evaluation	Process for evaluating the effectiveness of training
Training Matrix	A training/competency matrix is a tool used to document and compare the required competencies for a position with the current skill level of the employees performing the roles
Training Needs Analysis	Analysis for identification of the training needs of the organization from a business and employee perspective
Training	Organized activity aimed at imparting information and/or instructions to improve the recipient's performance or to help him or her attain a required level of knowledge or skill.

Term	Definition
Training Plan	A document describing the organization's training programs for a measurement time period based on the assessment of the organization's training needs analysis
Training Provider	A training organization or instructor who receives training and becomes approved to deliver an accredited or non-accredited training program
UKAS	United Kingdom Accreditation Service
Unaccredited	The training provider or training provider's product has not been independently assessed in relation to defined standards
USA PMO Standard	USA Pasteurized Milk Ordinance Standard
USA	United States of America
USB	A small external flash drive that can be used with any computer that has a USB port
USDA	United States Department of Agriculture
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled
WHO	World Health Organization
Withdrawal	A food safety program that requires the FBO to withdraw food from the market where it considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed does not comply with the food safety requirements, and the food has left the immediate control of the initial food business
Work Environment	Set of conditions under which work is performed
Work Instructions	Detailed descriptions of how to perform and record tasks
WTO	World Trade Organization