CZECH UNIVERSITY OF LIFE SCIENCES PRAGUE

Faculty of Economics and Management

Department of Trade and Accounting

Diploma Thesis

Development of the Global Management Standard for the Food Processing Industry

Filip Mařák

Declaration

I declare that I have worked on my diploma thesis titled "Development of the Global Management Standard for the Food Processing Industry" by myself and I have used only the resources mentioned at the end of the thesis.

In Prague on the 8th April 2010 .....

Filip Mařák

Acknowledgement

I would like to thank Mrs. Ing. Petra Šánová Ph.D. for her advice and support during my work on this thesis.

Vývoj Univerzálního Standardu Managementu Kvality pro Potravinářský Průmysl

Development of the Global Management Standard for the Food Processing Industry

Souhrn

Cílem diplomové práce je ověřit hypotézu konstatující, že je možné, aby byl v prostředí výroby a zpracování potravin využíván jeden univerzální standard managementu kvality a zdravotní nezávadnosti potravin uznávaný po celém světě.

V literární rešerši je stručný úvod do problematiky, představení HACCP systému a třech hlavních standardů kvality a bezpečnosti výroby potravin – IFS, BRC a FSSC 22000.

Praktická část začíná případovou studií, ve které je představen systém managementu kvality a zdravotní nezávadnosti při výrobě potravin vyvinutý a využívaný nadnárodní společností. V návaznosti na tuto studii jsou standardy představené v literární rešerši porovnány a vybraný standard, FSSC 22000, je posléze porovnán se systémem využívaným výše zmíněnou společností za účelem definování doporučení pro tento standard. Univerzálnost FSSC 22000 a doporučení jsou následně otestovány auditem v prostředí malé české potravinářské společnosti.

Závěr, na bázi praktické části, potvrzuje hypotézu a zhodnocuje přínos navržených doporučení. Zároveň také zhodnocuje šance FSSC 22000, jakožto globálního standardu, v současném prostředí, kdy obchodní řetězce vyžadují různé standardy a tlačí tak výrobce k vícenásobným auditům a certifikacím.

Klíčová slova:

Kvalita, jakost, globalizace, potraviny, doporučení, standard, ISO, audit, implementace, výrobci potravin

Summary

The goal of this thesis is to prove the hypothesis that in food manufacturing industry, one universal quality and food safety management standard can be accepted by both manufacturers and retailers worldwide.

In literature overview, HACCP system and three most importent quality and food safety management standards, IFS, BRC and FSSC 22000, are introduced.

In results and discussion chapter, quality and food safety management system developed and used by a multinational entrepreneur is introduced in case study one. Standards introduced in the literature overview are then compared and out of them FSSC 22000 is selected as a potential global standard. FSSC 22000 is then compared with system used by a company in case study one in order to suggest FSSC 22000 improvements. Applicability of FSSC 22000 and suggested improvements are then verified by an audit conducted in a small regional company from the Czech Republic.

In conclusion, hypothesis is proved and suggestions to the standard are evaluated. Moreover, the chance that FSSC 22000 becomes a truly global standard is evaluated with regards to the actual situation, where different retailers require from food manufacturers to be certified against different quality and food safety management standards.

Key words:

Quality, food, food safety, standard, ISO, globalization, recommendation, audit, food manufacturers

Contents

CONTENTS 4

1 INTRODUCTION 6

2 OBJECTIVES OF THESIS AND METHODOLOGY 7

3 LITERATURE OVERVIEW 9

3.1 BASIC TERMS 9
3.2 HACCP SYSTEM 10
3.2.1 Seven Principles of HACCP plan *11*
3.3 GFSI RECOGNIZED STANDARDS 13
3.4 GLOBAL STANDARD FOR FOOD SAFETY - BRC 14
3.4.1 BRC Evaluation *15*
3.4.2 BRC Requirements *15*
3.5 INTERNATIONAL FOOD STANDARD – IFS 22
3.5.1 IFS Evaluation *22*
3.5.2 IFS Requirements *23*
3.6 FOOD SAFETY SYSTEM CERTIFICATION 22000 - FSSC 22000 30
3.6.1 ISO 22000 Requirements *31*
3.6.2 PAS 220 Specification *35*
3.6.3 FSSC Additional Requirements *37*
3.6.4 FSSC 22000 Audit Process Overview *37*

4 RESULTS AND DISCUSSION 38

4.1 CASE STUDY – X-FOOD 38
4.1.1 Overview *38*
4.1.2 Company and Q&FS Team Overview *39*
4.1.3 X-Food Quality Management System (QMS) *41*
4.1.4 X-Food QMS Requirements *42*
4.1.5 X-Food QMS verification, evaluation and continuous improvement *44*
4.1.6 Production plants certification against major quality management standards *44*
4.2 STANDARDS EVALUATION 44
4.2.1 X-Food QMS SWOT Analysis *45*
4.2.2 FSSC 22000 SWOT Analysis *46*
4.2.3 BRC SWOT Analysis *49*
4.2.4 IFS SWOT Analysis *50*
4.2.5 Comparison between BRC, IFS and FSSC 22000 ..... *51*
4.3 SELECTION OF POTENTIAL GLOBAL STANDARD AND ITS COMPARISON WITH X-FOOD QMS 55
4.3.1 X-Food QMS and FSSC 22000 Comparisson *56*
4.3.2 Improvement suggestions for selected standard *58*
4.4 CASE STUDY 2 – V+K MAŘÁKOVI 62
4.4.1 Overview *62*
4.4.2 V+K Mařákovi QMS *62*
4.4.3 Research and Interview *63*
4.4.4 Audit Evaluation *80*
4.5 CONSOLIDATION OF FINDINGS AND SUGGESTIONS 81

5 CONCLUSIONS 82

6 BIBLIOGRAPHY 83

7 SUPPLEMENTS 85

7.1 ABBREVIATIONS LIST 85

7.2 FSSC 22000 AUDIT CHECKLIST 86

1 Introduction

In the last decade, quality and food safety became a very important topic. Many scandals and worldwide threats (such as bird and swine flu, BSE, melamine scandal in China etc.) made consumers less trustful in the quality of food products and put a pressure on both food manufacturers and retailers. For big, multinational food manufacturers this issue is even more important as problems in any part of the world may cause serious damage to company brands worldwide. And because they usually have numerous production plants around the world, they have to ensure that raw materials will be of standardized quality and so will be the production process and the product delivery to customers. This led to a development of many quality management standards, some of which were introduced in the last decade of the 20th century.

Nowadays, retailers usually prefer one quality management standard and push their suppliers (food manufacturers) to be certified against it; otherwise the business contract may not be signed (or may be cancelled). This often leads to multiple audits and unnecessary investments, as different retailers require different standards. In order to prevent this situation the Global Food Safety Initiative (GFSI) developed a benchmark which compares quality management standards and recommends those standards which match GFSI requirements (the concept is called "Once Certified, Accepted Everywhere"). But in practice many retailers still require one particular standard, putting unnecessary pressure on food manufacturers. In 2005, ISO 22000 was introduced, followed by FSSC 22000 in 2009 (FSSC 22000 is based on ISO 22000) which has a potential to become a universal global standard, accepted by both manufacturers and retailers.

2 Objectives of Thesis and Methodology

The Hypothesis

The hypothesis is that there is a possibility of having a single global quality and food safety management standard accepted everywhere by both manufacturers and retailers.

The Goal

The goal of this thesis is to compare major existing quality and food safety management standards, identify a potential global standard among them and, based on research in two different food manufacturing companies, suggest improvements which might help the selected standard becoming the truly global quality and food safety management standard accepted by both food manufacturers and retailers and applicable no matter where products are manufactured and regardless the size of the food manufacturer.

Literature Overview

The purpose is to give readers an introduction into the problematic of the management of quality and food safety, briefly describe the history of the food safety management and present the most important standards which are in current use worldwide. To achieve this goal, a research of a scientific literature dedicated to this problematic was conducted as well as many internet resources and quality and food safety management standards were used.

Results and Discussion

The Results and Discussion part is divided into several thematic sections. In the first part a case study of a multinational enterprise was conducted in order to examine how an important global food manufacturing player manages its quality. Findings are based on interviews with members of the Global Quality & Food Safety Team of this company, examination of company materials related to the quality management system and experiencing everyday work within the team. For this purposes, the author of this thesis experienced a four weeks long

internship in the production plant of the company in United Kingdom, where the headquarters of the company's Global Quality & Food Safety Team is located. The name of the company was changed to "X-Food" for the purposes of this thesis, as information presented in this thesis are confidential.

The second section of Results and Discussion focuses on evaluating and comparing of the presented major quality and food safety standards, in order to select the potential global standard. Selected standard was then compared to X-Food Quality Management System to suggest improvements. For this purposes, SWOT analysis and comparison based on selected topics were used.

The last section of Results and Discussion is dedicated to a second case study. This case study was conducted in a small regional food manufacturer in the Czech Republic. Selected standard with suggested improvements was tested in order to find out whether this standard will be suitable not only for a big international company, but also for a small regional one. For this purpose, an on-site audit was conducted, followed by the applicability evaluation of the standard and suggestions.

Based on the experimental part, hypothesis is proved or disproved in the conclusion together with the summarization of findings.

3 Literature Overview

3.1 Basic Terms

By **quality**, we mean requirements on products, both analytic and sensory. Among analytic requirements, there are especially chemical requirements, such as humidity, ash content, fat content, sugar content etc. For their evaluation we usually need appropriate laboratory equipment. Among sensory requirements belongs evaluation of consistency, structure, color, taste smell and similar factors (STÁTNÍ ZEMĚDĚLSKÁ A POTRAVINÁŘSKÁ INSPEKCE, 2004).

Problematic **of food safety** is closely analyzed by the „White Paper on Food Safety" published by European Commission in 2000. This document defines the need of monitoring food supply chain from its beginning (so called "From Farm to Fork" approach). When a product which may harm consumers appear, the source of contamination shall be discovered – no matter if it was from the first subject in the chain or the last one.

To ensure that released products are of desired quality and safe, input processes, in-process control and output control systems are used. As laboratory control cannot, due to wide variety of products and production processes, guarantee the quality and safety of all products (especially those which were not subjected to the laboratory control), systems based on risk analysis were developed. These systems help to identify and control risks which may appear in the production process (ŠKOPEK, VOLDŘICH, 2004).

These quality and food safety management systems can be divided into two basic groups:

- Systems demanded by the law (Companies manufacturing products in and for the Czech market shall have HACCP system implemented)
- Voluntary systems demanded by retailers

For better understanding of why the voluntary quality management systems were developed, we must look into the problematic not from the national but from the global point of view. For example for Czech producers, retail chains are the most important customers and nowadays almost all of them are big multinational entrepreneurs. These retail chains want to ensure that products, they are selling are safe and of specified quality, especially when we speak about private label product (product sold under the retailer's brand). To achieve this, retailers push its suppliers to have their production plants certified against a selected standard which will guarantee that risks are controlled and the possibility of product failure is minimal.

3.2 HACCP System

HACCP (Hazard Analysis and Critical Control Point) is a preventive system. It prevents, identifies and evaluates the risk for a consumer before it appears. It introduces systems of monitoring and modification of procedures which makes system reliable and effective (HULEBAK, Schlosser, 2001).

HACCP was developed by the Pillsbury Company in 1959 as a means of assuring the safety of food produced for the U.S. space program. The National Aeronautics and Space Administration (NASA) wanted a "zero defects" program to guarantee the safety of foods astronauts would consume in space. HACCP, they recognized after surveying available control options, was the system that could provide the greatest assurance of safety while reducing dependence on finished product sampling and testing. Since Pillsbury presented the HACCP system at the 1971 U.S. National Conference of Food Protection, it has become gradually recognized as a valuable approach in the United States. In 1985 HACCP started to be used in Canada and Australia. In 1993, HACCP received worldwide recognition thanks to the publication of "HACCP and Guidelines for its Application" by FAO and WHO. In the same year, European Union published direction which makes following of HACCP system obligatory for food producers operating in EU (HULEBAK, Schlosser, 2001).

In the Czech Republic, HACCP started to be widely used in 1996. Obligatory implementation of HACCP system into companies' processes was introduced on the 1st January, 2000 for all food manufacturers, on the 1st July, 2002 for the high volumes food producing community caterers, on the 1st May, 2004 for all community caterers and on the 1st May, 2005 for all food retailers (HACCPSERVIS, 2007).

3.2.1 Seven Principles of HACCP plan

HACCP definitions and principles are based on the U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP System Guide. Under a HACCP System, if deviation occurs, indicating that that control has been lost, appropriate steps are taken to reestablish control in a timely manner to assure that potentially hazardous product does not reach to consumer.

1. **Conduct a hazard analysis.** The first step in establishing a HACCP system is to identify all hazards – biological, physical, or chemical -- that can be associated with the product. The hazard must be such that its prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food.

2. **Identify the CCPs in the process.** A critical control point (CCP) is defined as a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. All significant hazards identified during the hazard analysis must be addressed.

3. **Establish critical limits for preventive measures associated with each identified CCP.** A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. CCPs are most often based on process parameters, such as temperature, time,

physical dimensions, humidity, moisture level, water activity, pH, acidity, salt concentration, etc..

4. **Establish CCP monitoring requirements and procedures for using monitoring results to adjust processes and maintain control.** Monitoring consists of observations or measurements taken to assess whether a CCP is under control.

5. **Establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit.** If deviation occurs, corrective action plans shall be in place to determine the disposition of the non-compliant product, and to identify and correct the cause of the deviation to regain control of the CCP.

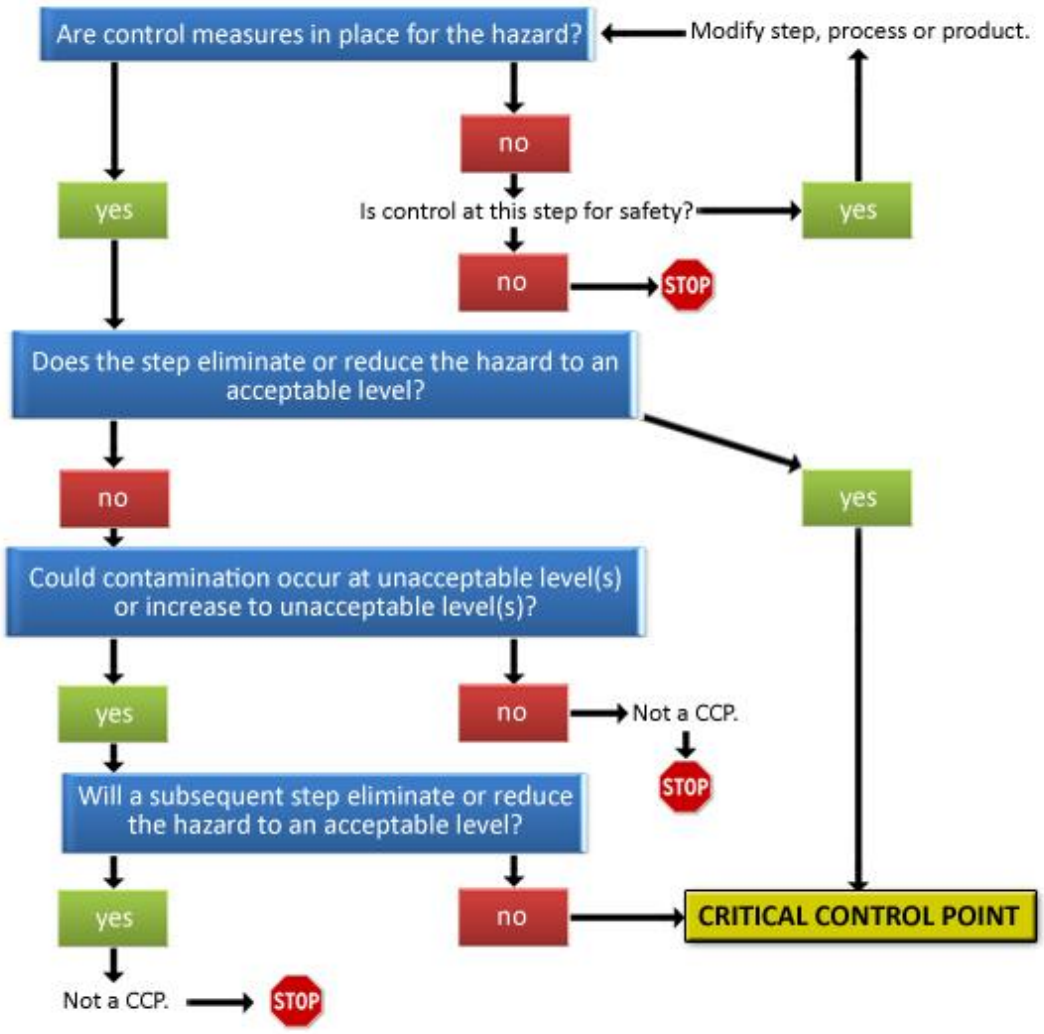
6. **Establish procedures to verify that the HACCP system is working correctly.** Verification activities consist of internal audits, analysis, sampling, evaluations and complaint by authorities and customers and shall be performed at least once a year.

7. **Establish effective recordkeeping procedures that document the HACCP plan.** HACCP plan and all associated records must be maintained on file at the establishment. Examples include records on incoming ingredients, product processing, packaging, storage, and distribution, and deviations and corrective actions. Records generated during operation of the HACCP plan must be maintained and available for review, and records shall contain actual values, rather than general terms such as "satisfactory," or "unsatisfactory."

(HULEBAK, Schlosser, 2001)

In the diagram 1, the process of CCPs definition is illustrated. From the diagram it is clear that the process consists of systematic questions asking related to risk removing and prevention.

Diagram 1 – Critical Control Points (CCP) definition process



Source: Southbank Institute International 2010

3.3 GFSI Recognized Standards

Global Food Safety Initiative (GFSI), co-ordinated by The Consumer Goods Forum, was launched in May 2000, in order to provide convergence between food safety management standards and establish a benchmarking process for different food safety schemes. The idea is the „Once certified, accepted everywhere" principle, which shall help food manufacturers secure more contracts with retailers when having only one of GFSI recognized standards

certified. This includes some of world's biggest retailers such as Tesco, Wal-Mart, Carrefour, Metro or Ahold (ISO 22000 TOOLS, 2009).

GFSI recognizes 6 major food safety management standards: IFS, BRC, SQF 2000, SQF 1000, Dutch HACCP and FSSC 22000 (Which includes ISO 22000. GFSI has only granted conditional recognition but it is expected that FSSC 22000 will be fully recognized in near future.). Because the goal of this thesis is not to describe all standards, only IFS, BRC and FSSC 22000 will be described in following chapters. These three were selected because of following facts:

- BRC is the world's leading standard thanks to more than 14 000 certification in more than 90 countries.
- IFS is widely recognized in the Czech Republic as well as in whole European Union.
- Although it has not been yet fully recognized by GFSI, FSSC has a potential to become the first truly global standard and since it has been introduced in 2009 it shortly became a respected standard by both food manufacturers and retailers.

3.4 Global Standard for Food Safety - BRC

The Standard was developed to assist retailers in their fulfillment of legal obligations and protection of the consumer, by providing a common basis for the audit of companies supplying retailer branded food products. The BRC Global Standard – Food encompasses the fundamental principles of the retailers' own standards and has been continuously reviewed to reflect the requirements of both retailers and their suppliers. It is not intended to replace the requirement of any legislation where this legislation requires a higher standard for a specific industry sector (BRITISH RETAIL CONSORTIUM, 2005).

3.4.1 BRC Evaluation

BRC is based on a checklist, where different aspects of production, management of production and related activities are described. Certification body will evaluate to which level a company meets these requirements, summarize results and decide whether company will receive the certificate or not.

Non-conformities are divided into four categories:

- Critical or major nonconformity against the 'statement of intent' of a 'fundamental' requirement
- Critical non-conformity
- Major non-conformity
- Minor non-conformity

3.4.2 BRC Requirements

BRC requirements are divided into seven chapters:

- *Senior Management Commitment and Continual Improvement*
- *The Food Safety Plan – HACCP*
- *Food Safety and Quality Management System*
- *Site Standards*
- *Products control*
- *Process control*
- *Personnel*

Senior Management Commitment and Continual Improvement

The company senior management shall demonstrate that they are fully committed to the implementation of the requirements of the BRC (Fundamental requirement no. 1).

The Food Safety Plan - HACCP

The basis of the quality and food safety management system is systematic and profound HACCP plan (Fundamental requirement no. 2). HACCP system is introduced in chapter 3.2.

Food Safety and Quality Management System

Food safety and quality policy and manual

The company shall develop and document a food safety and quality management policy and food safety and quality manual which describes how the requirements of the BRC standard are met.

Organizational structure, responsibilities and management authority

The company shall have a clear organizational structure and define the responsibilities, reporting relationships and job functions of those personnel whose activities affect product safety, legality and quality.

Contract review and Customer Focus

The company senior management shall ensure that processes are in place to determine any customer requirements and expectations with regard to product safety and quality, and ensure these are fulfilled.

Internal audit

Audit of systems and procedures which are important for safety, quality and legality of products shall be realized (Fundamental requirement no. 3).

Purchasing – supplier approval and performance monitoring

The company shall control purchasing processes critical to product safety, legality and quality to ensure that products conform to defined requirements.

General documentation requirements

The company shall archive documents which describe effective control of safety, quality and legality of products.

Corrective and preventive action

Senior management shall ensure that procedures exist to record, investigate, analyze and correct the cause of non-conformity against standards, specifications and procedures which are critical to product quality, safety and legality (Fundamental requirement no. 4).

Traceability

The company shall be able to track raw materials, intermediates and final products in all phases of the production process, expedition and storage. Where possible, company shall track its products to the final consumer (Fundamental requirement no 5).

Complaint handling

Product complaints system shall be developed.

Management of incidents, product withdrawal and product recall

The company shall have a plan and system in place to effectively manage incidents including product withdrawal and recall procedures.

Site Standards

External standards

Production plant shall be in a location where and designed the way that no risk of contamination of products is in place.

Security

Security shall be maintained to prevent access of unauthorized persons to production and storage areas.

Internal site standards

Production facilities shall be designed and maintained the way that the risk of product contamination will in control and it will comply with legal requirements (Fundamental requirement no. 6).

Utilities

Utilities to and within the production storage areas shall be constructed and maintained to effectively control the risk of product contamination.

Equipment

Machinery shall be suitable for production of company products and shall be used the way which will minimize the risk of product contamination.

Maintenance

A system of regular maintenance shall be developed for all items of equipment and plant which are critical for production of safe, quality and legal products.

Staff facilities

Staff facilities shall be sufficient to accommodate the required number of personnel.

Chemical and physical product contamination control

Procedures for control the risk of chemical and physical contamination of products shall be developed.

Housekeeping and hygiene

Housekeeping and cleaning systems shall be developed in order to ensure appropriate standards of hygiene and to minimize product contamination risk.

Waste/Waste disposal

A system for waste collection, sorting and disposal shall be developed.

Pest control

The company shall be responsible for minimizing the risk of pest infection.

Storage and transport

All facilities used for storage and transport of raw materials, intermediates, packaging materials, semi-finished products and final products shall be suitable for this purpose, in a good condition and shall meet hygienic requirements.

Product control

Product design/development

A risk analysis shall be done during the development of a new product in order to identify product's contamination risks and define necessary safety conditions.

Handling requirements for specific materials – materials containing allergens and Identity Preserved materials

Where raw materials and finished products require special procedures for handling specific materials (e.g. allergens or Identity Preserved status materials such as GMOs) these shall be in place to ensure that product quality, safety and legality are maintained (Fundamental requirement no.7).

Foreign body detection

A company shall make all necessary steps leading to identification, prevention, removing or minimizing of risk of contamination with metal and/or other unwanted materials.

Product packaging

Product packaging shall be selected in order to minimize contamination and quality-change risks and must be appropriate for the product use.

Product inspection and laboratory testing

Analysis determining safety, quality and legality of a product shall be done either by a selected company (on a contractual basis) or by the company itself.

Control of non-conforming product

The company shall ensure all non-conforming products is clearly identified, labeled and quarantined.

Product release

The company shall make sure that products are not dispatched until they went through all necessary procedures.

Process control

Control of operations

The company shall operate procedures that verify that used processes and equipment are capable of producing consistently safe and legal products.

Quantity – weight, volume and number control

The company shall operate a quantity control system which conforms to legal requirements and additional industry sector codes or customer requirements.

Calibration and control of measuring and monitoring devices

Monitoring devices used for critical control points control shall be calibrated according to an international norm. If this is not possible, the company shall demonstrate the basis by which standardization is carried out.

Personnel

Training

Company has to make sure that employees are going to be appropriately trained, educated and supervised (Fundamental requirement no. 8).

Access and movement of personnel

The company shall ensure that access and movement of personnel, visitors and contractors shall not compromise product safety.

Personal hygiene

All norms related to the personal hygiene shall be documented and respected by all employees and visitors of the production plant.

Medical screening

A company shall introduce medical screening procedures for all employees, visitors and contractors, who are going to work in premises, where the risk of product contamination is.

Protective clothing

Appropriate safety clothing, shall be worn by all employees who have direct contact with products and by contractors and visitors who work in or go to premises where products are treated.

3.5 International Food Standard – IFS

IFS Standard, based on the BRC standard was developed by the German Retail Federation (Hauptverband des Deutschen Einzelhandels). Its aim is to merge various requirements of retailers in one standard (BSI, 2009).

Aims of the ISF standard:

- To develop an external standard (in relation to the retailer) which will help to achieve the same results as when retailer's auditors are used.
- To develop a tool for securing food safety of private label brands.
- To cut costs caused by multiple audits.
- To provide documentation and audits in the supplier national language.
- To develop and easy results share system – the IFS-Audit portal

3.5.1 IFS Evaluation

Conformity with the standard is evaluated on the basis of checklist and scoring sheet. Based on achieved results, company can either receive certificate on Foundation level, or Higher level.

Each requirement of the standard is evaluated and on the basis of compliance with the standard, points are assigned to it.

Table 2 – IFS Requirements Evaluation

Result	Explanation	Points
A	Full compliance	20 points
B (deviation)	Almost full compliance	15 points
C (deviation)	Small part of the requirement has been implemented	5 points
D (deviation)	Requirement has not been implemented	0 points

Source: IFS Standard

Moreover, three special classifications are present in the standard:

NA The requirement is not applicable in the audited organization.

Major Major is given when there is a substantial failure to meet the requirement, which includes food safety and legal requirements. Also a major is given when the identified non-conformity can lead to a serious health hazard. In case a major is given, 15% of the achieved points are subtracted.

KO KOs are specific requirements defined by the standard. If any of these requirements are not fulfilled by the company, it will result in non-certification. There are 10 KO requirements defined by the standard which are highlighted in the description of requirements in the chapter 3.5.2.

3.5.2 IFS Requirements

IFS requirements are divided in to five chapters:

- *Senior Management Responsibility*
- *Quality Management System*
- *Resources Management*
- *Production Process*
- *Measurements, Analysis, Improvements*

Senior Management Responsibility

Corporate Policy / Corporate Principles

Top management shall draw up corporate policy, from which quality management objectives shall be defined.

Corporate Structure

The Senior Management shall ensure that employees are aware of their responsibilities and that mechanisms are in place to monitor the effectiveness of their operation (KO requirement no.1).

Customer focus

Procedures to indentify needs and expectations of customers shall be identified.

Management review

Top management has to review its own activity on a regular basis and propose improvements which will lead to a continual improvement regarding to quality management policies.

Quality Management System

HACCP

Plan according to HACCP Codex Alimentarius requirements shall be created (KO requirement no.2). HACCP system overview is located in chapter 3.2.

Documentation Requirements

All documentation shall be well arranged and always up to date.

Records Management

Records shall be treated the way a company will be able to prove effective management of safety, quality and legality of a product.

Resources Management

Human Resources Management

Personnel performing work that affects product safety, legality and quality shall have the required competence by education, work experience and/or training.

Human Resources

Requirements for personnel hygiene shall be defined, in place and applied by all relevant personnel contractors and visitors (KO requirement no.3).

Training

All employees shall be trained according to their job description.

Sanitary facilities, equipment for personnel hygiene and staff facilities

The company shall provide adequate staff facilities and hand hygiene facilities and boots cleaning facilities located where appropriate.

Production Process

Contract review

Review of contracts with company's customers shall be conducted to find out whether requirements on products and its specifications are defined.

Product specification

Products specifications must be adequate, accurate and in conformity with safety and legal requirements. Up to date products specifications must be exposed at an appropriate place together with ingredients specification (KO requirement no.4). This shall be in compliance with the recipe described in product specification (KO requirement no.5).

Product development

Analyzing and testing whether recipe and proposed procedures will lead to the production of a safe and legal product shall be done. Packaging and storage conditions, minimum shelf life and/or usable life of a product shall be defined.

Purchasing

Verification, whether acquired raw materials and intermediates will have expected impact on the final product.

Packaging

Packaging shall be in conformity with the legal frame connected with food safety and suitable for the product.

Factory environment standards

Requirements on buildings, plant internal organization and some specific requirements (on walls, floors, doors etc.) shall be defined. More than 100% fulfilling of requirements, their impact on safety and quality of produced products is considered.

Housekeeping and hygiene

Implementation of sanitation plans, monitoring of their fulfillment and documentation shall be done.

Waste/Waste disposal

All legal requirements connected with waste disposal shall be met. Information about waste disposal shall be documented.

Risk of foreign bodies, metal, broken glass and wood

Based on risk analysis, potential foreign body sources (e.g. raw material, machine components etc.) shall be identified. Procedures preventing product contamination shall be introduced and contaminated products shall be treated as non-conforming products (KO Requirement no. 6). Where needed, metal and/or foreign body detectors shall be installed.

Pest monitoring /Pest control

A company shall either make a contract with a company which is offering pests treatment services or have trained employees for regular control of buildings in terms of pests allocating and control.

Receipt of goods and storage

First In/First Out and/or First Expired/First Out principles for raw materials, finished products and packaging materials shall be implemented. Stored material/products storage conditions shall be met.

Transport

Procedures for products storage and dispatch and procedures for cars maintenance shall be implemented and documented.

Maintenance and repair

Maintenance plan shall be developed. Related processes including storage and manipulation with spare parts and machinery shall be documented.

Equipments

Verification whether equipment and machinery do not affect food safety and quality shall be done.

Process validation

In the event of changes to product formulation (e.g. rework, processing methods, equipment, packaging etc.), process characteristics shall be reviewed in order to assure that product requirements are complied with.

Traceability

Company shall develop a tracking system which allows indentifying the relation between product lots and their relation to batches of raw materials and packaging materials (KO requirement no.7).

Genetically modified organism (GMOs)

A system for tracking raw materials, intermediates and final products containing GMOs shall be developed as well as procedures preventing contamination of non-GMO products by GMO products.

Allergens and specific conditions of production

A system for identifying common allergens shall be developed. Allergens tracking system shall be developed and documented.

Measurement, Analysis, Improvements

Internal audits

Internal audits shall be conducted according to an agreed plan. (KO requirement no.8).

Site factory inspections

Factory inspection shall be planned and carried out on a regular basis.

Process control

Conditions critical for product safety and quality shall be monitored and documented. Machinery shall have an alarm system. In refrigerated areas, the temperature shall be monitored.

Calibration and checking of measuring and monitoring devices

Processes which need to be controlled and devices which are going to be used for this control shall be defined.

Quantity checking

The frequency and methodology of quantity checking shall be determined so that the legal requirements for nominal quantity are met.

Product analysis

A company shall do, or shall outsource, microbiological and physic-chemical analysis of its products on the basis of the control plan, where results are recorded. As a part of the check-out, sensory evaluation shall be done.

Product quarantine and product release

A product cannot be released unless all procedures were fulfilled, including analytical tests if necessary.

Management of complaints from authorities and customers

Complaints management and corrective action systems shall be developed.

Management of incidents, product withdrawal, product recall

There shall be an effective procedure for the withdrawal and recall of all products, which ensure that involved customers are informed as soon as possible (KO requirement no. 9).

Management of non-conforming products

A set of procedures for identification and disposal of non-conforming products shall be developed.

Corrective actions

Corrective action shall be clearly formulated, documented and undertaken, as soon as possible to prevent further occurrence of non-conformity. The responsibilities and the timescales for corrective action shall be clearly defined (KO requirement no. 10).

3.6 Food Safety System Certification 22000 - FSSC 22000

FSSC 22000, which consists of ISO 22000, ISO 22003 and PAS 220, was developed by Foundation for Food Safety Certification, which was established as a non-profit organization in 2004. The main reason for developing FSSC 22000 was the fact the ISO 22000 does not fully specify pre-requisite programs required to satisfy specific food safety concerns for food manufacturers.

ISO 22000:2005 Food Safety Management Systems - Requirements for any organization in the food chain, introduced on the 1st of September, 2005, was the first of a family on food safety management systems by ISO. ISO 22000 is designed the way that it can be used by all types of organizations within the food chain. ISO 22000 combines the Codex Alimentarius HACCP Hazard Analysis and Critical Control Points) principles and application steps, developed by Codex Alimentarius, with prerequisite programs. It uses the hazard analysis to determine the strategy for hazard control. Moreover, ISO 22000 is aligned with the requirements of ISO 9001 in order to enhance the compatibility of these two standards and to ease their joint or integrated implementation (FROST, FAERGEMAND, JESPERSEN, 2005).

Publicly Available Specification (PAS 220:2008) supplements the pre-requisite programs (PRPs) in ISO 22000, making it more complete and bringing it in line with the Global Food Safety Initiative (GFSI) requirements for benchmarking standards. PAS 220 specifies the exact requirements for PRPs. The specification applies to all organizations, regardless of size or complexity, as well as to all who are involved in the manufacturing step of the food chain and who wish to implement PRPs in such a way as to address the requirements specified in ISO 22000.

Moreover, ISO 22003, defining rules applicable for the audit and certification of a food safety management system (FSMS) complying with the requirements

given in ISO 22000:2005 (or other sets of specified FSMS requirements), and provides the necessary information and confidence to customers about the way certification of their suppliers has been granted (ISO, 2009).

3.6.1 ISO 22000 Requirements

Requirements of ISO 22000 are divided into five chapters:

- *Food Safety Management System*
- *Management Responsibility*
- *Resource Management*
- *Planning and realization of safe products*
- *Validation, Verification and Improvement of the Food Safety Management System*

Food Safety Management System

Documentation requirements

The food safety management system documentation shall include statements of a food safety policy and related objectives, procedures and records and documents important for development, implementation and updating of the food safety management system.

Management Responsibility

Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the food safety management system.

Food safety policy

Top management shall define, document and communicate its food safety policy.

Food safety management system planning

Top management shall ensure that the food management system is carried out to meet the general requirements and that the integrity of the food safety management system is maintained when changes are implemented.

Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined.

Food safety team leader

Top management shall appoint a food safety team leader.

Communication

The company shall establish systems for external and internal communication.

Emergency preparedness and response

Top management shall introduce procedures to manage potential emergency situations and accidents that can affect product quality, safety and legality.

Management review

Top management shall review the organization food safety management system at planed intervals to ensure its continuing suitability, and effectiveness.

Resource Management

Provision of resources

The organization shall provide adequate resources for establishment, implementation and maintenance of the food safety management system.

Human resources

The food safety team and the other personnel carrying out activities having an impact on food safety shall be competent and shall have appropriate education, training, skills and experience.

Infrastructure and work environment

The organization shall provide resources for the establishment, management and maintenance of the infrastructure and work environment needed to implement the requirements of this standard.

Planning and Realization of Safe Products

Prerequisite programs (PRPs)

The organization shall establish, implement and maintain PRPs to assist in controlling of food safety hazards.

Preliminary steps to enable hazard analysis

All relevant information needed to conduct hazard analysis shall be collected, maintained, updated and documented. Moreover:

- Food safety team shall be appointed.
- Raw materials, intermediates, finished products and intended use of finished products shall be described in documents to extend needed to conduct hazard analysis.
- Flow diagrams shall be prepared for the products or process categories covered by the food safety management system.

Hazard analysis

The food safety team shall conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety and which combination of control measures is required.

Establishing the operational prerequisite programs

Operational PRPs shall be documented and shall include definition of controlled food safety hazards, control measures, list of corrective actions, responsibilities and record(s) monitoring.

Establishing the HACCP plan

HACCP plan shall be implemented and documented. Description of HACCP system and its principles is located in chapter 3.2.

Verification planning

Verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities.

Traceability system

The organization shall establish a traceability system that enables the identification of product lots and their relation to batches of raw materials and intermediates. Moreover, the system shall be able to identify incoming material from suppliers and monitor the distribution of organization products to customers.

Control of nonconformity

The organization shall ensure that when critical limits for CCP(s) are exceeded, or there is a loss of control of operational PRP(s), products affected are identified and controlled with regard to their use and release.

Validation, Verification and Improvement of the Food Safety Management System

Validation of control measure combinations

The organization shall validate whether selected control measures are capable of achieving the intended control of food safety hazards, for which they are designated and whether control measures are effective and capable of ensuring production of quality, safe and legal products.

Control of monitoring and measuring

The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures.

Food safety management system verification

The organization shall conduct internal audits on a regular basis and the food safety team shall evaluate and analyze the individual results of these audits.

Improvement

Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication, management review, internal audit, evaluation of individual verification results, analysis of results of verification activities, validation of control measures combinations, corrective actions and food safety management system updating.

3.6.2 PAS 220 Specification

PAS 220 specifies requirements for establishing, implementing and maintaining prerequisite programs to assist in controlling food safety hazards in the food manufacturing processes of the food supply chain. It is applicable to all organizations which are involved in the food manufacturing processes of the

supply chain; and, PAS 220 is not designed nor intended for use in other parts of the food supply chain.

PAS 220 stipulates:

- *construction and layout of buildings and associated utilities*
- *layout of premises, including workspace and employee facilities*
- *supplies of water, air, energy and other utilities*
- *supporting services, including waste and sewage disposal*
- *suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance*
- *management of purchased materials*
- *measures for the prevention of cross contamination*
- *cleaning and sanitizing*
- *pest control*
- *personnel hygiene*
- *rework*
- *product recall procedures*
- *warehousing*
- *product information and consumer awareness*
- *food defence, bio vigilance and bioterrorism*

(LRQA, 2010)

3.6.3 FSSC Additional Requirements

A manufacturer should have an inventory of applicable foreign, regulatory and statutory requirements on food safety, including those that apply to: raw materials; services provided; and products manufactured and delivered. In addition, the manufacturer should comply with codes of practice related to food safety, customer requirements related to food safety and any other additional requirements on food safety determined by the customer.

The manufacturer should also ensure that all services (including utilities, transport and maintenance) which may have an impact on food safety, have specified requirements, are described in documents to the extent needed to conduct hazard analysis, and are managed in conformance with the requirements of PAS 220:2008, clause 9.

Finally, the manufacturer should ensure the effective supervision of the personnel in the correct application of the food safety principles and practices commensurate with their activity (SGS, 2009).

3.6.4 FSSC 22000 Audit Process Overview

The FSSC 22000 audit process is divided into two types of audit – the initial audit and surveillance audits. The purpose of the Initial audit is to decide whether company will receive the certificate or not. Purpose of surveillance audits is to ensure continuous improvement during the time company has a valid certificate. Certificate is valid for three years, initial audit is done in year one and surveillance audits are conducted at minimum once a year during years two and three. After this period, re-certification is required.

If a company has a valid ISO 22000 certificate, the initial audit is aimed only at PAS 220.

Audit evaluation

Unlike in BRC and IFS cases, the decision whether company will be certified against FSSC 22000 is not made on the basis of total sum of gained points.

Because in practice audit of FSSC 22000 is the audit of ISO 22000, audit and its evaluation is done on the basis of ISO standards dedicated to requirements on certification bodies and specific requirements for food safety management system. This includes ISO /TS 22003, ISO/EIC 17021, sections of ISO 19011 and IAF Guidance in ISO Guide 62. Additional requirements on certification bodies are provided in the FSSC 22000 – Requirements for Food Safety Systems in Compliance with ISO 22000:2005 and BSI-PAS 220:2008 document. This opens possibilities for both manufacturers and auditors, as they can focus only those requirements, which are important for securing production of safe and quality products.

4 Results and Discussion

4.1 Case study – X-Food

4.1.1 Overview

X-Food was established during the second decade of the 20th century and currently has leading brands in different food segments, for example in chocolate, sweets or pet food. It was originally established in United States, however today it's a multinational entrepreneur which has manufacturing plants in 68 countries and its brands are well known everywhere around the world.

For the company like X-Food, an effective quality management system (QMS) is one of its highest priorities. With many manufacturing plants located in significantly different regions (from cultural, economic, climatic and other points of view), only well designed and effectively maintained QMS can guarantee a production of products of a standardized quality. Although many of X-Food's products are produced and sold only in some regions (or their recipes vary), company keeps the same standard of production in all manufacturing plants in order to minimize the risk of releasing nonconforming products to the market

and by that putting the brand name in risk if any product harms consumers in any way.

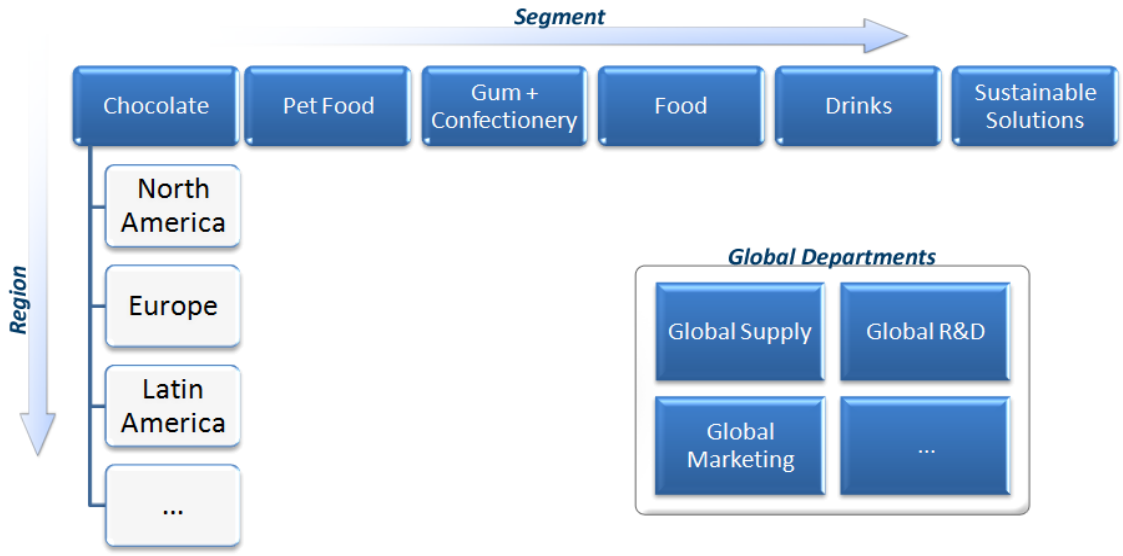
Because quality management in big multinational companies is such an important topic and because these big companies often have very specific structure, X-Food decided to develop its own quality management standard which fits its corporate structure. As X-Food produces majority of products under its own brands, for retailers it is often enough to know that X-Food has its own standard which keeps quality of their product at a very good level. However, in some cases, when a retailer requires certain standard or some products are going to be sold under retailer brand(s), manufacturing plant which is going to supply retailer with these products is certificated against the standard required by retailer.

In X-Food, quality and food safety related issues are managed by the Quality & Food Safety Team (Q&FS), which is part of the Research & Development Department (R&D). As we can see on the diagram 2, R&D is involved in all stages of the product quality cycle and all these issues are closely connected to the Q&FS Team as they are covered by company's QMS.

4.1.2 Company and Q&FS Team Overview

X-Food is divided into 6 segments according to their specialization. These segments are Chocolate, Food, Gum + Confectionery, Pet Food, Drinks and Sustainable Solutions. Each segment is then divided by regions plus there are cross-segment, cross-region departments (e.g. Global R&D, including Global Q&FS). Diagram 2 briefly sketches out this structure.

Diagram 2 - X-Food segments and regions breakdown



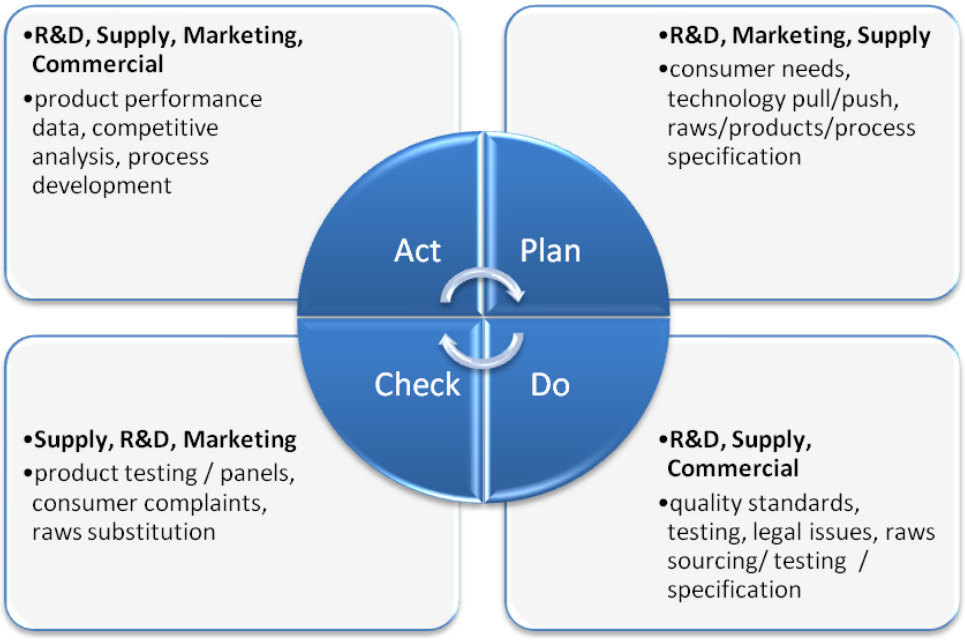
Source: X-Food internal documents

Within the Global Q&FS Team, there are 6 teams oriented at different areas of food quality and safety management, such as Q&FS Analytical Sciences Team, Q&FS Management Team or Q&FS Processes & Systems Team. Q&FS Management Team is oriented at keeping QMS and supportive standards and documents effective and up to date. It develops standards, communicate with regional R&Ds and with an independent auditor, who benchmarks the QMS against other quality management standards and helps in the further development of QMS. Moreover, Q&FS Management Team gather audit results, evaluates them and then suggest corrective actions and improvements, conducts training for employees / contractors and manage communities and best practices.

4.1.3 X-Food Quality Management System (QMS)

Until 2008, QMS was based on several worldwide recognized quality management standards and systems, including ISO 9001, Dutch HACCP, ISO 22000 or IFS. This helped the company having its manufacturing plants easily certified against certain standards if needed, as core components of the most standards used worldwide were included in X-Food QMS. In 2009, a transformation of the company's structure took place, changing it from a regional structure to a segment structure mentioned in chapter 4.1.2.. In connection to this, the company decided to improve its QMS. The new system, which is now being implemented, is based mainly on ISO 22000, PAS 220, ISO 9001 and company's internal standards and documents which cover various processes, from incident solving to key raw materials sourcing (e.g. cocoa). The idea of the standard is based on Deming PDCA (Plan, Do, Check, Act) Cycle:

Diagram 3 – X-Food Product Quality Cycle



Source: X-Food internal documents

Although X-Food built its new QMS on different quality management standards, one of the most important features is that the QMS is compliant with the most

important quality and food safety management standards globally. At the moment, X-Food QMS is in 99% compliance with IFS, BRC, ISO 22000, FSSC 22000, Dutch HACCP, SQF 2000 and ISO 9001 and the plan is to achieve 100% compliance by the end of 2010. This is benchmarked by an independent audit company to ensure that the benchmark is objective.

4.1.4 X-Food QMS Requirements

The core of X-Food QMS is the QMP Standard. Structure and requirements are similar to FSSC 22000, thanks to the fact that both X-Food QMP and FSSC 22000 are based on ISO 22000. Moreover, X-Food QMP includes requirements of ISO 9001 and some key requirements defined by the company. X-Food QMP consists of following chapters:

- *Quality and Food Safety Policy*
- *Management Responsibility*
- *Management of Quality and Food Safety Resources*
- *Planning and Realization of Quality and Safe Products*
- *Control of Documents and Records*
- *Verification and Internal Audits*
- *Continuous Improvement and Corrective/Preventative Action*

This document contains only general information and requirements related to quality and food safety. Specific requirements are defined in supportive standards and documents to this QMP standard. Diagram 3 shows main standards / documents used and where relevant, standard(s) and/or documents from which were developed, are mentioned.

Diagram 4 – X-Food QMS document structure

Source: X-Food internal documents

All of these standards / documents include in introduction a paragraph stating that all products shall be produced in compliance with national (or supranational – e.g. EU) requirements (of the country where final products are manufactured and country where these product are sold). As these requirements may vary from country to country, exact numbers were set on the basis of requirements of the most reliable and important countries / unions in the world (e.g. US, Canada, EU). Smaller countries usually adopt requirements of these big countries as their requirements are based on scientific research. In case X-Food requirements are not in compliance with national requirements following rules apply:

- National requirements are less strict than X-Food requirements => X-Food requirements are used
- National requirements are more strict than X-Food requirements => national requirements are used

Monitoring of national requirements and continuous update of global requirements is done by local R&D offices and Scientific and Legal Department.

4.1.5 X-Food QMS verification, evaluation and continuous improvement

X-Food QMS is audited in all manufacturing plants once a year. To guarantee objectivity, a respected multinational audit company is contracted for this task. Auditors are trained to be able to perform audit against this specific standard and to summarize their findings in a standardized document.

From this document, quantitative results are used to evaluate effectiveness of food quality and safety improvements and to compare development of production plants (with each other, with previous years, comparison of regions etc.). Output is then used to monitor their effectiveness and drive improvements.

4.1.6 Production plants certification against major quality management standards

As majority of X-Food product are branded products, QMS is benchmarked and audited by an independent audit company and X-Food has a very good image all around the world, many customers are satisfied with the fact, that X-Food has its own QMS. However, in some cases (e.g. when the product is sold under the customer private label or a customer policy requires it etc.), being certified against a certain standard is necessary. Thanks to the high compliance of X-Food QMS with all major quality management standards, this is not a big issue for X-Food manufacturing plants. The audits is conducted by the same audit company which conducts X-Food QMS audit and in practice it work the way that auditors spend two or three days more on the site to complete audit against selected quality management standard. This process is decentralized and without any interference of the Global Q&FS Team.

4.2 Standards evaluation

In order to compare three major quality and food safety management standards plus X-Food QMS, SWOT analysis and comparison with regard to selected topics

were used. SWOT analyses (in chapters 4.2.1. – 4.2.4.) were only the first step in the evaluation process as their goal was to summarize and standardize information about standards for the purposes of the main comparison in the chapter 4.2.5..

4.2.1 X-Food QMS SWOT Analysis

Strengths

- Designed to fit the company structure and processes required for production
- High compliance with major quality management standards
- Because it is a set of standards/documents, it can be easily maintained and continuously updated.
- The core ideas are applicable everywhere, but concrete processes can be different in different manufacturing plants.
- Complex system of data collection and evaluation makes it easy to compare production plants and suggest improvements.
- More strict requirements on quality management make it easier to be certified against major quality management standards.

Weaknesses

- The whole Q&FS system is designed for specific company structure.
- The whole system may appear non transparent and unreliable to customers.
- QMS is owned and maintained by the company itself and not by an independent body.

Opportunities

- 100% compliance with standards may bring even faster certification against major quality management standards or even make customers accept X-Food QMS.
- Closer cooperation with the audit company can bring improvements in the standard structure and content and increase the overall effectiveness of the standard.
- In case many suppliers and retailers decide to be audited against FSSC 22000, X-Food will benefit from it as its QMP and GMP standards are based on same documents as FSSC 22000 (except ISO 22003). This may improve the communication, traceability, and other aspects of their interaction.

Treats

- Future transformation of the company structure may cause decrease of effectiveness of QMS.
- Some of acquisitions may be rejected because it would be impossible to change structure of the acquired company to fit X-Food structure (this has happened in the past several times).
- As company grows, new segments are introduced and so are new product and technologies, QMS may become ineffective.

4.2.2 FSSC 22000 SWOT Analysis

Strengths

- The fact that FSSC 22000 consists of ISO 22000 and ISO 22003 makes it easy to integrate with ISO 9001 and other ISO standards.
- ISO 22000, the core part of FSSC 22000, is applicable to all companies in the food chain which helps the communication with regards to quality

and food safety issues and corrective actions. Moreover companies at all stages of the supply chain take into account safety hazards of the final product of the chain to the consumer and take measures to control those hazards.

- Continuous processes improvement is forced by analysis and consideration. HACCP is more important thanks to the need of validation and formal verification.
- ISO 22000, which is the core of FSSC 22000, is recognized in 159 countries including those which do not have their own national standards. National regulations and legislation are the integral part of FSSC 22000.
- It is focused on the whole organization, not on selected production lines.
- Two stage audit approach helps auditors to make a more detailed audit of the company.
- Thanks to the fact FSSC 22000 is based on ISO standards, it is more easily accepted in new or emerging markets (ISO brand awareness).
- ISO 22000 certified companies are able to easily move to FSSC 22000

Weaknesses

- Difficult to read/understand due to the generalization.
- Track record of the benefits of the integrated food chain approach has not been proven yet.
- Auditors are not experienced in FSSC 22000 certification compared to other standards.
- Quality is not directly addressed.

- Instead of having one single document, FSSC 22000 consists of three separate documents which makes it complicated for companies to navigate in it.
- It is still not fully recognized GFSI standard yet.

Opportunities

- GFSI recognition will help producers to make contracts with some big retailers (e.g. Wal-Mart, Tesco, Metro etc.).
- Good reputation of ISO standards may lead to recognitions on the national level.
- Big food manufacturers can force its smaller suppliers to be certified against FSSC 22000 which makes whole supply chain more connected and all communication processes more effective and simple.
- Because of similarities between GFSI recognized standards, it should not be hard for companies already certified against any of GFIS recognized standards to move to FSSC 22000.

Threats

- In case GFSI recognition will take more time, companies may decide to be certified against some other standard.
- Some customers may require other standards over FSSC 22000 because of good experiences with them.
- Companies who already have any of GFSI standards implemented might not want to switch to FSSC 22000.

4.2.3 BRC SWOT Analysis

Strengths

- Improved HACCP focus (since the latest version of BRC).
- Detailed description of pre-requisite programmes.
- Clear definition of incident management procedures.
- Daily focus on control of operations.
- Address laboratory testing of products.
- Well established standard on main markets and the leader among quality management standards worldwide.
- BRC is connected with other BRC standards, such as Global Standard for Storage and Distribution or Global Standard for Packaging and Materials.

Weaknesses

- Some fundamental requirements are overstated. Moreover, some fundamental requirements imply some requirements of second importance.
- Preventive actions are not defined.
- Quality aspects may dilute focus on food safety.

Opportunities

- Potential advantage in new markets over its competitors due to its good reputation built during 12 years on the market.
- Auditors are experienced in BRC certification procedures.
- Standard has been shaped over a long time so core features are tested and concepts proved.

Threats

- New standards can bring new concepts which can lead to moving companies from BRC.
- Because ISO standards are more used worldwide than BRC standards in general, companies may decide to be certified against ISO 22000 or FSSC 22000 as these are closely connected to other ISO standards.
- In developing countries and in countries in transition, ISO standards may have better image than BRC standard (thanks to wide use of ISO 9001) which may cause that both manufacturers and customers will prefer ISO 22000 or FSSC 22000 over BRC.

4.2.4 IFS SWOT Analysis

Strengths

- Instead of following described procedures, a company can develop its own solution based on the risk analysis. The auditor then checks whether these procedures are effective enough.
- IFS has a good name in continental Europe and is strongly supported by main European retailers, especially by German ones.
- Addressing due diligence requirements to both the supplier and the retailer.
- All requirements are in one document. The evaluation is clear.
- IFS is based on ISO 9001, therefore it can be combined with this quality management system.

Weaknesses

- Small importance outside Europe.

- IFS is only for food processing companies and companies that pack loose food products.
- IFS was developed by French and German retailers and therefore lacks the independence.

Opportunities

- The expansion of French and German small and medium retailers abroad may cause that more companies from that countries will be audited against IFS.
- Some retailers may prefer IFS as it is mainly built for securing quality and safety of private label products. (e.g. German Aldi or Lidl which are based on private label products)

Threats

- Because IFS is focused on a specific area of the food supply chain, in case the trend leads towards standards consolidation throughout the whole food supply chain, retailers and manufacturers might switch to FSCC 22000 or other standards applicable in the whole food supply chain.
- Possible weakening of position of the German and/or French retailers may lead to deterioration of IFS position.

4.2.5 Comparison between BRC, IFS and FSSC 22000

Although BRC and IFS have many different requirements, we can treat them as equal as these differences do not disadvantage one against another and they have many important things in common. However, these features are not common with FSSC 22000 and therefore comparison was conducted between BRC and IFS on one side and FSSC 22000 on the other side, to find out which standard has the potential to become the truly global standard.

Ownership of the Standard

IFS & BRC	FSSC 22000
Owned by institutions managed by retailers.	Owned by an independent institution.

BRC & IFS were developed and are owned by institutions managed by retailers in order to secure the quality and safety of private label products. Because of this, some requirements in these standards might be considered as an advantage for retailers against food manufacturers. FSSC 22000 is owned by an independent institution and its components were not developed by retailers (ISO 22000 and ISO 20003 was developed by ISO and PAS 220 was developed by British Standards Institute (BSI)).

Applicability with Regards to the Position in the Food Supply Chain

Only for food manufacturers.	ISO 22000 is applicable in the whole food supply chain.

Although FSSC 22000 is designed only for food manufacturers, ISO 22000 is universal and can be used by all companies across food supply chain. This brings synergy and improves cooperation with suppliers/customers of food manufacturers. BRC and IFS are focused only on food manufacturers.

Applicability with regards to the type of products

Only for food manufacturing.	ISO 22000 is applicable to related products and services.

IFS and BRC applies only on food production (in case of BRC, there is a standard from BRC standards family related to packaging), whereas ISO 22000, core part of FSSC 22000, applies also to related product and services, such as contact materials, machines, packaging, pets control products and many others.

Standard Target

How things are done? (Compliance with exact requirements)	Are things done the way which will assure production of safe products? (Process based Audit)

IFS and BRC uses checklist and according of the level of compliance with the standard, points are given to the company. The total sum of gained points determines whether company receives certificate or not. FSSC 22000 uses a process based audit, which his, except some additional requirements, the same as for all ISO standards. This allows auditors to evaluate the company's compliance with FSSC 22000 requirements according to the production processes and the risk each process poses. Requirements on certification bodies are described in chapter 3.6.4..

Audit Approach

Control, whether the requirements are fulfilled.	Control, whether the company is able to manage hazards.

When auditing against IFS or BRC, auditor controls whether standard requirements are fulfilled. This basically means following the standard checklist. In case of FSSC 22000, auditor is more focused on results and the systematic approach used to achieve them.

HACCP Compliance

Fundamental requirement, but not the core component.	Built around HACCP.

In IFS and BRC, HACCP is an important part and requirement, but these standards do not systematically work with it and thus they are not connected with other chapters of the standards. ISO 22000, which is one of the corner-stones of FSSC 22000, is built around HACCP and it enhances it by adding PRPs

and operational PRPs. These components are systematically implemented into the HACCP structure so the whole system is still systematic but now more effective and consistent.

Convergence with ISO 9001

Compatible, but different.	The same structure brings convergence.

IFS and BRC are compatible with ISO 9001, but their structures are different and therefore they may bring an extra work when a company certified against BRC or IFS decides to be certified against ISO 9001 and vice versa. On the contrary FSSC 22000 has, thanks to the fact it consists of ISO 22000 and ISO 22003, the same structure as ISO 9001. Therefore the process of certification against one of these standards, when company has the other one, is easier and more fluent.

Audit Complexity

One Stage Audits	Two-stage Audit

IFS and BRC rely on the one stage audit. This may be enough to find out whether requirements of the standards have been met, but may not find out whether all processes implemented by the company really lead to the production of safe products. FSSC 22000 is based on the two-stage audit. The first stage is focused on the documentation control for both, the company's Food Safety Management System and its eventual supportive documents, and the second stage is an in-depth implementation audit aiming to find out whether all processes and safety measures are successfully implemented and are effective as expected.

Audit Frequency and Length of Certificate Validity

Frequency: once per period of certificate validity Validity length: 12 months (6 month when BRC requirements are not fully fulfilled)	Frequency: Initial audit – once per period of certificate validity Surveillance audits – at least twice per period Validity Length: 36 months

In case of IFS and BRC, certification is valid for one year (in case of having C as the BRC audit result, the BRC certificate is valid for 6 months only). This often means unnecessary expenditures, as companies have to pay the price for the full audit, even when they are certified against the standard for several consecutive years (this might vary – it depends on terms of trade between auditor and audited company). The FSSC 22000 certificate is issued for three years and requires one initial audit in year one, followed by at least one surveillance audit in both following years. Surveillance audits are conducted to find out whether the company drives improvements as required by the standard.

4.3 Selection of potential global standard and its comparison with X-Food QMS

From the comparison in chapter 4.2.5. it is obvious that FSSC 22000 should be considered as a potential global quality management standard for the food processing industry. Its weaknesses and threats described in chapter 4.2.2. might not be overlooked but its advantages are over retail-driven standards IFS and BRC are clear. Moreover, growing worldwide support of some major players in both manufacturing and retails (Wal-Mart recently stated that they will recognize FSSC 22000 and make contracts with manufacturers certified against it) might signalize that the whole supply chain may move to standards consolidation in following years.

As FSSC 22000 is quite a new standard (including the age of its components), it is likely that some significant updates and improvements will be introduced in following years. As the objective of this thesis is not only to select the potential global standard but also to suggest some improvements to the selected standard, a comparison between FSSC 22000 and X-Food QMS was conducted.

4.3.1 X-Food QMS and FSSC 22000 Comparison

The comparison between X-Food QMS and FSSC 22000 was not conducted to decide which of these standards is more suitable for the global area (the weaknesses of X-Food QMS described in chapter 4.2.1. are obvious), the focus was to find out what are the advantages of X-Food QMS over FSSC 22000 so some suggestions for FSSC 22000 improvement may be done.

Accent on Quality

X-Food QMS	FSSC 22000
X-Food QMS is the quality management system so the importance is not only put on issues related to the food safety but also on the quality itself. Chapters focused on the quality are based mainly on ISO 9001 standard.	FSSC 22000 is the food safety management system so the aim of the standard is to secure a production of safe products. The quality is not directly addressed in this standard.

Audit Frequency

Full audit is conducted every year in each site and business unit.	Full audit is conducted once in a three years, followed by at least two surveillance audits, one in year two and one in year three.

Link between Audit Results and Continuous Improvement

Data collected by auditors from all business units are consolidated and used for gaps identification and improvements. Data collection is one of the primary objectives for auditors.	Although the feedback from audits is useful for making improvements in the company, it is not the primary purpose of the audits. The purpose is to measure the compliance with the standard. Also the feedback comes in the form of a non-standard report (which may vary depending on the auditing company) without quantified results.

Audit Results Control

The audit results are controlled by the standard owner (the company itself) which guarantees that the audit is comprehensive, complete and objective.	Comprehensiveness, objectivity and completeness of the audit are not controlled by the standard owner (The Foundation for Food Safety Certification). Audited companies have to be certified against certain standards which guarantee the above listed factors (see chapter 3.6.4. for more information).

Drive for the Best Results

A high management commitment at the site level ensures that the goal is not meeting the "compliance" level of the standard, but meeting the "excellence" level.	The goal of the company is to achieve the compliance with the standard. Improvements above this level are not valued (no matter the level of improvements, the maximal results is always "compliance").

Share of the Best Practices

Different approaches from different sites are compared and in case there is any approach which can improve a production process, this approach is then communicated to other sites in order to promote improvements globally.	FSSC 22000 does not include any tools for sharing best practices within the company. Moreover, the best practices are not shared by any online portal or similar tool, which is understandable as this knowledge is the competitive advantage of a company.

4.3.2 Improvement suggestions for selected standard

From the comparison in the chapter 4.3.1, the most important difference between X-Food QMS and FSSC 22000 is the emphasis on quality. Although quality and food safety are closely connected and they are in most cases meeting food safety requirements, putting an emphasis on quality into FSSC 22000 may lead to wider acceptance of FSSC 22000 among those retailers, who favor BRC or IFS at the moment – especially those who rely heavily on private label products.

Because quality-related chapters in X-Food QMS are based mainly on ISO 9001, there might be two ways how quality can be addressed by FSSC 22000.

- Companies who adopt FSSC 22000 are also certified against ISO 9001. This guarantee that quality related issues are covered.

- A new chapter dealing with quality issues is implemented into the standard. This chapter will be based on ISO 9001 and will cover only selected issues described in ISO 9001 to secure that the quality is sufficiently addressed by FSSC 22000.

If a company has already been certified against ISO 9001 before the certification process against FSSC 22000, the audit will not include the chapter about the quality, because the company has already fulfilled these requirements.

If a company has not been certified against ISO 9001 before the certification process against FSSC 22000, the audit will also cover the quality related chapter based on ISO 9001.

If a company has been certified against FSSC 22000 while being certified against ISO 9001 and loses the ISO 9001 certificate, a surveillance audit will follow in order to find out, whether the company is in compliance with FSSC 22000 quality related chapter requirements.

Other features of X-Food QMS compared to FSSC 22000 are in most cases company specific and are not directly connected to the quality and food safety requirements. Therefore these are not to be recommended as additions to FSSC 22000. On the other hand, some of them, such as the link between audit results and continuous improvement or the drive for the best results may be considered as beneficial additions to FSSC 2200. However, as these are not directly connected to the quality and food safety requirements with which the company has to be in compliance but they are more oriented on the framework and the output of the FSSC 22000 audit, their implementation into FSSC 22000 is not described in this thesis.

Quality related requirements suggested to be added to FSSC 22000

Consumer/customer related processes

Determination of products requirements

A company shall determine requirements specified by the customer, including requirements for delivery and post-delivery activities and requirements not specified by the customer, but necessary for intended use of the product. Moreover, regulatory requirements shall be defined, depending on the market where products are produced and sold.

Review of requirements related to the product

Prior to the production, requirements shall be reviewed in order to check whether the product requirements are defined. Any updates of customer requirements received are implemented and the company must be able to meet these updates.

Product Design and Development

The company shall plan and control the design and development of all new products to ensure that the final product is of high quality, safe and legal. These include a definition of food safety and quality requirements, review and verification procedures and responsibilities and authorities connected to the design and development processes.

Inputs

Inputs to the design and development stages shall include as follows:

- Requirements related to quality and food safety
- Regulatory requirements related to the product
- If designed product is partly or fully based on any other previous products/designs, these products/designs shall be referenced

Outputs

Outputs shall be as follows:

- Meet quality, food safety and regulatory requirements defined in the input stage
- Provide appropriate information for the production
- Define or reference product quality and food safety acceptance criteria/limits
- Specify any characteristic of the product that is essential for its safe and proper use

Design and development review, verification and validation

Review, verification and validation shall be performed in order to find out whether input requirements were met and that the designed product is capable of meeting defined product requirements related to quality and food safety. All records shall be maintained and archived.

Control of product and production quality

In order to assure the quality of the product, controls shall be conducted. This control shall include as follows:

- Control of product and process descriptions and specifications
- Control whether used equipment is suitable for the production
- Control whether suitable monitoring and measuring devices are in place
- Control of corrective actions related to equipment malfunction or other non-conformance issues
- Control of product conformance at the end of the shift or when product batch is finished

Measuring and testing of the product

Control of the product quality characteristics shall be conducted at an appropriate stage of the production process to ensure that the defined criteria were met. Results shall be recorded and archived. Product release shall not be made until this control is completed, unless it was approved by responsible authority or by the customer (if applicable).

4.4 Case study 2 – V+K Mařákovi

4.4.1 Overview

V+K Mařákovi is a small regional entrepreneur established in 1995 in Opava, Czech Republic. Since then, the company specialized on food wholesale. Main commodities traded were drinks in PET bottles, drinks in Tetra Pak boxes and products of Pekárny Pardubice, followed by Goldfein CZ s.r.o. (main products were baked confectionary products such as gingerbreads, cakes and swiss rolls). In 2008 V+K Mařákovi started a production of its first baked product, a honey-based cake called Medánek. In 2009, production was extended by variety of cakes and at the beginning of 2010, a new gluten-free product range was introduced. V+K Mařákovi is a family owned business and employs 19 employees plus few part-time workers hired when needed. At the moment, only Medánek can be found in a wider distribution, but as gluten-free product range, which includes gluten-free Medánek and gluten-free confectionery is getting more attention by Czech Celiac Association (Sdružení Celiaků České Republiky), possible expansion and distribution via major retailers is likely to happen.

4.4.2 V+K Mařákovi QMS

V+K Mařákovi adopted and implemented HACCP system, which is required by the law. This system is not certified, but is monitored by Czech Agriculture and Food Inspection Authority (Státní Zemědělská a Potravinářská Inspekce). The company is not certified against any external standard and has not introduced any internal standard since its foundation.

4.4.3 Research and Interview

The research in the company was based on an audit, which consisted of interview with the employee responsible for quality and food safety of company products, research of company materials related to quality and food safety and evaluation of the company production plant. This audit was less complex that the standard FSSC 22000 audit, as the goal was not to find out, whether the company is ready to be certified against FSSC 22000, but whether FSSC 22000 is, together with proposed updates, applicable in a small regional company. The information collection was based on chapters of ISO 22000, PAS 220 and proposed quality related chapter.

Part 1: ISO 22000 requirements

Food Safety Management System

General requirements

V+K Mařákovi's food safety management system is based on legal requirements of the Czech Republic, which means on the HACCP system. Certification of the system is not required, however it is controlled by Czech Agriculture and Food Inspection Authority (Státní Zemědělská a Potravinářská Inspekce) irregularly. Requirements defined by the legal framework of the Czech Republic are not sufficient to meet the criteria of FSSC 22000, but the company might be able to modify its food safety management system to meet the criteria of the standard.

Documentation requirements

At the moment, the documentation does not meet the criteria of the standard, but it may be updated to be in conformity with the standard.

Management Responsibility

Management commitment

Although the commitment to the development and improvement of the food safety management system is obvious in the company, there is no written proof of it. For the purposes of the standard, the company is able to develop a written document which will prove this commitment.

Food safety policy

The food safety policy of the company has not yet been defined as it is not required by the law. Development of this document should be no problem for the company and will be developed if the company decides to be certified against FSSC 22000.

Food safety management system planning

The food safety management system planning used for the development of the V+K Mařákovi food safety management system is not sufficient to meet the criteria of FSSC 22000, but the company is able to fulfill these criteria by changing the planning process.

Responsibility and authority

Responsibilities and authorities are divided between two main technologists, of which one is also one of top managers and owners of the company. All employees are obliged to report any problems with the food safety management system either to one of the two defined technologist, or to the other top manager/owner of the company.

Food safety team leader

As the food safety team has not been officially defined, food safety team leader is missing. But because the responsibilities between two main technologists had already been defined and one of them is the senior technologist, the team and

the leader exist in practice. The process of defining members of the food safety team and who the leader is, is therefore a formality.

Communication

No standardized systems of the internal and external communication related to food safety have been defined. Regarding the internal communication, thanks to the size of the company and the number of employees, the communication about food safety is not causing any issues. The communication with business partners and authorities on food safety issues is done when necessary.

Emergency preparedness and response

Because it is not required by the legal framework, no such procedures have been defined.

Management review

The food safety management system is not reviewed according to the FSSC 22000 criteria. It was only reviewed due to the suggestions given by Czech Agriculture and Food Inspection Authority (Státní Zemědělská a Potravinářská Inspekce) after its control.

Resource Managements

Provision of resources

The company has put aside resources necessary to meet the regulatory requirements on the food safety management system. In case of being audited against FSSC 22000, they are able to allocate resources necessary to meet the criteria of the standard.

Human resources

The company cares for having competent employees in order to produce safe, high quality and legal products. All employees involved in the production have

the appropriate education and skill. If needed, the training is conducted by the company to enhance the knowledge and skills to carry the production activities without any quality and food safety problems.

Infrastructure

The company provides resources necessary to keep the infrastructure in the proper condition. Concrete infrastructure conditions do not fully comply with the standard but in order to be in compliance with it, the company is able to allocate as many resources as necessary.

Work environment

The company provides resources necessary for the establishment and maintaining the proper work environment. For the purposes of the standard, the company is able to provide more resources if necessary.

Planning and Realization of Safe Products

General

As Prerequisite programs and Operational prerequisite programs are not required by the law, V+K Mařákovi are not in compliance with the general requirement of this chapter. Applicability of prerequisite programs in the company was audited and the results are in this chapter after the ISO 22000 Requirements (part 2 of the audit results).

Prerequisite programs (PRPs)

Applicability of prerequisite programs in the company was audited and the results are in this chapter after the ISO 22000 Requirements (part 2 of the audit results).

Preliminary steps to enable hazard analysis

Some of the requirements, such as development of the flow diagrams or definition of raw-materials, ingredients and product-contact materials have been fulfilled. For the purposes of the standard, the company is able to create a food safety team and specify the intended use of products.

Hazard analysis

In order to meet the regulatory requirement, the company has already conducted the hazard analysis. However, it would be necessary to conduct a new hazard analysis in order to meet the requirements of the standard.

Establishing the operational prerequisite programs

Operational prerequisite programs were not defined, but in order to meet the requirements of the standard, the company is able to develop them.

Establishing the HACCP plan

HACCP plan was defined for each Critical Control Point. In order to fully meet the requirements of the standard, the company shall do some minor updates of HACCP plans, but in general the company´s HACCP plans are in compliance with the standard.

Verification planning

Verification activities are not defined by the company. However, the company is able to define them in order to be in compliance with the standard.

Traceability system

V+K Mařákovi uses traceability system based on batches. If necessary, the company is able to track to which customer products from certain product batch were sold or from which supplier the ingredients were purchased. The traceability system is in compliance with EU directive EC 178/2002.

Control of nonconformity

In case the critical limits for CCP(s) are exceeded, products are identified and necessary actions are conducted in order to either eliminate the risk of affecting the safety of the product or to prevent the release of the product. The company is able to implement and/or update the necessary requirements of the standard regarding the loss of control of operational PRP(s), corrective actions, handling of potentially unsafe products, evaluation for release and withdrawals to be in compliance with the standard.

Validation, Verification and Improvement of the Food Safety Management System

General

As requirements of this chapter are connected with the food safety management team, no requirements are fulfilled completely. However, some of them are partially fulfilled and the company is able to create a food safety management team and to meet the requirements of this chapter in order to be in compliance with the standard.

Validation of control measure combination

Validation of control measures has not yet been conducted. Control measures were selected on the basis of literature research and the knowledge of responsible employees. Validation can be conducted if necessary.

Control of monitoring and measuring

Used monitoring and measuring devices (thermometers, weighs) were, at the time of purchase, calibrated according to the relevant international standards which gives the evidence required by the standard.

Food safety management system verification

No internal audits have been conducted yet to evaluate and analyze the status of the food safety management system. The company is able to conducts these audits to meet the requirements of the standard.

Improvement

Majority of tools which shall be used for driving improvements are not used within the company at the moment. However, in order to meet the requirements of the standard, the company is able to implement them.

Part 2: PAS 220 Requirements

In this chapter, requirements defined by PAS 220 on various aspects of production are compared with the actual status in the company. Moreover, applicability and relevance of the requirement are analyzed.

Construction and Layout of Buildings

General requirements, environment, location of establishment

V+K Mařákovi fulfills the requirements of this chapter. Production plant and the connected warehouse are of a good condition. Site boundaries are marked by a fence. Production plant is located in a small village where no risk of contamination from local environment is present.

Layout of Premises and Workspace

General requirements, internal design, layout and traffic patterns

Internal layouts of the production plant are adequate for the production of V+K Mařákovi products. When designing movement patterns of material, people and products, potential contamination sources were taken into consideration.

Internal structures and fittings

Walls and floors in the process area are appropriate for the production and are easy to wash and clean. External opening windows are insect screened. Doors are closed when not in use.

Location of equipment

Equipment is located according to flow diagrams and with regards to the need of its cleaning and maintenance.

Laboratory facilities, temporary/mobile premises and vending machines

Because V+K Mařákovi contracts external laboratory facility, this sub chapter is not relevant. The same applies for temporary/mobile premises and vending machines as the company does not use any of these premises and does not have any vending machines in the production plant.

Storage of food, packaging materials, ingredients and non food chemicals

Storage areas are appropriately designed. The protection against dust, condensation, drains, waste and other sources of the potential contamination is in place. Storage area is ventilated and where necessary (for example in the fridge), the temperature control is applied. All materials and products are stored on wooden pallets and with sufficient space from the walls for the purposes of the pest control. Raw materials, intermediates and final products are stored separately. Cleaning materials and chemicals are stored in separate, secure room.

Utilities – Air, Water, Energy

General requirements

Distribution routes for utilities are adequately designed to minimize the contamination of raw materials, intermediates and final products. The quality is not monitored by the company - the quality of the tap water (the only water

used in the production process) is monitored and guaranteed by the distributor and the quality of air in the area where the production is located is considered as without any risk.

Water supply

The only water used for the production and cleaning is the tap water. Its quality is guaranteed by the distributor and therefore is considered as adequate for the intended use.

Boiler chemicals

No boiler chemicals are used in the production.

Air quality, ventilation, compressed air and other gases

Air is not directly used in the production process. Ventilation is adequate in order to remove any unwanted steam, dust, and odors and to facilitate drying after cleaning. Compressed air and other gases are not used in the production process.

Lightning

The intensity of the lightning in the production areas is adequate to allow employees to operate in a safe and hygienic manner. Light fixtures are appropriately protected.

Waste Disposal

Containers for waste and inedible or hazardous substances

Containers are adequately located in the production and storage areas, clearly indentified and appropriate for the intended use.

Waste management and removal

The waste is segregated and adequate space is provided for the waste storage. The frequency of the waste removal from the production areas is appropriate to avoid accumulation of the waste. At the end of each shift, the waste is removed from the production areas. Labeled materials considered as waste are treated as general waste and no special actions are in place in order to prevent the reuse of the trademark. However, this requirement is of a small relevance for V+K Mařákovi as the trademarks of the company are not the target of possible plagiarism.

Drains and drainage

Drains are designed appropriately and the capacity is adequate for the intended use.

Equipment Suitability, Cleaning and Maintenance

Hygienic design and product contact surfaces

Used equipment is designed for the use in food manufacturing. Product contact surfaces are impermeable, rust and corrosion free, smooth and easily cleanable.

Temperature control and monitoring equipment

In the production, there is one convection oven used for periodic production. Requirements of the temperature and the length of baking given by the product specification are met and the temperature control is provided by a thermometer which is part of this convection oven.

Cleaning plant, utensils and equipment

Sanitation plans are in place, including the definition of what to clean, when to clean, what to use for cleaning and who is responsible for these tasks. In case of equipment cleaning, procedures on how to disassembly and clean used

equipment are specified. The result of cleaning process is controlled by the shift manager. No verifying methods have been defined.

Preventive and corrective maintenance

As the only monitoring devices are the thermometers calibrated by the manufacturer, no preventive maintenance programs for monitoring devices have been developed. A corrective maintenance is carried out the way that there is no risk of contamination of raw materials, intermediates and final products.

Management of Purchased Materials

Selection and management of suppliers

There is no written and systematic process for the selection, approval and monitoring of V+K Mařákovi suppliers. Majority of supplied products are checked by the top management and main technologists before a contract is signed to find out whether these products will have the expected impact on V+K Mařákovi products. The only exception is gluten-free flour, which was also tested by an independent laboratory facility to find out whether the flour specification is correct. For the purposes of the standard the company will be able to document this procedure and to prepare similar systematic procedures for other supplies.

Incoming material requirements (raw/ingredients/packaging)

The verification of the quality and safety of the acquired material is controlled during unloading (control of seals, condition of material packaging). Acquired material specification is compared to the product specification to control whether acquired material is the one defined by the product specification. Non-conforming materials are returned back to the supplier and this return is documented. Unloading of the material is always controlled by the responsible person (either storage manager or a member of the top management).

Measures of Prevention of Cross Contamination

Microbiological cross contamination

Cross contamination issue was taken into consideration when the hazard analysis was conducted and the product flow was designed. Raw materials/intermediates and final products taken from the convection oven are processed at different tables and each of them is located on the other side of the process area. Storage facilities for raw materials, intermediates and for final products are divided by a wall to prevent the cross contamination.

Allergen management

This subchapter is relevant because the company produces not only classical baked products, but also gluten-free baked products. In order to prevent the cross contamination by the flour with the normal amount of gluten, products with normal flour are not produced during shifts when gluten-free products are produced. Before the beginning of the production, apart from regular cleaning procedures, special cleaning procedures are used on the equipment where some minimal amount of normal flour may still be present (e.g. roll flat machine). At the moment, the average amount of gluten in V+K Mařákovi products is around 30mg/kg in the final product. As defined by the law, products with gluten amount up to 100mg/kg of final product are considered as "gluten free" and products with gluten amount up to 20mg/kg in the final product are considered as "naturally gluten free." The goal of the company is to meet the 20mg/kg of the final product criteria in 2010.

Physical contamination

In the process area, no glass equipment is used (except durable glass window on the convection oven). Parts of equipment are adequately covered to prevent a potential physical contamination. Employees are instructed what they can and cannot wear into the process area.

Cleaning and Sanitizing

Cleaning and sanitizing agents and tools

Facilities and equipments are designed and maintained in a condition which enables easy wet and/or dry cleaning. Cleaning and sanitizing agents and chemicals are properly labeled and are suitable for the intended use. They are stored in a separate storage area.

Cleaning and sanitizing programmes

The cleaning and sanitizing programmes are defined for process areas, storage areas and other parts of the production plant. In each program, there is a definition of the area and the equipment which has to be cleaned and/or sanitized, when and how frequently will this take place, who is responsible for this task and how the result is controlled.

Cleaning in place (CIP) systems

This subchapter is not relevant for V+K Mařákovi as there are no systems in use which can be cleaned by CIP systems.

Monitoring sanitation effectiveness

The effectiveness of cleaning and sanitation programs is controlled by employees responsible for cleaning and sanitation results (e.g. shift managers, facility manager) and if needed, the cleaning and sanitation systems are updated to increase their effectiveness.

Pest Control

Pest control programs

At the moment, there are no written pest control programs used by the company. Pest control is conducted by a contracted company on the basis of its developed program.

Preventing access

Building, doors, windows and ventilation are kept in an appropriate condition to prevent pest access to V+K Mařákovi premises.

Harborage and infestations

Materials are stored appropriately to prevent the infestation. In case the stored material is infested, it is removed from the area and necessary steps to prevent contamination of other stored material are conducted.

Monitoring and detection

Pest monitoring and detection is done by placing traps in selected areas of V+K Mařákovi production plant. Traps are designed for the intended use and their locations do not pose any risk for the company products. Traps are regularly checked in order to identify the possible pest activity.

Eradication

If there is an evidence of infestation, a contracted company is contacted and necessary steps are conducted to locate and eradicate pest. This is conducted by a trained person to prevent possible contamination of raw materials, intermediates and final products and the whole process and the result are documented.

Personnel Hygiene and Employee Facilities

Personnel hygiene facilities and toilets

The company provides the appropriate number of hygiene facilities and toilets for the need of its employees. These facilities are not directly connected to the process and storage areas. Equipment for washing, drying and sanitizing hands is located at appropriate places including the entrance to the process area.

Staff canteens and designated eating areas

Staff canteen is located in the V+K Mařákovi production plant premises, but it is not directly connected with the process and storage areas. The food sold in the canteen is not produced in the production plant but it is delivered by an external company and it is either consumed after the delivery or warmed up in a microwave. All food provided by the external company or brought by employees can be stored and consumed only in the canteen area (appropriate equipment, such as refrigerator or plates and cutlery are available for employees).

Work wear and protective clothing

Employees are provided with the appropriate work wear. Visitors or contractors who enter process areas receive specific protective wear.

Health status

Employees, before they can start working in the process areas, undergo a medical examination where they receive a certificate that they can work for the processing industry. They don't need to undergo this examination if they already have a valid certificate.

Illness and injuries

An employee who does not feel good shall report this to the shift manager. Depending on the feeling, the employee is sent either home or to a medical examination. Any wounds or burns shall be appropriately covered.

Personal cleanliness and behavior

All employees are trained in order to know what kind of jewellery they may or may not wear when and where they are obliged to wash and sanitize hands and where they are allowed to smoke or to take their medicine. Fingernails shall be kept clean and trimmed and use of nail polish and false nails is prohibited.

Rework

Storage, identification, traceability and usage

The rework material is appropriately labeled so it cannot be exchanged with the final products by accident. There is also a specification whether the rework is gluten-free or not. The rework specification is defined so that the quality of rework cannot negatively affect the quality of the final product.

Product Recall Procedures

At the moment, no product recall procedures are specified. Top management sees this as a problem and a document describing product recall procedures is going to be developed during 2010.

Warehousing

Warehousing requirements

Storage areas are in the appropriate condition for the intended use. Where necessary, control of the temperature and humidity is installed. For all raw materials and intermediates, FIFO system is applied. Cleaning agents and chemicals are stored in the area separated from the storage of the raw materials and intermediates.

Vehicles, conveyances and containers

All vehicles used for the transport of V+K Mařákovi products are designed for this purpose. Company at the moment owns one truck used for the transport of products, the rest of transportation is provided by customers or contractors.

Product Information/Consumer Awareness

Product information and labeling

Packaging contains information required by the law. Because there is no packaging and labeling machine in use in the company, packing of products and

labeling is made by employees who control that every product has the right label.

Food Defense, Biovigilance and Bioterrorism

The V+K Mařákovi company premises are equipped by an alarm system connected to the security agency. During the time when the alarm system is switched off (e.g. when there are people at work), the only access for unauthorized persons is to the company shop, which is open for five hours per day during weekdays. Other entrances are locked and the only access for such persons is through the main entrance, where a bell and an intercom are connected to the office.

Proposed Quality Related Chapter

Consumer/customer related processes

At the moment, the product specification is defined by the company. This specification is in compliance with the regulatory requirements of the Czech Republic, which is the only country where V+K Mařákovi products are sold. If there are any special requirements defined by the customer, necessary changes are made to meet these requirements.

Before releasing the product specification, the whole document is controlled by both main technologists to find out whether the product specification is the same as decided and all previously confirmed updates are not included in the specification.

Design and development quality planning

Development of a new product is in V+K Mařákovi is a non-systematic process. Ideas mainly come from the top managers or the main technologist and it is usually on a trial and error basis. In case when an initial idea is accepted by the top management, product requirements of this subchapter are partly fulfilled as

requirements related to the quality and food safety and regulatory requirements are taken into consideration, but other requirements are not met. However, for the company it won't be a problem to develop a systematic plan for the development of new products.

Control of product and production quality

Criteria specified by this subchapter are almost fulfilled by the company. For each task described in the subchapter, there is a responsibility assigned to an employee (for example one technologist is responsible for the products and process description and specification, the shift manager is responsible for the control of the product conformance at the end of the shift or when product batch is finished etc.). To be in the full compliance with the requirements of this chapter, the company shall demonstrate (for example in a written form – a poster in the process area) that when conducting these tasks, one of the reasons is also to drive for quality.

Measuring and testing of the product

Product controls are conducted at appropriate stages of the production (e.g. consistency before baking, color and consistency after baking etc.). However, the criteria are not clearly defined and it is more on the responsible person (the shift manager or the main technologist) to decide whether the products are in conformance or not. Results of the final control are recorded. In order to meet the criteria of this subchapter, the company shall specify what is going to be controlled, in what stage of the production and by whom.

4.4.4 Audit Evaluation

The audit, conducted in order to find out whether FSSC 22000 is, with or without proposed changes to the standard, applicable in a small, regional company proved the universality of the standard. Either with or without the proposed quality related chapter, there are no requirements which may cause

insoluble problems for the company and therefore cause that the company cannot be certified against FSSC 22000.

Regarding the company itself, there are requirements, which are fully or partly met at this stage as these requirements are more of those, which are necessary to be met in every food production company. In order to be in compliance with the standard, there will be a lot of changes to the documentation needed as well as the revision of some fundamental tools, such as the HACCP system. But for the company, although it will be time and money consuming task, it should not be unrealizable to fulfill the criteria of the standard and it will for sure pay off in increased work effectiveness and achieving of possible new contracts.

We can say that thanks to the generality of ISO 22000 and the fact, that a company shall accept only those prerequisite programs from PAS 220, which are relevant, FSSC 22000 may be applicable in all food processing companies. And although the audit did not bring any concrete suggestion for the standard improvements, it proved its functionality.

4.5 Consolidation of findings and suggestions

To conclude the findings from both case studies and comparisons we can state that FSSC 22000 has the potential to be the truly global standard for the food processing industry. It may need more of the field work to bring better and more concrete changes to the standard (for example audits and evaluation of quality and food safety management standards in companies positioned in other parts of food supply chain), but at the moment its applicability in the processing companies was proved.

Regarding improvements to the standard suggested in the chapter 4.3.2., we can state that the company is able to fulfill the suggested criteria in the proposed quality related chapter. It is always hard to measure quality related improvements as the company does not have that many quality issues so the proposed results won't be reflected for example by a significant drop of the

non-conforming production, but it should be reflected in the long term period in for example customer satisfaction.

Regarding other possible future improvements, chapter 4.3.1. pointed out some features, which may be in the future incorporated into the standard in some ways. But as the only suggestions which can be tested by an audit were taken into consideration, these possible changes were not recommended. Their effects and values added shall be tested by some further work.

5 Conclusions

To conclude this thesis, it can be stated that hypothesis specified in chapter 2 was proved. There is a possibility of having one single global quality and food safety management standard, which will be accepted by both manufacturers and retailers. From the comparison of three major quality and food safety management standards, FSSC 22000 was selected as it offers versatility, its core part (ISO 22000) can be used in all parts of food supply chain and putting a great importance on HACCP system as a tool for safe manipulation and production of products.

The research and the audit in the experimental part showed us, that it can be used in any food manufacturing company, no matter whether the company is a large multinational entrepreneur, or a small regional producer. It was not verified, whether it can be, without any problems, used in other parts of supply chain, which shall be verified by some further work. Moreover, from the results of the experimental part, a recommendation of adding a chapter related to the quality was derived. Although requirements specified in this chapter may be covered by some other chapters, quality is not directly addressed in FSSC 22000 which may cause that some retailers (especially those who heavily rely on private label products) may require other quality and food safety management standards to secure quality and safety of these products.

Although the results are in favor of FSSC 22000, it is hard to predict whether it will really become a global standard, as markets, requirements of retailers and habits of producers differ significantly in different parts of the world. The decision of major retailer brands (such as Walmart, Tesco or Carrefour) may play a key role – if they decide to accept FSSC 22000, smaller companies may follow them. And, vice versa, preference of any other standards by these major retailers may cause that the situation will be the same as nowadays – different retailers who require different quality and food safety management standards and therefore a bigger pressure and unnecessary time and money consuming multiple audits and certifications for producers.

6 Bibliography

1) ISO web page - http://www.iso.org/iso/catalogue_detail?csnumber=39834 – downloaded 28.1.2010
2) LRQA web page - http://www.lrqausa.com/standards-and-schemes/141639-PAS220FoodSafety.aspx - downloaded 28.1.2010
3) Bureau Veritas web page - http://www.us.bureauveritas.com/wps/wcm/connect/BV_USNew/local/home/news/issue_4_cert_fssc_offering – downloaded 11.2.2010
4) ISO 22000 Tools web page - http://www.22000-tools.com/iso-22000-GFSI.html - downloaded 27.1.2010
5) Web page of "Výzkumný Potravinářský Ústav Praha" - http://www.vupp.cz/czvupp/04bezlepkove/index.htm - downloaded on 21.3. 2010
6) White Paper on Food Safety. Published by Commision of the European Communities, Brussels, 2000

7) Škopek B., Voldřich M.: Výroba potravin a jejich uvádění do oběhu. Verlag Dashöfer, 2004. Licence no. 04PW2134.

8) Rolková D., Mikulášková M., Šuška M., Voldřich M.: Komentované vydání ISO/FDIS 22000:2005. Národní informační středisko pro podporu kvality. Praha 2005. ISBN 80-7283-185-2

9) British Standards Institution web page - http://www.bsi-emea.com/Food+Safety/Standards/IFS.xalter - downloaded 8.11.2009

10) Hulebak K., Schlosser W.: HACCP History and Conceptual Overview - http://www.ce.ncsu.edu/risk/abstracts/hulebak.html - downloaded 8.11.2009

11) Southbank institute International web page - http://www.sbi.net.au/site/online/PREVIEW/HACCP/Critical%20Control%20Points/ccp/pages/decision_tree.htm - downloaded 22.1.2010

12) British Standards Institution: PAS 220:2008. British Standards Institution, 2008. ISBN 978-0-580-62878-8

13) Sansavat S., Muliyil V.: Understanding the FSSC 22000, SGS, 2009. Downloaded from www.sgs.com/foodsafety - 11.2.2010

14) Mařák M: Implementace Standardu IFS. Bakalářská práce. Česká Zemědělská Univerzita v Praze, 2007

15) International Food Standard, IFS, 2007

16) BRC Global Standard for Food Safety: Issue 5. British Retail Consortium, 2008. ISBN 9780117037915

17) Web page of Czech Agriculture and Food Inspection Authority (Státní Zemědělská a Potravinářská Inspekce) -

http://www.szpi.gov.cz/docDetail.aspx?docid=1003018&nid=11386&chnum=6 – downloaded on 25.11. 2009

18)Internal documents of the X-Food company

19)Internal documents of the V+K Mařákovi company

20)HACCP Servis web page - http://www.haccpservis.cz/ - downloaded on 25.11. 2009

21)Šebestová M., Staněk M.: Komentované vydání ČSN EN ISO 19011. ČNI, 2003. Catalogue number 91288

7 Supplements

7.1 Abbreviations list

IFS	-	International Food Standard
BRC	-	British Retailer Cnsortium
SQF	-	Safe Quality Food
GFSI	-	Global Food Safety Initiative
FSSC	-	Food Safety System Certification
ISO	-	Internal Organization for Standardization
HACCP	-	Hazar Analysis and Critical Control Points
ICMFS	-	International Commission on Microbiological Specification for Foods
FAO	-	Food and Agriculture Organization
WHO	-	World Health Organization
NACMCF	-	U.S. Natioanl Advisory Committee on Microbiological Criteria for Foods
CCP	-	Critical Control Point
FSIS	-	Food Safety and Inspection Service
GMO	-	Genetically Modified Organisms
PAS	-	Publicly Available Specification

PRP	-	Prerequisite Program
FSMS	-	Food Safety Management System
IAF	-	International Acreditation Forum
BSI	-	British Standards Institution
QMS	-	Quality Management System
Q&FS	-	Quality and Food Safety
R&D	-	Research and Development
QMP	-	Quality Management Process

7.2 FSSC 22000 Audit Checklist

Part 1 – ISO 22000 checklist

Food Safety management system checklist

Has the company developed and documented food safety management system which is in compliance with the requirements of FSSC 22000?

Is the required documentation created and appropriately maintained?

Management responsibility checklist

Is there evidence to show management commitment to Food Safety system application?

Does the company have a food safety policy?

Is the planning process related to food safety management system sufficient to meet the criteria of the standard?

Were responsibilities and authorities distributed?

Does company appoint a food safety team leader?

Are effective systems of external and internal communication in place?

Does the top management introduce procedures for managing potential emergency situations and accidents that can affect quality and safety of products?

Is the food safety management system appropriately reviewed?

Resource management checklist

Does the organization allocate resources necessary for the establishment and maintenance of the food safety management system?

Does employees who have an impact on legality, quality and safety of products appropriate education, skills and training to carry out their work?

Is the infrastructure adequate to the production of company products?

Is the work environment adequate to the production of company products?

Planning and realization of safe products

Are prerequisite programs and operational prerequisite programs in place to secure quality and safety of products?

Was all information necessary for the hazard analysis collected and documented?

Does the company conduct a hazard analysis? Was this hazard analysis complex enough to meet the criteria of the standard?

Were HACCP plans developed for each CCP?

Are any verification plans/procedures in place?

Is there any traceability system in place? Is this system complex enough to meet the criteria of the standard?

Are products considered as nonconforming appropriately identified and maintained?

Validation, verification and improvement of the food safety management system

How the control measures were selected?

Doe the company conduct validation of selected control measures?

Is there evidence, that used monitoring and measuring devices are capable of the sufficient control of products and/or processes?

Is there an audit plan in place used for the evaluation of the food safety management system?

Are outputs from communication, management review, internal audits, evaluation of individual verification results, analysis of results of verification activities, validation of control measures combinations, corrective actions and food safety management system updating used for the continuous improvement of the food safety management system?

Part 2 – PAS 220 checklist

Construction and layout of buildings

Are premises used for production and storage of company products appropriate?

Can the environment of the company premises put company products in any risk?

Are site boundaries appropriately marked?

Layout of premises and workspace

Are internal layout, traffic patterns and internal structures and fittings of the production plant adequate for the production of company products?

Is equipment located according to flow diagrams and is easy to clean and maintain?

Does the company have a contract with and external laboratory facility?

Are there any vending machines located in the company premises?

Are storage areas appropriately protected against dust, drains, waste and other source of potential contamination?

Is there an appropriate ventilation system in storage areas?

Are raw materials, intermediates and final products stored the way that pest control can be easily conducted?

Are raw materials, intermediates, final products, cleaning materials and chemicals stored in different storage areas?

Utilities – air, water, energy

Are provision and distribution routes for utilities appropriately designed and controlled?

What kind of water is used for the production of the company products? (Bottled / tap)

How the quality of the water used in the production process is secured?

Are there any boiler chemicals used in production?

Is air used as an ingredient?

Is compressed air or other gases used in production process?

Is ventilation adequate?

Is lightning appropriate for the needs of employees and are light fixtures protected?

Waste disposal

Are containers for waste adequately located in the production and storage areas?

Is waste management and removal appropriate for the production of the company products?

Are drains adequately designed and located?

Equipment suitability, cleaning and maintenance

Does the design of used equipment and product contact surfaces meet the criteria of the standard?

Is the equipments used for thermal processes capable of meeting the temperature defined in the product specification?

Are any sanitation plans in place? Does the company define responsibilities for and verification procedures of sanitation processes?

Have any corrective and preventive maintenance programs been developed?

Management of purchased materials

How raw materials and intermediates are acquired? Is this process in compliance with the requirements of the standard?

When, how and by whom is controlled acquired material?

Measures of prevention of cross contamination

How is the risk of potential cross contamination managed?

Are there any allergens used in production? How is the risk of contamination of products without allergens by allergens managed?

How is the risk of physical contamination managed?

Cleaning and sanitizing

Is the used equipment suitable for cleaning and sanitizing? Are cleaning agent suitable for the intended use and appropriately stored?

Dos the company develop any cleaning and sanitizing programs?

Does the company develop any cleaning in place systems?

How is the effectiveness of cleaning and sanitizing programs monitored?

Pest control

Does the company develop any pest control programs?

Are buildings, doors, windows and ventilation in a condition which prevents pest access to the company premises?

How material is stores with regards to the risk of infestation?

How pest monitoring and detection are conducted?

What is done when there is an evidence of infestation?

Personnel hygiene and employee facilities

Does the company provide an appropriate number of hygienic facilities and toilets for its employees? Are these facilities directly connected to the process and storage areas?

Are staff canteens and designated eating areas located the way that the risk of product contamination is minimized?

Does the company provide appropriate protective clothing for employees, visitors and contractors who enter process and storage areas?

How is health status of employees controlled?

How illness and injuries are reported and managed?

Does the company define any requirements regarding personal cleanliness and behavior?

Rework

How reworks are managed?

Product recall procedures

Does the company develop any recall procedures for its products?

Warehousing

Is the condition of storage areas appropriate for the intended use? Are there any monitoring devices in place? What system of material management is in place? How does the company store chemicals and cleaning agents?

Does the company own any vehicles used for the product transportation? Are these vehicles suitable for the intended use?

Product information / Consumer awareness

Does the product packaging contain all necessary information? Does the company introduce any procedures for packaging control to ensure that products have the right label?

Food defense, biovigilance and bioterrorism

How is the unauthorized entrance to the company premises prevented/managed?

Proposed quality related chapter checklist

Does the company take into consideration product specifications given by its customers? Are regulatory requirements of a country where products are produced and/or sold taken into consideration?

Who is responsible for the product specification and how is this specification reviewed?

How does the company develop new products?

Is this process systematic or nonsystematic?

Are quality related issues taken into consideration?

Is product quality and production quality appropriately controlled?

Does the company divide responsibilities regarding quality control of product and production?

How are product controls conducted?

Who is responsible for this control?

Are product controls specified in a form of a written document, including when, what and by whom the product will be controlled?