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CICLO XXXII

Making quality certifications effective for SMEs

Opportunities in the agri-food field amongst perceptions, experiences and evidences

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Abstract

Nowadays food security faces increasingly complex issues concerning bioterrorism, the protection of natural resources, the protection of workers, fair trade and solidarity. At the same time, public awareness of issues such as sustainability regarding the future of new generations and safeguarding the planet is increasing.

In the current context of global trade for a company it is increasingly essential to have a proven certificate of compliance with the standards recognized by the market. Undoubtedly, the obligation to apply the HACCP system in all agri-food sectors has brought food safety to such high levels ever before. Private quality standards ensure a further guarantee of risk prevention not only in terms of food safety but also in terms of environmental protection and sustainability.

This paper analyses the system of global trade combined with the issue of food safety by shedding light on issues such as accreditation, the coexistence of public standards and private standards, food crises and the health surveillance system, and finally the global distribution system.

The literature review aimed to outline a coherent picture of the current set of knowledge to identify trends in published research. The thesis, the methodologies, the strengths, the limits and the results of the various works consulted have been assimilated to carry out this work. Through extensive research on the subject, the work of other researchers has been critically assessed with a positive approach.

The topics addressed by the research project in the experimental section concern the degree of compliance of some small agri-food companies with the requirements of the private standards adopted. The procedures used in the research included a customized design phase on each production company studied. This involved the creation of work groups whose purpose was to analyse the corporate *status quo* and implement a series of positive actions aimed at creating a general agreement around the established objectives. In a case the data collected was analysed with the Principal Component Analysis to assess the degree of improvement in the path towards certification. In the other case, in addition to implementing a series of actions aimed at ensuring compliance with the prerequisites for food safety, the available data were processed in Linear Programming in order to optimize different production lines.

In this context, the identification of the main risks relating to the company as well as the correct criteria for managing these risks, and the ability to achieve the objectives is a fundamental requirement for a proper business management. It is also clear that companies have to be in tune with the demands of commerce. They have to implement measures to ensure adequate levels of compliance with food safety standards. However, SMEs do not always fully apply the prescribed specifications. Consequently, the need to simplify the procedures to harmonize the fairness between legal rules and voluntary norms is still a growing research area.

In conclusion, this study may be of benefit to small and medium-sized enterprises that intend to deepen their knowledge of global trade and want to qualify their quality management system and their products in order to achieve conformity certifications.

Sommario

Oggigiorno la sicurezza alimentare affronta questioni sempre più complesse che riguardano il bioterrorismo, la tutela delle risorse naturali, la tutela dei lavoratori, l'equità del commercio e la solidarietà. Parallelamente aumenta la sensibilità dell'opinione pubblica sui temi come la sostenibilità che riguardano il futuro delle nuove generazioni e la salvaguardia del pianeta.

Nel contesto attuale del commercio globale per un'azienda è sempre più indispensabile possedere una comprovata attestazione di conformità agli standard riconosciuti dal mercato. Indubbiamente l'obbligo di applicare il sistema HACCP in tutti i settori agro-alimentari ha portato la sicurezza alimentare a livelli talmente elevati mai raggiunti in passato. Gli standard privati di qualità assicurano un ulteriore garanzia di prevenzione dei rischi non solo in termini di sicurezza dei prodotti alimentari ma anche in termini di tutela ambientale e di sostenibilità.

In questo lavoro si analizza il sistema del commercio globale coniugato al tema della sicurezza alimentare ponendo luce su aspetti quali l'accreditamento, la coesistenza di norme pubbliche e standard privati, le crisi alimentari e il sistema di sorveglianza sanitaria, ed infine il sistema della distribuzione a livello globale.

La revisione della letteratura ha mirato a delineare un quadro coerente dell'attuale insieme di conoscenze per identificare le tendenze nella ricerca pubblicata. La tesi, le metodologie, i punti di forza, i limiti e i risultati delle varie opere consultate sono stati assimilati per svolgere questo lavoro. Attraverso una ricerca approfondita sull'argomento, il lavoro di altri ricercatori è stato valutato criticamente con un approccio positivo.

I temi affrontati dal progetto di ricerca nella sezione sperimentale riguardano il grado di compliance di alcune piccole aziende agroalimentari ai requisiti richiesti dagli standard privati adottati. Le procedure adottate nella ricerca hanno compreso una fase di progettazione personalizzata su ogni realtà produttiva studiata. Ciò ha comportato la costituzione di gruppi di lavoro il cui scopo è stato di analizzare lo *status quo* aziendale e di implementare una serie di azioni positive volte a creare consenso consapevole intorno all'obiettivo stabilito. In un caso i dati raccolti sono stati analizzati con la Principal Component Analysis per valutare il grado di miglioramento nel percorso verso

la certificazione. Nell'altro caso, oltre a implementare una serie di azioni volte a garantire il rispetto dei prerequisiti per la sicurezza alimentare, i dati a disposizione sono stati elaborati in Linear Programming al fine di ottimizzare differenti linee produttive.

In questo contesto, la capacità di raggiungere un obiettivo è un requisito fondamentale per la moderna gestione aziendale. È anche chiaro che le aziende devono essere in sintonia con le esigenze del commercio. Devono implementare misure per garantire livelli adeguati di conformità agli standard di sicurezza alimentare. Tuttavia, le PMI non applicano sempre pienamente le specifiche prescritte. Di conseguenza, la necessità di semplificare le procedure per armonizzare le norme giuridiche e le norme volontarie nel rispetto del loro rigore è tuttora un'area di ricerca in crescita.

In conclusione, il presente studio potrà essere di beneficio per le piccole e medie imprese che intendano approfondire la conoscenza del commercio globale e vogliano qualificare il proprio sistema di gestione della qualità ed i propri prodotti al fine di conseguire certificazioni di conformità.

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List of acronyms

AAC	Administrative Assistance and Cooperation
AIC	Italian Coeliac Association
B2B	Business to Business
B2C	Business to Consumer
BAP	Best Aquaculture Practices
BRC	British Retail Consortium
BSE	Bovine Spongiform Encephalopathy
CAGR	Compounded Average Growth Rate
CAS	Chemical Abstracts Service
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCPs	Critical control points
CDC	U.S. Center for Disease Control and prevention
EC	European Community
ECDC	European Centre for Disease prevention and Control
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ENRD	European Network for Rural Development
ESA	European Seed Association
ETP	Ethical Tea Partnership
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FBOs	Food and feed business operators
FDA	U.S. Food and Drug Administration
FEFANA	European Association of Special Feed Ingredients and their Mixtures
FLO	Fairtrade Labelling Organizations International
FSSC	Food Safety System Certification
GAA	Global Aquaculture Alliance

GAPs	Good agricultural practices
GATT	General Agreement on Tariffs and Trade
GFSI	Global Food Safety Initiative
GHPs	Good hygiene practices
GlobalGAP	Global Good Agricultural Practices
GMO	Genetically Modified Organism
GMPs	Good manufacturing practices
GPOs	Group Purchasing Organizations
GRMS	Global Red Meat Standard
GSSI	Global Sustainable Seafood Initiative
GWP	Global Warming Potential
HACCP	Hazard analysis and critical control points
HARPC	Hazard Analysis method and Risk-Based Preventive Controls
HFAC	Humane Farm Animal Care
IFIF	International Feed Industry Federation
IFOAM	International Federation of Organic Agriculture Movement
IFS	International Featured Standards
IMF	International Monetary Fund
ISEAL	Intern. Social and Environmental Accreditation and Labelling Alliance
ISTAT	Italian National Statistical Institute
JFMA	Japanese Feed Producers Association
MSC	Marine Stewardship Council
NGOs	Non-governmental organizations
NOP	U.S. National Organic Program
OECD	Organization for Economic Co-operation and Development
OPEC	Organization of Petroleum Exporting Countries
PCA	Principal Component Analysis
PDO	Protected Designation of Origin
PGI	Protected Geographical Indication
ppm	parts per million
RA	Rainforest Alliance
RASFF	Rapid Alert System for Food and Feed

REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SAI	Social Accountability International
SAN	Sustainable Agriculture Network
SFIS	Specialty Feed Ingredients Sustainability
SOP	Standard Operating Procedure
SQF	Safe Quality Food standard
TRACES	Trade Control and Expert System
TSG	Traditional Specialities Guaranteed
UNI	Italian National Unification Agency
USDA	United States Department of Agriculture
vCJD	variant of Creutzfeld-Jacob Disease
WHO	World Health Organization
WTO	World Trade Organization

Dissertation Structure

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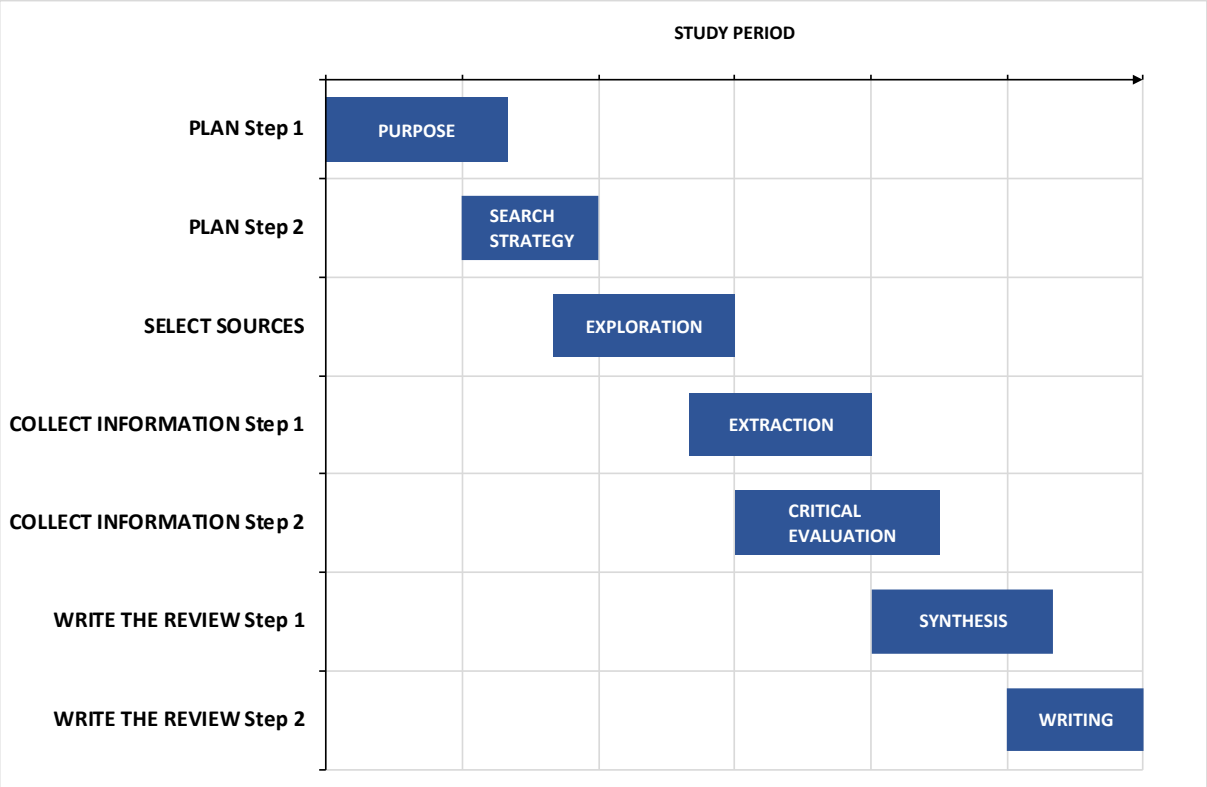
Introduction

Preface to the research study

The introduction provides a broad examination of what has been published on the topic in order to place this work within the broader academic discussion on the topic. We considered the point of view of the different sources, the convergence and divergence of the conclusions. In this context, the present work has sought its place on the basis of the research results.

Figure 1. Planning of the literature review study for this research.



(Chart created by the author)

Due to the complexity of the subject, there has been a predominantly thematic approach to reviewing the literature, which has examined the technical, economic and social aspects. In addition, the different aspects of the topic have been linked and organized in order to identify changes over time due to scientific progress and changed conditions of global trade.

The purpose of this literature review is to examine the impact of legal and voluntary rules on business management to support the quality standards of the processes, products and services provided. To study the effect of implementing standards on business performance, research has primarily been considered over the past two decades. Overall, the application of legal rules and the implementation of voluntary rules were found to be the most effective means of ensuring food safety and opening the doors to the global market.

In summary, the introduction presents the general aspects of quality, accreditation and certification. In addition, the technical aspects of the prerequisites and requirements to ensure food safety are outlined. Finally, harmonization between public and voluntary private standards is outlined, taking into account modern production sustainability needs to protect the planet and future generations.

In this context, this research work assessed the compliance of some companies with the legal requirements and specifications of the voluntary standards. Furthermore, it analysed the degree of awareness of management regarding the management, production and economic choices made.

Background

Chapter 1

Quality and certification

Food quality in today's context

Nowadays, technological progress has reached high levels but at the same time a profound economic crisis challenges global well-being and safe and sustainable food production. These are challenges to be faced and completed successfully. Food safety is based on hazard prevention, risk control from the production site to the point of consumption along the entire supply chain. The guarantee of quality and safety can only be achieved through the joint efforts of governments, supranational institutions, producers, processors, wholesalers, traders, distributors, retailers and consumers. So, now more than ever one of the important issues is that the commitment of all parties is able to maintain the level of food safety in the world.

Evolution of the concept of quality

Quality is a property applicable to individual objects, projects, processes, actions and things, which characterizes particular functions, activities, uses, aspects and conditions. The definition of quality has changed over time. In the classical age of the fourth century BC, according to the western philosophical thought of Aristotle[1], quality distinguishes two objects on the basis of peculiar characteristics and therefore describes a specific difference. Therefore, the quality is given by the characteristics of the object that can be determined with the help of one or more of the five senses. Later, in the Middle Ages, the meaning of quality handed down from school philosophy, that is, the concept of quality defined as material, or real, was flanked by the concept of hidden or hidden quality, intended as a characteristic of the object that is not perceived with the senses but through its effects (De Crescenzo, 2017). In the modern age in the 16th century, René Descartes[2] he stated that knowledge of all knowledge can be understood according to a sure method of rationality, clarity and distinction. According to the

[1] Aristotle was a Greek philosopher (Stagira, 384-83 BC – Calcide, 322 BC). He was, with Socrates and Plato, one of the greatest thinkers of the ancient past and of all time. (Source: Treccani)

[2] René Descartes (31 March 1596 – 11 February 1650) was a French philosopher and mathematician. He is considered the founder of mathematics and modern philosophy. (Source:Treccani)

rational thinking of Galileo[3], the so-called primary quality refers to each objective and authentic property of the object as form and quantity, measurable and describable. While secondary qualities, such as colours, smells, flavours and sounds, influence the sense organs and are therefore subjective. In this capacity, they would provide inaccurate information on the intrinsic qualities of objects. On the contrary, according to the empirical thought of Locke[4], there are no scientific principles that can be considered absolutely valid, to the point that reason requires the constant support of experience to avoid reaching wrong conclusions. In the contemporary age, the concept of quality embraces a wide range of values and meanings. In the broadest sense, quality characterizes an object, a product, a professional, a service or their whole, as regards the functional aspects of use and performance. In the current era of global trade, the connotation of quality is always included with the value of positivity. In addition, to achieve the concept of quality, the well-being of society passes through the protection of the environment, the promotion of conditions in emerging countries, animal welfare and a rational use of natural resources. Consequently, the level of well-being of society, that is the quality of life, extends beyond the quality needs of products and services. In this context, quality certification takes on the meaning of certifying the high value of the entire production chain and of maintaining the high value of a product or service in increasingly competitive market conditions.

[3] Galileo Galilei (15 February 1564 - Arcetri, 8 January 1642) was an Italian physicist, astronomer, philosopher, mathematician and academic, considered the father of modern science. (Source:Treccani)

[4] John Locke (August 29, 1632 – October 28, 1704) was a British philosopher and physician, theorist of modern empiricism (which places in sensory and perceptual experience the only valid source of knowledge) and one of the most influential advancers Enlightenment and criticism. The Enlightenment in the 17th century, in addition to the political aspects, was characterized by the affirmation of the strict use of reason and empirical method in science. Later, according to the philosopher Kant (Königsberg, 1724 - 1804), criticism presupposes that cognitive activity has limits beyond which one cannot go without producing empty knowledge, therefore a knowledge that is no longer such. (Source:Treccani)

Quality and trade

The globalization of the agri-food market has stimulated the progress of food technology in the sectors of preparation, processing and packaging, in order to allow the distribution of products for safe consumption. This involved sharing efforts and responsibilities throughout the supply chain. The supply chain often crosses national borders and includes production, processing, transportation, storage, retail outlets and even the consumer's home. Globally, actors in the supply chain have an obligation to comply with national and supranational food safety Regulations to provide safe products in line with the expectations of retailers and consumers. In recent decades, numerous codes of good practice have been issued that help members of different categories of the agri-food industry to implement their food safety management systems. These codes of good practices have been implemented with the aim of allowing better compliance with the requirements of international standards. In this context, government institutions still play a leading role in establishing basic food safety standards to protect public health. However, the efforts of governments must be continuous because the evolution of scientific knowledge and the consequent industrial technological development require the timely updating of existing standards.

On the one hand, private standards operate in compliance with the law, meeting the specific needs of the market whose complexity requires the fulfilment of the food safety needs of large distributors. On the other hand, it is important to remember that maximizing profits or the ability to make the most profit with reduced operating costs is one of the major results desired by retailers. It appears to be a priority to minimize the costs caused by product compliance disputes. Furthermore, it is necessary to rationalize the costs related to logistics by optimizing the different phases of the supply chain. The role of the mandatory legislative framework, in addition to protecting food safety, is also to merge the pressures of the interests of the food industry with the needs of consumers in terms of environmental protection and sustainable development. Private certification schemes have evolved by embracing sustainability needs in the interest of interested parties. Although public standards are the minimum quality standard and protect the public health of consumers, they do not allow agri-food companies to differentiate (Fulponi, 2006), while the application of private standards would seem more rigorous.

In order to obtain a greater share of the national, regional and international market, the voluntary use of private standards allows a better characterization of the company (Smith, 2009). These factors mean that although public standards are universally adopted, private standards tend to be the dominant form of control in the agri-food system. Certifications are often required by large commercial chains operating in more developed markets, but the interaction and mutual influence between public and private quality standards is significant. The affirmation of voluntary standards has changed the parameters of market competition from the centrality of prices to that of centrality of quality (Henson & Reardon, 2005). Certifications can include products, services, management systems or other related activities. Organizations are committed to continuously improving the quality of their products and services for consumers. Compliance with certification requirements, as established by certification bodies, indicates that the company has specific knowledge, quality, skills and abilities. Ultimately, certification demonstrates that organizations perform quality-managed processes by applying standards requirements and improving practices. Thus, they would prove qualitatively better than non-certified competing organizations.

EU food safety rules

Council Directive 93/43 / EEC of 14 June 1993 on food hygiene and the subsequent hygiene package dictate the general principles and specific rules for the production of food products along the food supply chain. The European Union's hygiene rules focus on the need to protect public health in an effective and proportionate way to the risks. The rules that establish specific requirements for the hygiene of food and animal products have been in force since 2006 and are aimed at food and feed business operators (FBOs) and the competent authorities responsible for controls. The sharing of responsibilities identified by the new legislation is very clear. Food and feed business operators are responsible for effective control of food production. They must ensure compliance with the new EU food hygiene rules. In addition, for FBOs other than primary production producers, these procedures must be based on the principles of hazard analysis and critical control points (HACCP). The EC Regulations for food and feed business operators include No. 852/2004 on general hygiene of food products and No. 853/2004 on specific hygiene standards for products of animal origin. According to

Regulation (EC) No. 852/2004, after primary production and associated operations, FBOs at any stage of food production, processing and distribution must implement procedures based on HACCP principles. The EC Regulations for the competent authorities include No. 854/2004 on specific rules for the organization of official controls on products of animal origin intended for human consumption and No. 882/2004 on official controls to guarantee the verification of conformity of feed with food law about animal health and welfare. In particular, Regulations (EC) No. 854/2004 and No. 882/2004 establish specific rules for the organization of controls and to ensure the verification of compliance of the implementation and the correct management of the HACCP system in food businesses.

Quality certifications

As is known, the agri-food production system includes the phases of purchasing raw materials, processing of products, packaging, storage, transport, distribution and trade. General Food Law (EC) No. 178/2002 introduced responsibility for all food and feed operators in the production of safe food. According to the law, they must have a system that allows them to identify the suppliers and customers of their products in order to guarantee traceability[5]. Since 2006, a package of European Regulations has entered into force to guarantee legislative food safety. At the same time, large retailers have developed quality control systems on their suppliers to ensure the safety of products placed on the market. This approach has allowed the development of many standards that have become benchmarks in recent years. These standards are certified by third-

[5] Supply chain traceability means the possibility of reconstructing - from the batch code on the packaging - all the steps in the production of a food together with the documentary system that accompanies the product from the field to the table. Instead, with traceability we mean the possibility of reconstructing the reverse path "uphill" thanks to the information available along the supply chain.

party certification bodies accredited by national accreditation bodies[6]. Furthermore, while in the recent past a massive commercial development of organic products has started (Willer et al., 2017), today sensitivity to the concept of sustainability of agri-food production is growing. This new trend aims to support integrated and sustainable production in order to have an overall positive impact on the planet, on the workers concerned, on businesses and finally on the economy of the food industry.

According to Accredia (2019), the Italian national accreditation body, the number of product and system certifications has remained stable in recent years. The main reason is that market demands push companies to invest in competitiveness through complex inspection and verification systems that are implemented through certification. Companies want to gain credibility, reputation and competitiveness in order to increase corporate income (Il Sole 24 Ore, 2015). For example, with regard to the organic products sector, in the Emilia-Romagna region alone in June 2018, 5040 farms were certified covering 15% of the agricultural area cultivated in the region. Another 1200 certified companies have been involved in the processing and marketing of these products (Emilia-Romagna Region, 2018). Therefore, accreditation is an added value for companies and represents a guarantee of the quality of processes and products. We must not forget that it is also an important tool of trust for consumers. Today, large retailers increasingly use accreditation to protect their market and consumers, and it has become a custom in commercial relations as it requires a qualified assessment of compliance with the parameters. Companies that have the ambition to become certified know that they have a commitment that goes far beyond the already strict legal rules and / or EU Regulations. Ultimately, the quality management systems, if applied

[6] The International Accreditation Forum is the worldwide association of accreditation compliance assessment bodies in the field of management systems, products, services, staff and other similar compliance assessment programs. The European Cooperation for Accreditation (EA) is a European association of national accreditation bodies, officially recognized by their national governments, for compliance assessment. The Italian Accreditation Authority ACCREDIA, a member of the EA, is indicated by the Italian Government and recognized on the national territory to attest to the compliance of certification and inspection bodies.

correctly, guarantee design, development, production, distribution and after-sales assistance. They allow a reduction of costs in the supply chain in both economic and public health terms.

Regulatory and voluntary certifications

Regulatory certifications have legal value throughout the European Union and refer to the protection of typical products as described in the following paragraph. In addition, there is a series of voluntary certifications issued by accredited third-party bodies that certify the compliance of systems, processes and products with specific technical management standards. Regulatory and voluntary certifications guarantee compliance, quality and safety of processes and products and, as already mentioned, retailers require their suppliers to meet these standards. The interesting thing is that the process of acquiring and maintaining the certification allows the agri-food company to offer a better product. Optimizing the various factors of production, supply and logistics that together contribute to the result, meet the requirements. However, all the factors involved must be consistent in order to achieve an optimal balance between production, profit and quality of the system. Below are some of the most popular certifications that do not neglect the certification schemes of organic products. Indeed, organic products are experiencing a period of considerable commercial development and expansion (Willer et al, 2017).

Regulated European certifications

Table 1. Regulated European certifications

Reg. (EU) 2273/2017	Regulation amending Regulation (EC) No. 889/2008 concerning the application of Regulation (EC) No. 834/2007 of the Council concerning organic production and labelling of organic products, with regard to organic production, labelling and controls.
Reg. (EC) 834/2007	Regulations on organic production and labelling of organic produce.
Reg. (EU) 1151/2012	Regulations on quality regimes for agricultural and food products: PDO, Protected Designation of Origin; PGI, Protected Geographical Indication; TSG, Traditional Specialities Guaranteed.
Reg. (EC) 479/2008	Regulations on the common organization of the wine market: PDO (wine) Protected source name; PGI (wine) Protected geographical indication.

Voluntary System certifications

The rigorous approach to quality guarantees an organization's ability to structure and manage its resources and production processes in such a way as to identify and satisfy the needs of customers and stakeholders, i.e. those who have interests in the activity of an organization or company and influence its decisions.

Table 2. Voluntary system certifications

UNI EN ISO 9001[7]	Quality management system.
ISO 14001	Environmental management system.
OHSAS 18001[8]	Workplace health and safety management system.
ISO 22000	Food safety management system; requirements for any organization in the food chain.
FSSC 22000[9]	Certification of the food safety system on food processing; methods in agriculture and food packaging production.

[7] UNI: Italian National Unification Authority. EN (CEN): Comité Européen de Normalisation. ISO: International Organization for Standardization.

[8] OHSAS: Occupational Health and Safety Assessment Series. By March 2021 companies already equipped with a Management System for Health and Safety in the Workplace according to the OHSAS 18001: 2007 standard will have to migrate to the ISO 45001 standard.

[9] FSSC: Food Safety System Certification.

Voluntary Process Certifications

They are complementary to system certifications. The approach to the process is based on the evaluation of the production processes to provide products that conform to the production methods. It is interesting to note that the UNI 11233 standard on integrated production systems can be considered the link between conventional agriculture and organic agriculture.

Table 3. Voluntary Process Certifications

ISO 22005	Traceability in the food and food chain.
Non-GMO[10]	Production free from genetically modified organisms.
UNI 11233	Integrated Production Systems in Food Supply Chains.

[10] GMO: Genetically Modified Organisms.

Voluntary Product certifications

They are complementary to system certifications. The approach to the product aims to ensure product compliance with certain requirements that directly characterize the ability to meet the needs of large retailers.

Table 4. Voluntary product certifications

BRC[11]	Good manufacturing practices.
IFS[12]	Food safety insurance and production process optimization.
GlobalG.A.P.[13]	Good agricultural practices for crop production, livestock farming and aquaculture.

[11] BRC: British Retail Consortium.

[12] IFS: International Food Standard.

[13] GlobalG.A.P.: Global Good Agricultural Practice.

Biological Certification Schemes

EU Organic

The Organic logo is the label issued by the European Union to distinguish organic farming products. Each operator (farmer, processor, trader, importer or exporter) is checked at least once a year or more often on the basis of risk assessment and in accordance with strict environmental and animal welfare standards. With the EU organic logo on packaging, consumers are informed of where the agricultural raw materials used in that product were grown. A code number issued by the supervisory authorities is also displayed.

USDA Organic

USDA [14] Organic is the label issued by the United States Department of Agriculture for agri-food products compliant with the National Organic Program (NOP) which establishes the standards for the production, handling and labelling of all organic products. The NOP also manages a manual for use by professionals of the sector which includes indications, instructions, notes on approaches and other documents that describe the biological standards required to provide and apply a uniform definition on the market for the term organic.

[14] USDA: United States Department of Agriculture.

Religious Certification Schemes

Halal

In the food sector, *halal* certification ensures that food, in addition to complying with European hygiene and safety Regulations, is prepared and compliant with Islamic doctrine. In Italy, the World Halal Authority (WHA) is the body responsible for the *halal* audit of food, livestock, cosmetic and pharmaceutical companies. In addition to the company identification data, a *halal* certificate shows the WHA product code in alphanumeric code, the category of the product (food) and the period of validity (Camera di Cooperazione Italo-Araba, 2019).

Kosher

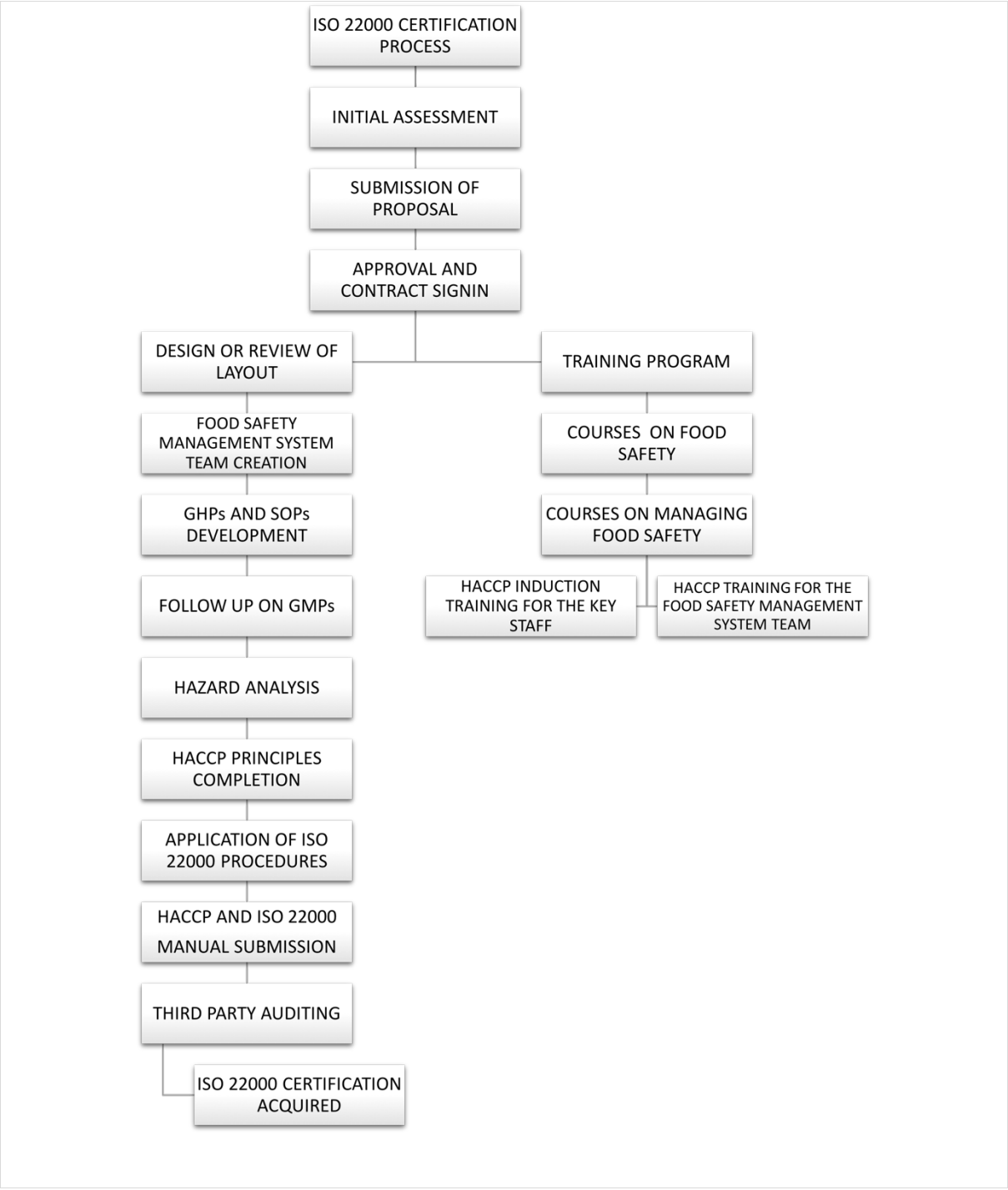
Kāshēr or *kosher food*, are prepared according to *kashrut*, the Jewish food precepts. *Kosher* products comply with current food safety Regulations. In the United States, the Union of American Orthodox Jewish Congregations known as the Orthodox Union is one of the oldest Orthodox Jewish organizations and, thanks to its *kosher* supervision service, guarantees compliance with the requirements of the *kosher* disciplinary (IKU Israel Quality Assurance, 2019).

Certification process

In short, and by way of example, a certification process includes the analysis of the documentation and the certification audit[15], the assessment of the certification body and the issue of the certificate. The surveillance audit follows, generally every 12 months, and the certification audit upon expiry, usually after 3 years.

[15] Auditing is the process of reviewing processes and certification of company systems by independent professionals (auditors), often organized in specialized auditing companies.

Figure 2. Diagram of the ISO 22000:2005 certification process.



(Chart created by the author)

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Chapter 2

Accreditation

Accreditation and certification

According to Michael Scriven's theory, the evaluation of the quality of a product, process, profession, institution, service, etc., presupposes that the exact characteristics of the object of evaluation are established upstream (Wanzer, 2019). The next step characterizes the methods for measuring or making these characteristics measurable and the frequency of audits. Finally, it is essential to establish the figure of the evaluator. It can be a qualified auditor serving an accreditation body or a certification body (Scriven, 2003). Global commodity trading is complex. It requires continuous monitoring and evaluation of the safety of the products traded (Ropkins, 2003). This guarantee can be ensured by independent certification bodies which in turn must be accredited by the national accreditation bodies. The latter are established by the governments of many countries with the primary purpose of ensuring that third-party certification bodies - those that actually certify - are subject to the control of an authoritative body to ensure its fairness. In other words, accreditation is the independent evaluation carried out, in relation to recognized standards, on certification bodies in order to guarantee impartiality and competence. National accreditation bodies, whose authority is protected by the laws issued by their respective national governments, are delegated to accredit certification bodies operating in the relevant territory. The accreditation of a certification body is usually voluntary. As mentioned, it is conducted by government agencies operating in accordance with the international standard ISO / IEC 17011[16] and the rules established in international mutual recognition agreements. As a result, subjects such as accredited bodies and laboratories could be more competitive in the certification market. Accreditation is mandatory for bodies and laboratories that carry out activities in sectors regulated by European or national directives or Regulations, such as organic food

[16] The UNI CEI EN ISO / IEC 17011: 2018 standard on conformity assessment and the requirements for accreditation bodies that accredit conformity assessment bodies, dictates the requirements for competence, regular and consistent operation and impartiality of the accreditation that assess and accredit conformity assessment bodies (UNI - Ente Nazionale Italiano di Unificazione, 2019).

products and guaranteed geographical indications, which can be placed on the market only after they have been certified as conforming to the reference standards.

Table 5. Essential glossary of quality assessment.

ITEM	DESCRIPTION
Accreditation	It is a process by which an authoritative body formally recognizes the competence of a certification body to provide certification services against an international standard.
Certification	It is a process that involves an audit, according to which the accredited certification bodies provide written guarantees that the food safety requirements and management systems and their implementation comply with the requirements.

(Source: GFSI, 2019)

Accreditation bodies

Both European Commission Regulation No. 765/2008, which establishes the standards for market accreditation and product marketing supervision, and the ISO / IEC 17000 series standards, provide the set of rules to which they are aligned EA (European Cooperation for national accreditation) and accreditation bodies. EA is a European association of national accreditation bodies that are officially recognized by their respective national governments for the assessment of certification, verification, inspection, testing and calibration conformity (EA, 2019). For example, the UK Accreditation Service, UKAS, is the UK's national accreditation body which guarantees the technical competence and authority of certification and testing bodies (UKAS, 2019). On the other hand, in Italy there is Accredia, the only national accreditation body indicated by the Italian government. Ensures that certification and inspection bodies and test and calibration laboratories have the skills to assess compliance with the reference standards of products, processes and systems, also for the agri-food sector (Accredia, 2019). Overseas, the American National Standards Institute, ANSI, is a private non-profit organization that sets industry standards for the United States (ANSI, 2019). ANSI is a member of ISO. The International Organization for Standardization (ISO) is an independent international non-governmental organization that develops international

standards applicable to public and private companies (including agri-food) to support process innovation (ISO, 2019).

Table 6. National accreditation bodies.

COUNTRY	**ACCREDITATION BODY**
Austria	AKKREDITIERUNG AUSTRIA
Belgium	BELAC
Bulgaria	BAS
Canada	Standards Council of Canada
Croatia	HAA Croatian Accreditation Agency
Cyprus	CYS-CYSAB (Cyprus Organization for the Promotion of Quality)
Czech Republic	CAI (Czech Accreditation Institute)
Denmark	DANAK
Estonia	EAK
Finland	FINAS Finnish Accreditation Service
France	COFRAC (Comité français d'accréditation)
Germany	DAkkS (Deutsche Akkreditierungsstelle GmbH)
Greece	ESYD
Hungary	NAH
Ireland	Irish National Accreditation Board
Italy	ACCREDIA
Latvia	Latvian National Accreditation Bureau (LATAK) State Agency
Lithuania	National Accreditation Bureau
Luxembourg	OLAS
Malta	National Accreditation Board (NAB, Malta)
Netherlands	RVA (RvA)
Norway	NA (Norsk Akkreditering)
Poland	PCA (Polish Centre for Accreditation)
Portugal	IPAC (Instituto Português de Acreditação, I.P.)
Romania	RENAR

Slovakia	SNAS (Slovak National Accreditation Service)
Slovenia	SA (Slovenian Accreditation, Slovenska akreditacija)
Spain	ENAC
Sweden	SWEDAC
Switzerland	SAS (MRA)
Turkey	TURKAK (Turkish Accreditation Agency)
United Kingdom	UKAS

(Source: http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=ab.main)

Multilateral agreements

Through the signing of multilateral agreements or agreements between three or more parties, such as agencies or national governments, the equivalence on the market of certifications, inspections, verifications, tests and calibrations carried out by accredited bodies and laboratories is ensured (EA, 2018). The negotiated agreement is legally applicable and provides for an agreement for the adoption and acceptance of a minimum performance standard. The purpose of multilateral agreements is to reduce technical barriers to trade, facilitate trade and ensure the quality of products and services. Peer review[17] requires a community of experts in a certain field, qualified and able to perform reasonably impartial reviews. Therefore, accreditation bodies can work on this mutual recognition substrate.

International Accreditation Forum

The International Accreditation Forum is the worldwide association of accreditation bodies for certification bodies in the field of conformity assessment of management systems, products, services, staff and other programs (IAF, 2019). The

[17] Peer review or peer-to-peer evaluation, or peer evaluation, evaluates the performance of similar members with corresponding competencies.

purpose of the IAF is to guarantee the objectivity of national accreditation bodies to comply with recognized international standards. By developing a single global conformity assessment program, the IAF ensures that businesses and customers have guarantees on the results of verification, testing and inspection that should issue certifications.

International Laboratory Accreditation Cooperation

The International Laboratory Accreditation Cooperation is the world federation of accreditation bodies for inspection bodies and test and calibration laboratories. ILAC is responsible for the accreditation of conformity assessment bodies, including calibration laboratories, test laboratories, medical analysis laboratories and inspection bodies (ILAC, 2019). Through the application of national and international standards, governments, customers and consumers can trust the calibration and test results, inspection reports and certifications provided.

Auditing process

The certification activity involves procedures that end with the adoption of declarations of conformity, such as certificates, notifications and the like. In some of these acts, the aspect of the evaluation is as important as the moment of acquisition of the fact to be ascertained, the inspections and the issue of certificates. In other documents, communication outside of what has been acquired is relevant, as in information publications. In particular, the certificate of conformity is a declaration that certifies a state or quality that has been ascertained by a qualified and accredited third party. Companies can undergo a conformity assessment following a voluntary decision made within senior management. However, an increasing number of sectors subject to EU Regulations are planning to acquire a consistent certification. For example, for the agri-food sector, some categories of typical products can circulate on the market only after respecting the peculiarities of the product specifications (European Commission, 2019). In any case, the checks, inspections, tests and anything else must be carried out by accredited bodies and laboratories.

In the food sector, voluntary certification is carried out by qualified and accredited certification bodies able to demonstrate their organizational, technical and financial reliability. According to the classification of economic activities in Italy, the agri-food sectors are codified as sector No. 01 Agriculture, forestry and fishing and as sector No. 03 Food, beverage and tobacco industry. Companies wishing to confirm their commitment in order to acquire and maintain positions on the market are subject to the expected audits from which the certification of conformity derives.

According to the established requirements, the formal audit procedure allows accredited agencies to carry out inspections and compliance checks. In particular, attributes and characteristics of goods or services, the status of individuals or organizations and the procedures and processes of events or situations occur. The positive result of the audit certifies that the good or service provided fully meets the specific requests. Some rules allow the affixing of a certification mark which is the symbol authorized to be affixed to the goods after carrying out the tests prescribed by the specification.

1st, 2nd and 3rd parties' audits

The conformity assessment process involves carrying out checks carried out along the entire production and commercial chain. In other words, along the path from the field to the table. The audits are conducted in the interest of companies and consumers so that they can guarantee a final product in line with the principles of public health (Accredia, 2019).

A first-party audit is an internal audit carried out by expert supervisors of the company. The goal is to measure the strengths and weaknesses with respect to their own procedures and with respect to mandatory standards. The audit also serves to verify compliance with any voluntary standards adopted.

A second-party audit is a check performed by a customer on his supplier. Verify compliance with the contractual rules between the parties. However, the contractual rules must comply with the mandatory industry standards (packaging, labelling, etc.). The client company therefore protects its production by verifying that the raw materials, plants and services provided comply with public Regulations and recognized standards.

A third-party audit is performed by an independent certification organization free of conflicts of interest with the customer and its suppliers. The result of a third-party audit produces a certification of compliance with a certain standard or a finding of non-compliance. In this context, various aspects related to production are assessed, such as good agricultural practices, good manufacturing practices, management systems, environmental protection, workplace safety and sustainability programs.

The procedure for acquiring a certification formally begins with the mandate to a certification body. First of all, the certification body carries out a preliminary check of the company structures and production operations and performs an examination of the documentation. Therefore, an auditor authorized and appointed by the certification body performs an on-site audit. Finally, if the conditions of compliance with the chosen standard are detected, the certification body issues the certification and authorizes the customer to label its products or processes as certified. The certification must be checked and renewed periodically every year according to the standard protocol. The costs of the entire procedure are borne by the customer.

Features of the auditor

The UNI EN ISO 19011: 2018 standard on audits of management systems for quality, the environment and the health and safety of workers, is dedicated to the management of internal audits carried out by company personnel and external audits performed by the customer on the supplier. For third party audits performed by certification bodies, the main reference is ISO 17021-1: 2015[18]. To assess the competence of management system auditors, it is necessary to consider the level of education, the training received, the experience acquired in the task. In addition, the auditor must possess some role-specific peculiarities such as correct, diplomatic,

[18] The UNI CEI EN ISO / IEC 17021-1: 2015 standard on conformity assessment and requirements for bodies that provide audits and certification of management systems, indicates the principles and requirements for the competence, consistency and impartiality of the bodies which control and certify all types of management systems (UNI - Ente Nazionale Italiano di Unificazione, 2019).

insightful behaviour. While the chief auditor needs the necessary leadership qualities for staff conduct.

To carry out an audit, the team of auditors must work in harmony with some basic principles. The development of the skills of the individual members of the group and the simultaneous creation of shared knowledge within the group, allows the creation of a system of skills useful for the pursuit of the objectives set. The team's goal must be expressed in clear terms, it must be based on available and evaluable and measurable data. A clearly explained objective helps to consolidate cohesion among the members of the group and clearly defines the audit relationship with the work organization. The operating method to be adopted establishes the criteria that effectively guide and articulate the group's activities. A good method gives confidence to the group that is able to maximize its commitment.

Effective communication (Di Lauro, 2011) is the key that allows the group's work to function as it involves the exchange of information necessary to achieve the objectives of the results. It is important to strengthen the communication policy by creating more effective two-way communication with stakeholders. In fact, in the system of relationships that is established, it orients opinions and at the same time is influenced by them. When the roles of individual members are recognized, evaluated, developed and communication is open and understandable, the work of the group is productive following the leadership action carried out by the audit manager. The audit process operates in compliance with the principles of professionalism, independence, confidentiality, impartial presentation of the results and on the basis of the tests. Compliance with these principles is a prerequisite for providing relevant and appropriate audit results and for ensuring that different auditors, who work independently of each other, reach similar conclusions in similar circumstances. It is advisable to provide a logical and temporal sequence within which to apply the operational methods of an audit. In particular, it is necessary to define a calendar of meetings between the auditors and the representatives of the various business sectors. For particularly complex problems, the team leader can make use of experts with particular experience in that industrial sector or may decide to divide the scheduled meetings into different sessions. However, the planned activity period must always be short since it must not interfere with the production activity. It is possible to acquire oral information from company employees

on specific problems in their sector. In interviews, the questions are used to acquire the most information useful for the inspection. Simplified information on the processing of data and news should be provided to those who provide statements. The interview program plans to meet the company's executives according to the hierarchy indicated by the company organization chart, proceeding from the top to the base. The topics covered in the interview start from the description of the general framework of the company and then proceed to an ever-greater detail to identify the elementary processes and their managers and define the documentation of interest. At the end of the interview phase, the information and documents acquired are studied. Then, process mapping is done by drawing a graphical representation with flowcharts. The documents of the works will be kept, also in digital form, according to document security criteria.

Independence and objectivity of certification bodies

A first-party audit occurs when an audit is performed within your organization by your own auditing resource. This is often called an internal audit.

A second-party audit is performed by a supplier, customer, or contractor, often against their proprietary requirements.

A third-party audit is performed by an independent body against a recognized standard. Third party audits are a good way to ensure product control, safety and quality. These bodies are independent of other actors in the food supply chain, namely buyers and sellers (Jarosz, 2000). However, according to some studies it would seem that the increase in competition between the certification bodies accredited in the certification market (Hatanaka et al., 2005; 2008) could influence the objectivity of the same bodies (Anders et al., 2007).

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Chapter 3

Harmonization between public and private standards

Public standards and private standards

International food safety standards are increasingly detailed and rigorous (Havinga, 2018) and conscious consumers ask to monitor and guarantee public hygiene. Based on commercial practices, it appears that third party certification (TPC) has become the basic requirement for trade in food products through large retailers. In general, the government bodies in charge of the controls carry out the controls when they grant the authorization for the production, transport, storage and sale activities. Subsequently, these checks are performed periodically or on a sample or for health emergencies. Systematic control of processes and products, on the other hand, is carried out by TPC bodies which manage to cover practically all aspects that affect modern trade. The main certification and maintenance audits can therefore relate to management systems, good production practices, workplace protection, environmental standards and, especially in the agri-food sector, food quality and safety. Although private standards have improved under pressure from NGOs, consumer engagement and representation practices do not always exist. As a result, companies can often choose the standard best suited to their corporate policy. Governments, when they have to implement, for example, European Community Regulations and directives, must follow an approval process at various levels of national and regional government. Instead, private standard schemes are faster in practical application because they follow market demands in real time (Marsden, 2013). Nevertheless, in a context of continuous trade liberalization on a global scale, international organizations and governments are expected to continue to play a leading role in standardizing corporate responsibility (Gereffi & Lee, 2012).

It is a fact that private standards are a means of complying with public standards. It is equally true that state legislation increasingly refers to the principles of application of private rules. This type of interaction between public legislation and private precepts should increase the global harmonization of good practices in the agri-food sector. In the daily experience of companies, there are many public and private standards that sometimes seem to integrate, sometimes duplicate themselves or in some cases they may seem divergent. Indeed, this situation seems far from harmonization even if all food safety programs are inspired by the risk prevention method. Harmonization of public and private rules would seem to be a reasonable strategy against trade barriers which,

however, are often due to the specific nature of private rules (Medin, 2019). If there was a convergence of standards, exporters would simply have to conform to globally recognized standards rather than having to conform to different standards for different markets (International Trade Center, 2016).

Today food security addresses increasingly complex issues concerning bioterrorism, the protection of natural resources, the protection of workers, fair trade and solidarity. At the same time, public awareness of issues relating to the future of the new generations and the conservation of the planet is increasing. For some years, a gradual transition from public governance[19] to private food safety governance has been underway. This is probably due to the increasingly limited public resources necessary to develop a widespread control network in the sector with adequate technical skills, especially in the poorest countries.

In this context, the global agri-food market, which bases its existence on food safety, pushes sector operators towards private standards in order to assess compliance (International Trade Center, 2011).

Therefore, if on the one hand the growing adoption of private standards can in the long run weaken the role of governments, on the other the role of public Regulations is fundamental to protect public health and to counter market failures. In this regard, it is sufficient to recall the recent crisis caused by animal diseases of a diffusive and contagious nature and which has also represented risky situations for humans. Therefore, the role of governments seems to be mandatory in order to ensure consistency of the rules with the Regulations of the WTO (World Trade Organization) and in particular with the Sanitary and Phytosanitary Agreement and with the Technical Barriers to Trade Agreement.

In this context, agri-food companies find themselves respecting both public and private standards. Respect for public and private regimes therefore becomes a heavy commitment in terms of human, financial and technical resources, which many

[19] It is the set of procedures and principles that allow the management of a company, an institution, an organization in general (Source: https://www.garzantilinguistica.it/ricerca/?q=governance).

companies cannot face except with access to credit. The unfavourable alternative is a reduction in profit margin due to limited market access (Scuotto et al., 2019).

Context

The HACCP system[20] is a food safety management method that implements risk analysis and critical control points. HACCP addresses physical, chemical and biological risks and is used in the food industry to identify potential food safety risks during the food production and preparation process (Caswell & Hooker, 1996). On the one hand, the HACCP combined with the product traceability systems allows the monitoring of food safety through the inspection of process logs rather than the inspection of the finished product. Conceptual simplification involves the effectiveness of the preventive action with reduction of costs and damages. On the other hand, post-production checks of the finished product would not lead to useful results in terms of safeguarding food safety. While controls on the effective application of preventive systems to protect food are effective.

Given that HACCP is considered the method of safe production management, the subsequent commercial phase requires certificates of conformity, such as the certification of origin which is a document certifying the country of origin of a shipment. It is used among members of a commercial network for foodstuffs produced in different countries. The certificate of origin is commonly issued by a sales promotion office or a chamber of commerce in the exporting country. It is also defined as a declaration of origin and can be accompanied by a certificate of analysis which is an authenticated document, issued by a competent authority, which certifies the quality and authenticity of the exported animal and vegetable products.

In a competitive market like the current one, companies, in order to position their products and differentiate themselves from the competition, adopt private standards that

[20] In Europe, the legal obligation to apply the HACCP system derives from Regulation No. 852/2004 of the European Community which is part of the hygiene package. Regulation No. 852/2004 was implemented in Italy with Legislative Decree No. 193/2007 which repealed the previous Legislative Decree No. 155/97.

often exceed legal obligations. To assert their products, companies have formed national and supranational alliances in order to develop collective standards. To confirm this, we mention the British Retail Consortium (BRC), the International Food Standard (IFS), the Global Food Safety Initiative (GFSI) and the Global GAP. Undoubtedly, the advantage for retailers is that they can obtain supplies from an increasing number of suppliers considered safe. For suppliers, the advantage is that they can expand their market by collaborating jointly and in a non-competitive way. Instead, in the field of traditional raw materials such as cereals, sugar, tea, coffee, cocoa, the standards proposed by the aforementioned initiatives are less pervasive because in this case traceability is more important than labelling. For example, in the coffee sector, the 4C association is an initiative whose members are coffee producers, representatives of the coffee trade and industry. The 4C association also includes civil society organizations such as VENRO[21] and Oxfam[22]. The main goal of these non-profit organizations is to make globalization fair and reduce global poverty. The 4C Association does not assign a quality label but has produced a code of conduct for coffee companies in order to create the basic conditions on which to build initiatives for fair trade and organic agriculture (4C Services GmbH, 2018).

Role of international agreements

On the one hand, the establishment of the WTO in 1995 has overcome the problem of commercial barriers due to tariffs and quotas and has allowed the growing diffusion of public and private standards. On the other hand, the original problem reappears in the form of non-tariff barriers. To counter this phenomenon, a series of international agreements to support the WTO have been developed, such as the Sanitary and

[21] VENRO is the Association of German Development and Humanitarian Aid NGOs. Its central objective is to build a proper globalization, with a special emphasis on eradicating global poverty. The organization is committed to implementing human rights and conserving natural resources.

[22] The programs, of the Oxford Committee for Famine Relief, Oxfam, address the structural causes of poverty and related injustices and work primarily through responsible local organizations, seeking to improve their effectiveness.

Phytosanitary Agreement (SPS), the Agreement on Technical Barriers to Trade (TBT, the Technical Barriers to Trade Agreement), the Trade Related Intellectual Property Rights Agreement (TRIPS) and the Disputes Settlement Process (DSP).

The Sanitary and Phytosanitary Agreement establishes basic rules for food safety and sanitary rules for animals and plants. Under the agreement, countries can develop their own standards as long as they are science-based and applied only to the extent necessary to protect the health and life of people, animals and plants. The qualifying point is to eliminate unfounded and arbitrary discrimination between countries where identical or similar conditions prevail.

The Technical Barriers to Trade Agreement aims to ensure that standards, labelling, customs forms, tests, certification procedures and other technical aspects do not create unnecessary obstacles to trade. This agreement provides the clause that member countries can still adopt their own legitimate policies for the protection of public health and the environment in light of specific facts.

The Trade Related Intellectual Property Rights Agreement has introduced specific global minimum standards in international trade. WTO members have undertaken to adapt their laws to minimum protection standards and to compliance with detailed obligations for the application of intellectual property rights.

The Dispute Settlement Process is a mechanism used to resolve disputes resulting from non-compliance with the commitments made by the signatories in an international agreement. Since the WTO agreement entered into force in 1995, the dispute resolution system has gained in importance because the signatory members have often resorted to it. At any time, numerous disputes are active in one of the different stages of the process. The dispute resolution office has handled around 570 disputes filed by WTO member countries since 1995. Not all of these disputes have been formally resolved. Mediation for an agreed solution is often the preferred method of solving the problems under discussion (WTO, 2019).

Role of international bodies

The Codex Alimentarius Commission (CAC) is a commission created jointly by FAO (Food and Agriculture Organization) and WHO (World Health Organization) in 1963. As of 2019, it has 194 member countries. It promotes coordination of all work on

food standards undertaken by governmental and non-governmental organizations in order to harmonize them. In addition, it has developed food standards, guidelines and codes of conduct on raw and processed materials, food hygiene, pesticide and contaminant residues, analysis and sampling and labelling methods. All this to protect consumer health and ensure adequate international trade relations (FAO, 2019).

The Codex Alimentarius is a set of guidelines and codes of good practice aimed at the safety and quality of foods produced and marketed worldwide. It is a series of recommendations developed on the basis of the best scientific knowledge of the moment that deal with topics such as additives, pesticides, contaminants and biotechnology. These recommendations are voluntary for the Member States and form the basis for food safety legislation in various countries. The purpose of the Code is to develop food safety, based on science and compliant with Regulations, in order to provide consumer protection, relevant information on the labelling and prevention of fraud and consequent economic damage (FAO, 2019). The Codex Alimentarius standards represent the doctrinal and pragmatic basis of national Regulations and are considered by the WTO as a point of reference for food safety standards and international trade. Although they are voluntary, these rules are virtually mandatory.

ISO, International Organization for Standardization, is an independent international non-governmental organization based in Geneva, Switzerland, to which 164 national standardization bodies belong in 2019. For example, in Italy the Italian National Unification Body (UNI) is a member of ISO and is a private non-profit association recognized by the State and the European Union pursuant to Regulation (EU) No. 1025/2012. The purpose of the ISO is to develop voluntary standards recognized globally based on market needs to facilitate international trade and technology transfer through the development of international standards. In this sense, the World Trade Organization recognizes the important role played by ISO for the international harmonization of standards (WTO, 1998). According to ISO 2019 press reports, this organization has so far published over 22,500 international standards and related documents. The scope of these standards covers practically all sectors of the economy, commerce and services, including the food safety sector. Within ISO, it manages CASCO, the Conformity Assessment Committee, which develops policies and publishes standards relating to conformity assessment. The standards are developed by

experts from member institutions whose purpose is to share knowledge and develop it (ISO, 2019). ISO has also developed international voluntary standards for accreditation bodies. In fact, the ISO / IEC 17011 standard specifies the general requirements for the bodies that carry out accreditation. In turn, the certification bodies must carry out the activity according to the standards of the ISO / IEC 17021-x series which specify the required requirements.

The Food and Agriculture Organization (FAO) is a United Nations agency whose goal is to achieve food security for all and to ensure people have regular access to sufficiently high-quality food products. elevated to reward them for leading an active and healthy life. Currently, FAO operates in over 130 countries worldwide and has 194 member states. The organization facilitates partnerships between governments, for the development and collaboration between civil society and the private sector to achieve food and nutrition security and towards sustainable models of agriculture, rural development and management of natural resources.

Certification as a way to access the global market

Food safety incidents have a significant cost for economies. For example, in 2013 in the United States the cost was about 7 billion dollars due to the recall and withdrawal of unsuitable products and as a consequence of the payment of damages following legal actions (Hussain & Dawson, 2013). These costs represent controversy, lost markets and loss of consumer confidence. Numerous public and private regulatory initiatives have been presented to restore public confidence in the global food security guaranteed by the public government. In particular, multinationals in the food sector and non-governmental organizations have promoted certification protocols, third-party audits and transnational commercial practices. Due to the apparent inadequacy of public Regulation in the face of global public health problems, private food safety governance is gradually seeking to replace public Regulation with private standards that have more flexible and market-oriented policies (Lin, 2013).

In this context, the initiative of large groups in the agri-food sector was to implement certification programs designed to ensure that their supply chain around the

world follows certain guidelines. Therefore, a certified food safety management system demonstrates the organization's commitment and ability to control food safety risks in order to guarantee compliance with quality standards and mandatory standards. This implies that the company carries out analyses on objectives, research and development policies, economic and human resources, attribution of responsibility and that it is aware of every important element. At the moment, in the agri-food sector, various standards are in place for assessing the conformity of management systems that guarantee food safety and compliance with the principles of sustainability. The best known are ISO 9001, ISO 22000, BRC, IFS, SQF, FSSC 22000 and Global GAP. For the feed sector, the voluntary reference standards are GMP + and Fami QS. Depending on the needs of the company, market objectives and mandatory requirements, the senior management of a company can choose between the various voluntary certification schemes, the appropriate one.

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Chapter 4

Food surveillance system

About the perception of food safety

Specific agencies have been set up in industrialized countries to ensure public health surveillance and control of diseases of all origins, including food. From planting to harvesting vegetables or during the breeding of animals, food supply involves a complex network of production and commercial relationships that include processing, preparation, packaging, labelling, distribution and final consumption. There is a growing demand and supply of all kinds of food products throughout the year, and therefore the supply chain is becoming increasingly international, which means that some stages of the process take place in other countries. In the global food supply network, trade management can be confusing as products and semi-finished products may be subject to different regulatory regimes in different countries. This fact may represent a problem of harmonization and mutual recognition of standards for national government food safety agencies. But other factors influence the perception of food safety. The sensitivity of consumers to food diseases has significantly increased after the outcry of recent negative events such as spongiform encephalopathy (2000), avian influenza (2003), dioxin in pork (2008 and 2011), influenza swine (2009) and other minor events (Bánáti, 2011).

The spread of foodborne diseases

According to data released during the International Food Safety Conference held in Addis Ababa in Ethiopia in February 2019, over 600 million people worldwide fall ill each year due to food contaminated with bacteria and viruses, parasites, toxins or chemicals. In addition, deaths from unsafe food from the point of view of hygiene and health amounted to around 420 thousand. The negative impact and the consequent economic damage caused by food-borne diseases mainly fall on developing countries (FAO, 2019). According to the 2017 European Union summary report on zoonoses (EFSA and ECDC, 2018) the severity of human cases is determined by the degree of hospitalization and the mortality rate. Based on data collected and published by the European Food Safety Authority in 2017, listeriosis was the zoonosis with the highest hospitalization and mortality rate, followed by West Nile fever infection.

Table 7. Reported hospitalisation and case fatalities due to zoonoses in confirmed human cases in the EU, 2017.

Diseases	**Pathogen**	**No. human cases**	**Proportion hospitalized (%)**	**Case fatality (%)**
Campylobacteriosis	*Campylobacter jejuni*	246,158	30.5	0.04
Salmonellosis	*Salmonella spp.*	91,662	42.5	0.25
Yersiniosis	*Yersinia enterocolitica*	6,823	33.4	0.07
Stec infections	*Shiga toxin-producing E. coli*	6,073	37.5	0.50
Listeriosis	*Listeria monocytogenes*	2,480	98.6	13.80
Q-fever	*Coxiella burnetii*	928	Na	1.35
Echinococcosis	*Echinococcus granulosus or E. multilocularis*	827	54.3	0.40
Brucellosis	*Brucella spp.*	378	60.1	0.78
Tularaemia	*Francisella tularensis*	321	61.8	0.60
West Nile fever	*West Nile virus*	212	87.6	12.00
TB caused by M. bovis	*Mycobacterium bovis*	185	Na	Na
Trichinellosis	*Trichinella spiralis*	168	74.7	0.00
Congenital toxoplasmosis	*Toxoplasma gondii*	40	Na	0.00
Rabies	*Lyssavirus*	1	Na	Na

(Source: European Food Safety Authority and European Centre for Disease Prevention and Control, 2018)
[key: NA (not applicable) as the information is not collected for these diseases]

In the past, the outbreak of a food-borne disease was limited to a particular region. Nowadays, despite the fact that industrial processes, such as pasteurization and canning, have made many foods safe and practically eliminated some diseases, diseases still persist due to the conditions of transport, storage and preparation for consumption of foods that can geographically influence the people far from the production site. To date,

there are over 250 different food-borne diseases caused by a variety of bacteria, viruses and parasites (CDC, 2019).

The fight against foodborne diseases

With the expansion of global agri-food trade, food safety Regulations are a necessary constraint to safeguard consumer health. The global food supply can introduce food safety risks that can often increase through the food chain. In fact, along the supply chain some products, such as vegetables, are subject to different stages such as cultivation, harvesting, processing, conservation and distribution, with a certain risk of propagation and multiplication of the dangers. In addition, the availability of food products throughout the year can increase the risk of food-borne diseases resulting from these productions. According to recent reports from the World Health Organization (WHO), despite the development and application of stricter Regulations based on scientific research, food diseases are still a public health problem. Up to 22 diseases are caused by 31 different dangers such as parasites, bacteria, toxins, viruses and chemicals (World Health Organization, 2015). Although the origin of some foodborne illnesses may be unknown, most are attributable to pathogens such as *Escherichia coli, Campylobacter, Salmonella non-typhoid* and *Norovirus*. In general, pathogenic microorganisms can be transmitted to crops in various ways: water contaminated by wastewater and used for irrigation, contaminated washing water, wild and domestic animals crossing the fields, unsuitable post-harvest treatment of fruit and vegetables, cross-contamination by equipment or workers, etc.

Food Safety in Europe

Europe's food safety policy is aimed at ensuring food hygiene wherever it comes. It includes animal health, including livestock, pets and wild animals, plant health for good seeds and control of contaminants and residues within recognized acceptance limits. In Europe, the European Commission implements an integrated food safety policy to ensure effective control systems and assess compliance with EU standards on food safety and quality, animal health and welfare, protection of food and plants. In addition, it manages international relations with third countries and international

organizations on food safety, animal health and welfare, nutrition and plant health. Numerous bodies are responsible for applying the EU's security policy:

- the European Center for Disease prevention and Control (ECDC, 2019) is responsible for identifying, assessing and communicating current and emerging threats to human health from infectious diseases;
- the European Food Safety Authority (EFSA, 2019) has the mission of providing scientific advice to the European Commission, the European Parliament and the EU Member States on food safety;
- the Rapid Alert System for Food and Feed (RASFF, 2019) ensures the flow of information to allow for a rapid reaction when public health risks are detected in the food chain. Effectively shares information between the national food safety authorities of the EU Member States, the European Commission, EFSA, the European Seed Association (ESA, 2019) and the European Free Trade Association (EFTA, 2019). The latter body includes Iceland, Liechtenstein, Norway and Switzerland as well as the EU countries.

Following the known food crises and based on the recommendations of the Codex Alimentarius, the political authorities have legislated on various aspects of quality. Quality understood as food safety is guaranteed in Europe by the hygiene package, which includes:

- Regulation (EC) No. 178 of 28 January 2002 which establishes the general principles and requirements of food law, establishes the European Food Safety Authority (EFSA) and determines procedures in the field of food safety;
- Regulation (EC) No. 852 of 24 April 2004 on the hygiene of food products;
- Regulation (EC) No. 853 of 24 April 2004 laying down specific hygiene rules for food of animal origin;
- Regulation (EC) No. 854 of 29 April 2004 which establishes specific rules for the organization of official controls on products of animal origin intended for human consumption;
- Regulation (EC) No. 882 of 29 April 2004 on the official controls necessary to verify compliance with feed and food law and compliance with animal health and welfare standards;

- Regulation (EC) No. 183 of 12 January 2005 which establishes the requirements for feed hygiene.

The quality requirements linked to tradition, typicality and territory have been protected by the legislator with the issue of Community Regulations on products with protected designation of origin (PDO), protected geographical indication (PGI), traditional specialty guaranteed (TSG).

The market and opinion groups have expressed the need for sustainable development understood as economic development compatible with the protection of the environment and resources for future generations. This request was implemented with the introduction of the organic production system governed by Regulations (EC) No. 834/2007, No. 889/2008, No. 1235/2008 and subsequent amendments, concerning organic production and labelling of Organic products.

Another quality aspect linked to the territory is represented by the European Network for Rural Development (ENRD) in which Italy participates. The purpose of the network is to promote rural development, programs, projects and other related initiatives. The goal is to stimulate the competitiveness of the agricultural sector; ensure sustainable management of natural resources and climate action; achieve balanced territorial development of rural economies and communities, including job creation and maintenance. The development of policies for agricultural areas in European countries takes place through the exchange of experience and knowledge between sector operators, institutions and all those who work and live in rural areas (Van der Ploeg & Roep, 2003).

Additional concerns for public opinion and government authorities stem from the use of pesticides in crops and from increased resistance to antibiotics in humans and animals. In this regard, an extract of the conclusions of the Council of the European Union on the fight against antimicrobial resistance published in 2016 is reported:

<< The Council of the European Union ...

... recalls that antimicrobial resistance is a cross-border threat to health which cannot be sufficiently addressed by one Member State alone and cannot be confined to a geographical region or one Member State, and therefore requires cooperation and coordination between Member States ... a number of EU-level measures have already been taken in the veterinary field ... to reduce the risk of antimicrobial resistance ... such as those provided for in Regulation (EC) No. 1831/2003 on additives for feeds that

prohibit the use of antibiotics as growth promoters ... ... expresses concern about the data provided by the OECD, according to which it is estimated that around 700,000 deaths may be caused annually globally by antimicrobial resistance. Compared to a world without antimicrobial resistance, the economic impact associated with current antimicrobial resistance rates can reach around 0.03% of GDP in 2020 in OECD countries, 0.07% in 2030 and 0.16%. by 2050. This would result in cumulative losses of approximately $ 2.9 trillion by 2050 ... >>

The aforementioned EU Council document therefore follows the recommendations for implementing national action plans against antimicrobial resistance and establishing a voluntary peer review system between countries where representatives of one or more Member States carry out a mutual evaluation of their plans. national action. This peer review system between countries would complement other existing assessment tools or audit activities such as those of the European Center for Disease prevention and Control.

The Rapid Alert System for Food and Feed

The unanimous approach adopted to combat the risks for food and feed is the preventive control that identifies the source of the risks for food safety and develops mitigation strategies to eliminate or reduce the risks to acceptable levels before consumption. The approach of relying on inspections on the final product is definitively overcome because it is ineffective and late. Therefore, the protection of internal markets and consumer health is the top priority achieved through advanced production, processing, distribution and retail systems that comply with sector legislation. In order to control public health risks from food, the European Community-wide Rapid Alert System for Food and Feed (RASFF) was set up, organized as a network in which the European Commission, EFSA and the member states of the European Union. The diffusion of alarms must guarantee both the completeness of the information and the timeliness of the communication. Notifications are communicated and shared between Member States via real-time online transmission. The activity of the alarm system involves the withdrawal of products dangerous for human or animal health. According to the 2017 RASFF annual report, compared to the previous year there was a significant increase of 11% in alert notifications for products placed on the market that could have

caused serious risks to human health. Furthermore, following the scandal of fipronil[23] in summer 2017, the European Commission recognized the need to integrate the RASFF network with the Administrative Assistance and Cooperation network (AAC). The AAC network is a communication system developed by the European Commission for EU countries to exchange data on non-compliance with food and feed legislation. The AAC network consists of a part dedicated to food fraud and another part dedicated to any request for assistance and administrative cooperation that does not present human or animal risk profiles, health risks, not falling within the scope of the RASFF, and / or suspected of fraudulent practices.

The Traces platform

In the field of food safety, the European Commission has activated the Traces system (Trade Control and Expert System). It is an IT platform, an online management tool to effectively guarantee and follow the path of both internal and import-export food products. In this way, administrative practices for trade are accelerated thanks also to export certificates harmonized with European legislation. Traces is used for commercial management by as many as 70 countries worldwide, including 28 European Union countries, 4 countries belonging to the European Free Trade Association and 38 non-EU countries. With the Traces system it is possible to manage food risks by being able to track all movements of shipments of animals, plants, food and agri-food products (European Commission, 2019).

Regulatory updates

From 14 December 2019 onwards, a new Regulation on official controls will be applied in EU food law. It is Regulation (EU) 2017/625 which repeals the rules relating

[23] The presence of fipronil residues in eggs was not related to its use as a pesticide but was due to the illegal use of fipronil used as a veterinary drug in breeding. Fipronil is a pesticide whose use has been prohibited on plant production since 2014. Currently it is only allowed in products against fleas and ticks for pets, while it is forbidden to use animals on livestock farms for the production of food (Ministero della Salute, 2017).

to official controls of food products, Regulation (EC) No. 882/04 and Regulation (EC) No. 854/04. In summary, the system of official controls will be harmonized in a single measure by integrating controls on food, feed, animal health and welfare, plant protection products and plant protection products, standardizing procedures (Van der Meulen, 2019).

Food safety in the US

The Food Safety Modernization Act is the legislative provision through which the United States completely reconfigured food safety management in 2011 (De Giorgio, 2017).

It is worth mentioning that, in terms of food safety and management of alleged risks, legislative initiatives in Europe are precautionary. In other words, a product is considered fit for consumption only in the presence of an evident absence of risk. On the contrary, in the United States, provided that all food preparations must in any case comply with universally recognized safety standards, the products are previously authorized as long as the risks considered as further and possible are not evident and demonstrated.

These different approaches are reflected, for example, in the management of genetically modified organisms, in the use of hormones and antibiotics in breeding and in the use of pesticides (US FDA, 2019).

Surveillance bodies in the USA

In the United States of America, the Food and Drug Administration (FDA) and the Center for Disease Control and prevention (CDC) are government agencies interested in food safety. Assuming that almost all foods undergo different stages of collection, processing, production and distribution, often carried out in different countries, it is stated that along the supply chain it is possible that the products may be improperly formulated and packaged or that they may being deliberately contaminated, counterfeited or adulterated (US FDA, 2019). With its action, the FDA guarantees the protection of public health by ensuring the security of food supply, the efficacy and safety of medicines for human and veterinary use, biological products, medical devices and cosmetic products. The FDA also ensures supply chain security against emerging

or intentional threats to public health. The CDC has the institutional task of supervising, preventing and suggesting the most appropriate interventions in case of infections and epidemics from pathogens, also of food origin.

Private standards to ensure food safety

It is common practice for food business operators to be responsible for food safety. The food industry must guarantee the hygiene of food products at all stages of the supply chain for both domestic and imported products. Importers are responsible for compliance with regulatory requirements for imported food and ingredients. These must be free from contamination from cultivation, breeding and storage environments, including waste treatment, the use of fertilizers, etc. In this regard, EFSA recommends manufacturers to include Good Agricultural Practices (GAP), Good Hygienic Practices (GHP) and Good Manufacturing Practices (GMP) in their practices (Allende et al., 2006). To avoid recalls and damage to its reputation, the food industry has intensified its efforts in the field of safety control, traceability of food products and environmental issues. In other words, the food industry has focused on quality in the broadest meaning of the word, recommending specific standards for the supply chain (Trienekens & Zuurbier, 2008). These standards are not mandatory by law, but their widespread application on the international market makes them de facto mandatory. Safe Quality Food Standard (SQF), British Retail Consortium (BRC), International Featured Standards (IFS), Food Safety System Certification (FSSC), GLOBAL GAP, Best Aquaculture Practices (BAP) and Global Red Meat Standards (GRMS) are all recognized by the Global Food Safety Initiative (GFSI) which brings together the main players in the food sector to encourage the continuous improvement of food safety management systems worldwide. This represents a consolidated point of reference in the globalized trade of food products.

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Chapter 5

Traceability

Supply chain control and traceability

In recent decades, the way we manage a product from processing to sales has changed significantly. In the past, it was probably more difficult for manufacturers and supply chain operators to know where the products came from and where they were while the goods travelled through the vast distribution network. Today the management of traceability has become a fundamental requirement of the complex supply chain network. Traceability is a requirement required by almost all voluntary food safety certification systems. In addition, it is increasingly part of the supply contracts. The burden that commercial partners must bear is the apparently simple one of connecting the physical flow of goods to the flow of information along the supply chain. Instead it is not as simple as we will see (Adam et al., 2016). Nowadays, products and ingredients come from all over the world and if, for example, some substances are contaminated, it is absolutely necessary to know as soon as possible who transformed the ingredient or product and where all the final products were distributed and sold. The new information technologies allow increasingly easy management of the complexity of events along the entire supply chain.

Despite the efforts of all manufacturers and commercial partners, there is no zero risk and there may be accidents related to the path related to quality. And so non-compliant products can still enter the market circuit and, if they are carriers of chemical, physical or microbiological dangers, they can undermine the health of the consumer. When a public health hazard is identified, the implementation of traceability must allow for rapid withdrawals and targeted recall of products, limiting as far as possible the potential impacts on public health. Consequently, the economic and reputation damage of the company can also be limited.

It should be emphasized that traceability cannot prevent counterfeiting but can facilitate detection and therefore make it more difficult to reach the point of sale for counterfeit products. Due to their nature, food fraud can potentially escape traceability checks as they occur on another plane. In addition, they can cause economic harm to the food sector and cause harm to consumer health.

Traceability regulations

The concept of traceability has been incorporated into national and international legislation such as, for example, Regulation (EC) No. 178/2002 of the European Parliament and the US law on the modernization of food safety of the FDA. In Italy the competent authorities are the Ministry of Health - Department of public veterinary health and food safety, the Central Inspectorate for the protection of quality and fraud prevention of agri-food products (ICQRF), and the Regions through the veterinary services of Italian public health service (MIPAF, 2019).

With an increasing number of products and volumes of transactions in which a company is involved, it is necessary that the same companies and their logistics service providers have perfect access to the related information on flows along the supply chains. This must be done in real time. The aim is to make the right decisions to optimize transport and logistics processes i.e. the simplification of paperwork, the more accurate supply of stocks, the optimized management of transport and even the actions aimed at reducing CO_2 emissions in the context of environmental protection.

Traceability also affects the trust consumers have in a brand when they buy a product. A company that provides reliable product information acts on consumers' perception of the company's image. It is perceived as a company on which everyone can rely in the sense of the truthfulness of the declarations on the label and ethical statements.

Feature of traceability

It is noteworthy that interoperability is a characteristic of a system that takes into account the social, political and organizational factors that influence the system itself. This is equivalent to saying that interoperability allows for consistent services in the presence of operational factors managed by different subjects. In other words, in traceability systems interoperability provides a method to overcome jurisdictional, geographical and linguistic limits. Only in this way can the identification of a product or ingredient be certain and unequivocal for all the commercial partners involved.

The distinctive character of the traceability of being able to trace upstream and the traceability of following any product or ingredient downstream at any point along the

supply chain is independent of the number of commercial partners and process steps involved.

Traceability is closely linked to the labelling system. In a supply chain, traceability allows you to access product information about their origin, where the ingredients come from and how they were processed, who was involved, where they are destined and where they are currently located. It can therefore be said that the products and ingredients are labelled with certainty, the operators involver are identified. Furthermore, the fact that the related documentary information is recorded and shared along the entire supply chain, means that traceability allows you to promptly characterize a problem and identify non-compliant products (Kondo, 2010). For example, in the case of beef, the lots must be labelled with the mandatory information required by Regulation (EC) No. 1760/2000 which establishes a system for the identification and registration of cattle and provides provisions for the labelling of beef and beef products.

Table 8. Operational requirements for recalls/withdrawals.

STAGE	NOTIFY THE CUSTOMER	NOTIFICATION TO THE COMPETENT AUTHORITIES	NOTIFY PUBLIC OPINION
ZERO TIME	1. Blocking the distribution and sale of the product. 2. Identification of the customers to whom the product was supplied.	Inform the competent authority and ask what the exact procedure for the specific problem is.	Decide what method and means of communication will be taken towards the customers, the point of sale, the website, the type of press release, etc.
BY 2-4 HOURS LATER	Inform the customers of the recall and what they need to do.	Send preliminary information about the product, the problem, the place of manufacture, where it was sold, etc.	Identify the person responsible for managing contacts with the public.
	Confirm in writing the instructions including all product information (datasheet, image).	Provide a distribution list of all customers with names, phone numbers, addresses.	Make a poster, press note or other on the company's quality assurance policy.
	---	Send a draft statement to the competent authorities before the official communication.	Make a corporate hotline operational to respond to any requests for information.
	---	Inform about the arrangements for withdrawal and subsequent disposal.	Prepare adequate answers to difficult questions.
	---	---	Use the website or even social media to inform you that everything is under effective control.
TO 24 HOURS	Confirm the agreements taken with the customer for the recovery of the product withdrawn from the market.	---	Place relevant alerts on the local press on the success of the event.
	---	---	If It is relevant, place alerts at places of sale.
	---	---	Place communications on the website and social network on the success of the event.
POST-EVENT	Record the quantity and lots of product withdrawn.	Formalize the closure of the procedure.	---

(Chart created by the author on the basis of EC Regulations No. 178/2002 and the US FDA's Manual of Regulatory and Recall Procedures)

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Chapter 6

Globalization

International trade

After the Second World War, a global reconstruction plan was launched. In particular, in 1947 the general agreement on customs tariffs and trade (GATT) was established which was to be subsequently replaced by a United Nations agency called the International Trade Organization (ITO) which however was never established. However, the action of GATT in conjunction with the International Monetary Fund (IMF) and the World Bank has been very successful and has contributed to the reconstruction and global economic development. GATT played the institutional role until 1994 involving 130 countries. In 1995, following multilateral trade negotiations, GATT was replaced by the World Trade Organization (WTO) set up to monitor and liberalize world trade. The purpose of the new organization was to spread economic well-being globally in order to reduce political tensions between countries. Thus, it was agreed to apply new rules for international trade, liberalize trade, resolve trade disputes and increase the transparency of trade relations.

In this context, in the face of a nominal commitment to counter the action of the lobbies, some groups of wholesalers operating at a multinational level have had the opportunity to significantly expand their profits (Kelloway & Miller, 2019). During the 1990s, large retailers began to expand on a large scale and increase profits in order to gradually reverse power relations with processing companies. In North America and Europe, they avoided creating companies with processing industries to avoid taking on additional business risks (Marsden et al., 2017). The rise of large retailers was also favoured in a certain way by consumers who in those years had more disposable income for leisure, personal care and healthy eating, favouring progressively fresh and natural foods and prepared and ready-made foods to use (Reardon & Berdegue, 2002). At the same time, public Regulation, although constituting the basis on which private rules have been developed, has shown a reduced capacity for promptness and flexibility in managing market relations. On the one hand, this has opened up space to the private Regulation sector which still today seems to better manage the transformation of social, political and economic relations throughout the global agri-food system (Hatanaka et al., 2006). The capital invested and the products of the national markets faced each other in a global competition, placing profit at the centre of their interest. On the other hand, this

has created movements of opinion through non-governmental organizations whose ethical concerns have concerned environmental protection, animal welfare and the conditions of the workers involved (Lawrence, 2005).

Non-governmental organizations

Non-governmental organizations (NGOs) are non-profit associations that operate in the field of cooperation and development at local, national or international level. NGOs declare their independence from governments and their policies. They are structured as associations or foundations and can collaborate with public institutions[24].

The field of action of NGOs is wide: it includes topics regarding the defence of human rights, environmental protection, agriculture, cooperation, crafts, professional training, development, credit, etc.

Having been facilitated by the development of global communication networks, they have laid the conditions for increasing public awareness of issues of common interest. Following the liberalization of the market, these organizations feared the possibility of negative effects of globalization on agriculture, workers, the environment and animals. In this context, after a first phase of criticism of the actions of the

[24] In Italy, non-governmental organizations receive around 60% of grants from institutional donors, such as the Italian Ministry of Foreign Affairs, the European Union, Regions, autonomous provinces, local authorities and the United Nations agency to carry out their activities. The remaining approximately 40% of the contributions come from private sources such as companies, voluntary tax levies, foundations and churches (FOCSIV, 2019).

The Italian governmental agency for development cooperation (AICS) is a public agency controlled by the Italian Ministry of Foreign Affairs. Manages the list of recognized non-governmental organizations in Italy. As of 2019, 227 organizations are listed (Italian Ministry of Foreign Affairs, 2019). In Italy the first NGOs started their activity around the 1970s, driven by innovative ideas of solidarity and international cooperation. With Law No. 49/1987 the Italian state recognized these institutions. In the 2000s the European Union finalized the financing of these organizations for a more appropriate management of the proposed projects. Law No. 49 was repealed by No. 125/2014, currently in force, which goes beyond the category of Non-Governmental Organization (NGO) to introduce Civil Society Organizations (CSOs).

To date, with the global economic crisis, these organizations are experiencing a moment of reconfiguration of their projects (Open cooperazione, 2019).

governments, they found it more effective to focus their actions and requests directly on the companies perceived as responsible for various problems (Bain & Hatanaka, 2010). With strong consensus and recognition by public institutions, they now form opinion groups capable of influencing environmental policy and promoting the development of poor countries. Furthermore, with a view to ensuring a future for the next generations, pressure groups are set up on current governments to propose possible alternative ways of social and productive progress. And so, they have taken an active role in defining new private certification standards in fair trade (Spaargaren & Oosterveer, 2010).

It is noteworthy that they have helped develop programs such as the Marine Stewardship Council, the Forest Stewardship Council and the Rainforest Alliance. These certification programs operate according to the criteria of respect for the environment and environmental sustainability, so that companies select high quality raw materials and abandon, as far as possible, operating practices capable of depleting the resources of the sea, of the soil and forests. Behind these pressures, large production and distribution groups have changed their approach by adopting policies based on ethics and sustainability.

The evolution of agri-food trade relations

Nowadays, in line with the liberalization of trade, an ever-increasing number of food products across national borders and reach the consumer through large retailers. This commercial channel has become almost predominant on a global level, leading to the concentration of exchange and distribution activities through some operators. Due to the global dimension of food trade, the management of food safety, quality and sustainability goes beyond the level of national Regulations and self-control. Private quality and food safety management standards have become the most suitable tools for supply chain organization and market development. Overall, mass retailers, taking advantage of their central position in global trade, have taken an active role in developing rules and procedures to ensure food quality and to direct and control the supply of food. Since global trade is a prerogative of a kind of oligopoly, the space for competition has been reduced because large distribution chains obtain goods on similar economic terms (Boström et al., 2015). Therefore, the differentiation between distributors takes place by acting on a series of more intangible elements, such as brand,

reputation, packaging, advertising campaigns and so on. In this regard, the introduction of niche products such as organic ones, fair trade, and typical local products, wants to show the consumer the consideration of ethical, social, environmental and animal welfare aspects in the context of commercial practices. However, we sometimes see unfair marketing practices that emphasize certain sustainability issues for unfounded reasons. These marketing practices are called greenwashing and can undermine the relationship of trust with consumers in the geographical areas of the world where an adequate civic sense of respect for the environment and social issues has already been achieved (Zanasi et al., 2017).

Market integration

Since the end of the ‘80s, a situation of market unification connected with the growth of economies and social and cultural connections between the peoples of the various geographical areas has been emerging worldwide. This coincided with the progressive reduction of obstacles to the free movement of people, goods and capital, favouring large multinational companies that have increasingly operated independently of individual countries. Multinational corporations have acquired credit from international financial institutions and have influenced the economic policy choices of governments. The tendency to reduce obstacles to the free movement of goods and capital has been extended to involve most countries by putting aside more restrictive policies. The global political framework is characterized by the progressive increase in economic integration between the various countries even if there are still major imbalances. Indeed, as regards the effects of globalization, the views of economists are a source of open debate (Mahutga & Smith, 2011). For some economists, the increased influx of investment in developing countries can help narrow the economic divide between developed and poorer countries. For others, the potential positive effects of globalization processes would not be equally distributed in developing countries, while in developed countries there would be social tensions between those who would benefit from globalization processes and those who would be disadvantaged, for example, workers whose production activities are transferred abroad (La Stampa, 2018).

Stakeholders and shareholders

In the past, traditionally, the *stakeholders* were represented by customers, investors, suppliers and company employees. Currently a new galaxy of subjects is part of the so-called emerging stakeholders. These are institutional controllers, partners, communities, lobbyists, potential investors, public opinion, the media, competitors, and others. So, it can be said that the stakeholders are all those figures that gravitate around the organization and that in some way influence its social and commercial policies

In addition to the stakeholders, the *shareholders* are noteworthy. They include those who in some way finance the business organization or with their own capital, the shareholders holding capital shares, or through credit, financial operators such as banks and credit institutions. Shareholders can be considered part of the stakeholders.

Overall, these subjects have placed new demands and objectives on the world of agriculture and the food production sector. Consequently, the political authorities had to intervene by legislating on the various aspects of quality while safeguarding food safety.

Trade and new global economic crises

According to the OECD[25]-FAO Agricultural Outlook Report 2018-2027, the deflated real prices of most agricultural products are expected to remain stable or slightly decrease for the period under review but will still be higher than the beginning of the 2007 crisis. The economists who drafted the report predict that the growth in food supply will keep pace with the growth in demand. But this picture assumes a weak recovery in the economy accompanied by a stable oil price policy and abundant global food stocks that keep markets stable (OCSE-FAO, 2018). A decade ago, with the 2008 recession, it was thought that the crisis that started could cause a possible increase in world hunger. According to FAO reports, before the crisis, when food prices were lower than ever, around 900 million people did not have enough food, while in 2015 people

[25] Organization for Economic Co-operation and Development.

who did not eat enough fell to 800 million. A significant figure given that poor populations spend a high percentage of their scarce financial resources for food. Furthermore, farmers in poor countries around the world turn out to be net food buyers rather than food sellers. According to the aforementioned OECD-FAO report, the relative reduction of world hunger has paradoxically occurred thanks to some continuous obstacles to the development of poor countries. Typically, these countries do not have sufficient infrastructure such as ports, airports, storage facilities, highways, etc. This backward situation has relatively protected them from the effects of the international crisis, cushioning their effects. Furthermore, at the local level, economic support policies have been implemented for the poorest sections of the population to preserve the demographic consistency of the nations. This allowed those populations the effective ability to purchase food for food. Ultimately, it would seem that the 2008 recession has only marginally affected these already poor and developing countries. However, according to the FAO report, an unexpected peak in oil prices, a vigorous growth in the economy accompanied by an increase in financial returns, could lead to another peak in agri-food prices within the next decade with consequences still to be assessed. In this context, we must add the uncertainty caused by climate change which, regardless of the causes, seems to be real and negative (The World Bank, 2019).

Overview of the evolution of capitalism

According to economists like Boyer (2007) capitalism develops through a series of distinct phases in which each phase includes an accumulation regime associated with its own way of social and political Regulation. In this context, an accumulation regime is defined as a stable and reproducible relationship between production and consumption, while the modality that exercises a regulatory function is constituted by state and private institutional forms, social practices, habits and rules that regulate relations to ensure economic stability.

After World War II, economic accumulation was based on mass production and mass consumption of uniform and standardized manufacturing products. In fact, the so-

called Fordist regime, also called Fordism[26], was applied as a virtuous choice. The increase in workers' income led to an increase in the amount of consumer goods required. And so higher wages and greater economic availability and propensity to spend led to the production of mass production which was accompanied by greater labour productivity.

In 1973 the industrialized countries were hit by a serious economic crisis that turned out to be second only to that of 1929. For reasons related to the American economy and their foreign policy, which belong to history and are the responsibility of historians, that country decided to adopt a protectionist policy with tariffs of up to 10% on imports. At the same time, the oil producing countries belonging to the Organization of Petroleum Exporting Countries (OPEC) increased the price of oil by 70% and reduced their imports of goods from abroad.

This situation triggered an international economic crisis (Bina, 1985) and marked the decline of Fordism and the advent of post-Fordism[27].

During the period of application of Fordism, the surpluses of agri-food production in North America and Europe together with agro-industrial technologies were exported to developing countries. Remember that, as in other production sectors, the agri-food production sector was also characterized by parameters such as price and quantity. In the subsequent period, characterized by post-Fordism, international trade gradually moved towards a progressive deRegulation towards the removal of trade barriers. Since then, in the agri-food sector, the emphasis has been on quality understood as safety,

[26] The Fordist regime is a system of industrial and political organization, implemented since 1913 by Henry Ford in his car factory. Based on the principles of Taylorism, it aimed to increase production efficiency through rigorous planning of individual operations and production phases, the general use of the assembly line, a complex of incentives to work (higher wages, shorter working hours, etc. (Source: Treccani)

[27] Post-Fordism is characterized by the adoption of technologies and organizational criteria that place new emphasis on the specialization, qualification and flexibility of workers. The industry, having abandoned the traditional series production, acquires greater production and organizational flexibility, adapting its offer to a demand, in particular for consumer goods, which is increasingly diversified and subject to very sudden changes. The emblematic method of post-Fordism is the inventory management system named *just in time*. (Source:Treccani)

nutritional value, labelling, packaging, brand, etc., all aspects which, on the basis of public Regulations that legitimize their definition, become the basis for Regulation of the global agri-food system. To date, large retailers are competing on quality with reference to food safety sanctioned through the quality certifications of production processes and foodstuffs. In this context, the growing awareness of public opinion and consumers towards the methods of production, safety, quality and sustainability of the agri-food sector has directed consumption and exchanges towards products that are ethically acceptable or perceived as such. Organic products are an emblematic example (Ritzer, 2007).

Economic aspects of trade

In economics, oligopoly is a market situation characterized by the presence of a limited number of competing sellers offering similar but not necessarily identical goods and services. In recent decades, major retailers have led to an oligopoly situation which has led to a relative lack of price competition.

Actually, competition between operators involved other parameters, such as quality, freshness and ease of use. Furthermore, the offer of food products is mainly complete due to the global market and no longer linked to seasonality. This wide range of products always available is made possible by the simultaneous development of transport at increasingly competitive prices. Of course, this required effective traceability plans for goods in the transport sector (Raikes et al., 2000).

Add to this that the consumer is constantly subject to new products or, better to say, new forms of product presentation. Since the market is in fact oligopolistic, it happens that the marketing innovations introduced by one operator are soon copied by others. This translates into a homogeneity of the productions which however differ on particular aspects such as brands and other aspects that “personalize” the products. In this regard, consider the ready-to-eat food products offered in the most varied ways but on the same level from the point of view of food safety.

Another particular aspect to consider is the oligopsonistic[28] nature of the fresh products market in which there are only a few buyers, the large retailers, while the offer is made up of a plurality of supplier companies. A typical example is the coffee market where a myriad of small producers sells to a few important international traders. In this case, it is the buyers, the large retailers, who have market power.

From an economic point of view, the prices set in the oligopoly markets, and also in oligopsony, create a lower incentive to invest in the production of a particular product since it can only be sold in a market with few buyers (Prodi, 2012). International buyers covering most of the global market are large and few. They are able to strongly influence the pricing and consequently manage to obtain most of the value that is created in these production chains (Prodi, 2012).

Global value chains

After globalization, a new method of organizing production and work emerged. We have gone from the trade-in-goods which is the exchange of goods, to the trade-in-tasks which is the exchange of phases of the processes necessary for the production of these goods. Starting from the design of a new product line to distribution on the shelves, all intermediate stages can be performed in companies located in different countries. In this way companies from different countries add value shares to the product (Banca d'Italia, 2016).

The interesting aspect concerns the economic growth of the countries involved in the globalized market. It has been established that the highest rates of economic growth have occurred in the countries participating in the international division of labour. This suggests that a country's long-term economic development is conditioned by its participation in the structure of the international division of industry (Mahutga & Smith, 2011).

[28] The word came from the greek ὀλίγοι (oligoi) few, and ὀψωνία (opsõnía) purchase. Oligopsony is a market in which there are numerous potential sellers but a small number of buyers. Under oligopsony, buyers are in a strong position to dictate terms and can pass many costs and risks on to the supplier. (Source: Treccani)

In this context, third party certifications acquire a high value, but in developing countries they can represent a significant obstacle for small and medium-sized manufacturers and suppliers. Actually, they cannot invest adequately to get certified, so they ha è to focus their sales on less profitable local markets. Furthermore, the reduced accessibility to the information and knowledge necessary to implement the standards required by large retailers in industrialized countries could constitute an additional obstacle. On the other hand, large producers and therefore large suppliers have sufficient financial resources to invest in upgrading production plants with new technologies. They can also invest in highly qualified workers to monitor and document the processes to be certified (Busch & Bain, 2004). This situation launches a virtuous circle that allows them to access new markets and potentially increase revenues and invest a large part in research and development.

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Chapter 7

Sustainability

The concept of sustainability

The concept of sustainability implies the idea of economic development that guarantees the needs of current generations without thereby alienating the opportunities for future generations. In particular, the concept of sustainability has gone from an initial ecological dimension to a wider dimension which takes into account the social, environmental and economic aspects of global development, including food safety (Bevilacqua, 2014).

The United Nations in 2015 drafted the Agenda 2030 resolution which represents the reference point for sustainable development to be implemented within the next decade (UNRIC, 2019). The goal is to promote well-being taking into account the three key dimensions of sustainable development, namely economy, environment and society.

In this context, the agri-food sector is engaged in the development of methods for assessing the environmental impact of food and drink products, in the development of voluntary environmental communications by companies towards consumers and interested parties, promoting the continuous improvement of environmental performance along the supply chain. The process affects current and future generation and affects all nations, both industrialized and developing (United Nations, 2015). In the long term, sustainable development requires a change in the global economic and social system in order to mitigate the impact of human activities, including agriculture, on the environment and reduce the consumption of resources. At the same time, it is necessary to guarantee the economic efficiency of the process and social cohesion. In other words, the lifestyle of all industrialized and developing countries must be harmonized to ensure the ecological balance of the planet and the prosperity of future generations by reducing the level of poverty. This means that we must maintain, conserve and increase, where possible, the stocks available on the planet and increase those on natural, human, economic and social capital.

The natural capital of the planet, or natural resources and processes, is the basis of human activities and life itself.

Human capital does not mean the simple number of individuals, but the wealth of skills possessed and the state of health and economic well-being.

Economic capital is the means by which activities that promote business development are carried out.

Social capital is the set of governmental and private institutions that combine human and economic capital in harmony with natural capital to achieve welfare objectives (Schweizerische Eidgenossenschaft, 2019).

According to a recent FAO 2018 report on sustainable food systems, sustainable development[29] in the agri-food sector from an economic point of view should ensure added value for all actors in the supply chain. Therefore, it should guarantee profits for companies, better wages for workers, guarantee of food supplies and higher tax revenues for governments. From a social point of view, sustainable development of the agri-food sector should be fair with regard to the distribution of added value, the improvement of working conditions, the human nutritional level and animal welfare.

Finally, a sustainable system cannot ignore environmental aspects such as the impact of production processes on land, water and air use.

Socially responsible trade

The agri-food certifications promoted by NGOs place food safety and fair profit at the centre of their attention. In recent years, new certification schemes have been created such as Rainforest Alliance (RA), Marine Stewardship Council (MSC), Fairtrade Labelling Organizations International (FLO) and International Federation of Organic Agriculture Movements (IFOAM). The main effect of these programs has been to make the consumer feel like an active part in directing food production and the commercial system to make them act socially responsible.

[29] The set of economic, social and institutional transformation processes that can lead to a better life condition than the previous one represent the development of a region or a community. According to a study by Oya (2017) on salaries of employees, their overall family income and their standard of living do not seem to fully benefit from the certifications. This probably seems to be due to socio-economic factors deeply rooted in the territory which are not substantially influenced by the certifications.

In addition, retailer chains have developed their own certification schemes that are sensitive to social and environmental aspects (Barrientos & Dolan, 2012). An example is Social Accountability 8000 (SA 8000: 2014), an international certification standard prepared by the Accreditation Council of Economic Priorities Agency, now called Social Accountability International (SAI). SA 8000 certifies some aspects of corporate management relating to corporate social responsibility. This includes respect for human rights, respect for workers' rights, protection against the exploitation of minors and guarantees of safety and health in the workplace. The purpose of this standard is to improve working conditions worldwide and above all to define a standard that can be verified by accredited certification bodies.

Similarly, Fairtrade International is a non-profit international organization responsible for the Fairtrade certification mark. It aims to support the most disadvantaged workers and farmers in developing countries, offering them the opportunity to enter the international trading system in conditions of transparency and fairness in order to improve their working and living conditions.

In general, fair trade standards are rules that all actors in the supply chain can adhere to, i.e. farmers, workers, exporters, importers and food processing companies.

The environmental impact of agriculture

It should be noted that the reference standards for the LCA [30] (Life Cycle Assessment) are ISO 14040: 2006 which describes the principles and structure for the

[30] Annex VI of the European Commission Recommendation of 9 April 2013 - concerning the use of common methodologies for measuring and communicating the environmental performance during the life cycle of products and organizations - shows guidelines for the calculation of gas emissions greenhouse related to land use modification which has an impact on climate change.

In the Recommendation, land use is defined ≪ the impact category of the environmental footprint concerning the use (occupation) and conversion (transformation) of the territory with activities such as agriculture, road construction, houses, mines, etc. Land use considers the effects of land use, the area of the territory concerned and the duration of its occupation. The transformation of the soil considers the extent of the changes in the properties of the soil and the surface involved ≫.

assessment of the life cycle of products, and the standard 14044: 2006 which specifies the requirements and provides guidelines. The aforementioned products must be understood as including the means of production and the infrastructure necessary to produce them, or factories, tractors, means of transport, warehouses, etc.

In general, a sustainability study to evaluate products, services and organizations includes, in addition to the LCA, also the assessment of the carbon footprint and water footprint. These indicators describe an organization's activities and performance in terms of sustainable development, providing a framework of economic, environmental and social performance, considering both the positive and negative aspects. The result is the environmental product declaration. Over the years, various software has been developed (Pulina et al., 2017) to evaluate the environmental effects of agri-food production, particularly in the livestock sector.:

- Boustead consulting model (Dealy, J. M., 1980);
- Open LCA (www.org);
- Holos from Ministry of Agriculture and Agri-Food of Canada (www.agr.gc.ca/holos-ghg);
- USDA Dairy Gas Emissions Model, United States Department of Agriculture (https://www.ars.usda.gov/northeast-area/up-pa/pswmru/docs/dairy-gas-emissions-model/).

According to a FAO Statistics Division report (Tubiello et al., 2014), greenhouse gas emissions[31] from agriculture, forestry and other land uses (AFOLU) have been steadily increasing in the decade prior to 2012. The main agricultural emissions from crops and livestock would come from enteric fermentation (40%), manure left by grazing animals (16%), synthetic fertilizers (15%) and rice fields (10%). For example,

[31] During the entire life cycle or of a product, several greenhouse gases can be emitted, each with a greater or lesser capacity to retain heat in the atmosphere. The global warming potential of each gas is calculated in units of carbon dioxide equivalents (CO_2^{eq}) thus providing - in carbon footprint units - a useful measure for comparison.

the greenhouse gas associated with synthetic fertilizers is nitrous oxide (N_2O) which has a global warming potential[32] i.e. about 300 times that of CO_2 .

The pressure to support sustainability

The request for system certifications in the agri-food sector remains strong and the European Union, with its policies, places accreditation[33] at the centre of free trade agreements as a model for the good performance of international markets (Accredia, 2019). At the same time, non-governmental organizations (NGOs) also favoured by the spread of global networking have sensitized public opinion on issues of common interest. The main issues put at the centre of attention concern the defence of human rights, environmental protection, agriculture, cooperation, crafts, professional training, development, credit, etc.

[32] Definition: "Each individual climate-changing gas is characterized by its own Global Warming Potential (GWP or Global Warming Potential). The GWP is the measure of how much a molecule of a certain greenhouse gas (carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons and sulfur hexafluoride) contributes to the greenhouse effect; the index is based on a relative scale that compares each gas with carbon dioxide, whose GWP has by definition the value 1. The value of the GWP is valid within a certain interval of time and can therefore change in the medium term; in fact, the GWP of a certain molecule depends on the time interval in respect of which it was calculated. Thus, methane has a GWP of 25 over the course of one hundred years but equal to 72 over the twenty years. The GWP therefore represents the relationship between global warming caused in a given period of time by a particular substance and heating caused by the same amount of carbon dioxide. Nitrous oxide, for example, has a GPW (100 years) equal to 298: this means that a ton of nitrous oxide released into the atmosphere causes an increase in the greenhouse effect equal to that caused by the emission of 298 tons of CO_2. The use of GWP weight factors allows both to combine the emissions of the individual greenhouse gases and assess global warming, and to identify the contributions of the individual emission sources to the overall formation of greenhouse gases" (Source: Agenzia Regionale per la Protezione dell'Ambiente della Lombardia).

[33] The International Accreditation Forum is the worldwide association of accreditation conformity assessment bodies in the field of management systems, products, services, personnel and other similar conformity assessment programs. The European cooperation for Accreditation (EA) is a European association of national accreditation bodies, officially recognized by the respective national governments, for conformity assessment. The Italian Accreditation Body ACCREDIA, member of the EA, is indicated by the Italian Government and recognized on the national territory to attest the conformity of the certification and inspection bodies.

This made people aware of the need to necessarily believe a new model of consumption of products and services offered according to the paradigms of sustainability.

Following the globalization of the market, these organizations feared the possible negative scenarios on agriculture, workers, the environment and animals. In this context, after an initial phase of criticism of government actions, they found it more effective to focus their actions and requests directly on the production companies perceived as responsible for various problems (Gereffi & Lee, 2014). With strong consensus and recognition by public institutions, they now form opinion groups capable of influencing environmental policy and development initiatives in poor countries.

As a rule, NGOs agree with the principles of the United Nations 2030 Agenda. As a result, they have taken an active role in defining new private certification standards in fair trade. For example, they helped develop programs such as the Marine Stewardship Council, the Forest Stewardship Council and the Rainforest Alliance. These certification programs operate according to the criteria of respect for the environment and environmental sustainability, so that companies choose high quality raw materials and abandon, as far as possible, operating practices capable of depleting the resources of the sea, the soil and forests. Under these pressures, large production and distribution groups have changed their approach by adopting policies based on ethics and sustainability.

The social effects of sustainability

The sustainability of agri-food production implies a balanced use of resources, promotes the conservation of soil fertility and uses renewable energy sources. It also promotes non-chemical pest control methods, safeguards natural biological balances and protects biodiversity[34]. The concept is that in addition to the legitimate economic

[34] In general terms, biodiversity is understood as the variety of all living things: the different plants, animals and microorganisms, the genetic information they contain and the ecosystems they form. Biodiversity is usually studied at three levels: genetic diversity, species diversity and ecosystem diversity. These three levels integrate to create the complexity of life on Earth.

interests of the market, it is certainly useful to preserve the ecosystem to guarantee the future of the planet and the well-being of present and future generations

Areas of agri-food sustainability programmes

Fishing

Sustainable fishing is supported by those activities that leave the marine ecosystem intact, preserving the population of income fish over time and safeguarding other species. A sustainable fishing program provides for effective business management with regard to equipment, fishing downtime and the effects of fishing on the marine habitat.

Compliance with the principles of the Marine Stewardship Council (MSC) certifies that marine products are fished sustainably. The main food retailers, many fishermen's companies and associations and important environmental organizations join the MSC program (Ponte, 2012). This independent non-profit organization promotes an eco-labelling scheme for fisheries certification, the purpose of which is to verify compliance with eco-sustainable fishing practices by awarding an MSC eco-label to companies that meet the assessment standards.

Another sustainable fishing program is the Best Aquaculture Practices (BAP). It is a third-party aquaculture certification plan compliant with the Global Food Safety Initiative (GFSI) and the Global Sustainable Seafood Initiative (GSSI). In summary, the objectives of the Global Food Safety Initiative are to harmonize the various food safety management systems through recognition documents. The Global Sustainable Seafood Initiative's approach is to adopt the FAO Code of Conduct for Responsible Fisheries (CCRF), the FAO Guidelines for the Eco-label of fish and fishery fishery products maritime / inland and FAO technical guidelines for aquaculture certification. The purpose of these codes is to pursue the objective of minimizing the environmental impact of fishing to meet a growing global demand for fish products. BAP certification is managed by the Global Aquaculture Alliance (GAA), a non-profit organization dedicated to respecting environmental operators and their communities, animal welfare and ensuring food safety. Aquaculture facilities rated as compliant with the BAP scheme can bear the mark.

Agriculture

Sustainable agriculture is the set of activities that guarantees the conservation of biodiversity and tends to improve land use methods. Another aim is to improve commercial practices and consequently positively influence consumer behaviour.

Rainforest Alliance is a non-governmental organization that promotes sustainable agriculture. The goal is to implement management systems for agricultural businesses in respect of natural resources and the living and working conditions of the community. It develops guidelines and provides training to entrepreneurs interested in reducing the environmental impact of their activities in line with safeguarding their profits. Agri-food companies that adhere to these sustainable practices and comply with these requirements can apply for and obtain the Rainforest Alliance Sustainable Agriculture Standard certification.

Forestry

Forestry is the complex of activities related to the sowing, conservation and use of forests. Sustainable forestry ensures the protection of forests with a high environmental value and the protection of endangered species. In addition, it assigns a part of the territory as a natural reserve, establishes, through guidelines, how to manage timber, guarantees development opportunities and decent conditions for workers in the sector and protects the rights of local communities. Compliance with these requirements ensures that the Forest Stewardship Council certification is obtained.

The feed industry

In Europe in 2015, the Specialty Feed Ingredients Sustainability (SFIS) project studied the ingredients to help mitigate the environmental impact of pig and poultry production systems. The SFIS consortium is managed by the International Feed Industry Federation (IFIF) and the European Association of Special Feed Ingredients and their Mixtures (FEFANA). It includes the American Feed Industry Association (AFIA), the Japanese Feed Producers Association (JFMA) and the Brazilian Feed Industry Association (Sindirações), as well as companies active in the production of feed and special feed ingredients.

SFIS research investigated low-protein diets [35] containing amino acids and phytases in pig and poultry farms. The overall study results appear to indicate a significant reduction in global warming potential, as well as the potential for eutrophication[36] and acidification due to livestock production. In the future, this will be considered a useful mitigation measure to reduce the environmental impact of animal production (IFIF, 2015).

Key sustainability-based certification schemes

Nowadays the voluntary standards of the agri-food sector promote supply chain management methods in the context of modern globalized trade. In this context, the national accreditation organizations attest to the competence, independence and impartiality of the certification bodies that carry out inspection and verification of processes and products. This complex structure, in addition to guaranteeing food security, plays an important role as a development engine for economic growth, the creation of business opportunities, the creation of jobs, the reduction of poverty, and the development of scientific research.

[35] Livestock are often given plant-based food such as soybeans which are rich in phytic acid. Cattle have no problems because in their many stomachs they have bacteria that can hydrolyze phytic acid by releasing phosphate ions that can be assimilated by the animal.

Pigs and chickens, on the other hand, have only one stomach and most of the phytic acid passes through it undigested. This causes two problems: animals need another source of phosphate to grow, and also the phytic acid present in their manure if released into the environment can cause eutrophication of rivers and lakes. To solve both of these problems, animal feed is often added with the phytase enzyme which hydrolyzes the phytic acid in the stomach of animals (Source: https://www.pianetachimica.it/mol_mese/mol_mese_2018/09_Fitasi/Fitasi.htm).

[36] It is an event of trophic enrichment of lakes, ponds and, in general, of bodies of water with weak exchange; it is due to the washing away of fertilizers used in the cultivation of the surrounding lands or to organic pollution produced by human activities or to industrial waste products. It causes the so-called phytoplankton blooms which, by lowering the oxygen content, make the environment unsuitable for other species, e.g. fish (Source: Treccani).

Fairtrade International

Fairtrade International is a non-profit multi-stakeholder[37] organization, it is an association of producers and national fair-trade organizations (Fairtrade, 2019). Fairtrade certification guarantees global supply chains that the established social, economic and environmental standards are respected and offers customers functional services for the production of products such as, for example, cocoa, coffee, honey, bananas, dried fruit, fresh vegetables, rice, spices, tea. The purpose of the Fairtrade standard is to guarantee fair working conditions and certify sustainable agriculture, measure the carbon footprint[38] and assess the impact of commercial practices (Bennett, 2017). Fairtrade International is a member of the International Social and Environmental Accreditation and Labelling Alliance.

Ethical Tea Partnership

Ethical Tea Partnership (ETP) is a non-profit organization that works with tea producers and tea industries. It was set up by some large British tea packaging companies to promote the tea industry as socially fair and sustainable. The ETP enters into contracts with independent third-party auditing agencies to ensure that manufacturing companies meet the requirements of the global ETP standard based on good environmental management practices (Loconto, 2010). In this sense, it is

[37] The stakeholders are all the subjects, individuals or organizations, actively involved in an economic initiative (project, company), whose interest is negatively or positively influenced by the result and by the progress of the initiative and whose action or reaction in turn influences the phases or completion of a project or the fate of an organization. An organization has a multi-stakeholder nature when it takes into account not only the legitimate interests of shareholders, that is stockholder, but also those equally legitimate of other stakeholders: employees, consumers, suppliers, national and local communities and even the future generations, through sustainable development strategies that focus on the environment, health and safety (Source: Treccani).

[38] The carbon footprint is defined as the total emission of greenhouse gases caused directly and indirectly by an individual, an organization, a company, an event or a product. It is calculated by summing the emissions deriving from each stage of the life of a product or service.

understood that such practices should be implemented in tea plantations and production and processing factories.

Sustainable Agriculture Network

Sustainable Agriculture Network is an international network of non-governmental organizations independent of national and international governmental organizations. The mission of the network is to be a global network capable of transforming agriculture into a sustainable activity that acts in a world where agriculture contributes to the conservation of biodiversity and provides sustainable livelihoods (Jordan & Constance, 2008). Overall, this network promotes the development of rural areas, fights against uncontrolled deforestation, provides support to farmers to implement agricultural practices through a process of increasing skills. In this regard, the SAN / Rainforest Alliance[39] certification scheme monitors agricultural activities aimed at promoting the maintenance of water resources and healthy soils through cultivation practices that protect the environment. Ultimately, the aim is to improve the productivity and resilience[40] of companies to climate change and at the same time possibly increase the livelihood of farmers, workers and their families (Lubell et al., 2011). A further aspect linked to the sustainability of production is that compliance with the SAN standard can help reduce greenhouse[41] gas emissions from agricultural practices

[39] Rainforest Alliance is a non-governmental organization with the aim of working to conserve biodiversity and ensure sustainable living conditions, transforming land use practices, business practices and consumer behavior for the better.

[40] Resilience here takes on the meaning of a system's ability to adapt to changes.

[41] As is known, greenhouse gases are those gases of both natural and anthropogenic origin present in the atmosphere. They are transparent to solar radiation that enters the Earth and absorb and emit at specific wavelengths in the infrared radiation spectrum. In this way they retain part of the infrared radiation emitted by the earth's surface, the atmosphere and clouds. These properties cause the phenomenon known as the greenhouse effect. The main greenhouse gases present in the Earth's atmosphere are water vapor (H_2O), carbon dioxide (CO_2), nitrous oxide (N_2O), methane (CH_4) and sulfur hexafluoride (SF_6).

Humane Farm Animal Care

Humane Farm Animal Care (HFAC) is a US non-profit certification organization dedicated to improving the life of livestock from birth to slaughter. Certified Humane Raised and Handled is the standard developed by HFAC that certifies food products, such as meat, poultry, eggs and dairy products, as coming from structures that meet certain requirements for the treatment of animals on farms (Botreau et al., 2007).

Animal Welfare Approved

Animal Welfare is an American animal welfare certification organization. The mission is to ensure consumers that animals are raised outdoors (Lusk, 2011). The standard is approved by the USDA, the Department of Agriculture of the United States of America and is recognized for small agri-food companies that practice high-welfare agriculture for animals on open field pastures.

Marine Stewardship Council

Marine Stewardship Council (MSC) is an international non-profit organization whose mission is to promote sustainable fishing practices to protect life in the seas and safeguard the supply of fish and seafood for the future. Two voluntary certification standards relating to fishing and traceability have been developed. The certification of compliance with the *MSC fishing standard* is applicable to all fishing activities of marine or freshwater organisms and affects most types of fish and molluscs. The *MSC chain of custody standard* is a traceability standard applicable throughout the supply chain up to the final sale. Each company involved in the supply chain that manages or sells an MSC certified product must meet the requirements established by the scheme. This ensures that the fish comes from certified sustainable fishing (Ponte, 2012).

Ecolabel (for the European Union)

Ecolabel is a guarantee mark designed for all operators (manufacturers, importers, service providers, wholesalers or retailers) who want to stand out on the market for their commitment to the environment (European Union, 2019).

The European Union eco-label does not apply to food or feed. The link with the food industry concerns cultivation substrates, soil improvers and mulch[42] which are regulated by Commission Decision 2015/299 / EU of 18 November 2015.

[42] Soil improvers are substances which, due to their nutrient content or their particular chemical, physical and biological characteristics, contribute to the improvement of the fertility of agricultural land or to the nourishment of cultivated plant species or, in any case, to their better development. Mulch is the set of dry leaves and sticks that pile up on the ground under the trees or elsewhere, especially when it starts to rot (Source: Treccani).

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Chapter 8

Group Purchasing Organizations, Food retailers

The '90s and critical food safety events

Consumer confidence in public institutions and in the agri-food supply chain was, so to speak, violated by food scandals that raised great alarm among public opinion in the 1990s and following. At that time, a number of major international food safety crises occurred due to dioxin, Listeria and bovine spongiform encephalopathy (BSE). The latter caused the death of many people in the United Kingdom due to a variant of Creutzfeld-Jacob disease (vCJD), the human form of BSE (EFSA, 2019). These emergencies alarmed consumers, public opinion and national governments. Food producers and retailers began to adopt some safety programs but, without any coordination, the results were inconclusive. At the same time, the level of confidence of the processing industries and consumers reached a very low level. It was then that, driven by a wind of radical renewal regarding the approach to food security, private non-governmental organizations placed the assessment of the impact of agricultural practices on the environment at the centre of their initiatives. The aspects related to the exploitation of the resources of the territory, the welfare of the animals, and the working conditions of the farmers, also entered fully into this new way of setting up the agri-food sector. These initiatives have promoted sustainable agricultural practices to protect the environment and the poorest populations for global well-being and have encouraged the development of fair and supportive commercial practices.

Actions taken to counteract crises

Following what is briefly described, the operators involved along the agri-food chain both in the B2B and B2C areas[43] have developed a large number of standards in order to offer guarantees of hygiene and health safety on the products and services offered to their customers. To date, the main standards adopted are the BRC, IFS, FSSC 22000, GlobalGAP and QS, ISO 22000, ISO 22005 programs, as well as Regulation

[43] Business to Business (B2B) is the commercial exchange of products or services between companies. Business to Consumer (B2C) is direct sales to the consumer.

(EC) No. 834/07 for organic production and Regulation (EU) No. 1151 / 2012 for PDO, PGI and TSG productions.

Large retailers, thanks to their dominant position in the global commercial network, can use standards as a tool to manage the supply of food products (Boström et al., 2015). Supermarket chains are known to often ask their suppliers to voluntarily adopt specific standards in order to protect their reputation from unpredictable mishaps. Third-party certifications allow retailers to monitor the product throughout the supply chain. In this way, retailers achieve a substantial reduction in costs because both the monitoring of production processes and the strict responsibilities are transferred to their suppliers. This practice has indisputable advantages over first-party and second-party audits since third-party bodies carry out the audits. They verify that suppliers take all reasonable precautions to ensure that a food product complies with the food safety requirements of the laws. In confirmation of this, some studies (Busch & Bain, 2004) have verified that food safety monitoring is largely entrusted to third-party certification bodies. On the other hand, suppliers also feel the need to certify their compliance with the standards recognized by the global market if they wish to maintain or expand their market share. This is especially true when they wish to enter particular market segments such as, for example, organic products or non-GMO products. On the other hand, the commitment made in respecting the requirements of the standards and the consequent quality certification legitimizes suppliers in the eyes of consumers and interested parties (Hatanaka et al., 2006). In this context, companies facing investments in new equipment, logistics, management systems, staff training and so on, expect a positive response regarding the potential benefits in terms of development and market presence. Another important aspect plays the role of outsourcing activities [44] because it involves harmonizing its standards with those of the activities carried out externally. Last but not

[44] By implementing outsourcing, the company entrusts an activity of its own company to a specialized external company in order to reduce costs in certain processes to focus more on the company's core business. A typical example is the company that entrusts its distribution of goods produced to a logistics company for the phase relating to the warehouse and its management.

least, the central role of the system of traceability of goods which alone guarantees full and detailed knowledge of any food safety problem to trace it back to its origin

Trading and private standards in Europe

Over the years, all those quality standards have been successful, the aim of which has been to ensure the safety and quality of food along the supply chain. For example, in the UK, large retailers started asking their suppliers to be certified according to the British Retailers Consortium Global food standard scheme, and still require it. This standard, which arose in 1998, over time has become one of the main international standards for food safety. The international association Global Food Safety Initiative has accepted the BRC standard, considering it a valid tool to guarantee food safety along the entire supply chain.

In Austria, Switzerland, France, Germany and Italy, retailers ask their suppliers to be certified according to the International Food Standard (IFS) private scheme. This standard focuses its action on quality and the health and hygiene safety of food products, basing its management system on the principles of the HACCP method.

Finally, all suppliers of retailers, by applying Good Manufacture Practices (GMP) in the production, distribution and storage phases, demonstrate that they supply products that comply with the law and contractual specifications and therefore guarantee safe products.

Expansion of private standards

Despite the presence of an appreciable legislation on the safety of food products, further quality management criteria have been established through the certification of process and product management systems. Agricultural production and the food industry find a valid support in the quality management systems regulated by the ISO 9001 standard. In the same way, the food safety management system is regulated by the ISO 22000 standard, while the certification of the environmental management systems it complies with ISO 14001. Furthermore, the traceability of the supply chain is guaranteed by the ISO 22005 certification which guarantees the organization’s commitment to checking products entering and leaving the company.

Quality certification involves significant costs. In particular, it is possible to classify these costs into:

- costs to optimize business management regarding planning and organization;
- costs in terms of time and money to make staff aware of certification practices;
- costs related to inspections carried out by the certification body.

The main motivation that drives companies to seek quality certification is due to the increased competitiveness of the market. Huge financial resources are invested in large companies to raise awareness and educate staff on quality issues. For small businesses, where employee education can be simpler and more direct, the decision-making engine usually consists of a specific request from retailers in order to sell their products on a large scale. For this reason, quality certification, even if voluntary, often becomes an essential requirement, under penalty of exclusion from the market context. According to Accredia data, in March 2018 in Italy an important number of production sites were certified.

Table 9. Statistics on certified sites in Italy and in the Emilia-Romagna region concerning the quality management system in agri-food companies.

Standard	**Number of certified sites in Italy**	**Number of certified sites in the Emilia-Romagna region**	**Percentage share of the region over the whole of Italy**
UNI EN ISO 9001	122,774	10,046	8.2 %
UNI EN ISO 14001	22,008	1,881	8.5 %
BS OHSAS 18001	16,962	1,619	9.5 %
UNI EN ISO 22000	1,235	156	12.6 %
FSSC 22000	235	17	7.2 %
FAMI-QS	3	2	66.7 %
Total	163,217	13,721	8.4 %

(Source: Accredia, based on data updated in March 2018)

The distribution networks

In the agri-food sector, there are bodies that bring together the main European distribution chains to guarantee retailers and consumers regarding the origin of the products distributed.

Euro-Retailer Produce Working Group (Eurep) Good Agricultural Practices (GAP), i.e. EurepGAP now called GlobalGAP, is a group that identifies and defines the good agricultural practices to be applied so that the quality of the products is recognized within the commercial network (GlobalGAP, 2019).

Similarly, the International Federation of Organic Agriculture Movements is an international organization that deals with organic agriculture and promotes it through the codification of rules and Regulations for the organic field (IFOAM, 2019).

The food distribution network is structured to connect primary producers with consumers. Contacts are made through various commercial offices and various commercial intermediaries. Basically, the flow of products starts from primary producers, that is, small, medium and large farms that grow the products of the land or raise livestock. Their products can be acquired by central processing units, i.e. industrial companies that process primary products. Subsequently, wholesalers, who have the structure and function of commercial companies, transfer the goods to the distribution network. In Italy, large-scale food distribution is organized in chains of points of sale associated with commercial groups combined in an associative or cooperative form, such as, for example, Conad, or in retail chains connected to a single company group such as, for example, example, Esselunga.

The classic structures developed up to the first years of this decade saw the birth of the hypermarket, a retail operation in a fixed location divided into departments - food and non-food - each of which had, respectively, the characteristics of a supermarket and department store. The hypermarket thus represented the evolution of the supermarket. In particular, the grocery sector provides fixed-price sales, is organized as a self-service with payment on exit, and presents a vast assortment of foods for the most part pre-packaged in the same way as many non-food items in common use.

At the same time, in urban centres, retail trade has evolved towards the minimarket, a retail activity in a fixed location that operates in the food sector with the same characteristics as the supermarket.

Finally, in the non-food sector, trade has developed towards department stores, permanent retail structures with separate departments, each of which is intended for the sale of consumer goods and items belonging to product sectors (Mattioli & Füßer, 2012).

Table 10. Classification of sales facilities in Italy according to D.Lgs. 114/1998.

	Neighbourhood shops	**Medium Sales Facilities**	**Large Sales Structures**
Italian municipalities with a resident population of less than 10000 inhabitants	Sales Area not exceeding 150 sqm	Area between 150 sqm and 1500 sqm	Surface greater than 1500 sqm
Italian municipalities with a resident population of more than 10000 inhabitants	Sales Area not exceeding 250 sqm	Area between 250 sqm and 2500 sqm	Surface Greater than 2500 sqm

(Source: Mattioli & Füßer, 2012)

This classic food distribution format is experiencing a change in consumer habits who are no longer exclusively or almost exclusively linked to a trusted brand but often go to different points of sale to meet particular social needs (Panza, 2013). Typically, the consumer attends the mall as a social gathering place to meet, have lunch, shop and then distribute food shopping during the week. In this context, the task of marketing was to reposition the distribution of products on the market. In other words, a distinction was made between brands with branded products with their own personality, innovative and distinctive commercial activities were launched with apparently trivial forms of customer loyalty, such as the acquisition of catalogue prizes that can be acquired in based on the expenditure made. Often it is not only a pricing policy that attracts the consumer, but rather the satisfaction of the customer's expectations and needs (Il Sole 24 Ore, 2019). The idea is that the offer of the stores expands to include categories of consumers with different lifestyles. To do this, retailers commission market surveys to specialized agencies that use consumer panels to study new trends, the evolution of purchasing behaviour and changes in individual and family needs. The leading

companies in this field offer marketing support to retailers in identifying and optimizing the most suitable solutions for their commercial growth.

The economic crisis that began in 2008 has undermined the identity of the middle class by changing consumer habits. The current consumer is divided into two bands. A medium-low segment of the market to which a large part of the population belongs, which focuses on savings but without sacrificing quality. On the contrary, a high-end market has developed which pays great attention to the quality of the products, thus favouring the market of local farmers. Local products are offered, presented as a short 0 km chain with a very low environmental impact and presented as a safeguard for biodiversity (Il Sole 24 Ore, 2019). In this context, hypermarkets, traditionally frequented by the middle class, would currently be subject to a rethinking and reconfiguration by large distribution groups.

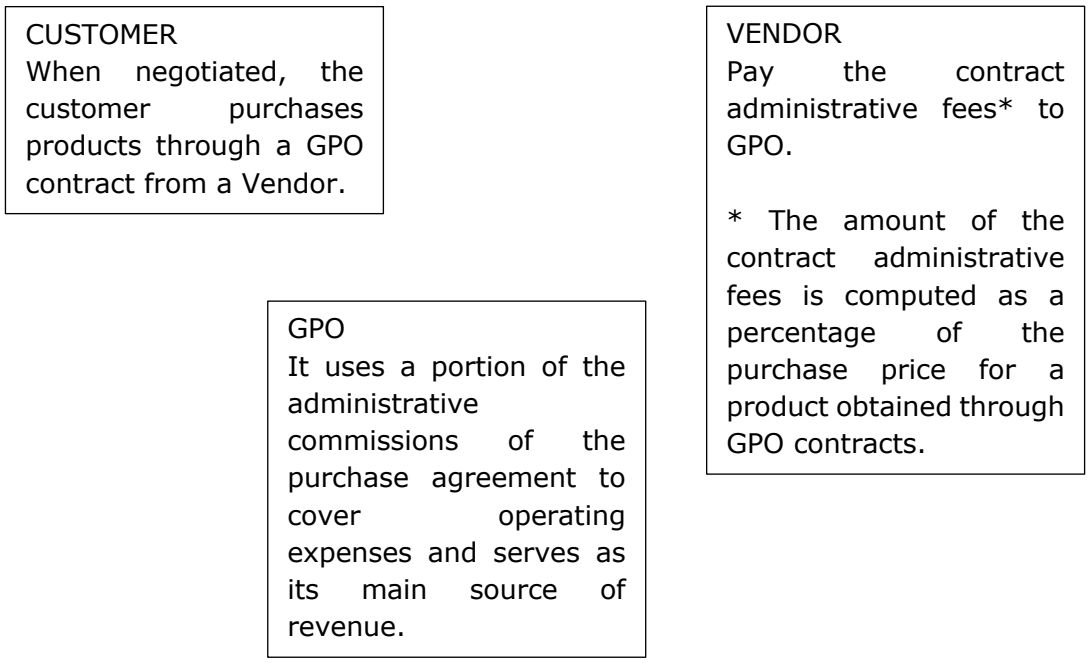
Group Purchasing Organizations

The purchase of goods through purchasing centres is a strategic tool spread all over the world both in the public and private sectors. Group Purchasing Organizations through strong international partnerships offer both better prices to their customers and growth prospects for suppliers. The clear aim is to obtain maximum profit by leveraging the strength of the expressed purchasing power by aiming to obtain better prices from suppliers.

The preliminary activities of aggregation and homogenization of commercial needs, containment and rationalization of expenses and sharing of solutions in the interest of all actors in the supply chain from producer to consumer, are essential criteria in the process of selecting suppliers for respect of those standards (Weinstein, 2006).

Purchases are not made directly by Group Purchasing Organizations. Upstream, they only set the price of the transactions. Downstream, purchases of goods are made by individual distribution chains in favour of their associates or sales outlets. Suppliers pay the administrative costs of the contract to GPO. The contract administration fee is calculated as a percentage of the purchase price for a product sold through GPO contracts.

Figure 3. Relationship between GPO, Vendors and Customers.



(Chart created by the author on the basis of a report by Linda T. Kohn, 2010)

Group Purchasing Organizations' services

As already mentioned, the Group Purchasing Organizations create sales channels for producers and suppliers. In addition, they provide their interlocutors with useful services such as benchmarking and e-commerce.

Benchmarking

The literal meaning of the word benchmarking is comparative analysis.

When organizations analyse the different aspects of their processes in relation to best practices adopted within a group of companies of the same purpose, then they are carrying out a comparative comparison (Mittal & Krejci, 2015). A natural complement to benchmarking is the development of strategic management plans to improve processes for the stated purpose of increasing the level of certain aspects and performance indicators. If in the past benchmarking was a unique periodic event, nowadays the new quality standards consider benchmarking as a continuous process during which organizations seek improvement where possible.

e-commerce

The literal meaning of the word e-commerce is the process of buying and selling products online also referring to electronic transactions.

In the field of e-commerce, inbound marketing has found space, which is a method of selling products that begins with the identification of customers who have expressed interest (called leads) towards a product or service. Then the manufacturer comes into direct contact with the customer to start a relationship that helps him in the needs (of products or services). This phase is delicate because in order for the relationship between the seller and the customer to continue it is necessary to understand the objectives that the customer has set himself, to implement the management of time and the tools to manage a commercial transaction which in the agri-food sector can be the supply of food (Severová et al., 2011). The final phase is not to persuade the customer to buy but to advise him in his purchase choice. Then, the customer who will perceive their satisfied needs will then move on to the concrete phase of the purchase.

Group Purchasing Organizations' evolution

Few Group Purchasing Organizations are at the top of the commercial chain and differ in history, governance and contractual practices. GPOs are financially strong entities with an essential intermediary function between producers and distributors. These business groups have developed greatly in recent decades, are very competitive and make the inclusion of new similar entities very difficult. This situation has raised some issues in public opinion.

One issue concerns the fact that these groups through their large-scale purchasing policies prevent the development of valid competition at the supplier level. Small companies or associations of supplier companies would have no way of reaching high levels of production such as to guarantee an economy of scale. As a result, they would not be able to compete with large suppliers. Another issue linked to the previous one is whether the prices of the products involved in the commercial transaction are actually the best possible considering the complex interactions of global trade. A further related topic concerns the duration of supply contracts which is often so protracted over time as to result in the definitive exclusion of small suppliers from the market. The combination

of these situations could reduce competition by creating an oligopoly situation (Marvel & Yang, 2008).

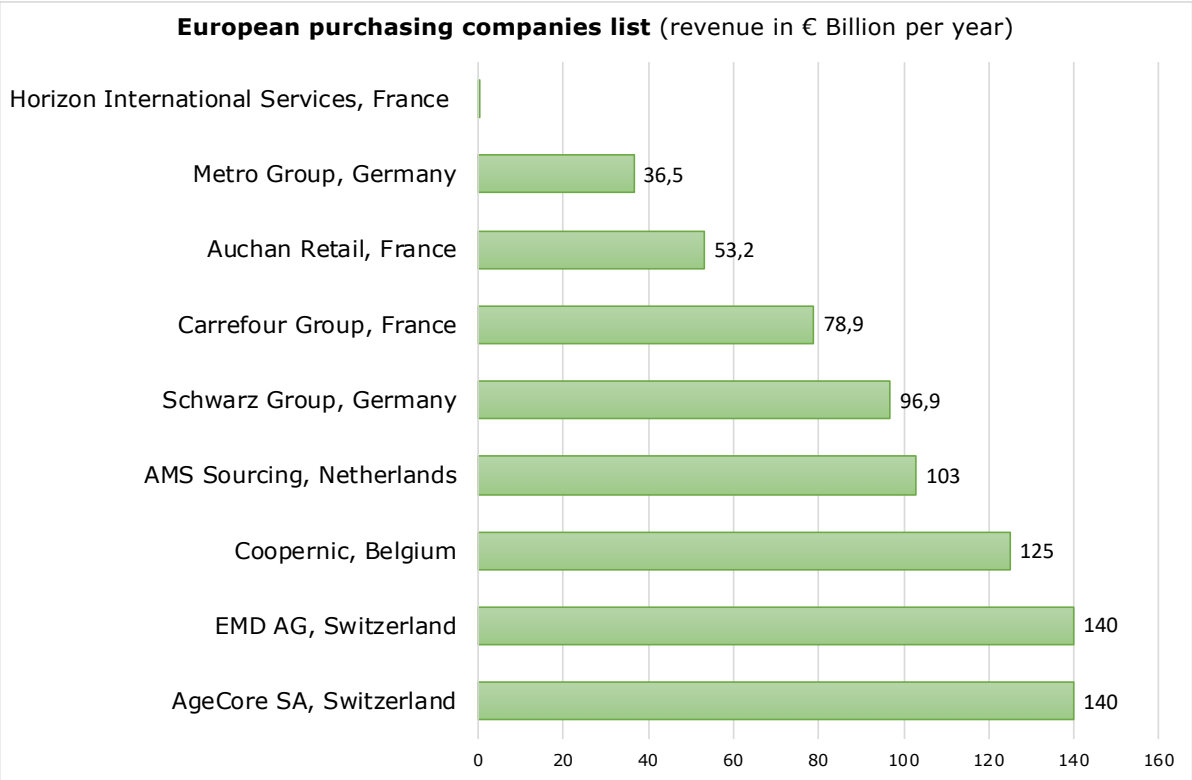
Table 11. Group Purchasing Organizations in Europe.

GPOs BASED IN EUROPE	**REVENUE IN $ BILLION (PER YEAR)**	**Approximate percentage rate without Horizon Int.**
AGECORE SA, SWITZERLAND	140.0 (2017)	18.1 %
EMD EUROPEAN MARKETING DISTRIBUTION AG, SWITZERLAND	140.0 (2017)	18.1 %
COOPERNIC, BELGIUM	125.0 (2015)	16.2 %
AMS SOURCING, NETHERLANDS	103.0 (2016)	13.3 %
SCHWARZ GROUP, GERMANY	96.9 (2017)	12.5 %
CARREFOUR GROUP, FRANCE	78.9 (2017)	10.2 %
AUCHAN RETAIL, FRANCE	53.2 (2017)	6.9 %
METRO GROUP, GERMANY	36.5 (2017)	4.7 %
HORIZON INTERNATIONAL SERVICES, FRANCE (ALLIANCE OF COMPANIES AUCHAN, METRO, CASINO, DIA)	No data available because it has been operational since 15th February 2019	NA

(Source: websites of the GPOs)

In fact, each purchasing centre generally does not exceed 20% of the market share (see table). Finally, the question arises of any conflict of interest between the Group Purchasing Organizations and the Food Retail Companies when their respective financial relationships meet (Day-Farnsworth et al., 2019).

Figure 4. Group Purchasing Organizations in Europe.



(Source: websites of the GPOs. Horizon is a multi-level commercial alliance between Auchan Retail, Casino Group, Metro Group and Dia. Please note no data yet available as it has been in business since February 2019)

Food retailers in Europe

The joint purchase of goods is very important in the activity of the purchasing groups because it has a positive impact due to the lower financial risks and the lower risks of food safety. By definition, the turnover of food retailers is represented by the revenue generated by the sale of goods or services or by any other use of capital or goods, associated with the main activities of the organization before deducting any costs or expenses. They are the first entry in a profit and loss account from which all expenses and costs are subtracted to finally reach net income. The table shows the main food retailers operating in the European continent and their economic impact in the food distribution sector.

Table 12. The European leading food and beverage retailers; revenue per year.

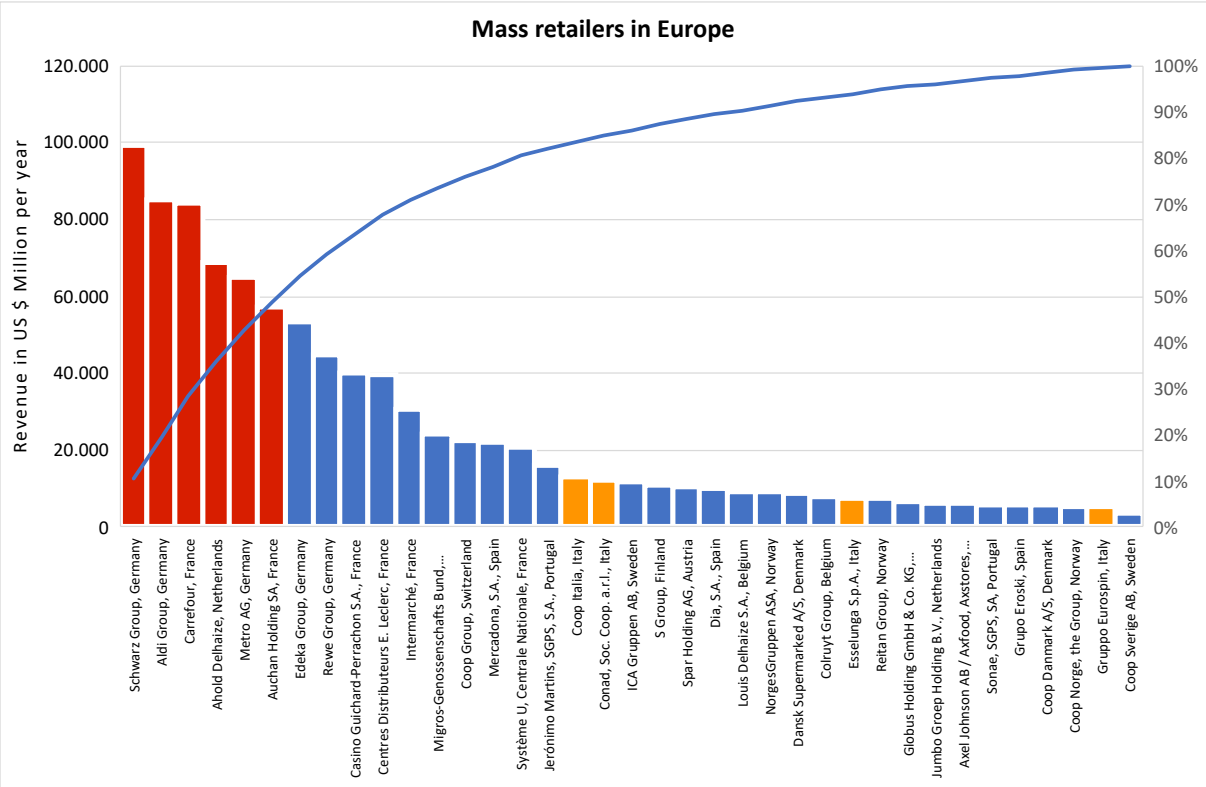
FOOD RETAIL COMPANIES BASED IN EUROPE	REVENUE IN US $ BILLION	BUSINESS ACTIVITIES
Schwarz Group[45], Germany	99,2	Hypermarket, Superstore
Aldi Group, Germany	84,9	Supermarkets
Carrefour, France	84,1	Hypermarket, Superstore
Ahold Delhaize, Netherlands	68,9	International food retailer
Metro AG, Germany	64,8	Diversified food and cash & carry retail
Auchan Holding SA, France	57,2	Hypermarkets, Outlets, Convenience stores
Edeka Group, Germany	53,5	Supermarkets
Rewe Group, Germany	44,6	Supermarkets, Diversified holdings
Casino Guichard-Perrachon S.A., France	39,8	Hypermarkets, Supermarkets, Discount chains
Centres Distributeurs E. Leclerc, France	39,6	Hypermarkets
Intermarché, France	30,7	Supermarkets
Migros-Genossenschafts Bund, Switzerland	24,1	Cooperative supermarkets
Coop Group, Switzerland	22,4	Cooperative supermarkets
Mercadona, S.A., Spain	21,9	Supermarket
Système U, Centrale Nationale, France	20,6	Supermarket
Jerónimo Martins, SGPS, S.A., Portugal	16,1	Discount store
Coop Italia, Italy	13,0	Hypermarket, Superstore
Conad Consorzio Nazionale, Dettaglianti Soc. Coop. a.r.l., Italy	12,3	Supermarket

[45] By way of information, Schwarz Group is the owner of the Lidl chain.

FOOD RETAIL COMPANIES BASED IN EUROPE	REVENUE IN US $ BILLION	BUSINESS ACTIVITIES
ICA Gruppen AB, Sweden	11,8	Supermarket
S Group, Finland	10,8	Supermarket
Spar Holding AG, Austria	10,4	Supermarket
Dia, S.A., Spain	9,8	Discount store
Louis Delhaize S.A., Belgium	9,1	Hypermarket, Superstore
NorgesGruppen ASA, Norway	9,0	Discount store
Dansk Supermarked A/S, Denmark	8,5	Discount store
Colruyt Group, Belgium	8,0	Supermarket
Esselunga S.p.A., Italy	7,6	Hypermarket, Superstore
Reitan Group, Norway	7,3	Discount store
Globus Holding GmbH & Co. KG, Germany	6,7	Hypermarket, Superstore
Jumbo Groep Holding B.V., Netherlands	6,0	Supermarket
Axel Johnson AB / Axfood, Axstores, Sweden	6,0	Supermarket
Sonae, SGPS, SA, Portugal	5,7	Supermarket
Grupo Eroski, Spain	5,6	Supermarket
Coop Danmark A/S, Denmark	5,6	Supermarket
Coop Norge, the Group, Norway	5,2	Supermarket
Gruppo Eurospin, Italy	5,1	Discount store
Coop Sverige AB, Sweden	3,6	Supermarket

(Source: The Balance Small Business, 2019)

Figure 5. The European leading food and beverage retailers.



Note please that the first 6 companies hold around 50% of the European market. Italian companies in orange. (Source: The Balance Small Business, 2019)

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Preface to case studies

The next three sections present detailed reports on research studies carried out in some companies. The conceptual tools, equipment and procedures used are described. The working groups that contributed to carrying out the research are also identified. Finally, the implications that can influence the agri-food sector are developed.

In the first case study, the company produces feed additives that aim to improve the intestinal absorption of nutrients by livestock. The topic of application of the FAMI-QS version 5.1 code of conduct in force at the time of the research study was discussed. The code represents a guideline for the production of quality feed in food safety. The code complies with Regulation (EC) No. 183/2005 which establishes the requirements for feed hygiene and promotes the development of guides on good manufacturing practices and good hygiene practices and the application of HACCP principles. In addition to evaluating GHP and GMP, reconfiguring the HACCP plan and drawing up an integrated management plan, the FAMI-QS Code audit checklist was used to carry out the study. In order to assess the progress over time of the level of compliance with the Code, each item of the Code has been assigned a differentiated score based on compliance or non-compliance with the requirements. Therefore, with the application of the analysis of the main components, the degree of compliance with the Code was assessed at the beginning and end of the study in an interval of about eight months.

In the second case study, the topic is that of gluten-free food and drink. The company in question is a brewery that produces different varieties of beer. Recently the brewery has introduced a gluten-free beer specifically designed for celiac customers who want to drink the drink while preserving the same sensory sensations offered by a normal beer. The system used by the company to obtain the gluten content within the legal limits is the use of a specific enzyme called endoprotease.

As is known, gluten-free foods are regulated by Regulation (EU) No. 1169/2011 and subsequent implementing Regulations. In Italy there is a label issued by the Ministry of Health which identifies foods with a gluten content of less than 20 ppm. In addition, it is possible to adhere to a voluntary labelling scheme called Spiga Barrata issued by the Italian Celiac Association. The company in question opted for the second option.

The choice was supported by the desire to accredit a line of products requested by the market.

The preliminary phase assessed compliance with good hygiene practices and the application of HACCP principles. The brewery's specific production processes have been studied according to the Good Manufacturing Practices of the Brewers Association's for Craft Brewers based in Boulder, Colorado, USA. As soon as the degree of compliance with the specifications was ascertained and corrective actions were implemented to achieve complete compliance with legal standards, the question of economic convenience in the production of different beers was addressed. In particular, with the Linear Programming methods (Chinneck, 2018) the different production options were compared.

In the third case study, placed in Appendix I, an already existing corporate HACCP plan was integrated. In particular, the company that produces jams, compotes, syrup, fruit pulp, extracts, fruit juices, nectar, muesli and herbal teas, has decided to create a new production line for a vitamin additive for jams, juices and other foods. with the aim of improving the nutritional properties of the finished product.

The work was carried out on two sides.

On the one hand, the correct execution of internal audits was verified according to Regulation (EC) No. 882/2004. The audits were aimed at verifying the correct application of the HACCP plan. This work was routinely performed by the company's staff and the documentation was recorded and archived at the company.

On the other hand, another research group of the University already present in the company for other reasons, monitored the compliance of the new product with the microbiological specifications relating to the maximum permissible levels of pathogenic microorganisms in food products pursuant to Regulation (EC). No. 2073/2005. The task of the working group was to integrate the information relating to the new product by preparing an additional document of the HACCP plan in order to make it available to the competent authorities in the field of food safety control.

Finally, in Appendix II a survey proposal is presented, for educational purposes only, which could represent a future field of investigation. In particular, the survey was designed to understand the approach of companies to the need to qualify their processes and products.

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Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

Chapter 9

Case Study No.1

A SME and FAMI-QS certification

Abstract

In the current context of global trade for a company it is increasingly essential to have a proven certificate of compliance with the standards recognized by the market. This study analyses the problems highlighted in a small company that has decided to acquire a quality certification. Undoubtedly the obligation to apply the HACCP system (European Union, 2011) in all the agri-food sectors has brought food safety to such high levels as never before. Private quality standards ensure a further guarantee of risk prevention not only in terms of food safety but also in terms of environmental protection and sustainability. The purpose of this research is to assess the degree of compliance of a small company to the requirements of a voluntary certification standard. In particular, the emphasis is placed on the specific features of a conformity assessment program that validates compliance with mandatory standards.

Compliance with the specifications of the FAMI-QS Code has been fully verified. The results of the study confirm that the challenges faced by an organization to expand into the market are demanding and that constant and motivated application work is necessary to achieve the objectives.

Introduction

The implementation of quality systems has become a universally accepted practice. The required requirements concern not only the product but also the management of the processes within the organization. It is no longer just an internal choice of the food industries, but it is a legal requirement. In the last decades a series of voluntary quality standards has been promoted by the mass retailers in order to allow food companies to access the global market. Companies that intend to become suppliers in local or global markets must assess whether the costs to comply with the requirements can be offset by the additional advantages offered by access to these markets. Measuring the costs and benefits of adopting a quality protocol is not a simple task as the company can often evaluate the results afterwards.

In this context, the company in question decided to adopt the Fami-QS Code of good practice. It is a quality management system whose application guarantees the implementation of the hygiene requirements regarding feed and animal feed, as required by Regulation (EC) No. 183/2005. The Community Regulation establishes the hygiene and safety requirements for the entire feed chain, including feed additives and premixes, while the FAMI-QS Code defines the operational conduct lines along the entire production and supply chain of feed and feed additives.

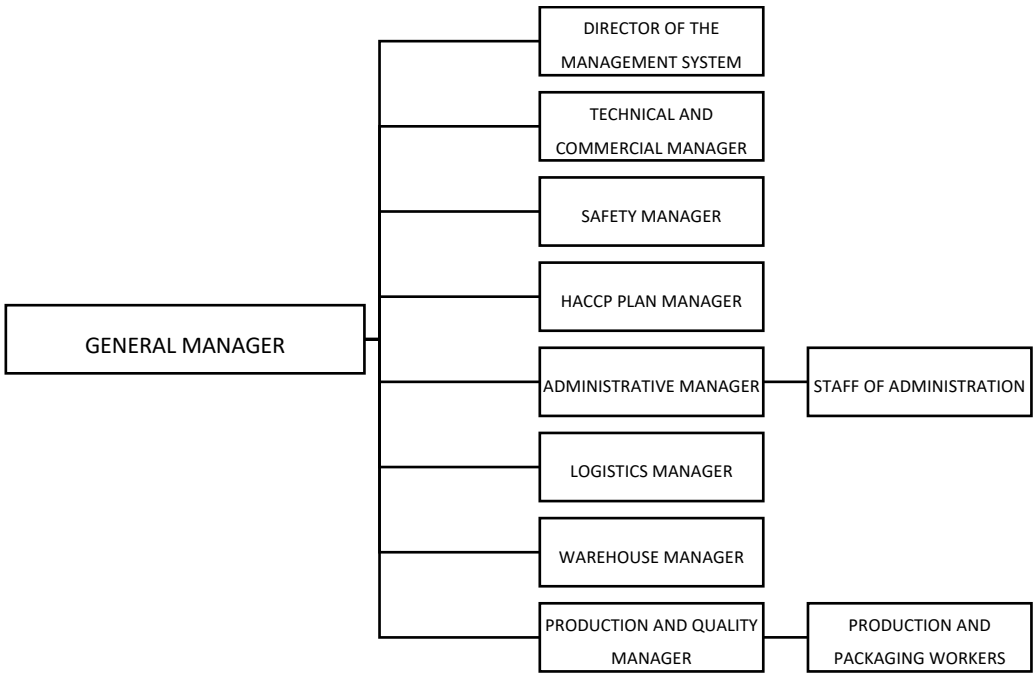
Company under review

The study was carried out for a year starting from December 2016. The host company, a small company, was founded in 1998 with headquarters in Reggio Emilia with the aim of wholesale trade in animal feed and additives. The company turnover was classified between 2 and 5 million euros in 2014 and 2015, and between 1 and 2 million euros in 2016. In 2016 the company starts a new activity in the production and distribution of raw materials, additives and complementary food products for the livestock industry. The production infrastructure is implanted in Bibbiano (RE) and is authorized for the marketing of feed additives, the marketing of feed premixes, the manufacture of feeds for third parties and the mixing of vegetable fats.

The company is authorized in accordance with to European Commission Regulations No. 183 of 2005 and No. 225 of 2012. The transfer of the office coincides with the transformation of the company from a simple retailer of third-party products to

a manufacturer of its own specialized lines of products related to feed additives. The market basin expands over time, from the local and national to the foreign one. It is precisely in this passage that the need arises to acquire a certification that certifies the conformity of processes and productions to the standards required by the global market. In the animal feed field, there are two applicable standards, the GMP Plus and the Fami-QS. This last standard is the one chosen by the company and this report intends to illustrate the problems faced to reach the goal.

Figure 6. Agristudio Srl company organization



Operating unit

The operational project has been carried out by a study group made up of representatives of the firm Agristudio and the University. In particular, Dr. Andrea Quartieri, head of production and quality, represented the company management. The academic contribution to the study was given by the present author, graduate Alice Boretti and Prof. Andrea Pulvirenti, at the time Director of the Doctoral School in Food

Biotechnology of the University of Modena and Reggio Emilia at the Department of Life Sciences.

Background

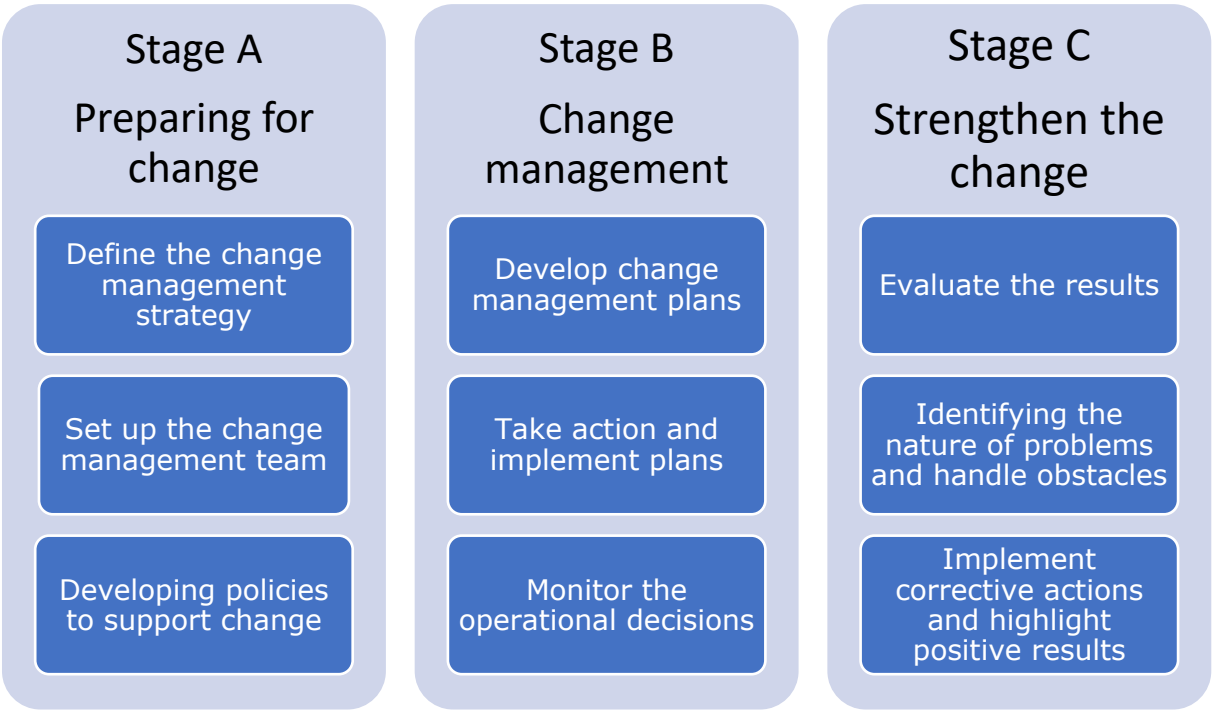
Transition management

In order to manage any innovation process, the project manager together with his management team must promote a sequence of activities to direct the transition phase towards the objectives set (D'Amato et al., 2016). In this delicate phase, the lack of a complete vision of what the socio-economic system can offer can lead a company in an undesirable direction.

The logical development of the project involves a series of questions to be answered. For example, in moving from a working method that only respects the mandatory rules to a voluntary accreditation method it is necessary to make a change or at least an integration of the procedures. In a company, the design and implementation of innovation are part of a complex decision-making process. In the innovation and change processes, all business areas are involved, such as marketing, production, research and development, each of which provides its own contribution (Silvestrelli, 2014). This delicate phase consists of three interconnected moments in which potential obstacles are identified and appropriate countermeasures are taken, data is collected, compliance is verified, problems are identified and solved and finally the projects are transformed into a feasible program. There are several design solutions on the market to help companies manage change professionally.

The most widespread models for managing organizational and process changes are the McKinsey models (McKinsey & Company, 2019), Kotter (Kotter International, 2019), Prosci 3-Phase Process for organizations and Prosci ADKAR Model for individuals (Prosci, 2019) and the Deming Cycle (Gorenflo & Moran, 2010).

Figure 7. Change management process



(Chart created by the author)

Suitability for change

To evaluate the company's willingness to change, it is important to consider the company organization, its history, cultural background, the number of employees, and interested parties such as lenders, suppliers, customers. The degree of readiness for innovation provides the team in charge with every useful element of study on the challenges and opportunities that may be encountered during the change process (Fonseca & Domingues, 2017). To effectively carry out this process, it is necessary to consider a few but essential factors. It is necessary to establish the extent of the change and identify the sectors concerned as well as the number of workers involved at all levels. It is necessary to know the system of values of the interested groups (management, workers, customers) and to evaluate in advance the level of resistance to change to be expected. Last but not least, it is crucial to assess the readiness of the organization to react to the proposals of the working group. Such proposals may concern, for example, the approach to production, process and documentation management, or risk management.

Communication of change

Communication must be effective. Change management necessarily goes through the creation of employee awareness of the need to change something. Therefore, the communication involves a careful analysis of the target and an accurate planning. The change management team must design a communication plan that addresses the needs of the employees and executives involved.

Each category of personnel has particular information needs based on their own role. At every stage of the process, communications should be designed to share the right messages at the right time. For example, early communications are structured to raise awareness about the reasons for business change and the risk of not changing.

Supporters of change

In a company, every step of change needs the supporting role played by senior management and company executives. The change management team needs to develop an action plan for corporate management whose commitment is the most important factor in change. This commitment results in active and perceptible participation by company executives throughout the process, through the creation of a coalition of intentions and direct communication with employees.

Management specificity

A manager has the power and duty to influence and direct the employee's motivation for change in order to encourage acceptance. The biggest obstacle to innovation can manifest itself in the inconsistent behavior of managers who thus become a source of resistance to change.

In this context, the role of the change management team to be set up ad hoc is to prepare a strategy to provide managers with useful tools to lead their employees successfully. It follows that an effective change is also achieved through the training of managers (Barbaro et al., 2011).

Implementation of training

Training must be implemented after assessing that all affected employees are aware of the need for change and willingness to support change. Training must take

place at the right time but above all it must develop the skills, knowledge and behaviours necessary to implement the change. Obviously, regulatory requirements must be the reference point for developing and providing training programs appropriate to the organization concerned.

Management of opposition to change

Some resistance from managers and employees is normal. It can be addressed with the support of methodologies and tools useful for perceiving problems in advance in order to plan the appropriate actions in time. In other words, it is useful to implement continuous two-way communication. Instead, persistent resistance can threaten the success of a project. This needs to be addressed in order to identify and fully understand the reasons, and then manage it appropriately (Miller & Rollnick, 2014).

Employee feedback and corrective actions

The process of change always creates effects on the business system. The evaluation of these effects serves to confirm or correct the process of change that is not one-way but involves employees. The planned and implemented corrective actions may interrupt the occurrence of negative and recurrent habits. A corrective action can be considered as a useful tool both for process control and for improving it.

Consolidation of change success

Continuous monitoring of the processes and corrective actions taken ensures that employees do not return to their previous *modus operandi*. In this regard, the adoption of a rewarding method and recognition of the positive results achieved serves to create the spirit of belonging within the organization and to consolidate virtuous behaviour.

Defining assessment indicators

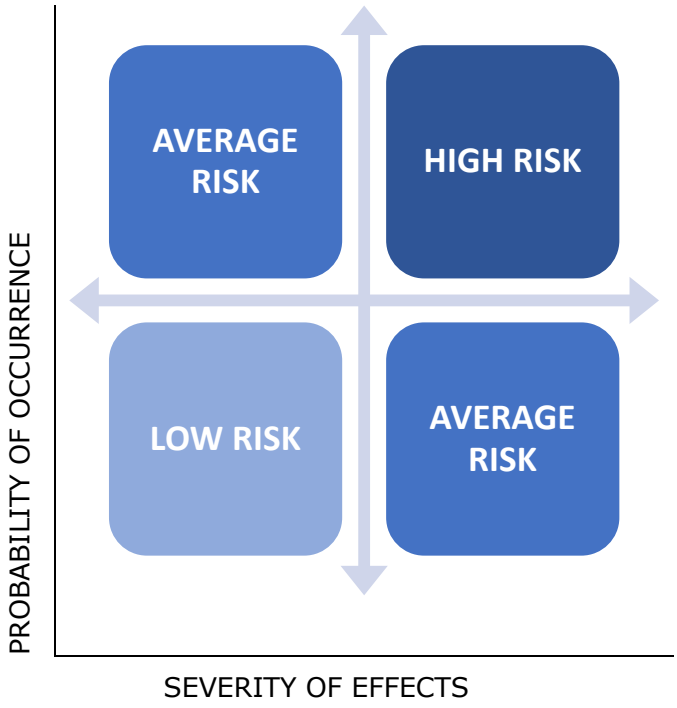
The analysis of the results of a project can only take place after taking measurements on specific indicators. The indicators are qualitative or quantitative variables whose purpose is to measure the level of achievement of the objective. These must be defined in relation to the objective to be achieved. It is important that the indicators are independent variables so that the measurements have full significance

(Elias, 2011). In this way, the analysis of the results can allow management to carefully evaluate the different aspects that characterize a change.

Risk management

Risk analysis and measurement techniques have the primary objective of assessing the expectation of risks and mitigating the severity of the effects. The areas involved depend on the business context, so process analysis, risk identification, preparation of risk mitigation plans and estimation of results are part of an effective risk management cycle. The goal is to create the conditions for corrective strategies that increase the chances of success and reduce the probability of failure of the control plan by minimizing uncertainty about the achievement of the organization's objectives (Barretta, 2017). The development of organizational models becomes functional for the management of technical, logistical and production processes. So, senior management decisions have to take into account risks and opportunities, creating the conditions for continuous improvement in each sector.

Figure 8. Risk matrix.



(Chart created by the author)

A possible different monitoring strategy

In a binary logic [46] the rightness of deductive reasoning assumes that each proposal, even complex, can only be assigned one of two truth values: true or false, or numerically 1 or 0.

Instead, in the real world, a purpose, an element, a decision, a concept, can be managed through the fuzzy logic closest to human reasoning (Zadeh, 1978; 1979). According to fuzzy logic, there is the possibility of representing an element as belonging to a set where it can assume all the values included in the interval between 1 and 0, true and false. In other words, in fuzzy logic a concept implies in itself uncertainty or a certain degree of true and at the same time a certain degree of false.

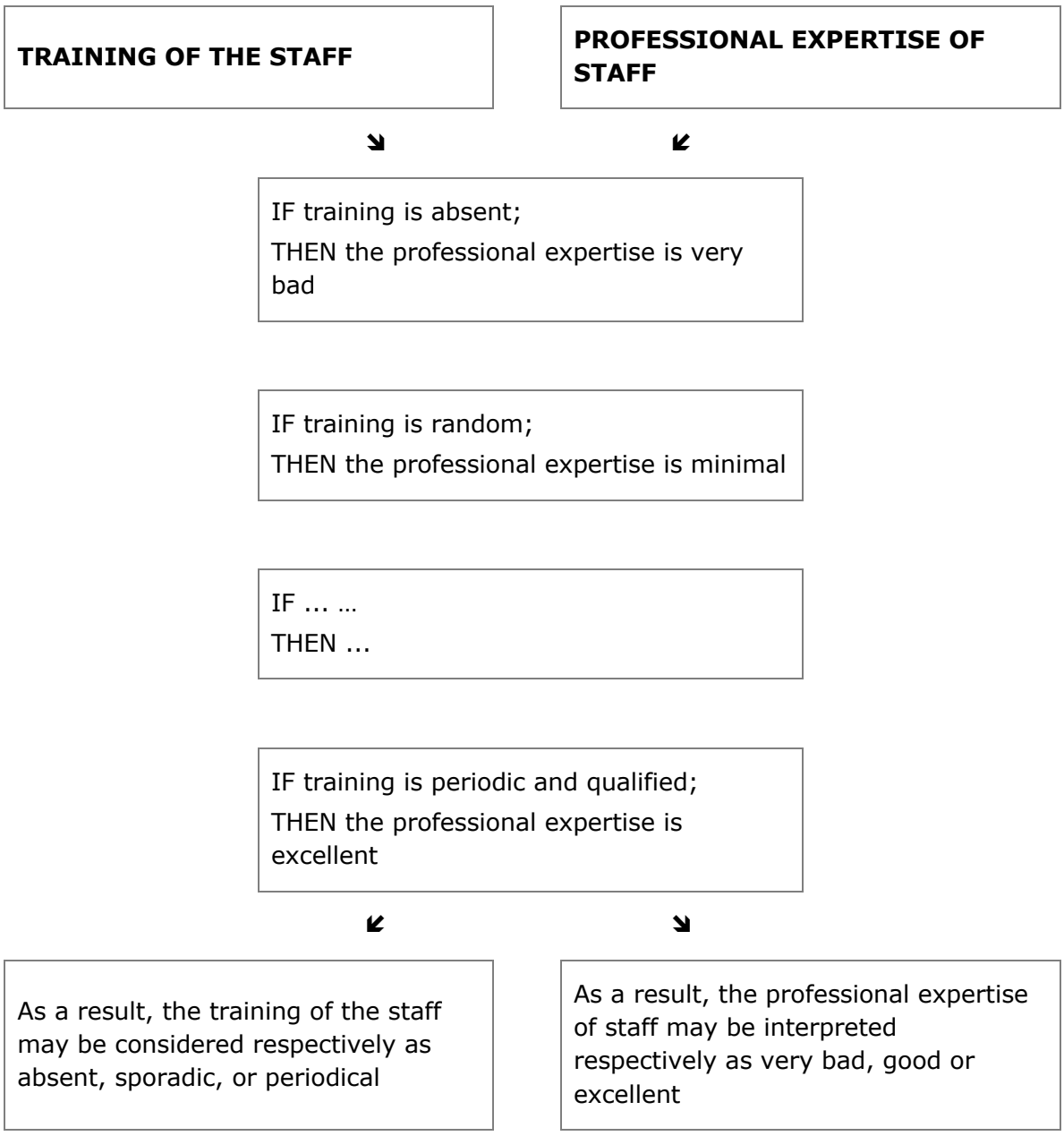
Fuzzy logic is applied in the field of systems control where there is a certain level of uncertainty of the variables in question. Fuzzy logic-based systems have rules expressed with intuitive language, such:

IF "parameter X is respected"	→	THEN "compliance is certain"
IF "Parameter X is not partially complied with"	→	THEN "compliance is partial"
IF "parameter X is not respected at all"	→	THEN "compliance is not there"

In order for the calculation system to interpret the established rules, it is necessary to define the terms. For example, parameter X could be staff training, as shown in Figure 9. It is necessary to clarify what is meant by compliance of parameter X because the compliance could be total, partial, or null. More formally, fuzzy inference is a method that interprets the values in the input vector and based on certain rules (IF ...; THEN ...) sets the values of the output vector.

[46] Binary logic means the correctness of deductive reasoning, admitting that only one of two values of truth, that is true or false, can be assigned to each statement. (Source: Treccani)

Figure 9. Fuzzy inference, an example.

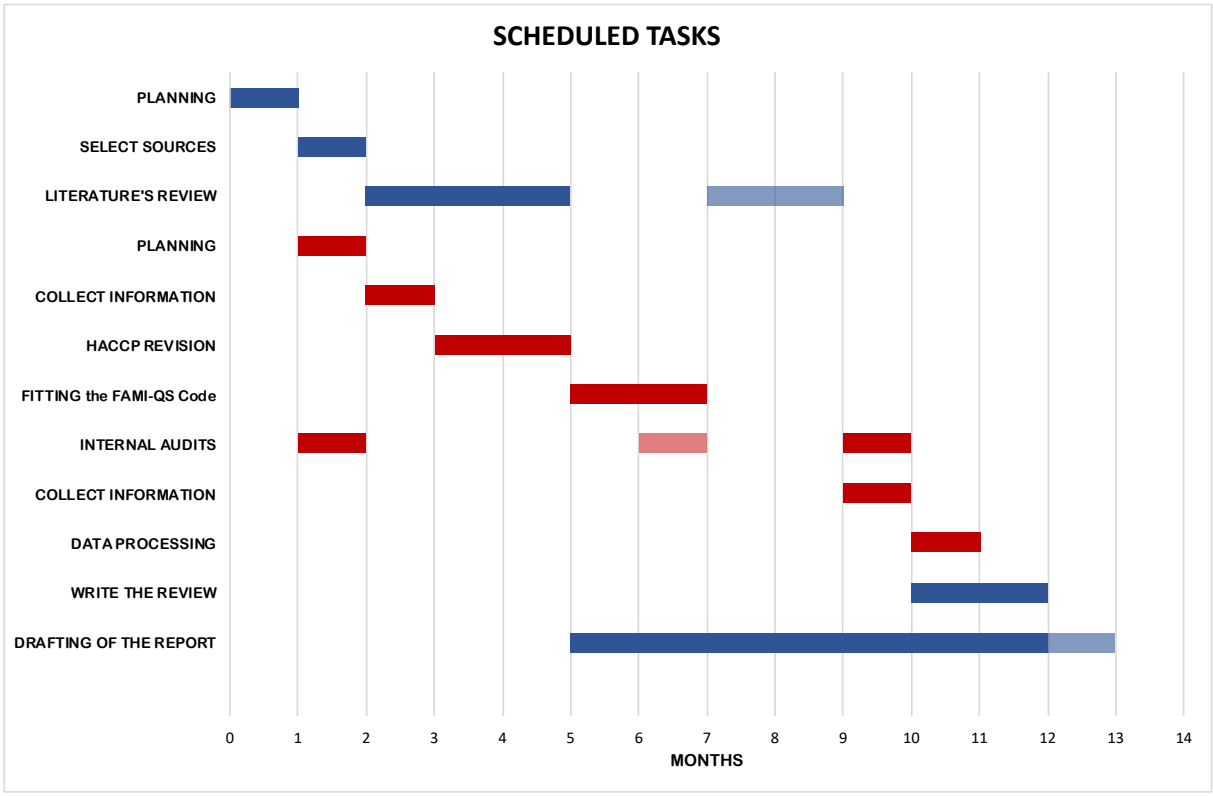


(Chart created by the author inspired by MathWorks data, https://it.mathworks.com)

Materials and methods

Project road map

Figure 10. Scheduled tasks from December 2016 to December 2017.



(Key: the complementary and supportive activities are in halftone, the experimental parts are in red, the preliminary and final stages are in solid blue)

Site inspection

During an introductory meeting with senior executives, managers and workers, our study group described the reasons for the operational change that was necessary to achieve the standards required by the FAMI-QS code. Based on the documentation provided by the company, it was decided to start a series of investigations on all the management aspects of the company. In particular, the introductory study concerned the internal reassessment of the requirements set by the local health company for carrying out the activities. Other aspects studied were document management, accident prevention plan, internal communications flow, good hygiene and good manufacturing

practices, warehouse management, water resource management, analytical control management, all the prerequisites for implementation of the self-control plan, and the application of the control plan based on the FAMI-QS scheme in pre-audit mode. The results showed some lack of compatibility. These differences were addressed in subsequent meetings with the staff in order to create awareness and obtain consensus on the proposed corrective measures.

Top workgroup tips

Product safety cards

It has been suggested that product safety sheets be set up in accordance with Regulation (EC) No. 1907/2006[47] and Regulation (EC) No. 453/2010[48].

A sample of a safety data sheet developed by our team is available in the annexes of this report.

Review of the quality management system

The integrated management manual, which has been revised, states:

- plan audits;
- establish verification methods;
- write down the controls;
- record the results of internal and external audits;
- evaluate suppliers;
- record customer complaints and requests;
- document process changes;
- report the results.

[47] Regulation (EC) No. 1907/06 concerning the registration, evaluation, authorization and restriction of chemical substances (REACH, Registration, Evaluation, Authorization and Restriction of Chemicals) and establishing a European Agency for chemical substances.

[48] Regulation (EC) No. 453/2010, amending Regulation (EC) No. 1907/2006.

Documentation management

The senior management was invited to adopt a standard operating procedure (SOP) for the management of documentation in accordance with the Fami-QS code (version 5.1, April 2009) for operators in the additives sector and feed premixes. A sample of standard operating procedure developed by our work group can be found in the annexes to the report.

Staff training

From the data collected, there is no omission to report regarding the continuous updating on what concerns food safety and traceability (EC Regulation No. 178/2002), food hygiene (EC Regulation No. 852/2004), hygiene of food of animal origin (EC Regulation No. 853/2004), marketing of feed additives (EC Regulation No. 183/2005 as amended by EC Regulation No. 225/2012).

Commodity control

Since sampling has never been implemented, it has been suggested to implement the relevant sampling procedure according to the guidelines of the Regulation (EC) No. 152/2009 as amended by Regulations (EU) No. 691/2013 and No. 51/2013.

Carry-over control

The company does not produce medicated feed for which there is no risk that pharmacologically active agents of a product are present in the processed immediately after. However, it is important that the feed complies with what has been agreed with the customer regarding the composition. Therefore, it is considered appropriate to implement the procedures to avoid the carry-over according to the indications of Annex 5 “Guidelines on carry-over” of the FAMI-QS Code.

Homogeneity of finished products

It does not seem that the methods for testing the homogeneity of the finished products have been adopted in the present and in the past. Nor are they planned for the future as the management believes that in the preparation phase the products are

processed in a mixer for a reasonable time deemed adequate to ensure product homogeneity.

Management of non-compliant products

There are no present and past events in the documents regarding non-compliant products.

Transport management

The transport of materials to and from the company is carried out by a transport company equipped with its own HACCP manual for the transport of feed additives plus feed premixes, and related raw materials.

Traceability management

From the data collected, the company usually keeps the documentation useful for the traceability of goods.

Collection management and product recall

Since it has never been implemented, it was decided to integrate the company management manual with an action plan drawn up in accordance with the note of the Italian Ministry of Health No. 0047556-15/12/2016-DGISAN-MDS-P (Ministero della Salute, 2017).

Complaints management

Since it has never been implemented, for the management of complaints it was proposed to set up a form to send to customers together with the products. The cover page of the form can be filled in by the customer to report the problem encountered, while the back page is for business use to indicate the corrective actions taken.

Management of non-certified products FAMI-QS Code

The FAMI-QS code allows companies to produce both certified and non-certified products in the same factory. But it is established that the processes are kept separate in space or time so as not to have carryovers. At the time of the study, there were still no certified productions. Furthermore, the production plant of the company did not have

such dimensions as to be able to separate the production lines of the certified products from those not certified and neither to double the production line. So, it was decided to produce the two types of production - certified and non-certified - in separate shifts in the future, declaring this possibility in the HACCP plan.

Questionnaires and interviews

The company management received questionnaires from us and was interviewed during the research. The aim was both to acquire useful elements for analysis and to instil awareness on some issues concerning food safety. These questionnaires formed the basis for a wide-ranging survey on the problems that a small company must face in the process of continuous improvement. A sample of questionnaires and interviews developed by our work group can be found in the annexes to this report.

Briefing to discuss best practice

The information gathered highlighted several problems that have been discussed at the meeting. They cover the forklift (approval, registration, authorization for outdoor activities); silos (dusts emitted outside); the dust suction system inside the plant (reduced suction capacity); waste disposal (disposal procedure, wastewater treatment); and finally, document management (document coding, archiving).

Results and discussion

Accordance with the requirements

Compliance with the requirements of the FAMI-QS code was tested in two stages 8 months apart.

As you know, the FAMI-QS Code is made up of 10 points.

Steps 1 to 3 concern the premise:

1) Introduction
2) Purpose
3) Terms and definitions

For the purposes of this study, internal audits were carried out on the outline of the Code taking into account the specifications from 4) to 10), carrying out the investigation on the following points:

4) Management system
    4.1. General requirements
    4.2. Management principles
    4.3. General documentation requirements
5) Management Responsibilities
    5.1. Management engagement
    5.2. Quality and safety policy
    5.3. Responsibilities, authority and communication
    5.4. Management representative
    5.5. Management control
6) Resource management
    6.1. Providing resources
    6.2. Human resources
    6.3. Infrastructure
    6.4. Maintenance and control of monitoring and measurement devices
    6.5. Cleaning
    6.6. Pest control
    6.7. Waste control
7) Product realization
    7.1. Product requirements
    7.2. HACCP Program
    7.3. Design and development
    7.4. Incoming Material Management
    7.5. Production of finished products
    7.6. Transportation
8) System review
    8.1. General requirements
    8.2. Internal audits

9) Checking for non-compliant products
   9.1. General requirements
   9.2. Complaints management system
   9.3. Recalls and retreats
   9.4. Crisis management
10) Statistical techniques

These 28 points include further specifications for a total of 232 items to be met. In the case in question, 3 items are not applicable, so compliance with the specifications of 229 items has been verified.

Table 13. Excerpt from the Code FAMI-QS checklist.

…	…
e	Is there a system in place to ensure management is kept up-dated on all relevant legislation, feed and food safety issues and other relevant guidelines?
4.3 General documentation requirements	
a	Does a written quality and safety policy exist?
B	Is there a Quality Manual in place?
C	Are documented procedures and records available?
…	… …
…	… …
5 Management responsibility	
5.1 Management commitment	
a	Can Management commitment to feed safety and quality be demonstrated?
5.2 Quality and Safety Policy	
a	Does the quality and safety policy specify the operator's objectives including regulatory and customer requirements?
…	…

Assignment of weighted values

The study group decided to evaluate based on 4 compliance levels: full compliance, minor non-compliance, major non-compliance, critical non-compliance. The goal was to encourage the progressive improvements obtained following the monitoring. The aim was therefore to make the efforts of staff and management profitable. The collected data was reworked by assigning weight classes based on the level of compliance.

In particular:

- +1 point for full conformity;
- -1 point for minor non-conformity;
- -3 point for major non-conformity;
- -5 point for critical non-conformity.

Interpreting the results

The tables shown in Addendum no. 1 summarize the analysis at the initial and final moment before starting the certification process. Thus, an improvement can be noted in the field of minor non-conformities and in that of major non-conformities. This consequently leads to an improvement in corporate performance regarding compliance with the Code. Unfortunately, a number of critical non-conformities persist throughout the reporting period and this situation precludes any possibility of clear compliance with the standard. In particular, at the time of the second internal audit, the Complaints Management System (point 9 of the FAMI-QS code) was not respected since a formal and documented procedure for the management of complaints had not yet been implemented. Furthermore, the formal procedure for the withdrawal of a product (to immediately inform the customer of any irregularities that could compromise the safety of the feed) has never been implemented and consequently has not been periodically reviewed to ensure that it complies with the integrated quality manual of the company and the mandatory technical specifications. And even more, point 8, System review - audit, highlighted the lack of internal audit planning. The tables show all the assessments and indicate how many conformities, minor non-conformities, major non-conformities and critical non-conformities were detected during the audits. The audits were carried out in accordance with the FAMI-QS V6 Code, version released on May 13, 2011.

Limitations of the study

Indeed, some situations have slowed down the path to certification. In particular, during the study period, the Production Director and Head of the Processing Department changed company for personal professional choices. The replacement of these important figures took place at different times and entailed the reconfiguration of the balance and dynamics of situation within the company.

In any event, in the tested period, as many as 44 items of the Code have improved regarding the degree of compliance. Respectively, critical non-conformities decreased by 5 units, non-conformities greater than 14 units and non-conformities less than 25 units. This shows that the study team's pragmatic and motivational drive has produced at least partially the desired effects. The most evident effects are observable in the Fami-QS instance concerning the Control of non-conforming product, and in the instance about the Management system. Minor improvements occurred in the other fields of the Code.

Statistical processing of data

t-test

The t-test is an effective method to tell if the difference between the results found between before and after an event or an intervention or a management measure is significant or if these results happened by chance.

A paired t-test is used to compare two population means where you have two samples in which observations in one sample can be paired with observations in the other sample. For example, before-and-after observations on the same subjects (e.g. veterinary drug's diagnostic test results before and after to assess whether the drug was effective, or as in the case of audits in the company).

Test interpretation

We supposed the company was undergone an internal audit before carrying out the FAMI_QS certification scheme (the Code) and then again after completing the prior stage. We wanted to find out if, in general, the management work leads to improvements

in compliance to Code (i.e. test scores). We were supposed to use the results to draw conclusions about the impact of this commitment.

There are two critical t values: one for a one-tailed test and one for a two-tailed test. It would be possible to perform a two-tailed test to verify that the second audit is more or less efficient than the first. But we don't care if it's worse, we just want it to be more efficient. So, simply we ran the one-tail test.

In this context, a paired t-test was conducted to compare the prerequisite of the FAMI-QS code in an internal audit in February and in an internal audit in October 2017.

We wanted to find out whether or not there was a significant difference between the average conditions. We thus found a significant difference in the scores for the February audit conditions (average = -8.392857143, variance = 175.1362434) and the October audit (average = -3.535714286, variance = 122.0357143); t (27) = -2.881923254, p = 0.003829353.

Table 14. Paired t-test

	FEBRUARY 2017	OCTOBER 2017
Mean	-8.392857143	-3.535714286
Variance	175.1362434	122.0357143
Observations	28	28
Pearson correlation	0.744341745	
Hypothesized Mean Difference	0	
df	27	
t Stat	-2.881923254	
P (T <= t) one-tail	0.003829353	
t Critical one-tail	1.703288446	
P (T <= t) two-tail	0.007658705	
t Critical two-tail	2.051830516	

At a glance, there seemed to have been a significant improvement but still many requirements were not met. Further study was still needed.

Factor analysis

Factor analysis is a mathematical technique that allows you to solve the correlations between variables in their determining causes, while the analysis of the main components is mainly aimed at the representation of the variability found in the sample rather than the interpretation of the correlations observed between measured variables. Like it, it causes the number of variables involved to be reduced to a set containing the most informative ones.

Principal Component Analysis

Principal Component Analysis (PCA) is a mathematical method that allows you to manage a number of possible related variables by reducing them to a significantly lower number of variables defined as main components. The PCA technique is useful for trying to analyze large datasets because it performs a transformation of the vector space[49] in order to reduce the dimensionality of the data set. In other words, the original dataset can represent many variables each with its own degree of importance or weight. Through a mathematical projection of these variables, the model can be interpreted with some virtual variables, the main components precisely. The analysis of the main components is useful for analyzing the structure of a set of multivariate observations, especially if you do not have preliminary information on how the measured variables are dependent or associated with each other (Treccani, 2019). This can make it easier for the researcher to identify any patterns, trends, or anomalies in the data set (Zaiontz,

[49] Linear space concerns the natural properties of the common three-dimensional space in which we act. In this space, given a point (origin) as a reference, two fundamental operations on the points (vectors) are defined: the possibility of adding together two vectors, producing a third, according to certain rules of coherence, and the possibility of multiplying a vector for a number, that is to make it flow along the straight line that joins it with the origin. In general terms, ≪ the vector space is the set of geometric vectors of the ordinary three-dimensional Euclidean space, between which the addition operation is defined, by the parallelogram rule, and the multiplication operation between a vector and a number real, called multiplication of a vector by a scalar. Once a Cartesian reference system XYZ with origin 0 is defined, a biunivocal correspondence is established between the vector space of the Euclidean vectors and the set of ordered triplets of real numbers R^3 that identify them ≫. (Source: Treccani)

2017). In addition, from the analysis of the main components, which is mainly aimed at the representation of the variability found in the sample, it is possible to formulate hypotheses regarding the influence that the single factors can have on the determination of the main i-th component.

Figure 11. An example of representation of the observations on two principal components.

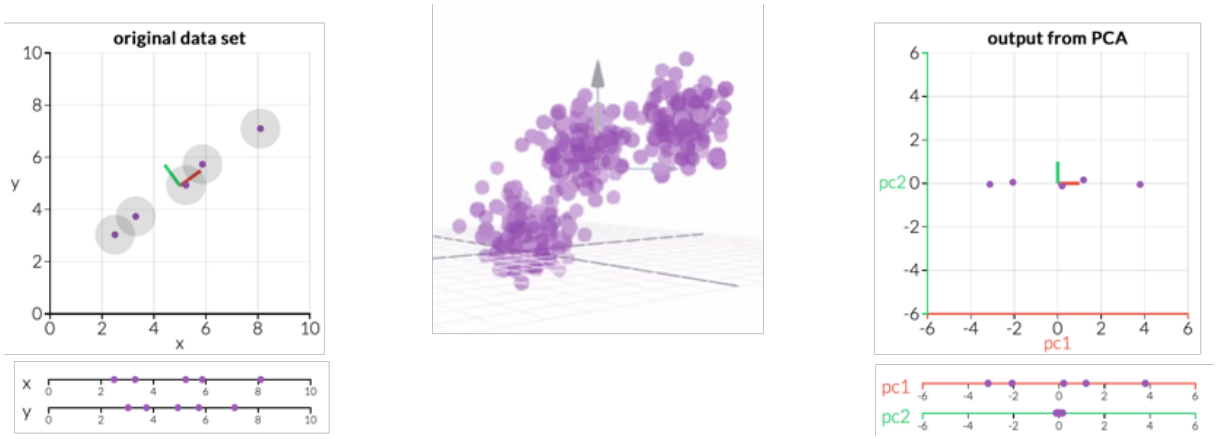
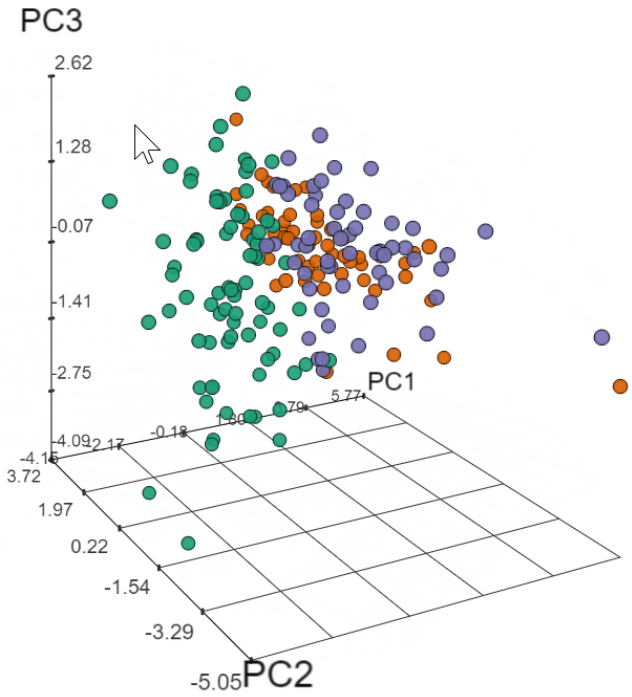


Figure 12. An example of representation of the observations on three principal components.



(Source: Cluster Analysis and Principal Components Analysis. https://www.rcharlie.com/blog/coachellar/)

In summary, the main purpose of the principal components analysis is to identify the hidden model in a set of data, reduce the dimensionality of the data by removing the background noise and redundancy in the data, and identify the related variables.

The PCA technique is particularly helpful when the variables within the data set are highly correlated. Correlation indicates that there are redundancies in the data. Due to this excess of information, the PCA can be used to reduce the original variables to fewer new variables which describe most of the variance in the original variables.

PCA meaning

PCA tool is particularly useful when dealing with a considerable number of variables from which you want to extract as much information as possible in order to work with a smaller set of variables (SAS, 2018). This occurs through a reduction of complexity through the linear transformation of the variables so as to project the original ones into a new Cartesian system in which the variables are ordered in descending order of variance. The analysis of the main components with reference to the variables P:

$X_1 , X_2 , ..., X_i , ..., X_P$

with i = 1, 2, ..., P,

allows identifying as many P variables:

$Y_1 , Y_2 , ..., Y_i , ..., Y_P$

different from the first ones,

with i = 1, 2, ..., P,

each of which is a linear transformation of the initial P variables.

The starting database is organized in a matrix, pointed out with X:

$$\vec{X} = \begin{bmatrix} X_{ij} \\ X_{ij} \\ \dots \\ \dots \\ X_{ij} \end{bmatrix} = \begin{bmatrix} X_{11} & \dots & X_{ij} & X_{1P} \\ X_{21} & \dots & X_{ij} & X_{2P} \\ \dots & \dots & \dots & \dots \\ \dots & \dots & \dots & \dots \\ X_{P1} & X_{Pj} & \dots & X_{PP} \end{bmatrix}$$

with i = 1, 2, ..., P

with j = 1, 2, ..., P

and where the rows represent the P observations made, and the columns are the P variables considered for the fact under analysis.

Given the matrix X containing P related variables, we want to get a matrix of new data Y composed of P variables uncorrelated with each other, which turn out to be a linear transformation of the first. The objective of the PCA consists in identifying suitable linear Y_i transformations of the observed variables that are easily interpretable and able to highlight and synthesize the information inherent in the initial matrix X.

The choice of the number of the main components

From the coordinate system that represents the raw data, the main components characterize a new coordinate system such that on the first axis there is the maximum variability of the system, on the second axis the second maximum variance of the system, beneath the first and greater than the successive, and so on. Obviously, the set of all the axes linked to all the main components explains the total variance. Starting from P variables (X_1 , X_2 , X_i … , X_P) with the aim to synthesize them in a lower number K of "artificial" variables, we can find up to P main components. The criteria used to reduce the number of main components from P to K with P ≥ K are essentially three.

The first criterion is to take only those components that represent at least 70 - 90% of the overall variability. In other words, indicating with λ_i the eigenvalues, we have to have:

$$\frac{\lambda_i + \lambda_i + \ldots + \lambda_K}{\lambda_i + \lambda_i + \lambda_i + \ldots + \lambda_P} \cong 0.70 / 0.90$$

where the numerator represents the variance of the first K main components, while the denominator represents the variance of all the main components P.

The second criterion is Kaiser's rule which states that we take only those components that have an eigenvalue $\lambda \geq 1$ or, alternatively, those components that have variance greater than the average calculated of λ_i.

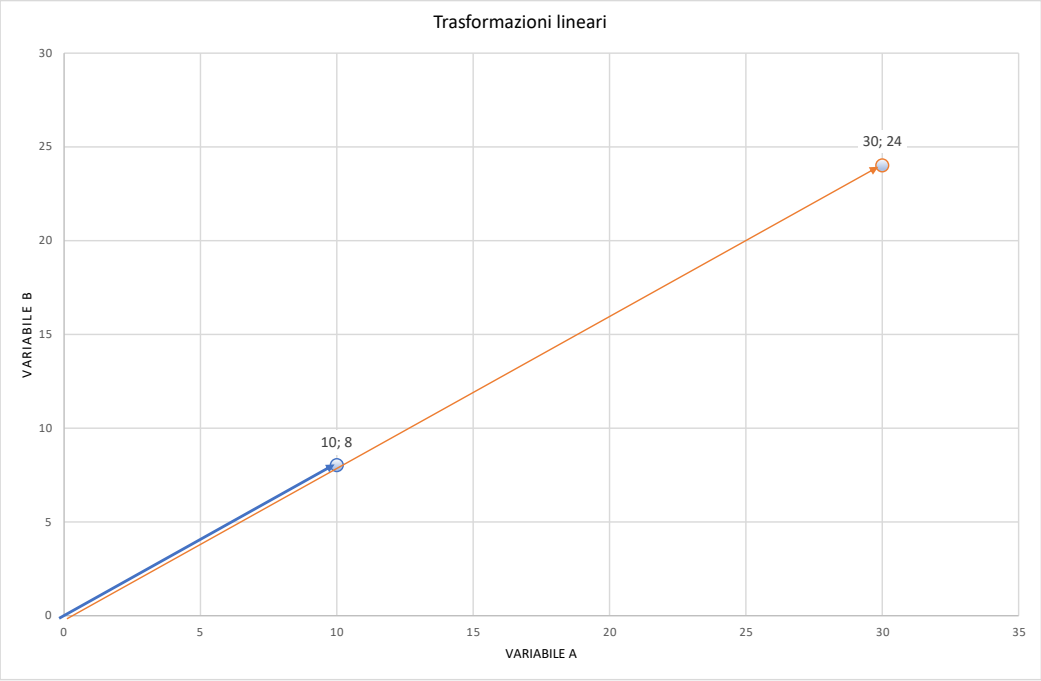
The third criterion uses the scree plot diagram, that is, the eigenvalue diagram. The order number of the eigenvalues from 1 to P is shown on the abscissa axis. The numerical value of the eigenvalues is on the ordinate axis. In this case, it is possible to

choose the number of main components, or the immediately lower number, corresponding to the point where the graph suddenly changes on a slope or beyond which the curve becomes slowly decreasing.

About eigenvalues and eigenvectors

When we have a large set of data, we can represent it with an array. We can use eigenvalues and eigenvectors to reduce the dimensional space after ensuring that most of the key information is maintained. To describe the process, it may be useful to give some preliminary definitions. Firstly, think back that a scalar is a quantity that can be defined by a number alone. A vector, on the other hand, must be specified by both a number and a direction. From a geometric point of view, a vector can be defined as a line segment having a specific direction and a specific length. So if we have, for example, an original vector *V* of coordinates [10, 8] that represents a point in space, in this case two-dimensional, and we multiply it by a vector or a scalar (for example, a scalar: 3) we get a new vector or a transformed vector [30, 24]. The new transformed vector does not change direction and is simply a scaled vector of the original vector. The scale factor is indicated by λ.

Figure 13. Linear transformation of a vector by a scalar.



(Chart created by the author)

Similarly, multiplying a certain vector *V* by a data matrix M yields another vector X such that the matrix has consequently made a transformation on the original input vector *V*.

$$\underset{\text{M}}{\begin{bmatrix} 5 & 4 \\ 2 & 3 \end{bmatrix}} \cdot \underset{V}{\begin{bmatrix} 10 \\ 8 \end{bmatrix}} = \underset{\text{X}}{\begin{bmatrix} 82 \\ 44 \end{bmatrix}}$$

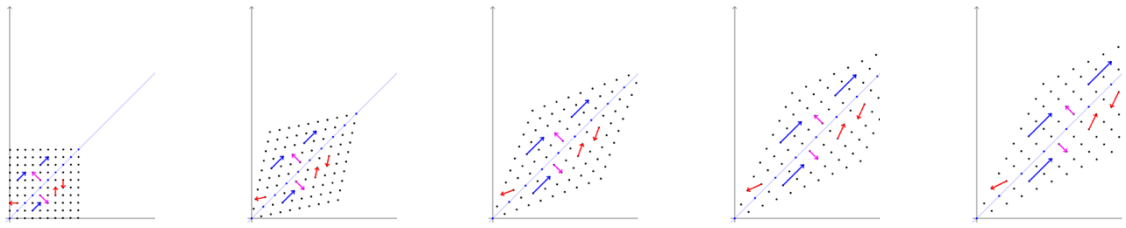
When any vector V is influenced by a given matrix M, it undergoes a transformation as illustrated in the sequence in the Figure 12.

Since the vectors shown in blue do not change direction then it is an eigenvector of the linear transformation M and the scale factor λ is the corresponding eigenvalue, so:

$$\text{M} \cdot V = \text{X} = \lambda \cdot V$$

The equation ($\text{M} \cdot V = \lambda \cdot V$) is called the eigenvalue equation.

Figure 14. Linear transformation of a vector by a matrix.



(Source : https://upload.wikimedia.org/wikipedia/commons/thumb/a/ad/Eigenvectors-extended.gif/300px-Eigenvectors-extended.gif)

Remember that the identity matrix I is the one that has the unit diagonally elements while all the other elements are null.

An example of a 2x2 identity matrix is shown below:

$$\text{I} = \begin{bmatrix} 1 & 0 \\ 0 & 1 \end{bmatrix}$$

By introducing the concept of identity matrix, the eigenvalue equation:

$$M \cdot V = \lambda \cdot V$$

it can be written like this: $M \cdot V = \lambda \cdot V \cdot I$

or: $M \cdot V - \lambda \cdot V \cdot I = 0$

namely: $(M - \lambda \cdot I) \cdot V = 0$

This equation presents non-zero values of the eigenvalues only if the determinant of the matrix $(M - \lambda \cdot I)$ equals 0 (zero).

The equation: $(M - \lambda \cdot I) = 0$

is called the characteristic equation of M.

Once the characteristic equation is given, it can be solved as shown below.

For example, the following 2 x 2 square matrix is given:

$$\begin{bmatrix} 5 & 4 \\ 2 & 3 \end{bmatrix}$$

Based on the foregoing, the characteristic equation to be solved is as follows:

$$\begin{bmatrix} 5 & 4 \\ 2 & 3 \end{bmatrix} - \lambda \cdot \begin{bmatrix} 1 & 0 \\ 0 & 1 \end{bmatrix} = 0$$

So:

$$\begin{bmatrix} 5 & 4 \\ 2 & 3 \end{bmatrix} - \begin{bmatrix} \lambda & 0 \\ 0 & \lambda \end{bmatrix}$$

You get it:

$$\begin{bmatrix} 5 - \lambda & 4 \\ 2 & 3 - \lambda \end{bmatrix}$$

Now calculate the determinant of the obtained matrix:

Matrix determinant $= (5 - \lambda) \cdot (3 - \lambda) - (4 \cdot 2) = 15 - 5\lambda - 3\lambda + \lambda^2 - 8 = \lambda^2 - 8\lambda + 7$

Solving the 2nd degree equation, $\lambda^2 - 8\lambda + 7$, with the formula:

$$(-b \pm \sqrt{b^2 - 4ac}) / 2a$$

then the following solutions are obtained whose values represent the eigenvalues:

$8 \pm \sqrt{64 - 28} = 8 \pm 6 =$

$= \lambda_1$ first eigenvalue = 14 (first solution of 2nd degree equation)

$= \lambda_2$ second eigenvalue = 2 (second solution of 2nd degree equation)

To calculate the eigenvectors, enter the values of λ in the equation:

$$M - \lambda \cdot I$$

So, with the first eigenvalue λ_1 we will have:

$$\begin{bmatrix} 5 & 4 \\ 2 & 3 \end{bmatrix} - 14 \cdot \begin{bmatrix} 1 & 0 \\ 0 & 1 \end{bmatrix}$$

$$\begin{bmatrix} 5 & 4 \\ 2 & 3 \end{bmatrix} - \begin{bmatrix} 14 & 0 \\ 0 & 14 \end{bmatrix}$$

And so, this is the first eigenvector of the given matrix M:

$$\begin{bmatrix} -9 & 4 \\ 2 & -11 \end{bmatrix}$$

With the second eigenvalue λ_2 we will have:

$$\begin{bmatrix} 5 & 4 \\ 2 & 3 \end{bmatrix} - 2 \cdot \begin{bmatrix} 1 & 0 \\ 0 & 1 \end{bmatrix}$$

$$\begin{bmatrix} 5 & 4 \\ 2 & 3 \end{bmatrix} - \begin{bmatrix} 2 & 0 \\ 0 & 2 \end{bmatrix}$$

And so, this other is the second eigenvector of the given matrix M:

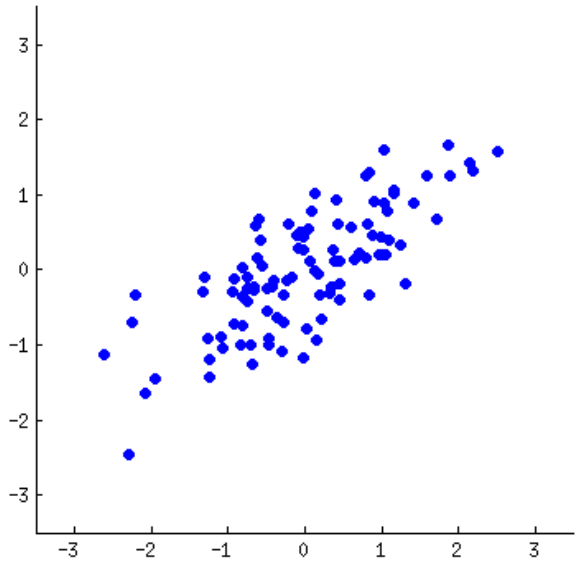
$$\begin{bmatrix} 3 & 4 \\ 2 & 1 \end{bmatrix}$$

To calculate arrays of data made from large multivariate observation databases, various commercial and academic software can help researchers for calculations. The main ones are: R, SAS, SPSS Statistics, XLSTAT, Minitab, Wincross, Survey reporter, Q Research software, and others. The usefulness of these software is that the enormous amount of manual work can be automated and make it simple to perform a sophisticated statistical analysis knowing the principles.

More on data analysis and information extraction

As is known, the average is the intermediate value between the upper and lower end in the set of multiple values considered. It is a central trend index of a data distribution. Variance is the arithmetic mean of the squares of the value deviations from their arithmetic mean. It is an index of data variability.

Figure 15. Scatterplot of normalized data.



By analyzing the variance, sample observations of phenomena dependent on one or more factors can be studied, in order to decide which factors are relevant and to estimate their effects. In essence, the variance gives us a measure of the amount of variability expressed by the data.

Given a set of normalized data[50] and reported on a Cartesian axis system, the PCA tries to establish relationships between the data through one of the possible straight lines such that it reflects the maximum variance. This line will be a main component. Another straight line orthogonal to the first will explain the subsequent noteworthy variance, and so below further orthogonal lines, as many as the size of the data, will constitute the main components.

Considering now the variables, the extent of the difference between them is expressed by the covariance. Now it may be that a variable varies because it is influenced by some factor.

A fortiori, if two or more variables vary, it is because they could influence each other or be affected by some latent variable.

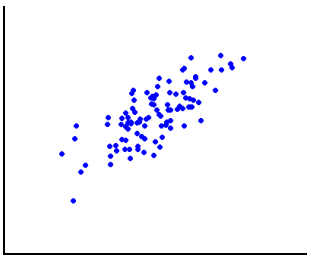
Typical covariance matrices are the following four examples[51] :

[50] Interestingly, sometimes the data of the source variables are not in themselves comparable. Think of the case where you want to compare athletes engaged in running tests where the unit of measurement is time and engaged in jumping tests where the unit of measurement can be a length or a height. Through data normalization procedures, these can be compared.

[51] Here are examples of matrices of size 2x2 where for each matrix are indicated the invented values, the corresponding formal matrix, and an example of a corresponding graph.

$$\begin{bmatrix} 3 & 1{,}3 \\ 1{,}3 & 2{,}8 \end{bmatrix}$$

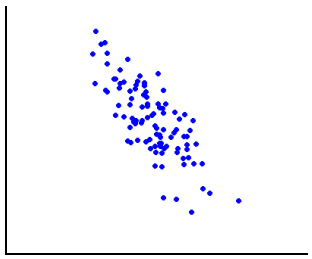
$$\begin{bmatrix} \sigma(x,x) & \sigma(x,y) \\ \sigma(y,x) & \sigma(y,y) \end{bmatrix}$$



Data scattered to the right at the top

$$\begin{bmatrix} 4 & -1{,}3 \\ -1{,}3 & 5 \end{bmatrix}$$

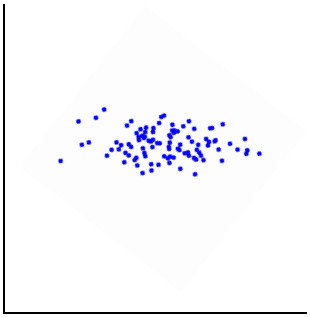
$$\begin{bmatrix} \sigma(x,x) & \sigma(x,y) \\ \sigma(y,x) & \sigma(y,y) \end{bmatrix}$$



Data scattered to the left at the top

$$\begin{bmatrix} 4{,}6 & 0 \\ 0 & 1 \end{bmatrix}$$

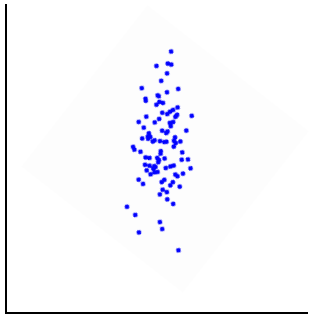
$$\begin{bmatrix} \sigma(x,x) & \sigma(x,y) \\ \sigma(y,x) & \sigma(y,y) \end{bmatrix}$$



Horizontally scattered data

$$\begin{bmatrix} 1{,}1 & 0 \\ 0 & 5 \end{bmatrix}$$

$$\begin{bmatrix} \sigma(x,x) & \sigma(x,y) \\ \sigma(y,x) & \sigma(y,y) \end{bmatrix}$$



Vertically scattered data

They have the elements on the top left σ (x, x) and on the bottom right σ (y, y) which respectively indicate the variance of the individual variable's "x" and "y". While the identical elements in the upper right σ (x, y) and lower left σ (y, x) represent the covariance between "x" and "y". As can be seen from the diagrams, the covariance matrices give an indication of how two variables vary together.

These matrices are called symmetric.

In summary, it can be said that while the dispersion of the data on the orthogonal axes is given by the variance while that along the eigenvectors is expressed by the covariance.

A further step may involve the rotation of the reference axes. In fact, since the eigenvectors of the covariance matrix are orthogonal to each other, they can act as new axes this time consisting of the main components. This can lead to information gain on the data set.

The structure of the PCA considered for the case study

The FAMI-QS Code checklist is designed to evaluate multiple management aspects. Includes questions about the management system, management responsibility, resource management, product realisation, system review, control of non-conforming products and statistical techniques.

The complete structure of the Fami-QS Code requirements is reported in Addendum No.1. Here, for the purposes of explanation, only point 4.1 of the Management System of the FAMI QS code is given:

4 Management system

4.1 General requirements

a) Is there a documented Management System (MS) in place?
b) Does the MS include regulatory, safety and customer requirements?
c) Does the MS cover all the operator's activities?
d) Are there other activities that conflict with the feed safety requirements?

Depending on the outcome of the audit, a different weight was assigned. And so, to the condition of full compliance has been arbitrarily attributed a positive weight of

+1, to the condition of minor non-compliance a negative weight of -1, to the major non-compliance a weight of -3 and finally to the situation of critical non-compliance a weight of -5.

The results of the audits were documented in February and October 2017.

The first internal audit verified the initial situation of the plant before starting with the certification process. The second audit took note of the results achieved following the corrective actions taken after the first audit.

The 28 points has been monitored by qualified company staff in order to assess the level of compliance with the FAMI QS Code.

A valid statistical method had to be adopted to give meaning to the data collected and identify trends or anomalies in the data set. In theory it would be possible to develop a series of scatter plots to determine the relationships between variables or observations. Of course, this method is neither feasible nor useful because the number of bi-varied graphs needed is equal to the number of simple combinations:

C (28, 2) = 28! / 2! (28-2)! = 378.

In the case in question we have a data set that refers to 28 main variables or the specifications that characterize the Code. In this case, the use of the Principal Component Analysis methods is appropriate, which allows you to analyze data sets referring to numerous variables.

Based on the analysis carried out, it was decided to preserve 2 of the 28 main components since the first two eigenvalues explain 80.078% of the variance.

Software used for recording and analysing measurement data

The data analysis for this paper was generated using the JMP® Version 15. SAS Institute Inc., Cary, NC, 1989-2019. A complete view of the tables showing the data base for the run of factor analysis are shown below.

Table 15. Audits results (raw data that is number of observations).

		CONFORMITY CLASS February 2017	CONFORMITY CLASS October 2017	MINOR NON-CONFORMITY CLASS February 2017	MINOR NON-CONFORMITY CLASS October 2017	MAJOR NON-CONFORMITY CLASS February 2017	MAJOR NON-CONFORMITY CLASS October 2017	CRITICAL NON-CONFORMITY CLASS February 2017	CRITICAL NON-CONFORMITY CLASS October 2017
		FEB FULL_C	**OCT FULL_C**	**FEB MIN_NC**	**OCT MIN_NC**	**FEB MAJ_NC**	**OCT MAJ_NC**	**FEB CRT_NC**	**OCT CRT_NC**
Point 4. General requirements	**OBS 4_1**	0	4	4	0	0	0	0	0
Point 4. Management principles	**OBS 4_2**	1	3	0	1	3	1	1	0
Point 4. General documentation requirements	**OBS 4_3**	4	10	7	1	1	1	2	2
Point 5. Management commitment	**OBS 5_1**	0	1	1	0	0	0	0	0
Point 5. Quality and Safety Policy	**OBS 5_2**	1	1	2	3	1	0	0	0
Point 5. Responsibility, authority and communication	**OBS 5_3**	3	3	1	1	0	0	2	2
Point 5. Management representative	**OBS 5_4**	0	1	0	0	0	0	3	2
Point 5. Management review	**OBS 5_5**	0	0	3	3	1	1	1	1
Point 6. Provision of resources	**OBS 6_1**	0	2	2	0	0	0	1	1
Point 6. Human resources	**OBS 6_2**	5	7	5	3	0	0	1	1
Point 6. Infrastructure	**OBS 6_3**	9	9	0	0	0	0	0	0
Point 6. Maintenance and control of monitoring and measuring devices	**OBS 6_4**	6	7	1	0	0	0	1	1
Point 6. Cleaning	**OBS 6_5**	6	6	2	2	0	0	0	0
Point 6. Pest control	**OBS 6_6**	10	12	2	0	0	0	0	0
Point 6. Waste control	**OBS 6_7**	2	2	0	0	0	0	0	0
Point 7. Product requirements	**OBS 7_1**	8	8	0	0	0	0	0	0
Point 7. HACCP program	**OBS 7_2**	8	11	1	0	2	0	2	2
Point 7. Design and development	**OBS 7_3**	0	3	4	1	4	0	0	4
Point 7. Handling of incoming materials	**OBS 7_4**	4	7	14	11	0	0	0	0
Point 7. Production of finished goods	**OBS 7_5**	18	19	1	1	1	0	3	3
Point 7. Transport	**OBS 7_6**	9	9	0	0	0	0	0	0
Point 8. General requirements	**OBS 8_1**	0	0	6	6	0	0	0	0
Point 8. Internal audits	**OBS 8_2**	4	5	2	1	0	0	4	4
Point 9. General requirements	**OBS 9_1**	1	8	2	3	0	0	9	1
Point 9. Complaint handling system	**OBS 9_2**	2	2	0	0	0	0	8	8
Point 9. Recall	**OBS 9_3**	0	2	2	1	3	0	4	6
Point 9. Crisis management	**OBS 9_4**	1	2	0	0	1	0	1	1
Point 10. Statistical techniques	**OBS 10_1**	0	2	4	3	0	0	1	0

Table 16. Weights assigned to the variables.

CLASSES	**CLASS CODE**	**WEIGHTS**
FULL CONFORMITY	FULL_C	1
MINOR NON-CONFORMITY	MIN_NC	-1
MAJOR NON-CONFORMITY	MAJ_NC	-3
CRITICAL NON-CONFORMITY	CRT_NC	-5

Table 17. Audits results (weighted data)

	FAMI-QS Paragraphs		FULL CONFORMITY CLASS February 2017 FEB FULL_C	FULL CONFORMITY CLASS October 2017 OCT FULL_C	MINOR NON-CONFORMITY CLASS February 2017 FEB MIN_NC	MINOR NON-CONFORMITY CLASS October 2017 OCT MIN_NC	MAJOR NON-CONFORMITY CLASS February 2017 FEB MAJ_NC	MAJOR NON-CONFORMITY CLASS October 2017 OCT MAJ_NC	CRITICAL NON-CONFORMITY CLASS February 2017 FEB CRT_NC	CRITICAL NON-CONFORMITY CLASS October 2017 OCT CRT_NC
1	Point 4. General requirements	OBS 4_1	0	4	-4	0	0	0	0	0
2	Point 4. Management principles	OBS 4_2	1	3	0	-1	-9	-3	-5	0
3	Point 4. General documentation requirements	OBS 4_3	4	10	-7	-1	-3	-3	-10	-10
4	Point 5. Management commitment	OBS 5_1	0	1	-1	0	0	0	0	0
5	Point 5. Quality and Safety Policy	OBS 5_2	1	1	-2	-3	-3	0	0	0
6	Point 5. Responsibility, authority and communication	OBS 5_3	3	3	-1	-1	0	0	-10	-10
7	Point 5. Management representative	OBS 5_4	0	1	0	0	0	0	-15	-10
8	Point 5. Management review	OBS 5_5	0	0	-3	-3	-3	-3	-5	-5
9	Point 6. Provision of resources	OBS 6_1	0	2	-2	0	0	0	-5	-5
10	Point 6. Human resources	OBS 6_2	5	7	-5	-3	0	0	-5	-5
11	Point 6. Infrastructure	OBS 6_3	9	9	0	0	0	0	0	0
12	Point 6. Maintenance and control of monitoring and measuring devices	OBS 6_4	6	7	-1	0	0	0	-5	-5
13	Point 6. Cleaning	OBS 6_5	6	6	-2	-2	0	0	0	0
14	Point 6. Pest control	OBS 6_6	10	12	-2	0	0	0	0	0
15	Point 6. Waste control	OBS 6_7	2	2	0	0	0	0	0	0
16	Point 7. Product requirements	OBS 7_1	8	8	0	0	0	0	0	0
17	Point 7. HACCP program	OBS 7_2	8	11	-1	0	-6	0	-10	-10
18	Point 7. Design and development	OBS 7_3	0	3	-4	-1	-12	0	0	-20
19	Point 7. Handling of incoming materials	OBS 7_4	4	7	-14	-11	0	0	0	0
20	Point 7. Production of finished goods	OBS 7_5	18	19	-1	-1	-3	0	-15	-15
21	Point 7. Transport	OBS 7_6	9	9	0	0	0	0	0	0
22	Point 8. General requirements	OBS 8_1	0	0	-6	-6	0	0	0	0
23	Point 8. Internal audits	OBS 8_2	4	5	-2	-1	0	0	-20	-20
24	Point 9. General requirements	OBS 9_1	1	8	-2	-3	0	0	-45	-5
25	Point 9. Complaint handling system	OBS 9_2	2	2	0	0	0	0	-40	-40
26	Point 9. Recall	OBS 9_3	0	2	-2	-1	-9	0	-20	-30
27	Point 9. Crisis management	OBS 9_4	1	2	0	0	-3	0	-5	-5
28	Point 10. Statistical techniques	OBS 10_1	0	2	-4	-3	0	0	-5	0
		MEANS	3,642857143	5,214285714	-2,357142857	-1,464285714	-1,821428571	-0,321428571	-7,857142857	-6,964285714
		DEV. ST.	4,339434045	4,44186433	2,984084768	2,380198293	3,300432872	0,944911183	11,58132048	10,03136615

Figure 16. Distribution table of weighed data.

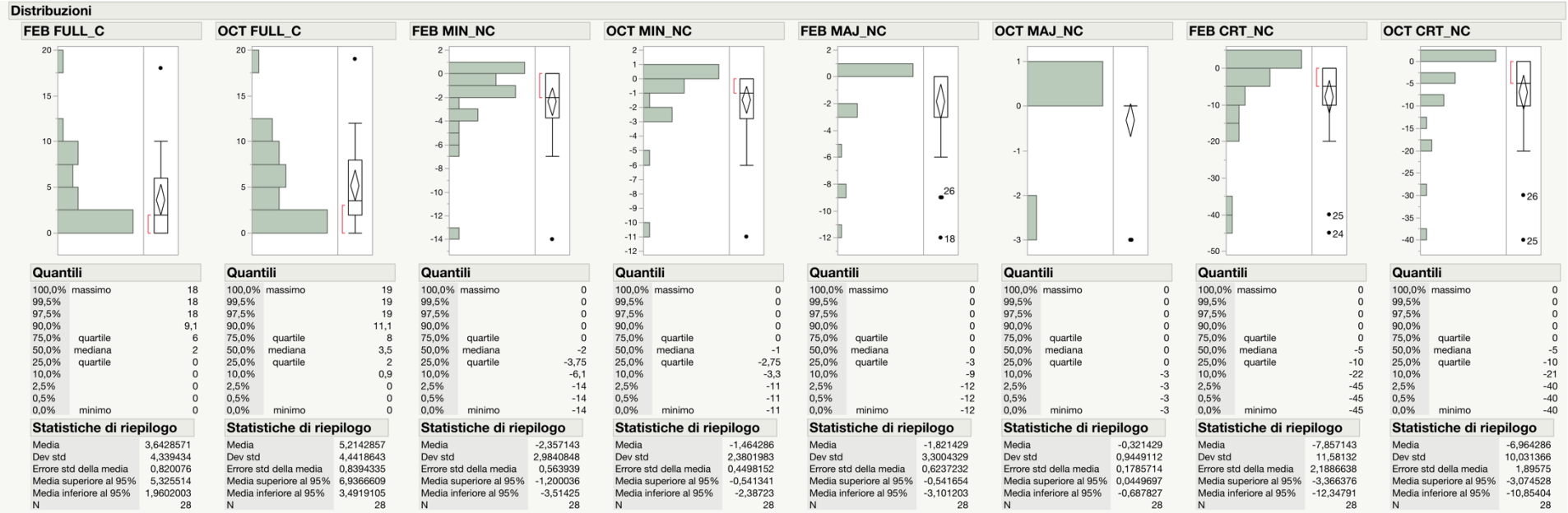


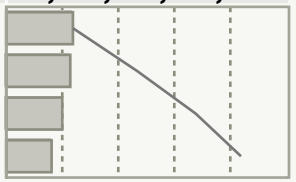
Table 18. Covariance matrix.

	FEB FULL_C	OCT FULL_C	FEB MIN_NC	OCT MIN_NC	FEB MAJ_NC	OCT MAJ_NC	FEB CRT_NC	OCT CRT_NC
FEB FULL_C	18,83069	17,63492	1,94180	1,56878	2,10317	0,65873	4,12698	2,42063
OCT FULL_C	17,63492	19,73016	-0,29101	0,95503	0,84921	0,29365	-3,25397	1,91799
FEB MIN_NC	1,94180	-0,29101	8,90476	6,01323	-0,34127	0,32540	-6,24339	-4,06085
OCT MIN_NC	1,56878	0,95503	6,01323	5,66534	-0,76587	0,06746	-2,30159	-5,01984
FEB MAJ_NC	2,10317	0,84921	-0,34127	-0,76587	10,89286	1,05952	-0,39683	11,84524
OCT MAJ_NC	0,65873	0,29365	0,32540	0,06746	1,05952	0,89286	-0,39683	-0,65476
FEB CRT_NC	4,12698	-3,25397	-6,24339	-2,30159	-0,39683	-0,39683	134,12698	77,51323
OCT CRT_NC	2,42063	1,91799	-4,06085	-5,01984	11,84524	-0,65476	77,51323	100,62831

Variable clustering

Table 19. Variable clustering. Cluster summary.

Riepilogo cluster

Cluster	Numero di elementi	Variabile più rappresentativa	Proporzione dei cluster della variazione spiegata	Proporzione totale della variazione spiegata	,2 ,4 ,6 ,8
2	2	OCT FULL_C	0,957	0,239	
1	2	OCT MIN_NC	0,923	0,231	
3	2	FEB CRT_NC	0,834	0,208	
4	2	OCT MAJ_NC	0,67	0,167	

Proporzione della variazione spiegata per clusterizzazione: 0,846

Clustering groups variables (columns) into groups that can be represented by a single component or variable.
Cluster variables can be used as a size reduction technique.

Table 20. Cluster elements.

Elementi del cluster

Cluster	Elementi	R-quadro con proprio cluster	R-quadro con successivo più vicino	Rapporto 1 - R-quadro
1	OCT MIN_NC	0,923	0,026	0,079
1	FEB MIN_NC	0,923	0,03	0,079
2	OCT FULL_C	0,957	0,006	0,043
2	FEB FULL_C	0,957	0,035	0,044
3	FEB CRT_NC	0,834	0,019	0,17
3	OCT CRT_NC	0,834	0,032	0,172
4	OCT MAJ_NC	0,67	0,014	0,335
4	FEB MAJ_NC	0,67	0,036	0,343

Table 21. Normalized components.

Componenti standardizzati

Variabile	Coefficienti del cluster 1	Coefficienti del cluster 2	Coefficienti del cluster 3	Coefficienti del cluster 4
FEB FULL_C	0	0,7071068	0	0
OCT FULL_C	0	0,7071068	0	0
FEB MIN_NC	0,7071068	0	0	0
OCT MIN_NC	0,7071068	0	0	0
FEB MAJ_NC	0	0	0	0,7071068
OCT MAJ_NC	0	0	0	0,7071068
FEB CRT_NC	0	0	0,7071068	0
OCT CRT_NC	0	0	0,7071068	0

Multivariate analysis

Table 22. Correlations.

Correlazioni

	FEB FULL_C	OCT FULL_C	FEB MIN_NC	OCT MIN_NC	FEB MAJ_NC	OCT MAJ_NC	FEB CRT_NC	OCT CRT_NC
FEB FULL_C	1,0000	0,9149	0,1500	0,1519	0,1468	0,1607	0,0821	0,0556
OCT FULL_C	0,9149	1,0000	-0,0220	0,0903	0,0579	0,0700	-0,0633	0,0430
FEB MIN_NC	0,1500	-0,0220	1,0000	0,8466	-0,0347	0,1154	-0,1807	-0,1357
OCT MIN_NC	0,1519	0,0903	0,8466	1,0000	-0,0975	0,0300	-0,0835	-0,2102
FEB MAJ_NC	0,1468	0,0579	-0,0347	-0,0975	1,0000	0,3397	-0,0104	0,3578
OCT MAJ_NC	0,1607	0,0700	0,1154	0,0300	0,3397	1,0000	-0,0363	-0,0691
FEB CRT_NC	0,0821	-0,0633	-0,1807	-0,0835	-0,0104	-0,0363	1,0000	0,6672
OCT CRT_NC	0,0556	0,0430	-0,1357	-0,2102	0,3578	-0,0691	0,6672	1,0000

Le correlazioni sono stimate per metodo A livello di riga.

PCA on non-scaled values

Table 23. Eigenvectors.

Autovettori							
	1 principale	2 principale	3 principale	4 principale	5 principale	6 principale	7 principale
FEB FULL_C	-0,14193	0,61130	-0,01062	0,30533	0,15157	-0,47648	-0,17429
OCT FULL_C	-0,21991	0,70153	0,07041	0,06527	-0,11062	0,42378	0,16128
FEB MIN_NC	0,06933	-0,20056	0,04372	0,74266	-0,20054	-0,35879	0,01130
OCT MIN_NC	0,04119	-0,11390	-0,04283	0,55760	-0,13712	0,64897	-0,01341
FEB MAJ_NC	0,09093	-0,06047	0,30540	0,17392	0,89543	0,16074	-0,10532
OCT MAJ_NC	0,00993	-0,01558	0,00597	0,06355	0,14850	-0,12564	0,96536
FEB CRT_NC	0,73166	0,22270	-0,62313	0,01704	0,12633	0,03520	0,00000
OCT CRT_NC	0,61750	0,16575	0,71385	-0,07399	-0,25683	-0,02496	0,01699

Eigenvectors express the link between the starting variables and the main component considered through the weights.

Table 24. Eigenvalues and test of Bartlett.

Autovalori

Numero	Autovalore	Percentuale	20 40 60 80	Percentuale cumulativa	Chi-quadrato	DF	Prob>ChiQu
1	321,8404	71,395		71,395	368,000	35,000	<,0001*
2	60,9029	13,510		84,906	203,732	27,000	<,0001*
3	40,2381	8,926		93,832	157,432	20,000	<,0001*
4	17,2843	3,834		97,666	95,422	14,000	<,0001*
5	8,2477	1,830		99,496	45,175	9,000	<,0001*
6	1,5860	0,352		99,848	.	5,000	.
7	0,6864	0,152		100,000	.	2,000	.

Eigenvalues measure the amount of variation retained by each major component. The eigenvalues are large for the first Principal Components, then they are gradually smaller for the subsequent ones. In other words, the first PCs correspond to the directions with the greatest amount of variation in the data.

The Bartlett test allows us to answer the question: are these processes the same?
The Bartlett test performs the hypothesis test for our eight process monitoring treatments. The null hypothesis is that the variance is the same for all treatments. The alternative hypothesis is that the variances are different for at least two treatments. The software calculates the Bartlett statistic and compares it with a chi-square value to determine if it is significant. The critical chi-square value is not indicated here, but rather the probability associated with the Bartlett test statistic. Since the confidence level is 0.05 and the probability is in all cases < 0.0001 we conclude that the variances are significantly different.

Figure 17. Scree plot.

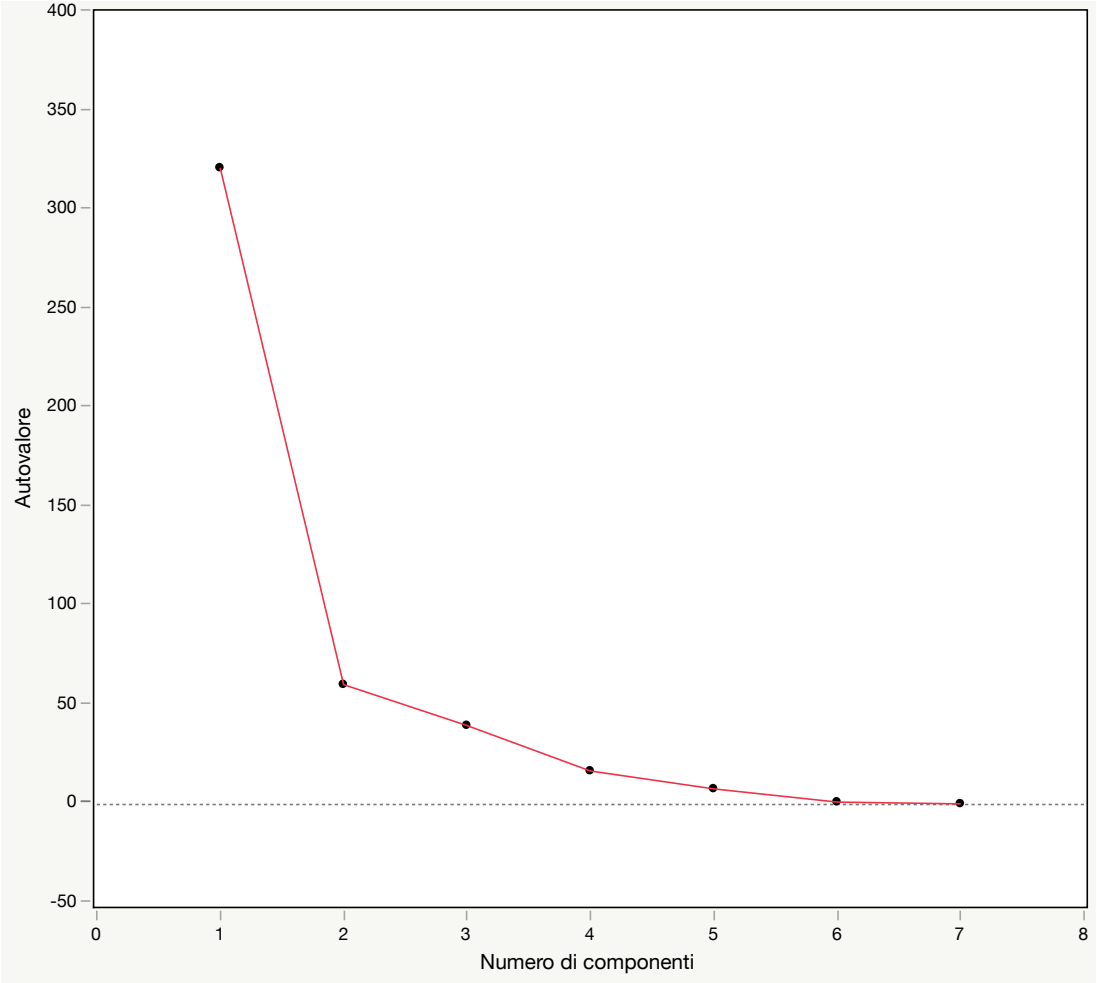


Figure 18. Score plot.

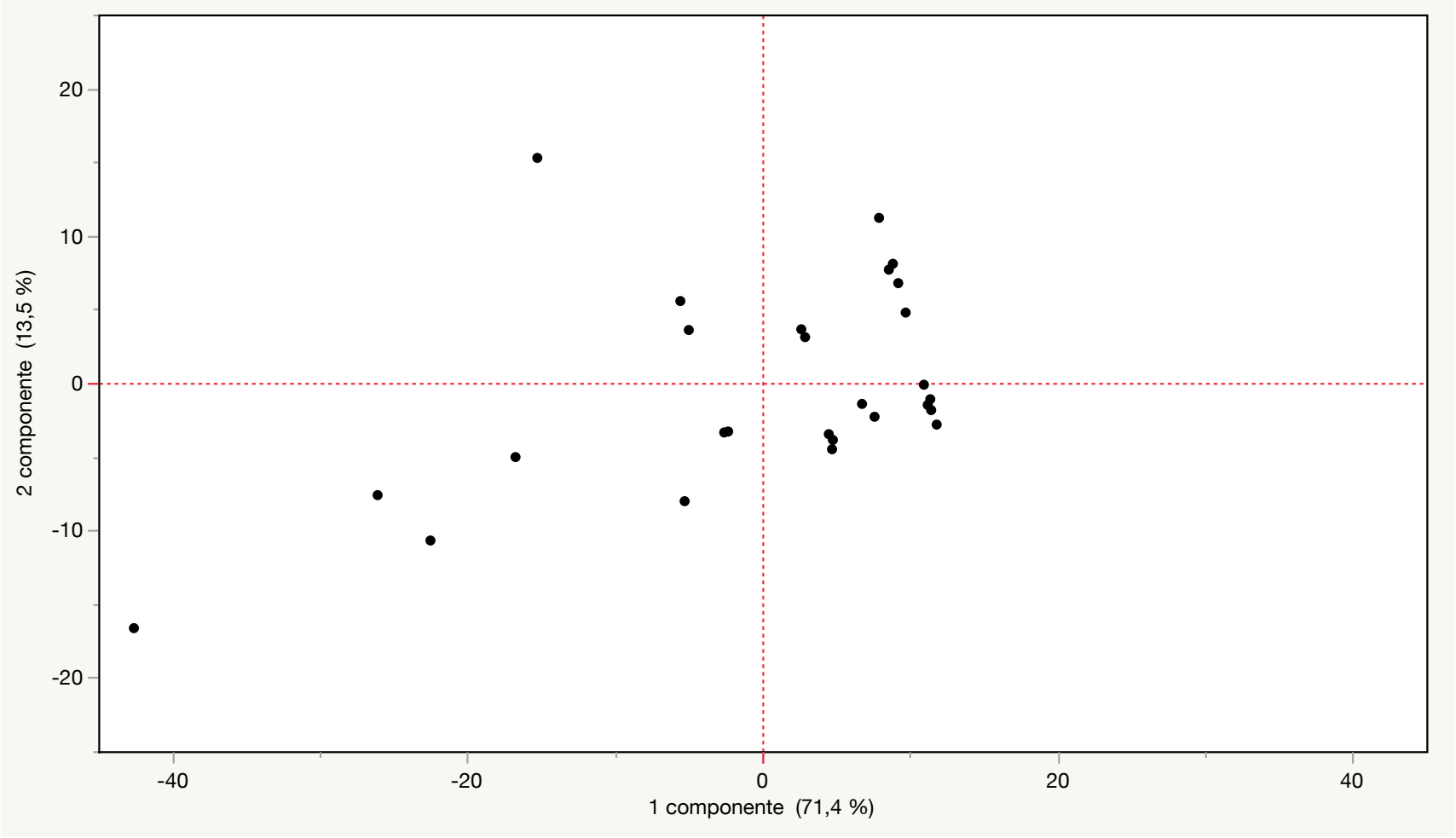
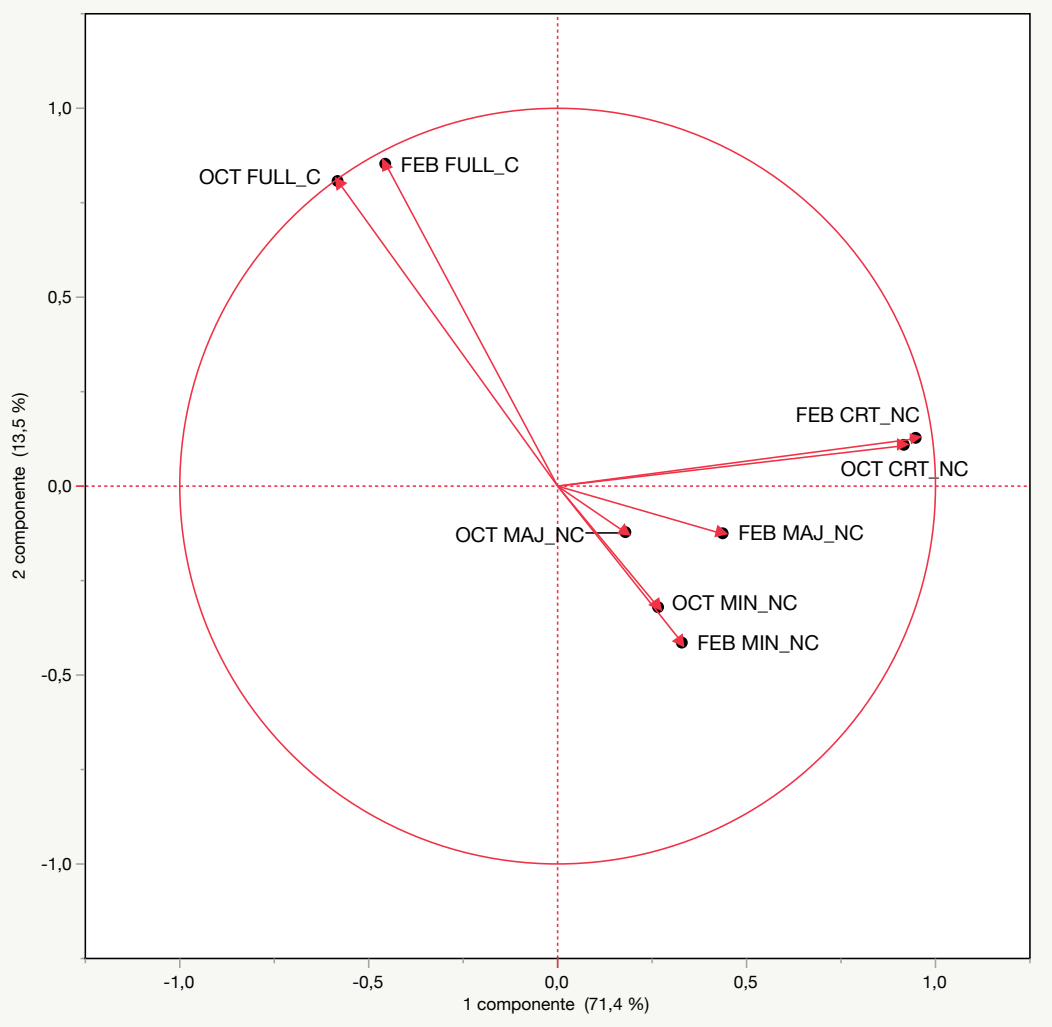


Table 25. Matrix of Variable correlation plot.

Caricamento matrice in corso							
	1 principale	2 principale	3 principale	4 principale	5 principale	6 principale	7 principale
FEB FULL_C	-0,45419	0,85097	-0,01202	0,22643	0,07765	-0,10704	-0,02576
OCT FULL_C	-0,58034	0,80533	0,06570	0,03991	-0,04673	0,07851	0,01966
FEB MIN_NC	0,33075	-0,41619	0,07375	0,82101	-0,15314	-0,12015	0,00249
OCT MIN_NC	0,26791	-0,32229	-0,09851	0,84050	-0,14277	0,29632	-0,00403
FEB MAJ_NC	0,43881	-0,12693	0,52109	0,19449	0,69171	0,05445	-0,02347
OCT MAJ_NC	0,18134	-0,12385	0,03854	0,26904	0,43430	-0,16113	0,81445
FEB CRT_NC	0,94958	0,12573	-0,28596	0,00513	0,02625	0,00321	0,00000
OCT CRT_NC	0,91827	0,10722	0,37535	-0,02550	-0,06114	-0,00261	0,00117

As for the relationships between all the variables:
the positively correlated variables are clustered together;
the negatively correlated variables are positioned on the opposite quadrants of the diagram;
the distance between the variables and the origin measures the quality of the variables on the factor map. In this regard, the variables far from the origin are well represented in the factor map.

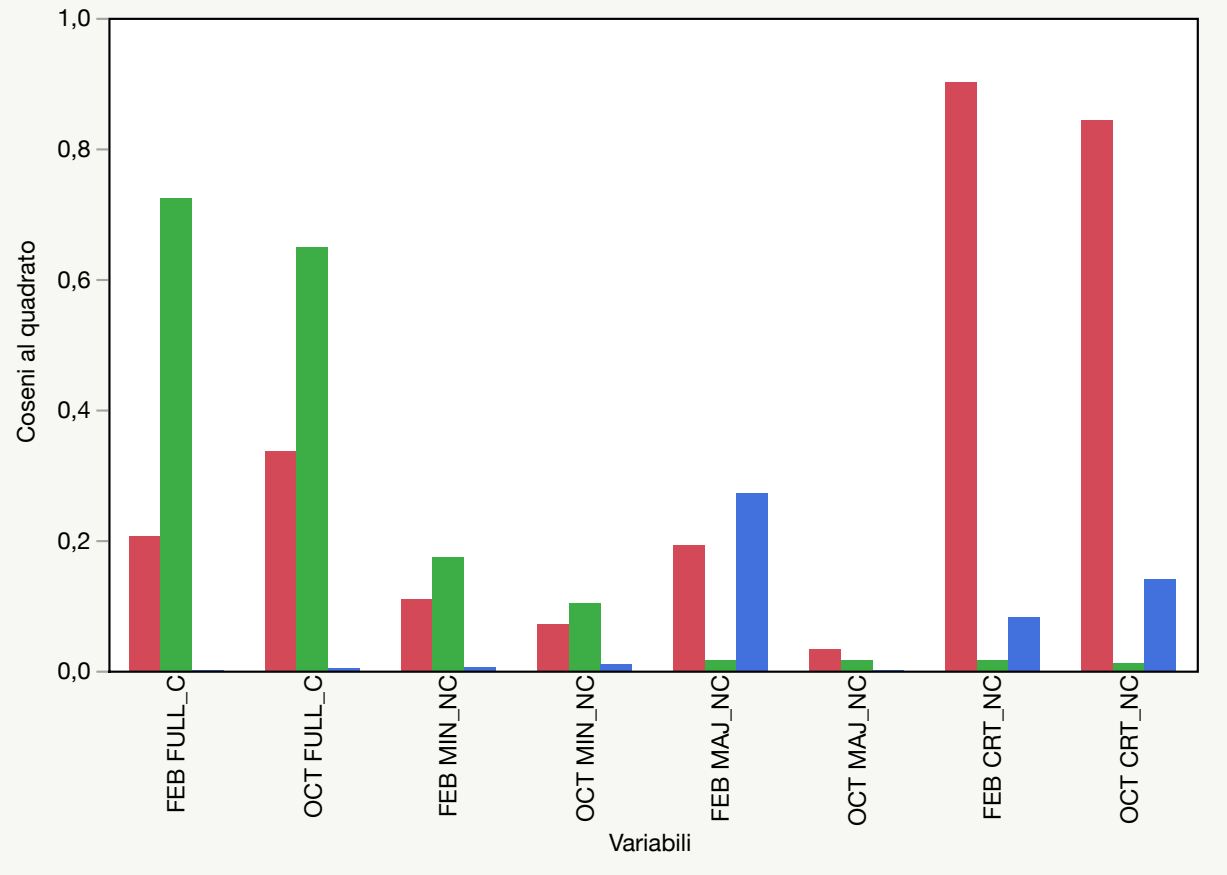
Figure 19. Variable correlation plot on PC1 and PC2.



As for the relationships between all the variables:

- the positively correlated variables are clustered together;
- the negatively correlated variables are positioned on the opposite quadrants of the diagram;
- the distance between the variables and the origin measures the quality of the variables on the factor map. In this regard, the variables far from the origin are well represented in the factor map.

Figure 20. Diagram of the cosines squared.



(Key: red = first component; green = second component; blue = third component.)

Squared cosine values are used to evaluate the representation.
In this regard, see the previous chart.
A high squared cosine value indicates a good representation of the variable on the main component; in this case the variable is positioned near the circumference of the correlation circle.
A low square cosine value indicates that the variable is not perfectly represented by the main components; in this case the variable is close to the center of the correlation circle.
For some of the variables, it may take more than 2 components to perfectly represent the data.

Conclusions

Over the past 20 years, the company has carried out the resale and sale of feed produced by third parties. In 2016, at the behest of the general manager, a new company project was launched whose purpose was to support the commercial activity with a production of feed additives.

This project entailed the reconfiguration of the company's staff with the addition of new highly qualified company figures and the professional updating of employees of all levels.

Initially, profound contradictions and difficulties emerged. The working group had to face resistance to change by creating consensus around the industrial project which also provided for certification of production.

With regard to the pre-certification process, all the problems encountered were highlighted and analyzed in order to find valid solutions.

After about 12 months of research, study and implementation of new procedures, the company has been put on the right track to achieve full compliance with legal and voluntary requirements. However, at the end of the study, further monitoring and verification interventions were planned to ensure the improvement and maintenance of the levels necessary for certification.

In conclusion, in order to implement the company's transition from reseller status to that of a manufacturer, the research team had to examine all the latent negative aspects and transform the incorrect modus operandi into a new approach to work. Only in this way was it possible to adopt a new management system compliant with the FAMI QS Code.

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Chapter 10

Case study No.2

A SME and the Gluten-free AIC labelling

Abstract

According to recent market research[52], the gluten-free beer market is expected to grow in the coming years thanks to greater awareness by interested consumers of the health benefits associated with the consumption of gluten-free products. As is known, people predisposed to celiac disease are affected by a condition that affects the intestinal epithelium of the digestive system. Gluten causes harm and there is currently no valid remedy for this disease. The only adequate treatment is to refrain from consuming gluten-containing foods

Table 26. Beer market in major markets. Value of retail beer sales, in US-millions.

	2013	2017	2018	2022	CAGR % 2013-2017	CAGR % 2018-2022
Global market	542,291	660,576	696,198	865,814	5.1	5.6
United States	96,237	103,990	106,459	118,810	2.0	2.8
China	66,341	84,728	91,086	121,571	6.3	7.5
Brazil	30,057	42,864	45,626	61,164	9.3	7.6
Japan	37,324	37,264	37,117	37,737	0.0	0.4
Germany	30,788	31,784	32,335	34,359	0.8	1.5

(Source: Canada Agriculture and Agri-Food, 2019)

[52] The research "Global Gluten-free Beer Market 2018-2022" published in February 2018 was done by the Technavio organization (www.technavio.com). Technavio declares that it presents a detailed picture of the market by way of study, synthesis, and summation of data from multiple sources. The analysts have presented the various facets of the market with a particular focus on identifying the key industry influencers. The data thus presented is comprehensive, reliable, and the result of extensive research, both primary and secondary.

Thanks to better diagnostic tests, there is an increasing prevalence of celiac disease in the population. In parallel, an increasing number of people are directing their food consumption towards gluten-free products, including drinks such as beer. According to market research, it has been predicted that the beer market, including the gluten-free market, will grow with a CAGR[53] (Compounded Average Growth Rate) of around 6% in the period from 2018 to 2022. In this context, the Ofelia microbrewery has undertaken the production of a new gluten-free beer produced from classic ingredients treated with specific enzymes to degrade gluten.

The purpose of this work was to collaborate with the company in the qualification process to obtain a gluten-free certification issued by the Italian Celiac Association. At the same time, compliance with the food safety specifications of the production was monitored. In addition, the theoretical proportion of the production lines was calculated to maximize the profitability of the products.

[53] Compounded Average Growth Rate represents the average percentage growth of a quantity over a period of time. Given for example the turnover A of a share in year X and the turnover B of a company in year Y, the revenue CAGR indicates the average annual percentage growth in revenues (Source: Borsa Italiana https://www.borsaitaliana.it/notizie/sotto-la-lente/cagr-259.htm)

Introduction

Context

The company under study is the Ofelia S.n.c. who started the craft business in 2012. From 2016 he changed his operating office in Sovizzo, Vicenza district, Veneto region (Italy), setting up a new brewery that currently has a production capacity of 12 hectolitres. Over the years, the company has participated in industry events obtaining a series of appreciation awards for some of its products. The Italian Food Guide 2019 of Slow Food mentions the Amitabh product in the major beers' category, the La Speltina product in the daily beers' category, and the Nevermild product in the slow beers' category.

The project

For the study on the "Glu Golden Ale" gluten-free beer production line, the Ofelia brewery has entered into a collaboration with the University of Modena and Reggio Emilia to implement the operating procedures necessary to obtain the gluten-free product certification in compliance with the Spiga Barrata technical specification by the certifying body of the Italian Celiac Association. For the development of this work, a working group consisting of the brewery staff and the university staff was set up. The brewery was represented by Dr. Andrea Signorini, master brewer, and by Dr. Lisa Freschi for the commercial, logistic and marketing aspects. The University collaborated on the project through Prof. Andrea Pulvirenti, the present author and graduate student Rìan Piccirillo. The stakeholder that promoted the start-up of the project were the customers of the brewery who, like the owners of the company, were looking for this line of products due to the greater sensitivity of the public towards celiac disease.

Beer production overview

The ingredients of beer

According to Italian Law of 16 August 1962, No. 1354 on the Hygiene discipline of the production and trade of beer, the legal definition of beer is:

<< the product obtained from the alcoholic fermentation with strains of *Saccharomyces cerevisiae* or *Saccharomyces carlsbergensis* of a must prepared with barley malt, also roasted, or wheat or their mixtures and water, made bitter with hops or its derivatives or both >>.

The fermentation of certain cereals in the presence of water, barley, yeast and hops produces beer. There are many varieties of beer. What they have in common is the bitter taste due to the hops and the low alcohol content compared to wine or spirits. In general, the percentage of alcohol contained in the beer, measured by the alcohol content[54], is 4 - 6% by volume, although some beers can reach higher levels.

Cereals

The cereal mainly used is barley but sometimes wheat, corn, rice, millet, sorghum, oats are used based on technological needs or local customs.

Botanical characteristics of barley

The different forms of barley grown belong to the *Hordeum vulgare* species. They differ according to the number of rows of grains of the ear. In short, the inflorescence of barley is an ear whose spine is made up of 20-30 items (portions corresponding to the internodal region) on each of which, in an alternate position, there are three single-spiked spikelets, one median and two lateral ones. The couplet barley, *Hordeum vulgare*

[54] According to article 12 of the Italian Legislative Decree 27 January 1992, No. 109 Implementation of directives No. 89/395 / CEE and No. 89/396 / EEC concerning the labeling, presentation and advertising of food products, the alcohol content is the number of parts by volume of pure alcohol contained in 100 parts by volume of the product at a temperature of 20°C. Another definition for alcohol measurement is ABV, alcohol by volume (Alcohol units, 2018).

distichon, has only 2 rows of kernels (commonly called grains) on the ear. The central spikelet of each node of the spine is fertile and the two lateral ones are sterile, and the ear has a strongly flattened shape. On the other hand, the polystic barley, *Hordeum vulgare exastichon*, has 6 rows of kernels on the ear. The three spikelets on each node of the spine are all fertile.

Figure 21. Growth stages of the barley plant and both couplet and polystic barley scheme.

(Sources: https://free3d.com/it/3d-model/barley-cartoon-stages-of-grow-3909.html, https://www.pinterest.it/pin/290200769719865260/)

Malt

Barley is wet with water and germinated in special tanks for a few days, until the seed root reaches a certain length, obtaining the so-called green malt. At this point the germination is stopped and the green malt is dried at a temperature of about 80°C. The resulting malt is mechanically cleaned from the buds and left to rest in the silos for the time required by the production protocols until malted barley is obtained.

Water

All water used in production processes must come from aqueducts or drinking water sources and be suitable for food use according to Legislative Decree 2 February

2001 No. 31 in implementation of the European Directive 98 / 83 / EC relating to the quality of water intended for human consumption, published in the Ordinary Supplement to the Italian Official Journal of 3 March 2001 No. 52 and with text updated to 29 August 2017 (Portale Acque, 2019).

The hops

The use of hops came from the need to give a bitter aroma to the beer which at the beginning showed a sweet taste due to the sugars present in the final drink (Vaccarini, 2015). Generally, the use of fresh, frozen or dried hops with a moisture content of less than 14% is permitted. Instead, hop extracts are not allowed. Hops, *Humulus lupulus L.*, is a dioecious flowering plant belonging to the Cannabaceae family whose female inflorescences are used to aromatize beer. The bitter hops give the beer its characteristic bitter taste while the aromatic hops contribute to the aromatic notes. These characteristics are to be attributed to the α-acids[55] and to the β-acids[56]. Other substances released by hops are polyphenols, to which the research attributes antioxidant properties (Perez et al., 2015) and tannins that contribute to characterizing the taste of beer (Van Cleemput et al., 2009). Additional volatile substances are lost during the boiling process even if, to a small extent, they contribute to the taste.

Yeast

Yeasts of the genera Saccharomyces are responsible for the transformation of malt starches into alcohol (Sicheri, 2010).

Low fermented beers are generically defined with the name of "lager". To make this type of beer, yeast of the species *Saccharomyces pastorianus* (former *Saccharomyces carlsbergensis*) is added to the must, which acts at temperatures

[55] Carboxylic acids with the substituent in alpha position, i.e. at the carbon adjacent to the carboxylic carbon.

[56] Carboxylic acids with the substituent in beta position, i.e. at the second carbon after that adjacent to the carboxylic carbon.

between 7 and 10°C and takes about 5 to 6 weeks to complete. ripeness. At the end of the fermentation, the remains of the yeast settle on the bottom. Hence the name "*low fermentation*".

The top fermented beers are generically defined with the name of "ale". In this case, yeasts of the species *Saccharomyces cerevisiae* and *Saccharomyces paradoxus* are added to the must, which act at temperatures between 12 and 23°C for a period of about two weeks to conclude the maturation process. What remains of the yeasts at the end of the process goes back to the top of the fermenter floating on the surface. Hence the name "high fermentation".

Spontaneously fermented beers are purely local and produced in Belgium. The particular aspect is that to trigger fermentation, the must is exposed to the air in order to facilitate the natural inoculation of yeasts and lactic bacteria peculiar to the environment. The microorganisms involved in fermentation are of the *Brettanomyces genus*. Such beers have a distinctive taste.

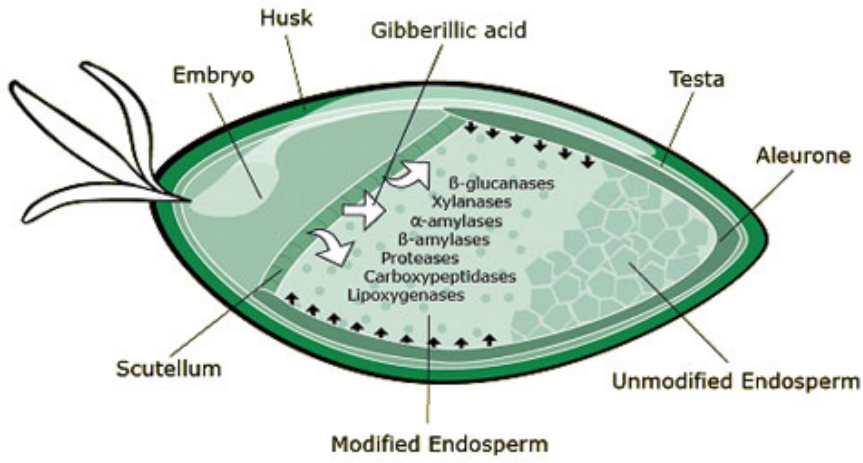
The industrial process

The current industrial process includes a sequence of stages such as malting, maceration, germination, drying, grinding, crushing, boiling, fermentation, filtration, carbonation, and packaging.

Malting

The malting stage includes the succession of the three phases of maceration, germination and drying.

Figure 22. Enzyme production during malting.



(Source: Sten et al., 2004. Biokemisk Forening, http://www.biokemi.org/biozoom/issues/522/articles/2368)

Maceration

The preparatory action consists in washing the barley seeds in order to eliminate residues and unwanted waste. So, the next step is to wet it with water so as to raise the relative humidity of the seed to about 45%. At this stage the starch gelatinizes.

Germination

The increased moisture in the seed induces a hormonal response that produces the development of the shoot and the development of specific enzymes that spread in the endosperm of the seed. In particular, enzymes of the α-amylase class hydrolyze starch into simpler sugars so that it is a substrate for yeasts. When the small root of the seed reaches a certain length just over half the length of the seed, then this is the time to stop germination.

Drying

Sprouted barley, or green malt, is subjected to a heat treatment at temperatures that reduce the activity of the enzymes. Breweries operate at different drying temperatures. In particular, for light malts the drying takes place at about 80°C, for dark malts at about 105°C, while for the so-called colored malts around 180°C. Sprouts are eliminated from the beans as they can adversely interfere in the production phase leading to unsuitable and unwanted turbidity and taste of the drink.

Based on the experience of the brewers, the malt thus obtained is left to rest for enough time to allow the enzymes to stabilize and develop the aromatic substances. It should be noted that the malt resulting from drying can be packed in bags to be marketed as such.

Grinding

Barley malt is shredded in order to amplify the useful surface of the starch of the caryoxide (defined as grain in the technical language) by exposing the enzymes in the subsequent stages of production.

Mashing

Barley malt, produced from the previous phases, is treated in water up to a temperature of about 65 - 70°C for not more than a couple of hours. At this stage, a series of active enzymes such as diastases, proteases and peptidases, β-glucanases and phytases, briefly described below, come into action. This process splits the malt starch into maltose thus obtaining the must. The must obtained is filtered to make it available for the next cooking phase.

Diastase

This class of enzymes includes α-amylase and β-amylase which hydrolyse the bonds between the glucose molecules making up starch. From biochemistry we know that α-amylase has an optimal activity in a temperature range of 63 - 76°C at a pH of 5.7 and β-amylase has a maximum activity between 55 and 65°C at a pH of 5.0.

α-amylase degrades starch into maltose, a sugar easily fermented by yeasts.

β-amylase degrades starch into dextrin.

Generally, a “dwell time” of about 30 - 40 minutes is required for the enzymatic action.

Protease and peptidases

These enzymes degrade the proteins in malt into amino acids that serve as necessary nutrients for effective yeast viability. Moreover, they have the effect of improving the retention of the foam of the beer and reducing its turbidity.

Their activity is best expressed at around 50°C at a pH between 4.2 and 5.3. The estimated time for the enzymatic action is about 20 to 30 minutes.

β-glucanase

The action of this enzyme consists in degrading the β-glucans. B-glucans form the walls of the vegetable structures of un-malted cereals which can sometimes be used in beer production. β-glucanase acts on the must in about 20 minutes at 37 - 45°C.

Phytase

The phytase enzyme helps to acidify the must. Currently, it is no longer used in the beer industry having been replaced by lactic acid.

Boiling

In the boiler, the must is brought to the boiling point for about an hour and hops are added at the same time. After boiling, the must is cooled and aerated. Then we move on to the important phase of fermentation.

Fermentation

In the fermenter the must is inoculated with the yeast, starting the alcoholic fermentation with the production of ethyl alcohol, carbon dioxide, aromatic components (esters) and further yeast. Fermentation is exothermic and produces an increase in temperature. Once fermentation is complete, the beer produced is cooled to room temperature.

Filtration

At the end of fermentation, the beer is cloudy due to the presence of various process residues. Filtration allows the removal of yeast and raw particles. The residues are washed and aerated to extract the yeasts which will be reused in the production cycle or marketed as beer yeast.

Carbonation

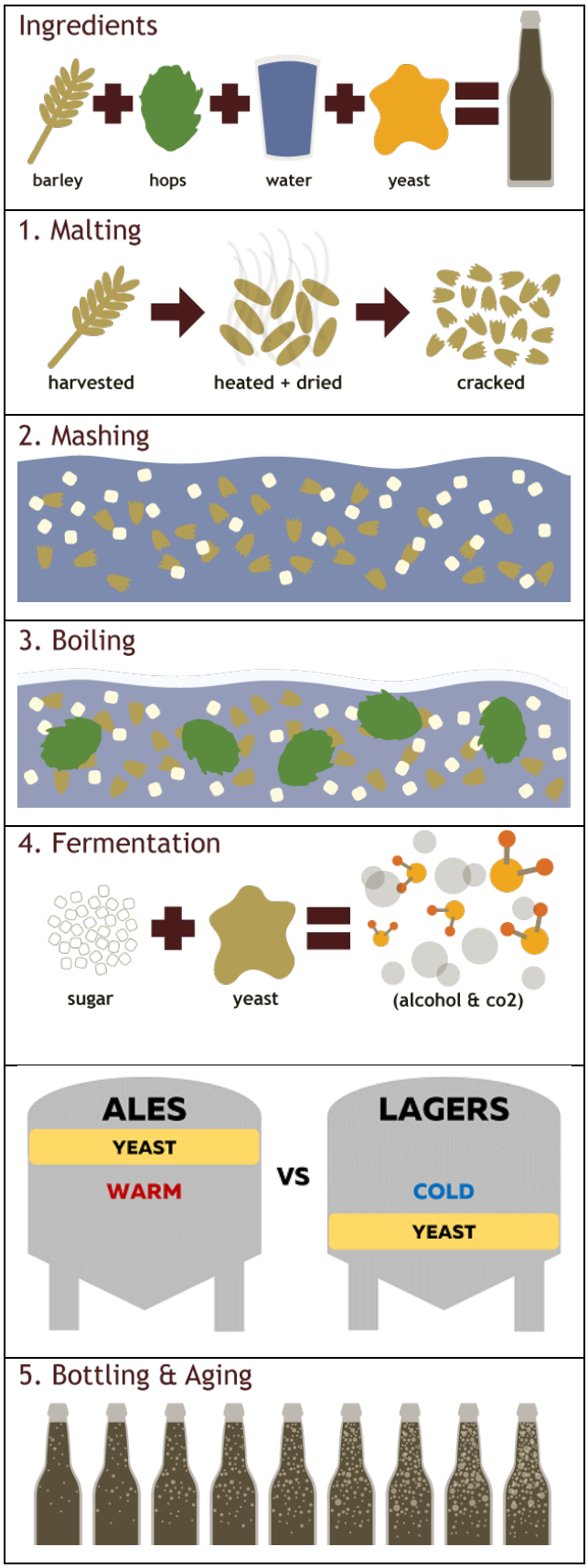
Carbonation is the process by which clarity and sparkling character is attributed to beer. In forced carbonation, the beer is cooled and introduced under pressure in a container containing carbon dioxide in the form of dry or liquid ice. High pressure and

low temperature maximize gas absorption. Instead, natural carbonation is obtained by adding sugars that ferment and produce CO_2 to the drink.

Packing

Through appropriate technological processes, the beer produced is packaged in kegs, cans or bottles. Then, it undergoes post-packaging pasteurization to ensure microbiological stability. In general, this operation takes place at 60°C for 5 - 20 minutes in the case of bottled or canned beer or at about 70°C in the case of packaging in 50-liter kegs. Finally, during the labeling phase, the codes of the production batches are affixed in order to guarantee traceability.

Figure 23. Simplified scheme of brewing.



Sugars formed during mashing - maltose and maltotriose - will undergo hydrolysis and form multiple molecules of the simple sugar glucose. This glucose will then be fermented by the yeast under anaerobic conditions into ethyl alcohol and carbon dioxide.

Gluten

Gluten components

Gluten is highlighted by mixing the water and flour of any cereal containing proteins of the prolamin and glutelin type. It is a viscous and elastic protein mass. In gluten, proteins are associated in fibrils with the formation of hydrogen bonds and hydrophobic interactions. These structures form like a three-dimensional grid with extensibility, elasticity and ability to retain fermentation gases in order to have the leavening effect of the dough. Wheat gluten proteins are made up of gliadin (prolamin class) and glutenin (glutelin class). The average composition of wheat gluten is 70 - 80% of proteins, 10% of lipids, 3% of starch and small quantities of other polysaccharides.

In some people gluten causes events of intolerance and sensitivity. The only viable remedy is a gluten-free diet by removing baked goods, bread, pizza, wheat pasta and, among drinks, beer.

Gluten is present in a wide variety of cereals such as barley[57], wheat[58], rye[59], oats[60], emmer wheat[61], kamut®[62].

On the contrary, cereals and pseudo-cereals corn[63], rice[64], millet[65], sorghum[66], and teff[67], can be taken by people intolerant to gluten.

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[57] Barley (*Hordeum vulgare*) is also grown in temperate climates. Most barley is used for animal feed, though it is also the source of the malt used in the brewing of beer (Source: Encyclopaedia Britannica).

[58] Wheat (various *Triticum* species) is a major cereal crop. Wheat is used to produce meal, breakfast cereals, and flour for bakery products. It can be cultivated in a wide range of soils but thrives in temperate climates (Source: Encyclopaedia Britannica).

[59] Rye, (*Secale cereale*) and its edible grain is chiefly used to make rye bread and rye whiskey (Source: Encyclopaedia Britannica).

[60] Oats (*Avena sativa*) are grown in most of the temperate regions of the world, especially in the United States, Canada, and northern Europe. Most of the oats produced are used in animal feed, although they may also be processed for human consumption (Source: Encyclopaedia Britannica).

[61] Emmer wheat or farro (*Triticum dicoccon*) has less gluten than wheat, making it a strong option for consumers who may have difficulty digesting wheat byproducts. Emmer, however, is not an alternative for people with celiac disease (Source: Emmer Urkorn, https://emmer.info/was-ist-emmer/).

[62] Kamut® brand khorasan wheat is an ancient grain to never be hybridized or genetically modified, always organically grown. It is an excellent source of protein, fiber, and many vitamins and is high in minerals including selenium. Khorasan is a variety of wheat and has gluten (Source: https://www.kamut.com/).

[63] Corn, or maize (*Zea mays*), is a major crop cultivated in most temperate climates, although the United States is the single largest producer. The grain is processed into a growing number of food products, including corn flour, corn oil, corn syrup, and many other by-products. Corn is used in the production of bourbon. Also, it is a very important animal feed (Source: Encyclopaedia Britannica).

[64] Rice (*Oryza sativa*) is the second largest cereal crop and is a staple food in all areas of Asia. Unlike wheat, which is generally raised on large farms and harvested mechanically, rice is usually grown on small paddies and harvested by hand. Rise is used in the production of sakel (Source: Encyclopaedia Britannica).

[65] Millet (various species) is locally grown in a number of countries both for human consumption and as livestock feed (Source: Encyclopaedia Britannica).

[66] Sorghum (*Sorghum vulgare*) is principally grown for use as animal feed (Source: Encyclopaedia Britannica).

[67] Teff (*Eragrostis tef*) is locally grown in a number of countries both for human consumption and as livestock feed (Source: Encyclopaedia Britannica).

Table 27. Approximate composition of cereal grains per 100 grams.

CEREALS	CRUDE PROTEIN	CRUDE FAT	ASH	CRUDE FIBRE	AVAILABLE CARBOHYDRATE
Brown Rice	7	2	1	1	64
Sorghum	8	4	3	4	63
Rye	9	2	2	2	72
Oats	9	6	2	2	63
Maize	10	5	1	2	64
Wheat	11	2	1	1	70
Barley	11	3	2	4	56
Pearl Millet	12	5	2	2	63

[Source: Eliasson and Larsson (1993); Alais and Linden (1991)]

Table 28. Percentage distribution of protein fractions. In evidence the cereals which are safe for celiac disease people.

CEREALS	ALBUMIN minimum rate	ALBUMIN maximum rate	GLOBULIN minimum rate	GLOBULIN maximum rate	PROLAMIN minimum rate	PROLAMIN maximum rate	GLUTELIN minimum rate	GLUTELIN maximum rate
Brown Rice	5	11	10	10	2	7	77	78
Sorghum	4	4	9	9	48	48	37	37
Rye	10	44	10	19	21 (secalin)	42 (secalin)	25	40
Oats	10	20	12	55	12 (avenin)	14 (avenin)	23	54
Maize	4	8	3	4	47	55	38	45
Wheat	9	15	6	7	33 (gliadin)	45 (gliadin)	40	46
Barley	12	12	8	12	25 (hordein)	52 (hordein)	52	55
Pearl Millet	15	15	9	9	21	38	24	38

[Key: in evidence the cereals which are safe for celiac disease people and in brackets the name of some prolamins. Source: Eliasson and Larsson (1993); Alais and Linden (1991)]

Prolamins

Prolamins are proteins insoluble in water. Their amino acid pool essentially includes proline (~ 14%) and glutamine (~ 40%). Hence the generic name prolamin. Other amino acids such as arginine, lysine and histidine are present in smaller quantities. The prolamins take the characteristic name based on the cereal of origin. And so, in the wheat we have gliadin, in the barley the hordein, in the oats the avenin, and in the rye the secalin.

Gluten sensitivity

Diffusion of coeliac disease

Celiac disease is an autoimmune disease caused by the ingestion of gluten in genetically sensitive individuals (Barone et al., 2014).

According to the data of the annual report to the Italian Parliament on celiac disease referring to the year 2017 and published in December 2018, in Italy 0.35% of the population is affected by celiac disease.

Coeliac disease

The mechanism that originates the unhealthy process is closely linked to the mode of action of the etiological factor and the reaction of the organism.

The pathogenesis involves an unwanted reaction of the immune system to gluten which causes damage to the small intestine. This happens when subjects intolerant to gluten take foods containing gluten for the preparation of which they use wheat, barley, rye, or oats. The intestinal villi become inflamed and atrophied, reducing the surface of the intestine available for the absorption of nutrients. The function of the villi is to allow the absorption of nutrients so that they cross the wall of the small intestine and pour into the bloodstream. If the villi do not work well, the person shows symptoms of malnutrition even if he follows a correct diet (Green & Cellier, 2007). The main symptoms of the disease are abdominal pain, diarrhea, constipation, vomiting, poor appetite, oral atrophy, steatorrhea, weight loss.

Therapy

At the moment, the gluten-free diet is the only valid therapy to eliminate symptoms and restore the functionality of the intestinal mucosa. The doctor may suggest that these patients take the advice of a dietician to develop a healthy but gluten-free diet. In this context, people with celiac disease can learn to critically read the nutritional labels of the food purchased and can take advantage of the restaurant service as recent Regulations require restaurant services to declare allergens that may be present in the dishes.

For most patients the diet can make symptoms disappear, cure previous intestinal damage and prevent worsening. Typically, the improvements are fairly immediate. The small intestine usually heals for three to six months in children, but it can take several years for adults (Lebwohl et al., 2018). Intestinal healing means that intestinal villi can again absorb nutrients and distribute them to the whole body.

To stay healthy, people with celiac disease must avoid gluten for the rest of their lives. Even a small amount of gluten can damage the small intestine. The damage can occur in all people affected by the disease, including people who have no obvious symptoms. Depending on the age of the subject at the time of diagnosis, some problems such as short stature and defects in tooth enamel may not improve.

In rare cases, damage to the intestine will continue to occur despite a completely gluten-free diet. People with this disease, known as refractory celiac disease, have severe intestinal damage that cannot be cured (Masotti et al., 2013). Since their intestines do not absorb enough nutrients, it may be necessary to feed them intravenously.

Gluten hidden in food

Gluten is found mainly in the foods that contain it but traces of it can also be found in products commonly used in food preparations. Among the hidden sources of gluten are additives, such as modified starch, preservatives and stabilizers, both often made from wheat. In addition, several cereal and rice-based foods are produced in companies that also produce wheat-based products. In this case the productions can be subject to cross contamination.

Food for celiacs

Some foods are naturally gluten-free such as rice, corn, meat, fish, milk, eggs, legumes, potatoes, vegetables and fruit. However, to allow a varied and complete nutrition from a nutritional point of view, the food industry produces gluten-free products specially formulated for celiacs.

To be called gluten-free, these foods must have a gluten content of less than 20 ppm[68]. Their production must be communicated to the Italian Ministry of Health so that they can be distributed to celiacs.

Pursuant to Regulation (EU) No. 828/2014, these products can bear the voluntary wording "gluten-free" followed by any additional wording such as, for example, "suitable for celiacs" or "suitable for people intolerant to gluten".

In Italy, for the purpose of labeling, these foods may bear the trademarks and wordings illustrated in the figure relating to the registration in the national register of gluten-free foods of the Ministry of Health and relating to the analogous list of gluten-free foods drawn up and updated monthly by the Italian Celiac Association[69](AIC) owner of the Spiga Barrata brand.

[68] For aqueous solutions, whose density is 1.00 g/ml, 1 ppm = 1 mg/liter or 1 μg/ml, where "g" and "ml" stand for gram and milliliter, and "μg" stands for micrograms.

In general terms, $ppm = \frac{grams\ of\ gluten}{grams\ of\ food} \cdot 10^6$

[69] Excerpt from the AIC website: << The Spiga Barrata brand ... guides people with celiac disease in the choice of packaged food products that are safe and suitable for the specific needs of a gluten-free diet ... Packaged food products bearing the Spiga Barrata logo comply with the regulatory limit of 20 ppm gluten ... and comply with ... the production, management and control requirements of the technical specification for the granting of the brand ... >>

Figure 24. Logos of the Italian Ministry of Health and AIC for gluten-free products.

The Spiga Barrata logo shown at the right is a registered symbol and property of the Italian Coeliac Association (AIC).

The regulatory environment

The Regulations on gluten-free products are manifold and can appear complex. Regulation (EC) No. 41/2009 of the European Commission has established harmonized rules on the correct information to be given to consumers about the total or partial absence of gluten in food. The Regulation sets the thresholds of 20 ppm and 100 ppm. Subsequently, Regulation (EU) No. 609/2013 was issued relating to food products intended for a particular diet. It defines the composition and information requirements for food intended for infants and young children, food for special medical purposes and daily dietary substitutes for weight control. The gluten-free products that before the Regulation No. 609/2013 were considered dietetic products intended for a particular diet, were excluded from this area because the legislator decided to regulate the presentation and labeling of gluten-free food all Internal Regulation (EU) No. 1169/2011 which determines what food information should be provided to consumers. In addition, Regulation No. 1169/2011 repealed the previous No. 41/2009. On the sidelines, the European Commission Delegated Regulation (EU) No. 1155/2013 has empowered the Commission to adopt delegated acts on how to indicate gluten in food. And so, in article 36 paragraph 3 of Regulation No. 1169/2011, letter d) has been added, which concerns the information that can be provided by food business operators on the absence of gluten,

or on its reduced presence, in food. Subsequently, the European Commission Implementing Regulation (EU) No. 828/2014 concerning the requirements to inform consumers about the absence of gluten or its reduced presence in food was published. This Regulation confirms the threshold values of 20 ppm and 100 ppm for gluten-free foods (gluten content <20 ppm) or reduced gluten content (<100 ppm). In addition, the definition of "diet product" is not used for these products, but the term "gluten-free" is part of the labeling of gluten-free foods.

Gluten-free labelling

The presence in some foods of substances capable of provoking the manifestation of serious diseases in sensitive subjects is a problem for consumers and for public health. Italian law No. 123/2005 "Rules for the protection of people with celiac disease" in art. 2 declares the purpose of << ... to favor the normal insertion in the social life of people suffering from celiac disease ... >> and therefore to allow them adequate nutrition. According to Regulation (EU) No. 1169/2011, the indications "gluten-free" and "with a very low gluten content", as governed by Regulation (EU) No. 828/2014 on the absence of gluten or on the its reduction, can be reported on the label on a voluntary basis. Furthermore, when a food is formulated to be expressly intended for celiacs, the term "gluten-free" on the label may be followed by the words "specifically formulated for people intolerant to gluten" or "specifically formulated for celiacs".

In Italy, companies that notify their products according to the provisions of Legislative Decree No. 111/1992, are included in the "National Register of gluten-free foods" so that the products can be paid by the national health system.

The National Register, established pursuant to art. 7 of the ministerial decree of 8 June 2001 relating to supplementary health care about products intended for a particular diet, as modified by the ministerial decree 17 May 2016, is periodically updated on a monthly basis (Ministero della Salute, 2019).

Cereals and pseudo-cereals gluten-free

Many foods are naturally gluten-free such as fruit, vegetables, meat, fish, dairy products, all provided that they have been processed in the absence of gluten-containing ingredients.

In addition to these foods, cereal-based flours or food-grade pseudo-cereals are on the market which provide nutrients such as fiber, minerals and proteins and which are gluten-free due to their natural composition.

The following plant species, sometimes grown in remote rural areas of the planet, are edible and gluten-free:

- *Amaranthus cruentus*, red amaranth;
- *Amaranthus caudatus*, love lies bleeding;
- *Amaranthus hypochondriac,* Prince-of-Wales feather or simply called prince's-feather;
- *Fagopyrum esculentum*, buckwheat (the fruit of the *Fagopyrum esculentum* plant);
- *Zea mays*, corn;
- *Panicum miliaceum*, millet;
- *Chenopodium quinoa*, marketed under the name quinoa;
- *Oryza sativa*, the common rice;
- *Sorghum vulgare*, that is the sorghum;
- *Eragrostis tef*, commonly called teff;
- *Digitaria exilis*, known as fonio.

The following tubers widely used in human nutrition are also gluten-free:

- *Solanum tuberosum L.*, the common potato;
- *Ipomoea batatas,* sweet or American potato*;*
- *Manihot esculenta,* known by various names such as cassava, mandioca, yuca, cassava.

Methods to degrade gluten enzymatically

Protease

Proteases are a class of enzymes of animal and plant origin capable of catalysing the cleavage of the peptide bond between amino acids in proteins, through a mechanism that uses a water molecule, so that the proteases are classified among the hydrolases.

Enzyme nomenclature

The enzymes are classified according to a scheme of the Enzyme Commission sanctioned by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology. The scheme classifies enzymes by classes based on the overall catalysed reaction providing information on the mechanism, substrates, products and cofactors. The EC number resolves the doubts about the identification of enzymes since each enzyme has different names due to customs and a universally accepted name. For example, for the enzyme EC 3.4.21.xx the first digit indicates the general type of reaction catalysed by the enzyme. Here the number 3 identifies a hydrolase or enzymes that promote a biochemical reaction of cleavage of molecular bonds in the presence of water. The second digit, in this case 4, indicates that it is a peptidase that acts on peptide bonds. The third number, 21, indicates a serine protease belonging to a class of proteases that base their catalysis mechanism on the presence of the serine, which is particularly reactive and essential for their enzymatic activity.

Table 29. Example of EC number classification scheme (processed on data https://enzyme.expasy.org/EC/3.4.21.26)

EC number	General type of reaction catalysed by the enzyme	Enzyme's sub-class	Enzyme's sub-sub-class	Accepted name	Alternative names
EC 3.4.21.26					
EC **3**.4.21.26	Hydrolases				
EC 3.**4**.21.26		Peptidase (act on peptide bonds)			
EC 3.4.**21**.26			Serine proteases		
EC 3.4.21.**26**				Prolyl oligopeptidase	Post-proline cleaving enzyme. Post-proline endopeptidase. Prolyl endopeptidase.

Commercial enzyme product named Clarex

Clarex[70] contains the enzyme prolyl endopeptidase (EC 3.4.21.xx)[71] obtained from a genetically modified strain of *Aspergillus niger*[72].

Generally, Clarex is an enzymatic product used in the fermentation process to reduce the content of proteins present in solution (Akeroyd et al., 2016). In fact, due to the simultaneous presence of polyphenols, large molecular complexes could form that would make beer opaque. Instead, with the action of Clarex the final beer will appear clear.

Beer naturally contains peptides and proteins derived from cereals used in the brewing process. Cereals such as, for example, barley and wheat, are a source of gluten. Although the protein material is partially hydrolyzed during fermentation, gluten-containing protein fractions are found in the final product. Because of this, people intolerant to gluten would be penalized as they would be barred from consuming beer.

There are several methods for degrading gluten. The company in question chose the enzymatic degradation of gluten through the use of a commercial product called Clarex. The reason for this choice lies in the willingness of management to offer its customers a gluten-free product that has the same organoleptic properties as a regular beer. In other words, it was decided to produce gluten-free beer with the same starting cereals and to maintain the same sensorial properties of taste and aroma as classic beers. The alternative would have been to use naturally gluten-free cereals and / or pseudo-cereals but without the guarantee of obtaining a product appreciated by customers from an organoleptic point of view.

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[70] https://ec.europa.eu/food/sites/food/files/safety/docs/codex_ccfa_48_cl-2015-11-fa_endopeptidase-a-niger.pdf

[71] The term proline endopeptidase is synonymous with prolyl oligopeptidase, EC (IUBMB) number 3.4.21.26. However, unlike oligopeptidase, the enzyme also acts on proteins (Edens et al., 2005; Kubota et al., 2005; Takahashi, 2013).

[72] *Aspergillus niger* is a common member of the microbial communities present in soils and plays a significant role in the global carbon cycle. It is a soil saprophyte with a wide range of hydrolytic and oxidative enzymes involved in the cleavage of plant lignocellulose.

Beers produced in this way must have gluten levels below 20 ppm. The verification of the gluten content in beer involves an analytical method approved by the Codex Committee on analysis and sampling methods (CCMAS[73], Codex Committee on Methods of Analysis and Sampling). The analytical method called ELISA[74] R5 is usually used on food matrices.

New perspectives

Some recent studies have tested a new technology for the reduction of gluten in beer by hydrodynamic cavitation used for the production of barley malts (Albanese et al., 2017). This method would be able to reduce the gluten content within the expected limits of 20 ppm. Furthermore, the beer would be produced with the same ingredients and the same recipes as the standard beers without the involvement of chemical additives or enzymatic compounds, and without the use of techniques such as filtration or ultrafiltration, preserving - in the researchers' intentions - the taste and aroma of the best craft beers.

[73] Report of the 26th Session of the Codex Committee on Methods of Analysis and Sampling (4 - 8 April 2005), Alinorm No. 05/28/23.

[74] ELISA means enzyme-linked immunosorbent assay.

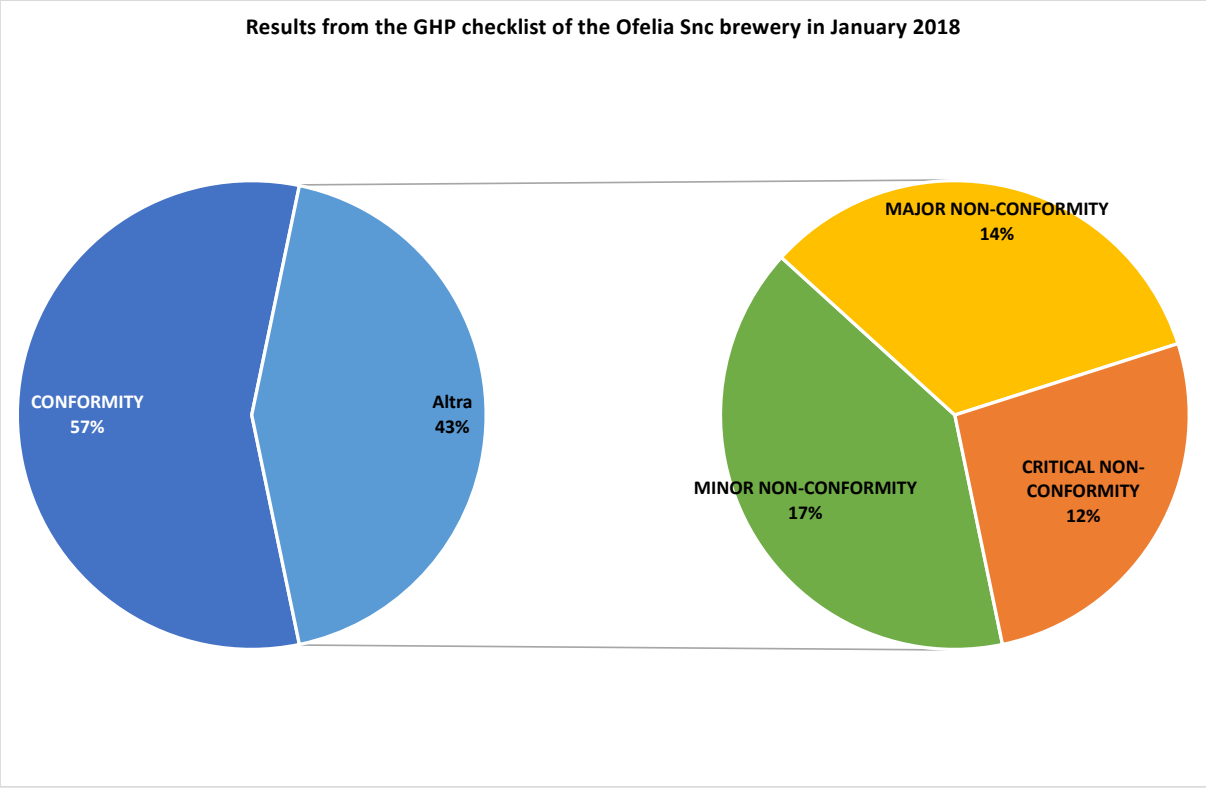
Results

The monitoring of the Good Hygiene Practices showed a consistency level of 56.5% in January 2018, as shown in the table.

Table 30. Audit summary on Good Hygiene Practices based on the GHP checklist carried out at brewery in January 2018.

AUDIT SUMMARY ON GOOD HYGIENE PRACTICES	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY
FINDINGS	39	12	10	8
%	56.5%	17.4%	14.5%	11.6%

Figure 25. Audit results based on the GHP checklist carried out at Ofelia Snc in January 2018.

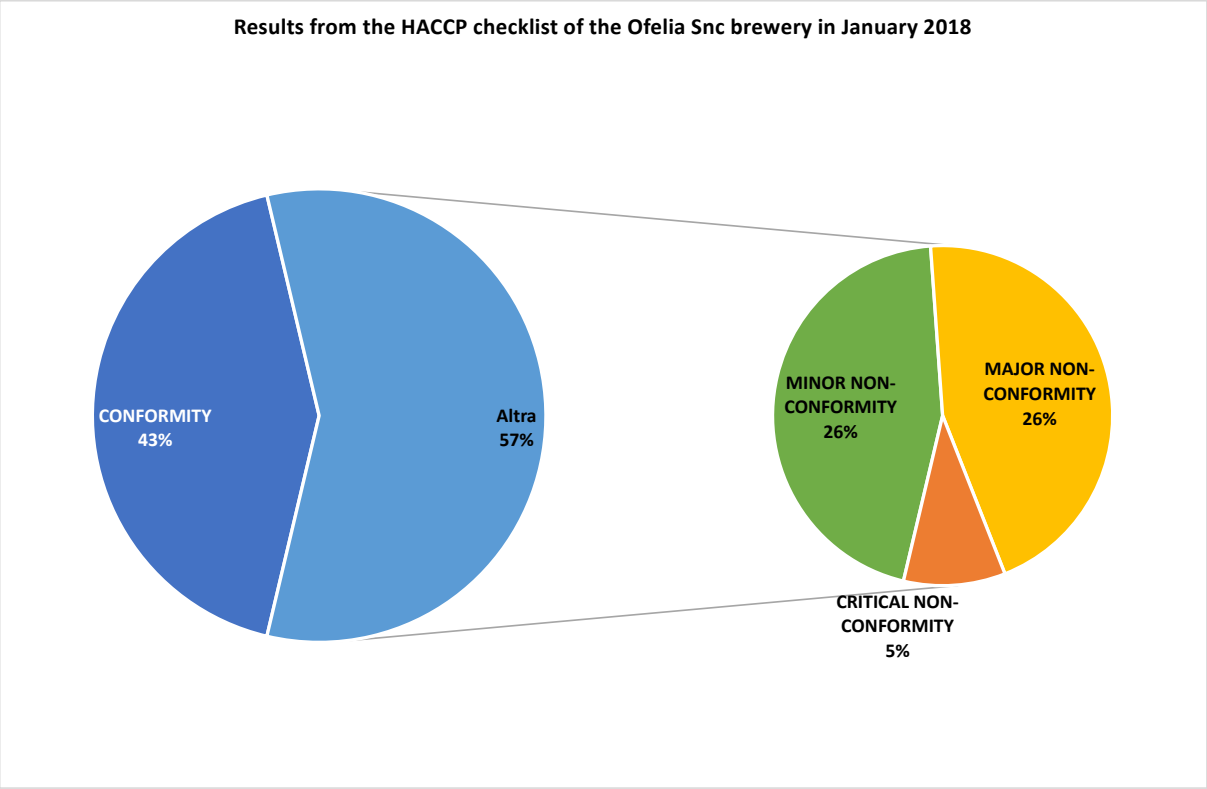


As regards the audit on the HACCP plan carried out in January 2018, 42.6% of the items were compliant as summarized in the table.

Table 31. Audit summary based on the HACCP checklist carried out at brewery in January 2018.

AUDIT SUMMARY ON HAZARD ANALYSIS AND CRITICAL CONTROL POINTS	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY
FINDINGS	23	14	14	3
%	42.6%	25.9%	25.9%	5.6%

Figure 26. Audit results based on the HACCP checklist carried out at Ofelia Snc in January 2018.

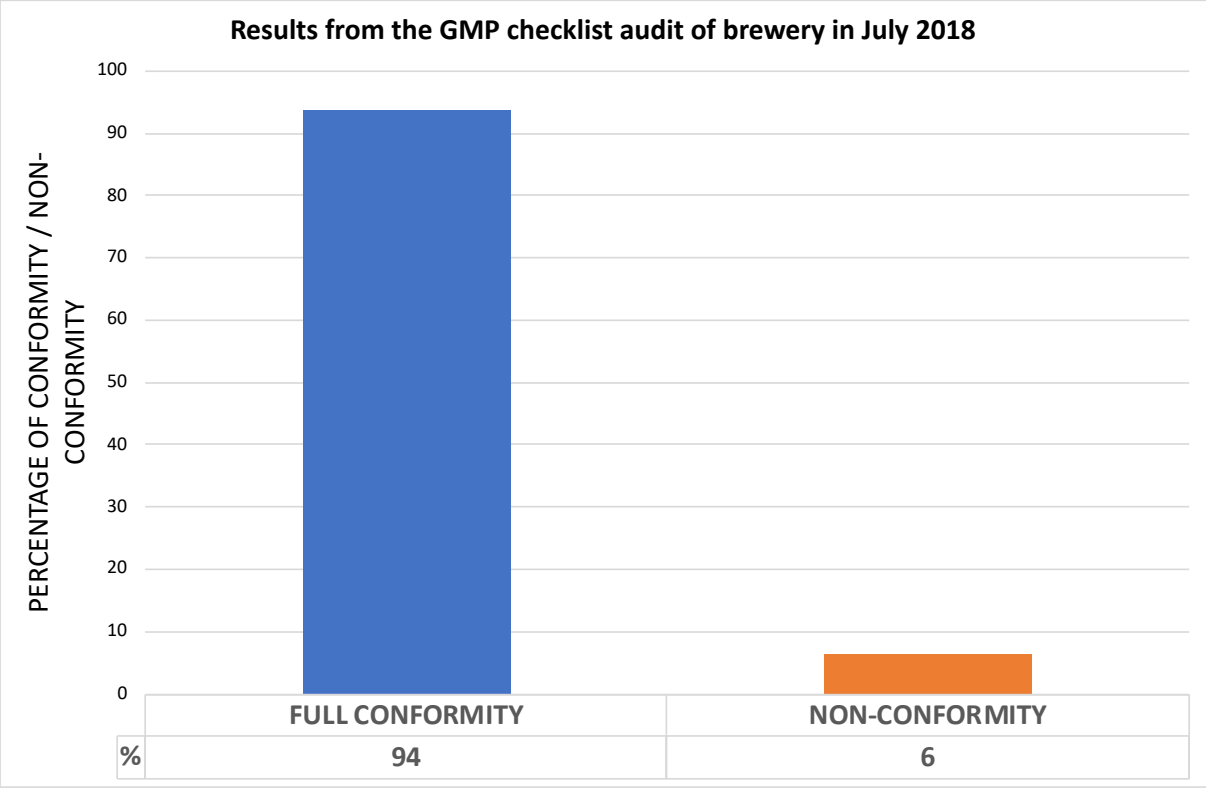


The audit on Good Manufacturing Practices specific to the brewery, carried out six months later, in July 2018, gave a compliance result of 93.6% as shown in the table.

Table 32. Audit results based on the GMP checklist carried out at Ofelia Snc brewery in July 2018.

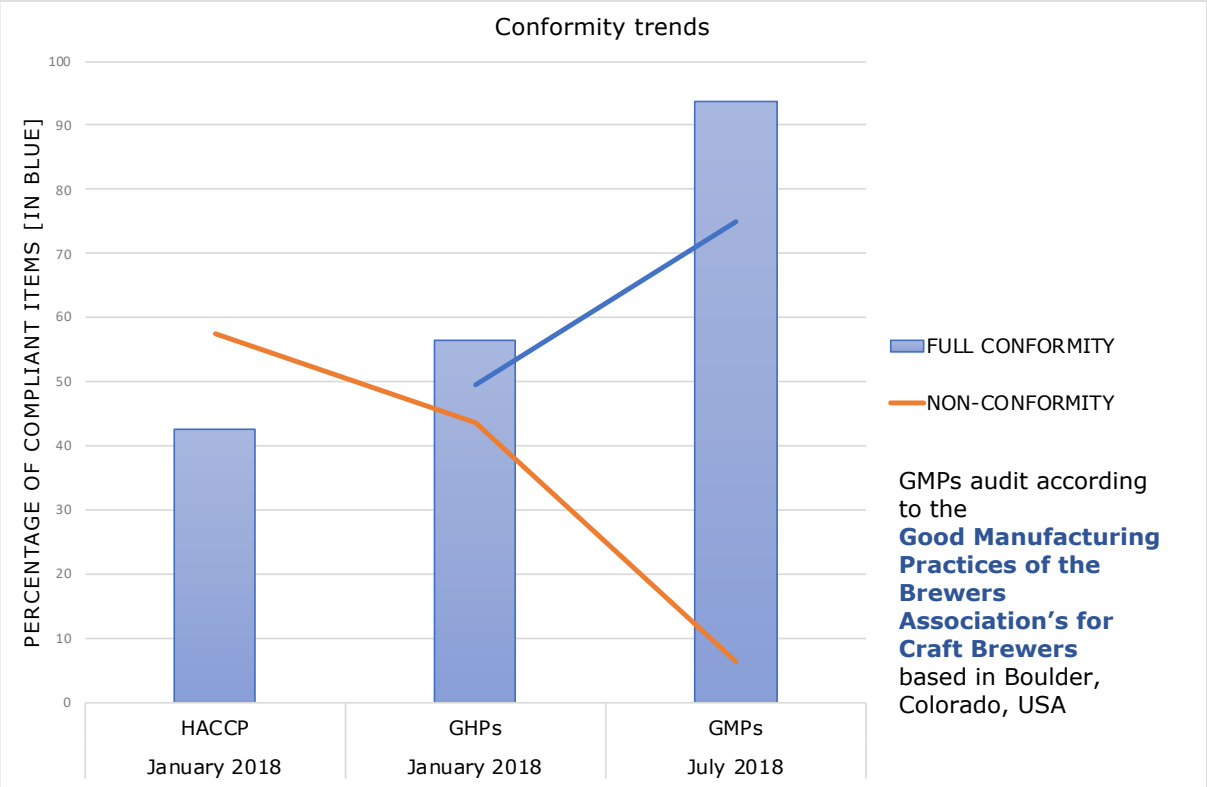
AUDIT SUMMARY ON GOOD MANUFACTURING PRACTICES	CONFORMITY	NON-CONFORMITY
FINDINGS	175	12
%	93.6%	6.4%

Figure 27. Audit results based on the GMP checklist carried out at Ofelia Snc brewery in July 2018.



From the data it is clear that the entire production process was fully operational in respect of compliance with the basic requirements. After achieving this result, it was decided to carry out another type of study. In particular, the chance of obtaining the maximum profit was assessed by achieving an optimal distribution of the productions. The topic is discussed later.

Figure 28. Summary of audits on HACCP, GHP and GMP.



Discussion and analysis

After the GHP and HACCP audits carried out at the beginning of this research study, there was a lack of compliance with some specifications.

Following this, the points to be focused and improved in order to achieve excellence has been discussed with the company management. At this stage it was decided to modify the procedures in order to comply with the guidelines of the Brewers Association for Small & Independent Craft Brewers, an association that cares for the interests of American craft breweries.

So, after implementing the appropriate corrective actions and after six months, an audit took place on the Good Manufacturing Practices of the aforementioned Brewers Association. This audit assessed 43 good practice items as described in detail in Addendum No. 2.

The results were almost optimal with a positive feedback of 93.6%. In fact, the commitment of the staff has become highly accurate in all phases of the production process. This has translated into special attention in the phases of receiving raw materials and shipping goods, in the storage operation, and in all operations related to the production of beer.

On the one hand, the achievement of this promising result has placed the company management and staff in an ideal condition to face the future phase of certification to obtain Spiga Barred labeling.

On the other hand, the study group took the opportunity to carry out a study of models and algorithms dedicated to the economic optimization of production.

Organizing the production line

The Regulation (EC) No. 852/04 on the hygiene of food products establishes that the responsibility for food safety lies with the food business operator, FBO. Food safety must be ensured throughout the supply chain, i.e. production, processing and distribution. The FBO is responsible for the HACCP plan and compliance with hygiene requirements based on Annex II of Regulation (EC) No. 852/04. Raw materials and semi-finished products for the production of gluten-free foods must be easily identifiable by appropriate labeling and stored in separate places. If this is not possible, it is allowed to use the same department as long as there is a clear identification of the materials. Alternatively, the production of gluten-free food preparations can be carried out on specific days or alternatively on the same day but at a different time of the day. In both cases it is necessary to provide for an accurate sanitization of the equipment, work plans, etc. before and after the work cycle.

These procedures must be clearly specified in the self-control plan, implemented, monitored and verified by the personnel responsible for the process. The implementation of the procedures must be demonstrated through the documentation. The documentation

should identify with certainty the person responsible for each specific procedure. Furthermore, the documentation should include the map of the industrial plant, the personnel training certificates, the recording of the monitoring, the definition of the allowed limits, the action plan in case of exceeding the limits, the measures or in case of interventions overtime and recording of corrective actions taken in case of non-compliance. The self-control plan must cover both “regular” and “gluten-free” production.

In this context, the preparation of clear, relevant, documentable and verifiable procedures takes on a priority role. Furthermore, the training of personnel regarding celiac disease is essential for the correct application of good processing practices. Staff training courses should focus on the following topics:

- epidemiology, that is the modalities of the onset, spread and frequency of the disease in relation to the conditions of the organism, the environment and the population;
- aetiology, i.e. the causes of the disease;
- pathogenesis, that is, the mechanism by which the morbid process takes place;
- clinical, i.e. patient observation;
- therapy;
- naturally gluten-free foods;
- how to prevent the contamination of food by gluten during the various phases of the production cycle;
- correct application of the self-control plan.

Table 33. Example diagram of self-control plan of the production cycle for gluten-free products with critical control points (CCP) to be determined during the plan design phase.

Step	**Hazard**	**CCP**	**Preventive actions**	**Monitoring**	**Corrective actions**
Procurement of raw materials.	Presence of gluten; cross-contamination.		Supplier accreditation. Raw materials with the following words: "gluten-free"; gluten-free diet products notified to the Ministry of Health; naturally gluten-free products. Identification of products during transport.	Checking the suitability of the transport; checking the compliance of the goods: original packaging intact; labelling compliance check: gluten-free, Spiga Barrata.	Rejection of non-compliant goods.
Storage of raw materials.	Product exchange; cross-contamination.		Storage in separate and well identified areas or containers; packages intact and adequately protected, if open.	Visual control.	Restoring separation; elimination of the product at the slightest suspicion of contamination or if it is not well identified.
Processing.	Cross-contamination.		Exclusive production lines; time differentiation of preparations; dedicated equipment and tools; defined procedures.	Visual control.	Alienation of the product following the slightest suspicion of contamination.
Finished product storage.	Product exchange.		Storage in closed, well-identified containers.	Visual control.	Alienation of the product following the slightest suspicion of contamination.
Labelling. Packing. distribution. Sale.	Product exchange.		Use of appropriate equipment; separate containers; suitable packaging.	Visual control.	Alienation of the product following the slightest suspicion of contamination.

Gap analysis

Normally a company follows consumer trends. However, it may happen that at a certain moment a gap becomes evident, a detachment, the gap between the actual offer of existing products and what the consumer requires. The organization must fill this gap to survive and grow. Another aspect concerns the economic-financial aspect of the company where the analysis between expected and desired profits can highlight an unwanted difference. A further aspect concerns that of compliance with the rules in the sense of the deviation of an organization from a regulatory principle or an international standard.

All this translates into defining a target for the organization's new activities and new products (Christian et al., 2001).

In particular, the work of the study group consisted of:

- a series of meetings with top management to define the purpose, objectives, activities, work program and progress of the work;
- a first visit to the structures of the Ofelia brewery where the interview with the owners took place and the company documentation was revised to verify the possible compliance with the HACCP plan. Further visits monitored the progress of the works.

Alternatives and Decision Criteria

Alternatives

From a technological point of view, several studies have highlighted particular methods for reducing or eliminating gluten from beer (Hager et al., 2014). The methods studied include the enzymatic hydrolysis of gluten (Van Landschoot, 2011), the preparation of beer from sugar solutions fermented with yeasts (Klisch, 2009), the use of raw materials such as pseudo-cereals or naturally gluten-free cereals (De Meo et al., 2011). For example, a good alternative seems to be beer made from rice. From the organoleptic point of view, it seems that we can get close enough to barley malt beer since the sensory profile due to the content of aromatic compounds seem similar.

However, it seems that some industrial process technological problems are to be improved (Montanari et al., 2009). In addition to rice, other starting cereals designed to produce beer are millet, sorghum and buckwheat (Kiss et al., 2011).

In this context, new plant selection strategies are being developed for the development of gluten-free alternative cereals. For example, a cultivar of a new ultra-low gluten barley has been studied in which the hordein (prolamin) content has been reduced to levels below 5 ppm (Tanner et al., 2015).

The decision criteria

Several factors influence decisions. In the case of the company under study, the aim is to obtain certification as for the Spiga Barrata labeling. Therefore, the priority is to implement the prerequisite program and the self-control plan in order to meet the requirements set by the standard. Furthermore, an essential point is the maintenance of the organoleptic properties of gluten-free beer at a level comparable to that of regular beers. Considering customer requests regarding the taste of beer, the company's management has opted for the method of enzymatic degradation of gluten which seems to be the most manageable even from the point of view of cross-contamination.

Tips and implementation plan

Monitoring reports are provided in Addendum No. 2. The specifications relating to Good Hygiene Practices, Good Manufacturing Practices and HACCP, have been subject to careful evaluation and discussion to implement a valid integrated management system. The action plan was structured in the short, medium and long term, giving priority to the interventions necessary for full compliance with mandatory standards. Therefore, full awareness of the necessary interventions allowed the company to prepare for compliance with the requirements.

In this context of progress towards the set objectives, at the end of the study group's activity (coinciding with the final year's graduate degree exam), the company found itself ready to start the certification process for the Spiga Barrata labeling.

Linear programming on beer production

For mathematical modeling according to the methods of Linear programming, three different production scenarios have been hypothesized to which to dedicate all the resources for a period of six months. In particular, it has been hypothesized to invest € 80,000 of resources to produce in one case only seasonal and gluten-free beers. In the second case, we thought about the opportunity to produce only seasonal and regular beers. Finally, the economic convenience of producing only regular beers and gluten-free beers was calculated. The following tables summarize the company's data for the first six months of 2018, while the following paragraphs illustrate the operating options.

Table 34. Production report for the first half-year of 2018.

	Wort, litres	Scrap, litres	Scrap %	Resulting beer, litres	Beer brewed by type%	Beer brewed, litres/die	Beer brewed, bottles/die
Regular beers	24,573	2,612	10.6	21,961	74.4	121	367
Gluten-free beers	1,911	199	10.4	1,712	5.8	9	28
Seasonal beers	6,307	467	7.4	5,840	19.8	32	97
Total	32,791	3,278		29,513		163	492

Table 35. Economic management report for the first half-year of 2018.

	Wort, expenses incurred €	Beer, sales revenue €	Profit €	Must, cost in € / litre	Beer, revenue from sales in € / litre	Profit in € / litre
Regular beers	59,634.67	89,128.75	29,494.08	2.76	4.10	1.34
Gluten-free beers	4,536.80	6,762.40	2,225.60	2.65	3.95	1.30
Seasonal beers	15,712.15	23,189.20	7,477.05	2.66	3.91	1.25
Total	79,883.62	119,080.35	39,196.73			

To create hypotheses for Linear programming, various software is available such as, for example:

- AIMMS (https://www.aimms.com);
- AMPL (https://ampl.com/products/ampl/);
- Gurobi Optimization (https://www.gurobi.com);
- The MathWorks, Optimization Toolbox (https://www.mathworks.com);
- and others.

In the book “Practical Optimization: a gentle introduction” by John W. Chinneck of Carleton University of Ottawa in Ontario, Canada

(http://www.sce.carleton.ca/faculty/chinneck/po.html)

the calculation procedure is implemented in Microsoft Excel which in this study was applied to solve only the first scenario.

Instead, free online software offered by PHP Simplex, http://www.phpsimplex.com/en/index.htm, was used to solve all the scenarios hypothesized in this study, including the first one.

In any case and confirming the results, both the procedure in Excel and that with PHP Simplex have produced the same results.

Modelling of the optimum production point for the following 2 product lines:

gluten-free beer and seasonal beers

As regards the first scenario, the calculation principles and procedures applied to apply the Linear programming method are shown.

The first step is to identify the objective function, the constraints of the problem and the non-negativity of the variables involved. The aim is to maximize the profit on the available financial resources used for the purchase of raw materials, for personnel expenses, for the purchase and maintenance of infrastructures and structures, for the amortization of investments and for the cost of money.

The equation:

$max\ Z = 1{,}30\ X_1 + 1{,}25\ X_2$

takes into account variables X_1, production of gluten-free beer, and variable X_2, production of seasonal beers. The coefficients of X_1 and X_2 indicate the profit per litre.

The non-negativity of variables is expressed by inequalities:

$X_1 > 0$

$X_2 > 0$

The constraints are established on the basis of the report on the production capacity of the plant during the half-year of about 19 hectoliters of gluten-free beer and about 63 hl of seasonal beers. The constraints are represented by the following inequalities expressed in liters:

gluten-free beer production limit	$X_1 \leq 1911$
seasonal beers production limit	$X_2 \leq 6307$
limit of global production considering waste	$X_1 + X_2 \leq 7552$

The parameters of the problem show that the production of gluten-free beer has a limit of about 19 hectolitres. That of seasonal beer is about 63 hectolitres. In both cases without considering production waste. With these reference parameters it is possible to calculate the optimum point with the simplex method.

Explaining proceedings

In this first hypothesis we thought of a production scenario in which to dedicate the financial resources for a half year € 80,000 to produce both gluten-free and seasonal beers. In the table, the coefficients of X1 and X2 indicate the profit per liter while the constraints are expressed in liters.

Table 36. Parameters of the optimization equation.

Objective function:	**max Z = 1,30 X_1 + 1,25 X_2**	
Non-negativity of variable X_1	$X_1 > 0$	
Non-negativity of variable X_2	$X_2 > 0$	
Constraint:	$X_1 \leq 1911$	gluten-free beer production limit
Constraint:	$X_2 \leq 6307$	seasonal beers production limit
Constraint:	$X_1 + X_2 \leq 7552$	limit of global production

The problem is converted into canonical form by adding the slack variables [75], so that inequalities become equations. As the constraint 1 is of type "*less than or equal to*" we should add the slack variable X3, and since constraint 2 is also of the "*less than or equal to"* type we should add the slack variable X4, and finally constraint 3 is still of type " ≤ " so we should add the slack variable X5, resulting a system of linear equations.

[75] In optimization problems, a slack variable is a variable that is added to an inequality constraint to transform it into an equality.

Function in standard form	Function in canonical form
Maximize:	Maximize:
Z = 1.30 X1 + 1.25 X2	Z = 1.30 X1 + 1.25 X2 + 0 X3 + 0 X4 + 0 X5
is subject to:	is subject to:
1 X1 + 0 X2 ≤ 1911	1 X1 + 0 X2 + 1 X3 = 1911
0 X1 + 1 X2 ≤ 6307	0 X1 + 1 X2 + 1 X4 = 6307
1 X1 + 1 X2 ≤ 7552	1 X1 + 1 X2 + 1 X5 = 7552
X1, X2 ≥ 0	X1, X2, X3, X4, X5 ≥ 0

On this basis we can build the first tableau of the Simplex method. Column Cb contains the coefficients of the added variables. Column P0 contains constant terms and constraints. The columns Pi (P1, P2, ..., etc.) contain the coefficients of the remaining variables Xi of the objective function.

Tableau 1							
			1.3	1.25	0	0	0
Base	Cb	P0	P1	P2	P3	P4	P5
P3	0	1911	1	0	1	0	0
P4	0	6307	0	1	0	1	0
P5	0	7552	1	1	0	0	1
Z		0	-1.3	-1.25	0	0	0

The output variable is P3 and the input variable is P1.

Now follows the second picture (Tableau 2) of the Simplex method.

Tableau 2							
			1.3	1.25	0	0	0
Base	Cb	P0	P1	P2	P3	P4	P5
P3	1.3	1911	1	0	1	0	0
P4	0	6307	0	1	0	1	0
P5	0	5641	0	1	-1	0	1
Z		2484.3	0	-1.25	1.3	0	0

The output variable is P5 and the input variable is P2.

The next is Tableau 3.

Tableau 3							
			1.3	1.25	0	0	0
Base	Cb	P0	P1	P2	P3	P4	P5
P3	1.3	1911	1	0	1	0	0
P4	0	666	0	0	1	1	-1
P5	1.25	5641	0	1	-1	0	1
Z		9535.55	0	0	0.05	0	1.25

As shown in the diagram and table, the optimal solution of the objective function Z is € 9535.55 with X1 = 1911 liters and X2 = 5641 liters.

Figure 29. Eligible area for profitable production.

In green color any area eligible for profitable production. The axes have dimensions in liters.

Table 37. Eligible values for profitable production.

	Gluten-free beer	**Seasonal beers**	
Point	X1 (liters)	X2 (liters)	Z (€)
O	0	0	0
A	1911	0	2484.30
B	1911	6307	10358.05
C	1911	5641	9535.55
D	0	6307	7883.75
E	1245	6307	9502.25
F	0	7552	9440.00
G	7552	0	9817.60

The most profitable combination is shown in green. The second choice is in blue. Points that do not belong to the possible region are shown in grey area.

Analyzing the graph, it can be seen that the three positive half-planes underlying the left of the 3 lines, horizontal, vertical and oblique, represent all the combinations of production programs obtainable. From the intersection of the half-planes, the only possible production area is obtained, here in green color, where it is possible to take advantage of the combination of the production lines of the two types of beer. At the maximum point of the objective function and against a spending commitment for a semester of € 80,000, it is possible to obtain a profit in the semester of approximately € 9,536 by combining the two productions appropriately. Any other distribution of production allows for a lower profit.

Modelling of the optimum production point for the following 2 product lines:

seasonal beers and regular beers

In this second hypothesis it is conceived in a production scenario in which to devote for a half-year the financial resources of € 80,000 to produce both seasonal and regular beers. In the table, the coefficients of X1 and X2 indicate the profit per litre whilst the constraints are expressed in litres.

Table 38. Parameters of the optimization equation.

Objective function:	**max Z = 1,25 X_2 + 1,34 X_1**	
Non-negativity of variable X_1	$X_1 > 0$	
Non-negativity of variable X_2	$X_2 > 0$	
Constraint:	$X_1 \leq 6307$	seasonal beers production limit
Constraint:	$X_2 \leq 24573$	regular beers production limit
Constraint:	$X_2 + X_3 \leq 27801$	limit of global production

As the constraints is of type "*less than or equal to*" we should add the slack variables.

Function in standard form	Function in canonical form
Maximize:	Maximize:
Z = 1.25 X1 + 1.34 X2	Z = 1.25 X1 + 1.34 X2 + 0 X3 + 0 X4 + X5
is subject to:	is subject to:
1 X1 + 0 X2 ≤ 6307	1 X1 + 0 X2 + 1 X3 = 6307
0 X1 + 1 X2 ≤ 24573	0 X1 + 1 X2 + 1 X4 = 24573
1 X1 + 1 X2 ≤ 29513	1 X1 + 1 X2 + 1 X5 = 29513
X1, X2 ≥ 0	X1, X2, X3, X4, X5 ≥ 0

The output variable is P4 and the input variable is P2.

Tableau 1							
			1.25	1.34	0	0	0
Base	Cb	P0	P1	P2	P3	P4	P5
P3	0	6307	1	0	1	0	0
P4	0	24573	0	1	0	1	0
P5	0	29513	1	1	0	0	1
Z		0	-1.25	-1.34	0	0	0

The output variable is P3 and the input variable is P1.

Tableau 2							
			1.25	1.34	0	0	0
Base	Cb	P0	P1	P2	P3	P4	P5
P3	0	6307	1	0	1	0	0
P4	1.34	24573	0	1	0	1	0
P5	0	4940	1	0	0	-1	1
Z		32927.82	-1.25	0	0	1.34	0

The output variable is P5 and the input variable is P1.

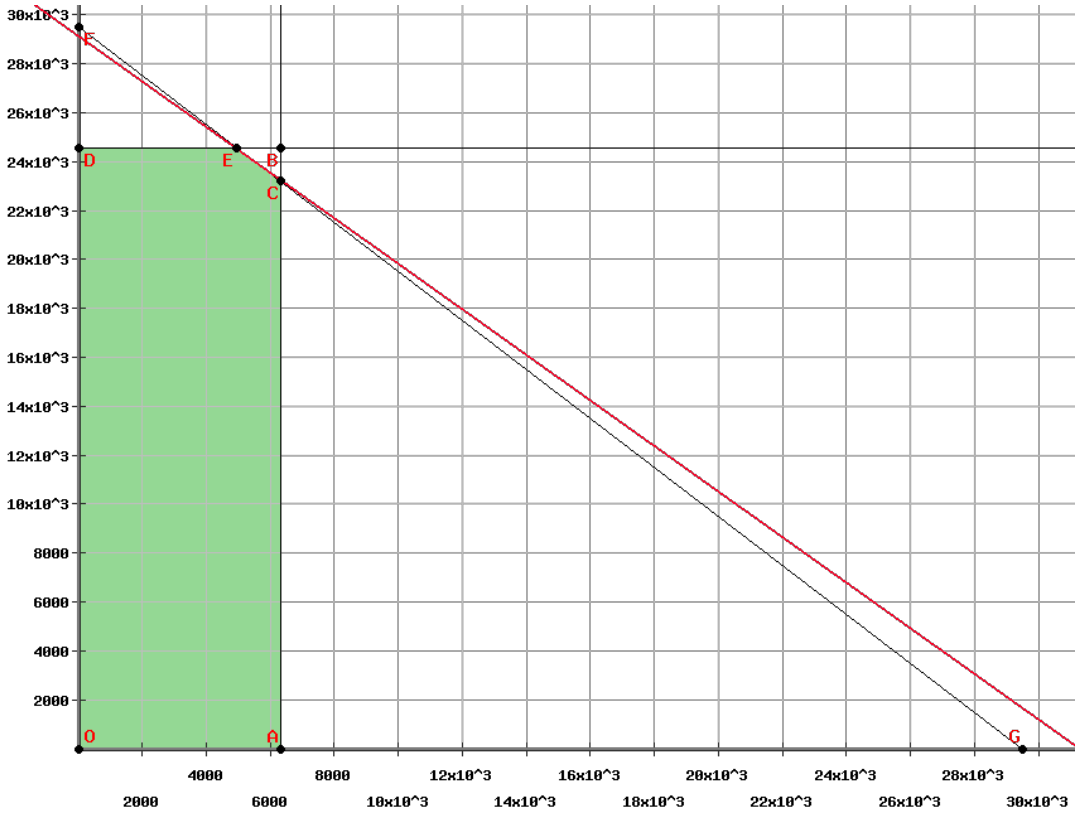
Tableau 3							
			1.25	1.34	0	0	0
Base	Cb	P0	P1	P2	P3	P4	P5
P3	0	1367	0	0	1	1	-1
P4	1.34	24573	0	1	0	1	0
P5	1.25	4940	1	0	0	-1	1
Z		39102.82	0	0	0	0.09	1.25

The optimal value of the solution is Z = 39 102.82

X1 = 4940

X2 = 24573

Figure 30. Eligible area for profitable production.



In green color any area eligible for profitable production. The axes have dimensions in liters.

Table 39. Eligible values for profitable production.

	Seasonal beers	**Regular beers**	
Point	X1 (liters)	X2 (liters)	Z (€)
O	0	0	0
A	6307	0	7883.75
B	6307	24573	40811.57
C	6307	23206	38979.79
D	0	24573	32927.82
E	4940	24573	39102.82
F	0	29513	39547.42
G	29513	0	36891.25

The most profitable combination is shown in green. The second choice is in blue.
Points that do not belong to the possible region are shown in grey area.

Modelling of the optimum production point for the following 2 product lines:

gluten-free beer and regular beers

In this other hypothesis, a production scenario is assumed in which to dedicate the financial resources of € 80,000 for a half-year to produce both gluten-free beer and regular beers. In the table, the coefficients of X1 and X2 indicate the profit per liter while the constraints are expressed in liters.

Table 40. Parameters of the optimization equation.

Objective function:	**max Z = 1,30 X_1 + 1,34 X_2**	
Non-negativity of variable X_1	$X_1 > 0$	
Non-negativity of variable X_2	$X_2 > 0$	
Constraint:	$X_1 \leq 1911$	gluten-free beer production limit
Constraint:	$X_2 \leq 24573$	regular beers production limit
Constraint:	$X_1 + X_2 \leq 23673$	limit of global production

Since the constraints are "*less than or equal to*" we should add the slow variables as shown in the following table.

Function in standard form	Function in canonical form
Maximize:	Maximize:
Z = 1.30 X1 + 1.34 X2	Z = 1.30 X1 + 1.34 X2 + 0 X3 + 0 X4 + X5
is subject to:	is subject to:
1 X1 + 0 X2 ≤ 1911	1 X1 + 0 X2 + 1 X3 = 1911
0 X1 + 1 X2 ≤ 24573	0 X1 + 1 X2 + 1 X4 = 24573
1 X1 + 1 X2 ≤ 23673	1 X1 + 1 X2 + 1 X5 = 23673
X1, X2 ≥ 0	X1, X2, X3, X4, X5 ≥ 0

The output variable is P5 and the input variable is P2.

Tableau 1							
			1.30	1.34	0	0	0
Base	Cb	P0	P1	P2	P3	P4	P5
P3	0	1911	1	0	1	0	0
P4	0	24573	0	1	0	1	0
P5	0	23673	1	1	0	0	1
Z		0	-1.30	-1.34	0	0	0

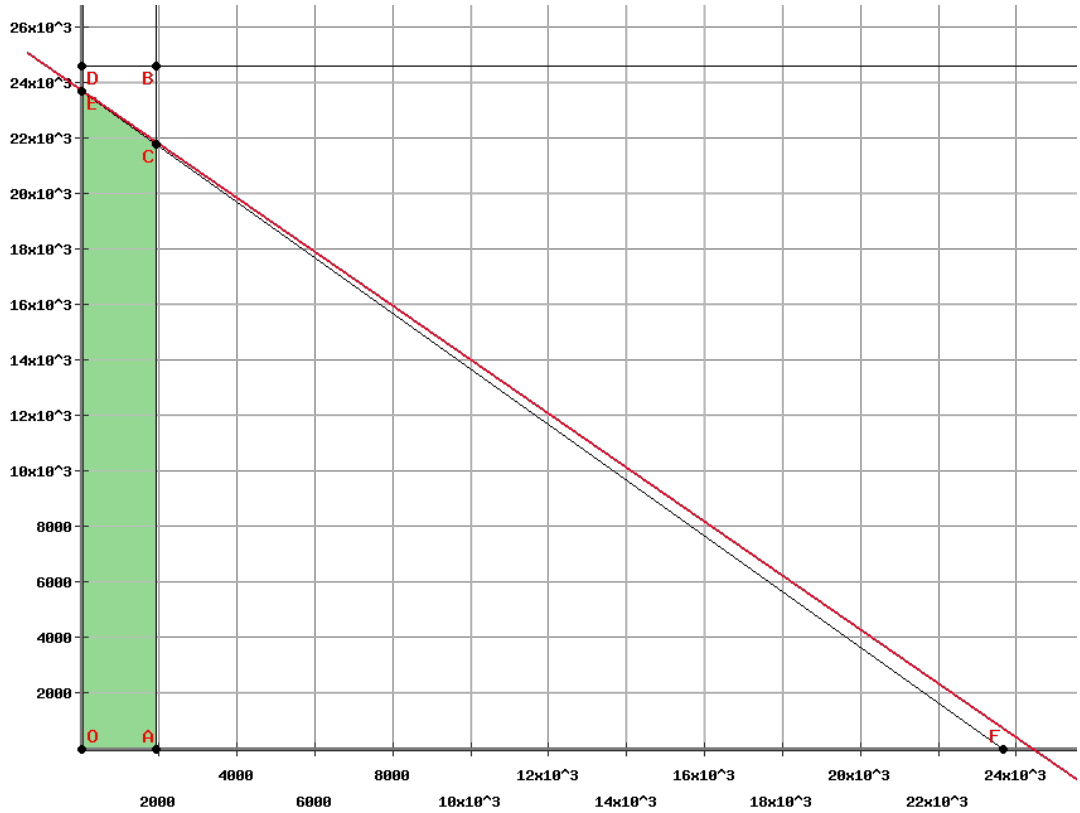
The optimal solution value is Z = 31721.82

X1 = 0

X2 = 23673

Tableau 2							
			1.30	1.34	0	0	0
Base	Cb	P0	P1	P2	P3	P4	P5
P3	0	1911	1	0	1	0	0
P4	0	900	-1	0	0	1	-1
P5	1.34	23673	1	1	0	0	1
Z		31721.82	0.04	0	0	0	1.34

Figure 31. Eligible area for profitable production.



In green color any area eligible for profitable production. The axes have dimensions in liters.

Table 41. Eligible values for profitable production.

	Gluten-free beer	**Regular beers**	
Point	X1 (liters)	X2 (liters)	Z (€)
O	0	0	0
A	1911	0	2484.3
B	1911	24573	35412.12
C	1911	21762	31645.38
D	0	24573	32927.82
E	0	23673	31721.82
F	23673	0	30774.9

The most profitable combination is shown in green. The second choice is in blue. Points that do not belong to the possible region are shown in grey area.

Discussing the results

In summary, we hypothesized three combinations of binary productions: gluten-free and seasonal beers, seasonal and regular beers, and finally gluten-free and regular beers. The purpose is to calculate the combination that can give the maximum profit. The assumption underlying the reasoning is that the company decides to produce only two product lines for a half-year rather than a combination of the three lines.

From the calculations made it would be more profitable to produce the first or the second of following combinations:

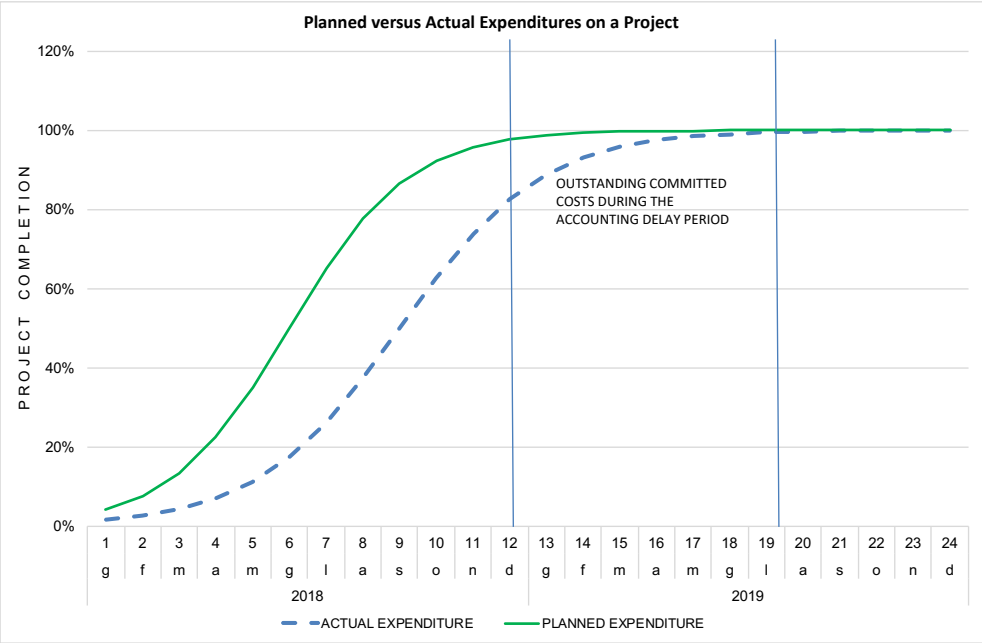
1) [seasonal beers + regular beers] with a profit of about € 39,103 (thirty-nine thousand one hundred three Euros) making it possible to produce both types;
   . alternatively: [seasonal beers + regular beers] with a profit of about € 38,980 (thirty-eight thousand nine hundred eighty Euros) making it possible to produce both types in varying proportions.
2) [gluten-free beer + regular beers] with a profit of about € 31,722 (thirty-one thousand seven hundred twenty-two Euros) but making only the production of regular beers possible;
   . alternatively: [gluten-free beer + regular beers] with a profit of about € 31,645 (thirty-one thousand six hundred forty-five Euros) making it possible to produce both types.
3) [gluten-free beer + seasonal beers] with a profit of about € 9,536 (nine thousand five hundred thirty-six Euros);
   · alternatively: [gluten-free beer + seasonal beers] with a profit of about € 9,502 (nine thousand five hundred two Euros) making it possible to produce both types in differing ratios.

Three binary production scenarios have been examined. The methods of Linear programming make it possible to speculate on the possible advantages of a productive combination compared to another. Respecting the constraints imposed by the problem, optimal solutions are such that any other distribution of production would only allow a lower profit.

Limitations of the study

Probably, the work done may have some limitations because it refers to a small company. Furthermore, the estimates of the effects of the production optimization model are based on the data of a single half-year provided by the company management. So, they may have been communicated inconsistently and probably influenced our model estimates. Moreover, the economic accounts provided do not take into account in a well-defined way the costs of the personnel in charge of the productive services, of the expenses for studies and research, of the maintenance and repair costs, of the testing costs, of the expenses for internal movements of materials, of the expenses for premises used for production and storage, amortization expense[76].

Figure 32. Planned versus actual expenditure on a project.



(Chart created by the author for illustrative purposes only, on basis of text Project Management for Construction by Chris Hendrickson)

[76] Depreciation is an administrative and accounting method that divides the cost of an activity for several years. The cost of the assets which retain their usefulness over time has spread over several years due to their economic duration.

According to Hendrickson (1998), the interpretation of a project's accounts is not simple until the completion of the project or when it is too late to influence the management of the project. During the project it is necessary to consider the problems associated with the use of resources, accounting, monitoring and control. Therefore, managers must know how to interpret accounting information for project management in order to have a global vision that is useful for the company.

Despite this, the work done can provide an idea for a decisive and effective policy to manage the challenges that a company decides to face. Future work could focus on motivational implications in achieving definite goals.

Final comments

On the basis of Law No. 123/2005, aimed at promoting an adequate food style for people intolerant to gluten, the goal of the company managers was to produce a beer with a gluten content <20 ppm to allow people with gluten intolerance to enjoy this drink. The collaboration between the study group and the company management has allowed the drafting and application of an integrated management system that addresses the aspects of food safety and economic convenience in the production of an alternative product such as gluten-free beer.

At the time of writing, the next step will be to formally start the certification process for labeling purposes according to the Spiga Barrata standard. Meanwhile, the micro-brewery has anticipated the times by offering gluten-free beer called Glu Golden on the market.

The work in the brewery was essentially divided into two operational phases and a study proposal for future developments.

In the first operational phase, the self-control plan was implemented with the HACCP system as a mandatory basis for any voluntary certification.

During the second phase, the corrective actions necessary to start the process of compliance with the voluntary standard chosen by the brewery were implemented. In this delicate phase, potential obstacles and appropriate countermoves have been identified and appropriate countermoves have been implemented. Monitoring, data

collection and checks made it possible to identify and solve problems. In this way the project turned into a feasible program.

In addition, a production optimization study was developed to get the most out of the various products. Linear programming methods have been used considering distinct pairs of production lines. For the future, the company could adopt this methodology for an estimate of the variables that contribute to the achievement of the maximum profit in compliance with mandatory standards, certification requirements and sustainability of production. This last aspect was discussed with senior management in the company for future developments.

To conclude, it should be considered that the market for gluten-free products represents a market practically free from the economic crisis (Bogue & Sorenson, 2008) since gluten-free foods are indispensable foods for a specific category of people for whom the price factor is not decisive in purchasing decisions.

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Regolamento (CE) No. 41/2009 della Commissione, del 20 gennaio 2009, relativo alla composizione e all'etichettatura dei prodotti alimentari adatti alle persone intolleranti al glutine. Non più in vigore, Data di fine della validità: 19/07/2016; abrogato da Regolamento (UE) No. 609/2013 del Parlamento europeo e del Consiglio

Regolamento (CE) No. 852/2004 del Parlamento Europeo e del Consiglio del 29 aprile 2004 sull'igiene dei prodotti alimentari.

Regolamento (UE) No. 1169/2011 del Parlamento europeo e del Consiglio, del 25 Ottobre 2011, relativo alla fornitura di informazioni sugli alimenti ai consumatori,

che modifica i regolamenti (CE) No. 1924/2006 e (CE) No. 1925/2006 del Parlamento europeo e del Consiglio e abroga la direttiva 87/250/CEE della Commissione, la direttiva 90/496/CEE del Consiglio, la direttiva 1999/10/CE della Commissione, la direttiva 2000/13/CE del Parlamento europeo e del Consiglio, le direttive 2002/67/CE e 2008/5/CE della Commissione e il regolamento (CE) No. 608/2004 della Commissione

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ADDENDUM No. 1

Case study No. 1

A SME and FAMI-QS certification

Annotation

As shown, some of the documents prepared by the working group are included in this addendum. Some of them are in Italian because they are specifically designed for the company and not for general use.

ATTACHMENT A – Database

Table 42. Accordance with the FAMI-QS compliance criteria checklists on the management system. Number of findings.

FAMI-QS items	Internal audit No. 2 of 28 October 2017					Internal audit No. 1 of 17 February 2017					Changes between the first and second audits			
	CONFORMITY CLASS	MINOR NON-CONFORMITY CLASS	MAJOR NON-CONFORMITY CLASS	CRITICAL NON-CONFORMITY CLASS	N/A	CONFORMITY CLASS	MINOR NON-CONFORMITY CLASS	MAJOR NON-CONFORMITY CLASS	CRITICAL NON-CONFORMITY CLASS	N/A	CONFORMITY CLASS	MINOR NON-CONFORMITY CLASS	MAJOR NON-CONFORMITY CLASS	CRITICAL NON-CONFORMITY CLASS
Management System														
General requirements	4	0	0	0	0	0	4	0	0	0				
Management principles	3	1	1	0	0	1	0	3	1	0				
General documentation requirements	10	1	1	2	0	4	7	1	2	0				
TOTAL SCORE Management System	17	2	2	2	0	5	11	4	3	0	12	-9	-2	-1
Management responsibility														
Management commitment	1	0	0	0	0	0	1	0	0	0				
Quality and Safety Policy	1	3	0	0	0	1	2	1	0	0				
Responsibility, authority and communication	3	1	0	2	0	3	1	0	2	0				
Management representative	1	0	0	2	0	0	0	0	3	0				
Management review	0	3	1	1	0	0	3	1	1	0				

TOTAL SCORE Management responsibility	6	7	1	5	0	4	7	2	6	0	2	0	-1	-1
Resource management														
Provision of resources	2	0	0	1	0	0	2	0	1	0				
Human resources	7	3	0	1	0	5	5	0	1	0				
Infrastructure	9	0	0	0	1	9	0	0	0	1				
Maintenance and control of monitoring and measuring devices	7	0	0	1	0	6	1	0	1	0				
Cleaning	6	2	0	0	0	6	2	0	0	0				
Pest control	12	0	0	0	0	10	2	0	0	0				
Waste control	2	0	0	0	0	2	0	0	0	0				
TOTAL SCORE Resource management	45	5	0	3	1	38	12	0	3	1	7	-7	0	0
Product realisation														
Product requirements	8	0	0	0	0	8	0	0	0	0				
HACCP program	11	0	0	2	0	8	1	2	2	0				
Design and development	3	1	0	4	0	0	4	4	0	0				
Handling of incoming materials	7	11	0	0	0	4	14	0	0	0				
Production of finished goods	19	1	0	3	2	18	1	1	3	2				
Transport	9	0	0	0	0	9	0	0	0	0				
TOTAL SCORE Product realisation	57	13	0	9	2	47	20	7	5	2	10	-7	-7	4
System review														
General requirements	0	6	0	0	0	0	6	0	0	0				
Internal audits	5	1	0	4	0	4	2	0	4	0				
TOTAL SCORE System review	5	7	0	4	0	4	8	0	4	0	1	-1	0	0
Control of non-conforming products														

General requirements	8	3	0	1	0	1	2	0	9	0				
Complaint handling system	2	0	0	8	0	2	0	0	8	0				
Recall	2	1	0	6	0	0	2	3	4	0				
Crisis management	2	0	0	1	0	1	0	1	1	0				
TOTAL SCORE Control of non-conforming products	14	4	0	16	0	4	4	4	22	0	10	0	-4	-6
Statistical techniques														
TOTAL SCORE Statistical techniques	2	3	0	0	0	0	4	0	1	0	2	-1	0	-1
GRAND TOTAL	146	41	3	39	3	102	66	17	44	3	44	-25	-14	-5

Assignment of weighted values

The collected data have been reworked assigning weight classes based on the level of compliance. In particular:

- +1 point for full conformity;
- -1 point for minor non-conformity;
- -3 point for major non-conformity and
- -5 point for critical non-conformity.

The following Table shows the weighted data.

Table 43. Internal audits on compliance with the FAMI-QS Code. Weighted findings.

FAMI-QS Code requirements	FEBRUARY 2017	OCTOBER 2017
Point 4. General requirements FULL-C	0	4
Point 4. General requirements MINOR-NC	-4	0
Point 4. General requirements MAJOR-NC	0	0
Point 4. General requirements CRITICAL-NC	0	0
Point 4. Management principles FULL-C	1	3
Point 4. Management principles MINOR-NC	0	-1
Point 4. Management principles MAJOR-NC	-9	-3
Point 4. Management principles CRITICAL-NC	-5	0
Point 4. General documentation requirements FULL-C	4	10
Point 4. General documentation requirements MINOR-NC	-7	-1
Point 4. General documentation requirements MAJOR-NC	-3	-3
Point 4. General documentation requirements CRITICAL-NC	-10	-10
Point 5. Management commitment FULL-C	0	1
Point 5. Management commitment MINOR-NC	-1	0

Point 5. Management commitment MAJOR-NC	0	0
Point 5. Management commitment CRITICAL-NC	0	0
Point 5. Quality and Safety Policy FULL-C	1	1
Point 5. Quality and Safety Policy MINOR-NC	-2	-3
Point 5. Quality and Safety Policy MAJOR-NC	-3	0
Point 5. Quality and Safety Policy CRITICAL-NC	0	0
Point 5. Responsibility, authority and communication FULL-C	3	3
Point 5. Responsibility, authority and communication MINOR-NC	-1	-1
Point 5. Responsibility, authority and communication MAJOR-NC	0	0
Point 5. Responsibility, authority and communication CRITICAL-NC	-10	-10
Point 5. Management representative FULL-C	0	1
Point 5. Management representative MINOR-NC	0	0
Point 5. Management representative MAJOR-NC	0	0
Point 5. Management representative CRITICAL-NC	-15	-10
Point 5. Management review FULL-C	0	0
Point 5. Management review MINOR-NC	-3	-3
Point 5. Management review MAJOR-NC	-3	-3
Point 5. Management review CRITICAL-NC	-5	-5
Point 6. Provision of resources FULL-C	0	2
Point 6. Provision of resources MINOR-NC	-2	0
Point 6. Provision of resources MAJOR-NC	0	0
Point 6. Provision of resources CRITICAL-NC	-5	-5
Point 6. Human resources FULL-C	5	7
Point 6. Human resources MINOR-NC	-5	-3
Point 6. Human resources MAJOR-NC	0	0

Point 6. Human resources CRITICAL-NC	-5	-5
Point 6. Infrastructure FULL-C	9	9
Point 6. Infrastructure MINOR-NC	0	0
Point 6. Infrastructure MAJOR-NC	0	0
Point 6. Infrastructure CRITICAL-NC	0	0
Point 6. Maintenance and control of monitoring and measuring devices FULL-C	6	7
Point 6. Maintenance and control of monitoring and measuring devices MINOR-NC	-1	0
Point 6. Maintenance and control of monitoring and measuring devices MAJOR-NC	0	0
Point 6. Maintenance and control of monitoring and measuring devices CRITICAL-NC	-5	-5
Point 6. Cleaning FULL-C	6	6
Point 6. Cleaning MINOR-NC	-2	-2
Point 6. Cleaning MAJOR-NC	0	0
Point 6. Cleaning CRITICAL-NC	0	0
Point 6. Pest control FULL-C	10	12
Point 6. Pest control MINOR-NC	-2	0
Point 6. Pest control MAJOR-NC	0	0
Point 6. Pest control CRITICAL-NC	0	0
Point 6. Waste control FULL-C	2	2
Point 6. Waste control MINOR-NC	0	0
Point 6. Waste control MAJOR-NC	0	0
Point 6. Waste control CRITICAL-NC	0	0
Point 7. Product requirements FULL-C	8	8
Point 7. Product requirements MINOR-NC	0	0
Point 7. Product requirements MAJOR-NC	0	0
Point 7. Product requirements CRITICAL-NC	0	0

Point 7. HACCP program FULL-C	8	11
Point 7. HACCP program MINOR-NC	-1	0
Point 7. HACCP program MAJOR-NC	-6	0
Point 7. HACCP program CRITICAL-NC	-10	-10
Point 7. Design and development FULL-C	0	3
Point 7. Design and development MINOR-NC	-4	-1
Point 7. Design and development MAJOR-NC	-12	0
Point 7. Design and development CRITICAL-NC	0	-20
Point 7. Handling of incoming materials FULL-C	4	7
Point 7. Handling of incoming materials MINOR-NC	-14	-11
Point 7. Handling of incoming materials MAJOR-NC	0	0
Point 7. Handling of incoming materials CRITICAL-NC	0	0
Point 7. Production of finished goods FULL-C	18	19
Point 7. Production of finished goods MINOR-NC	-1	-1
Point 7. Production of finished goods MAJOR-NC	-3	0
Point 7. Production of finished goods CRITICAL-NC	-15	-15
Point 7. Transport FULL-C	9	9
Point 7. Transport MINOR-NC	0	0
Point 7. Transport MAJOR-NC	0	0
Point 7. Transport CRITICAL-NC	0	0
Point 8. General requirements FULL-C	0	0
Point 8. General requirements MINOR-NC	-6	-6
Point 8. General requirements MAJOR-NC	0	0
Point 8. General requirements CRITICAL-NC	0	0
Point 8. Internal audits FULL-C	4	5
Point 8. Internal audits MINOR-NC	-2	-1

Point 8. Internal audits MAJOR-NC	0	0
Point 8. Internal audits CRITICAL-NC	-20	-20
Point 9. General requirements FULL-C	1	8
Point 9. General requirements MINOR-NC	-2	-3
Point 9. General requirements MAJOR-NC	0	0
Point 9. General requirements CRITICAL-NC	-45	-5
Point 9. Complaint handling system FULL-C	2	2
Point 9. Complaint handling system MINOR-NC	0	0
Point 9. Complaint handling system MAJOR-NC	0	0
Point 9. Complaint handling system CRITICAL-NC	-40	-40
Point 9. Recall FULL-C	0	2
Point 9. Recall MINOR-NC	-2	-1
Point 9. Recall MAJOR-NC	-9	0
Point 9. Recall CRITICAL-NC	-20	-30
Point 9. Crisis management FULL-C	1	2
Point 9. Crisis management MINOR-NC	0	0
Point 9. Crisis management MAJOR-NC	-3	0
Point 9. Crisis management CRITICAL-NC	-5	-5
Point 10. Statistical techniques FULL-C	0	2
Point 10. Statistical techniques MINOR-NC	-4	-3
Point 10. Statistical techniques MAJOR-NC	0	0
Point 10. Statistical techniques CRITICAL-NC	-5	0

(key: FULL-C = full conformity, MINOR-NC = minor non-conformity, MAJOR-NC = major non-conformity and CRITICAL-NC = critical non-conformity)

Table 44. Internal audits on compliance with the FAMI-QS Code. Cumulative weighted findings.

FAMI-QS Code requirements	FEBRUARY 2017	OCTOBER 2017
Point 4. General requirements	-4	4
Point 4. Management principles	-13	-1
Point 4. General documentation requirements	-16	-4
Point 5. Management commitment	-1	1
Point 5. Quality and Safety Policy	-4	-2
Point 5. Responsibility, authority and communication	-8	-8
Point 5. Management representative	-15	-9
Point 5. Management review	-11	-11
Point 6. Provision of resources	-7	-3
Point 6. Human resources CRITICAL-NC	-5	-1
Point 6. Infrastructure	9	9
Point 6. Maintenance and control of monitoring and measuring devices	0	2
Point 6. Cleaning CRITICAL-NC	4	4
Point 6. Pest control	8	12
Point 6. Waste control	2	2
Point 7. Product requirements	8	8
Point 7. HACCP program	-9	1
Point 7. Design and development	-16	-18
Point 7. Handling of incoming materials	-10	-4
Point 7. Production of finished goods	-1	3
Point 7. Transport	9	9
Point 8. General requirements	-6	-6

FAMI-QS Code requirements	FEBRUARY 2017	OCTOBER 2017
Point 8. Internal audits	-18	-16
Point 9. General requirements	-46	0
Point 9. Complaint handling system	-38	-38
Point 9. Recall	-31	-29
Point 9. Crisis management	-7	-3
Point 10. Statistical techniques	-9	-1

Table 45. Internal audits on compliance with the FAMI-QS Code. Summary of the previous Table divided by Subjects of Code. Weighted data.

	Point 4 of FAMI-QS Code	**Point 5 of FAMI-QS Code**	**Point 6 of FAMI-QS Code**	**Point 7 of FAMI-QS Code**	**Point 8 of FAMI-QS Code**	**Point 9 of FAMI-QS Code**	**Point 10 of FAMI-QS Code**
	Subject MANAGEMENT SYSTEM	Subject MANAGEMENT RESPONSIBILITY	Subject RESOURCE MANAGEMENT	Subject PRODUCT REALISATION	Subject SYSTEM REVIEW	Subject CONTROL OF NON-CONFORMING PRODUCTS	Subject STATISTICAL TECHNIQUES
FEBRUARY 2017	-33	-39	11	-19	-24	-122	-9
OCTOBER 2017	-1	-29	25	-1	-22	-70	-1

(Key: the numbers in the table are the results of the sum of the scores of the full conformity, minor non-conformity, major non-conformity and critical non-conformity)

ATTACHMENT B - Questionnaires and interviews (an excerpt)

Table 46. Workgroup questions sent to the company to monitor process management (26 May 2017)

Argomento	**Quesito**	**Risposta dell'azienda**	**Commenti e suggerimenti del Gruppo di studio**
ACQUISTO DI MATERIALI	Acquisto di materiali non a diretto contatto con materie prime, semilavorati, prodotti finiti, ad es. lubrificanti, detergenti, ecc.: È valutata la presenza di sostanze tossiche che possono contaminare i prodotti? e in caso affermativo, qual è la procedura adottata?	Sì, tramite le indicazioni riportate sul prodotto e le schede di sicurezza. Tali prodotti sono idonei alla pulizia di strumentazioni in ambito feed e food. Stessa cosa vale per i lubrificanti, idonei per uso alimentare e muniti di scheda di sicurezza, anche se, ragionevolmente, non vengono mai in contatto con lavorati o semilavorati.	È utile acquisire agli atti le schede di sicurezza menzionate nel riquadro qui a lato: Creare, se non già esistente, un faldone dedicato per la conservazione delle schede. Ciò al fine di consentire una rapida consultazione, se e quando richiesto dall'auditor.
MATERIE PRIME	Acquisto e provenienza delle materie prime: C'è assenza di oggetti estranei quali vetro, parti metalliche, corde, materiali sintetici, pietre, attrezzi, rivestimenti interni di	Tutte le merci arrivano su bancali confezionate in sacchi di carta polietilenata, oppure di plastica. Alcune materie prime arrivano in big bags da 500 – 1000 Kg., chiusi con il laccio apposito. Dopo aver prelevato il quantitativo di materiale necessario il	

	apparecchiature, materiali isolanti, legno, monili?	sacco viene richiuso per evitare contaminazioni.	
	C'è assenza di sostanze indesiderate, ad esempio metalli pesanti, pesticidi, come descritto nella Direttiva 2002/32/CE del PARLAMENTO EUROPEO e del CONSIGLIO del 7 maggio 2002 relativa alle sostanze indesiderabili nell'alimentazione degli animali?	Ogni prodotto noto per essere a rischio di contaminazione di metalli pesanti, pesticidi, etc. viene acquistato con apposita scheda di sicurezza del fornitore, e relativa certificazione, recante il valore dei metalli pesanti e delle diossine.	
	È presa in considerazione, nelle specifiche delle materie prime, l'assenza di contaminanti come microrganismi patogeni e virus?	No, le materie prime impiegate non si prestano allo sviluppo di virus o batteri, tranne una: la CRUSCA DI FARRO (supporto vegetale). Per questo motivo acquistiamo prodotto certificato esente dal fornitore.	
IMBALLAGGI	Acquisto, provenienza, utilizzo ed eventuale riutilizzo degli imballaggi: È esclusa la contaminazione da contenitori o da materiali per imballaggio o loro parti?	Big bags e sacchi di carta non vengono mai riutilizzati per il confezionamento dei prodotti immessi sul mercato, nemmeno per lo stoccaggio dei semilavorati.	
ACQUA	L'acqua proviene da fornitura idrica pubblica ed è utilizzata come ingrediente dei prodotti e anche nel processo di pulizia.	Abbiamo due linee per l'acqua, entrambe aventi origine dalla rete idrica pubblica presente sul territorio. La prima linea subisce un processo di demineralizzazione e viene impiegata	

	Tubi e serbatoi dell'acqua possono contribuire allo sviluppo di flora microbica. Inoltre, nell'acqua può avvenire dissoluzione di varie sostanze. Sono previsti e stabiliti sistemi di purificazione dell'acqua in funzione della qualità del prodotto?	in piccole quantità per abbassare la polverosità di alcuni mangimi minerali. La seconda viene impiegata per la pulizia ordinaria e straordinaria degli impianti e dei pavimenti, oltre che per uso igienico.	
MANUTENZIONI	Le attività di manutenzione possono interferire con i processi e con le fasi di produzione in corso. È valutata la possibile contaminazione delle apparecchiature a seguito delle operazioni di manutenzione?	Sì, vengono impiegati detergenti e strumenti diversi per differenti finalità (bagni, uffici, ambiente produttivo). Viene utilizzata l'idropulitrice per il lavaggio dei miscelatori, e l'acqua reflua raccolta in appositi contenitori. I reflui del lavaggio del pavimento (ambiente produttivo) vengono raccolti con aspiratore dei liquidi e smaltiti opportunamente. Nei tempi previsti per le attività di pulizia vengono sospese le produzioni.	Valutare l'utilità di riportare quanto descritto qui a lato nel piano di autocontrollo.
	Sono adottate misure preventive?	Utilizzo prodotti idonei ed accurato risciacquo.	Documentare nella apposita modulistica l'operazione di pulizia effettuata dopo l'intervento di manutenzione.

PULIZIA	Pulizia dell'ambiente di produzione. È ad un livello è accettabile?	Sì, come attestano le verifiche effettuate da AUSL, ARPA ed ufficio IGIENE PUBBLICA.	
	Pulizia delle superfici a contatto con le materie prime, semilavorati e prodotti. È ad un livello accettabile?	Sì, ogni settimana è previsto un ciclo di pulizia accurata; inoltre, al termine di ogni lavorazione particolarmente odorose o appiccicose, le strumentazioni vengono controllate e, se necessario igienizzate.	
	Possibile contaminazione se le apparecchiature non sono pulite ad un livello accettabile?	No, dopo ogni lavorazione i miscelatori vengono puliti con un getto di aria compressa.	
	Possibili residui di agenti detergenti?	Assolutamente no, visto gli accurati risciacqui effettuati anche con idropulitrice.	
	L'ambiente può causare contaminazione incrociata?	No, le nostre procedure di lavorazione prevedono prevalentemente l'impiego di prodotti stoccati nel silos, oppure l'uso dell'intera confezione dell'additivo.	
	La pulizia delle apparecchiature utilizzate con acqua può favorire lo sviluppo di microrganismi?	No, l'impiego pressoché costante di esteri di acidi grassi a media e lunga catena inibisce lo sviluppo di batteri GRAM+ e GRAM-	

FASI DI TRASPORTO IN INGRESSO E IN USCITA	Trasporto di grandi quantitativi sfusi e confezionati di ingredienti in entrata: Possibile contaminazione da carichi precedenti o carichi diversi trasportati sullo stesso veicolo. È assicurata la non contaminazione?	Le materie prime sfuse sono zeolite e calcio carbonato, per le quali i nostri fornitori usano mezzi appositamente destinati; viene effettuato almeno 1 controllo all'anno. Si esclude la contaminazione: a) il fornitore è monoprodutttore; b) vengono sempre utilizzati gli stessi silos per gli stessi materiali.	Conservare agli atti, per una rapida consultazione se e quando richiesto dall'auditor, gli accordi stipulati con il trasportatore.
	Trasporto di grandi quantitativi di prodotti sfusi e confezionati in uscita: Possibile contaminazione da carichi precedenti o carichi diversi trasportati sullo stesso veicolo. È assicurata la non contaminazione?	I nostri prodotti non vengono consegnati sfusi, solo in big bags, ogni sacco è dotato di etichetta. I prodotti in sacchi polietilenati, invece, vengono collocati su bancale, rivestiti di film plastico. Infine, tanto i big bags quanto i bancali vengono coperti da un cappuccio di plastica.	Conservare agli atti, per una rapida consultazione se e quando richiesto dall'auditor, gli accordi stipulati con il trasportatore. Effettuare ispezione visiva del mezzo di trasporto prima del carico.
STOCCAGGIO	Stoccaggio e conservazione degli ingredienti e delle materie prime, dei semilavorati e dei prodotti finiti. Sussistono le seguenti condizioni:	Vengono conservati sia all'interno che all'esterno dell'unità produttiva.	Allestire, prima dell'audit di certificazione, apposite strutture di protezione per lo stoccaggio all'aperto.
	Esposizione a pioggia, condizioni di umidità?	No, sono state acquistate strutture per lo stoccaggio di materiale all'esterno, al riparo dalle intemperie. Ad oggi, i prodotti collocati all'esterno, e confezionati in big bags o sacco di	Allestire, prima dell'audit di certificazione, apposite strutture di protezione per lo stoccaggio all'aperto.

		carta, vengono protetti con un cappuccio in plastica.	Evitare il diretto contatto col suolo dei prodotti per uso alimentare.
	Degradazione dovuta a formazione di condensa e sviluppo di muffa?	Se un prodotto sviluppa muffe viene rispedito al fornitore, oppure, smaltito come rifiuto.	Se non già prevista, allestire apposita modulistica da compilare se ne ricorre il caso.
	Contaminazione incrociata con altri materiali alimentari?	Esclusa. I sacchi aperti vengono risposti in appositi contenitori e prelevati utilizzando la paletta dedicata.	Assicurare che la "paletta dedicata" sia idonea all'uso (igiene, integrità, ecc.)
	Contaminazione con altri materiali non alimentari?	Esclusa. Tutti i prodotti acquistati sono per uso alimentare, anche i lubrificanti utilizzati nell'impianto. Fanno eccezione i detergenti (idonei alla pulizia di strutture del nostro tipo – HACCP). I prodotti per la pulizia degli uffici e dei servizi sono conservati ed utilizzati fuori dell'area produttiva.	L'idoneità per uso alimentare (food grade) deve risultare dalla documentazione da esibire su richiesta eventuale dell'auditor.
	Deterioramento del prodotto per scarsa rotazione delle scorte?	È previsto lo stoccaggio in apposita area, segnalata da cartello, e smaltito come rifiuto.	Documentare su apposita modulistica l'eventualità descritta qui a lato se ne ricorre il caso.
	Prodotti per specie animali diverse e mangimi medicati e non medicati non separati adeguatamente?	Non produciamo né commercializziamo mangimi medicati, né contenenti farine e grassi animali. I nostri integratori per specie animali	

		diverse, vengono identificati con un lotto, confezionati ed etichettati alla produzione. Non vengono stoccati prodotti sfusi. Nessun rischio di scambi di prodotti.	
SELEZIONE DELLE MATERIE PRIME E FORMULAZIONE	Selezione di materie prime per la trasformazione: È esclusa la selezione dell'ingrediente errato o della materia prima errata?	Al momento dell'arrivo le materie prime vengono controllate visivamente, verificata la corrispondenza con il cartellino, e solo dopo immesse nel ciclo produttivo. In caso di dubbi, il prodotto viene analizzato, e solo se rispondente ai requisiti, utilizzato. Il PLC che regola il sistema di miscelazione, accompagna poi tutta la selezione dei componenti, sia quantitativa che qualitativa.	
	Formulazione: È assicurata la corretta formulazione per gli usi previsti del prodotto?	Il PLC e il programma di formulazione sono interfacciati (il programma viene continuamente aggiornato secondo le normative vigenti), viene segnalata ogni anomalia di composizione del prodotto.	

MISCELAZIONE	Miscelazione degli additivi con altri additivi e supporti. È esclusa: Aggiunta e dosaggio errato di ingredienti?	PLC e programma di formulazione garantiscono la corretta esecuzione della formula. Eventuali anomalie rilevate allo scarico del miscelatore vengono valutate: a) tramite verifica delle rimanenze di prodotti (lo scarico delle giacenze di materie prime avviene in tempo reale); b) con analisi presso i laboratori certificati da noi utilizzati.	
	Miscelazione errata, distribuzione non uniforme degli ingredienti?	Operiamo secondo la seguente metodologia: 1) miscelazione di un premix concentrato di oligoelementi e vitamine: 2) successiva diluizione nel prodotto, per raggiungere il massimo dell'uniformità.	
	Contaminazione da olii e/o da agenti detergenti?	Non deteniamo oli NON ALIMENTARI nell'unità produttiva; i detergenti NON VENGONO IMPIEGATI durante la produzione.	
	Contaminazione da corpi estranei?	Il miscelatore dei liquidi è dotato di filtri e spruzzatori, che impediscono il passaggio di corpi estranei. I silos sono dotati di calamite e filtri, mentre per i prodotti in sacchi, l'operatore, sempre presente, effettua il controllo visivo.	

	Presenza di residui a causa di contaminazione?	Gli accorgimenti precedentemente indicati evidenziano come questa sia una possibilità remota.	
IMBALLAGGIO ED ETICHETTATURA	Imballaggio ed etichettatura dei prodotti in sacchetti, scatole, fusti, sacchi, contenitori intermedi per prodotti sfusi, flaconi, ecc.: È esclusa la contaminazione durante il processo di imballaggio?	Sì, è esclusa. Le operazioni di etichettatura vengono eseguite su di un tavolo, per una migliore adesione. Allo stesso modo vengono effettuati i confezionamenti in cartoni.	
	Identificazione dei prodotti con le apposite etichette in osservanza della legislazione vigente e per consentire il controllo e la rintracciabilità dei prodotti nei casi in cui sia necessario: L'etichettatura e l'identificazione errate del prodotto possono determinarne l'utilizzo errato o l'impossibilità di un ritiro completo qualora fosse necessario?	La stampa delle etichette viene effettuata al termine della produzione di ogni lotto. NON vengono stoccate etichette di nessun tipo fino al momento immediatamente precedente l'insaccamento. Ogni miscelata viene identificata da un numero di lotto, e per qualsiasi anomali siamo in grado di procedere al ritiro del prodotto in tempi brevissimi.	
SPEDIZIONE DEI PRODOTTI CONFEZIONATI O SFUSI	Spedizione di prodotti confezionati: È esclusa la contaminazione di scorte integre a causa di imballaggio danneggiato al momento del carico o durante la spedizione?	Gli imballaggi sono sottoposti ai seguenti processi, che garantiscono l'integrità fino all'arrivo dal cliente: 1) controllo dell'integrità del bancale (scheggiature, chiodi esposti); 2) sul fondo viene collocato un foglio di pluriball su cui vengono appoggiati i	Quanto descritto qui a lato: si presume sia descritto nel piano di autocontrollo, e nel caso di anomalie di processo, ciò venga documentato.

		sacchi; 3) al termine viene avvolto da un film di plastica; 4) il bancale viene coperto con un cappuccio impermeabile in plastica, e il tutto viene avvolto con il nastro adesivo.	È utile procedere all'ispezione del carico prima del trasporto. È utile archiviare la notazione di problemi eventualmente occorsi durante il trasporto.
	Spedizione di prodotti sfusi: È esclusa la contaminazione da olii, agenti detergenti, altre sostanze, se il trasportatore non è dedicato a un solo prodotto?	NON VENDIAMO PRODOTTI SFUSI.	

ATTACHMENT C - Safety data sheet

Table 47. Safety data sheet proposed for the ZL-MIX product.

SCHEDA DATI DI SICUREZZA
[ai sensi del Regolamento (CE) 1907/06 e del Regolamento (CE) 453/2010]

1.1 Denominazione commerciale ZL MIX
1.2 Usi pertinenti identificati dalla sostanza o miscela e usi consigliati
Mangime complementare minerale per bovini da carne
1.3 Informazioni sul fornitore della scheda dei dati di sicurezza
Produttore: Agristudio S.r.l.
Indirizzo: Via Terracini n. 9/c - 42021 Bibbiano (RE) - Italia
Telefono: +39 0522 875 928 Fax: +39 0522 875 749
PEC: agristudio@pec.it
1.4 Numero telefonico di emergenza
Responsabile: Ufficio tecnico
Telefono: +39 +39 0522 875 928 (disponibile in orario di ufficio)

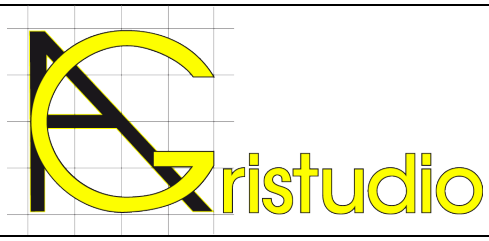
2.1 Composizione chimica[77]

Componenti principali	EC List n°	CAS n°	Quantità	Formula molecolare	Frasi H
Sodium bicarbonate	205-633-8	144-55-8	> 1,0 %	$CH_2O_3.Na$	---
Calcium carbonate	207-439-9	471-34-1	> 1,0 %	$CH_2O_3.Ca$	---
Calcium dipropionate	223-795-8	4047-81-4	> 1,0 %	$C_3H_6O_2.½Ca$	---
Choline chloride	200-655-4	67-48-1	> 1,0 %	$C_5H_{14}NO.Cl$	---
Zinc sulphate	231-793-3	7446-19-7, 7733-02-0	> 1,0 %	$H_2O_4S.Zn$	---
Hydroxy analogue of methionine	700-857-7	---	> 1,0 %	---	---
Zeolite (Silicic acid, aluminium sodium salt)	930-915-9	---	> 1,0 %	$(M_2/nO \bullet Al_2O_3 \bullet ySiO_2 \bullet wH_2O)$	---

[77] EC List number: includes the lists EINECS (European Inventory of Existing Commercial Chemical Substances), ELINCS (European LIst of Notified Chemical Substances), NLP (No-Longer Polymers). CAS number: it is a numerical identifier that uniquely identifies a chemical substance. The Chemical Abstracts Service, a division of the American Chemical Society, assigns these identifiers to each chemical substance described in the literature.

ATTACHMENT D – Standard Operating Procedure about complaints management

Table 48. Complaints management scheme.



GESTIONE RECLAMI

- **DATI DEL RICEVIMENTO DEL RECLAMO**
  Data del reclamo:
  Nome del destinatario:
  Mezzo di presentazione del reclamo:
  Numero di riferimento del reclamo:

- **PROBLEMA RISCONTRATO**
  Data del problema:
  Problema ricorrente sì/no?
  Tipo di problema:

- **VALUTAZIONE DEL RECLAMO**
  Causa:
  Gravità:
  Cliente:
  Rischi per ambiente/salute/sicurezza:
  Altri aspetti rilevanti:
  Necessità di azione immediata sì/no?
  Disponibilità di azione immediata sì/no?
  Probabilità di addebito sì/no?

- **RISOLUZIONE DEL RECLAMO**
  Provvedimento Richiesto sì/no?
  Azioni da intraprendere:

- **ITER DEL RECLAMO**

AZIONE	DATA	NOME	COMMENTI
Comunicazione col cliente			
Valutazione reclamo			
Ricerca sul reclamo			
Informazioni al reclamante			
Azione Correttiva			
Azione Correttiva verificata			
Reclamo Chiuso			

ADDENDUM No. 2

Case study No. 2

A SME and the Gluten-free AIC labelling

Annotation

As shown, some of the documents prepared by the working group are included in this addendum. Some of them are in Italian because they are specifically designed for the company and not for general use.

ATTACHMENT A

List of documents of Ofelia Snc brewery

Table 49. List of documents of the Ofelia Snc brewery relating to the interval from 11 January to 30 June 2018.

ITEM	DESCRIPTION
Attribution of denomination of the productive process stages	Cereal grinding; mashing (conversion of starches to fermentable sugars); must filtration; boiling of the must; must cooling; oxygenation of the must; yeast inoculation; fermentation; lagering (cold maturation); conditioning.
Number of product types	15.
Measurement data	See Excel file about “temperatures and pressures”.
Process name and table of measurements related to that particular process (for example, pressures, etc.)	See Excel file about “temperatures and pressures”.
Data on the number of non-conformities to the self-control plan	See Excel file about “non-compliance”.
Data on the number of technical maintenance interventions	See Excel file about “maintenance”.
Data on the number of extraordinary maintenance technical operations and number of production plant downtime	See Excel file about “maintenance”.
Data on substances used for installation cleaning operations	See Excel file about “non-compliance”.
Inventories of raw materials	See related Excel file.
Quintals of barley malt (specify also if pilsner or pale)	About 100 quintals per year including 40 shovels and 20 pils.

Quintals of cereals, in the case used	About 20 quintals of wheat malt and about 5 quintals of spelt[78], per year.
Kilograms of hops (specify by type)	See Excel file about “production”.
The quantitative availability of yeast (also specify which species)	See Excel file about “production”.
Enzyme availability (specify which)	Protease.
Availability of technical gases (specify which and how much)	Approximately 720 kg per year of CO_2
Quantitative energy availability (which is assumed to be unlimited)	Unlimited with a peak of 30 kw / h.
Quantitative availability of water (which is assumed to be unlimited) and quality of the water used (for example, declaration of analysis of the public aqueduct obtainable from the site)	Unlimited, consumption of about 400 cubic meters per year.
Data on the consumption of raw materials due to production processes and data on any waste produced on June 30, 2018	43 quintals of cereals and 93 kg of hops. No data available on any waste produced.
Total profit and per unit	See Excel file about “income statement”.
Costs faced for each type of beer	See Excel file about “income statement”.
Production volume for each type of beer	See Excel file about “production”.
Average workforce employed	There were 3 people in production and 2 people for all other activities.

[78] Spelt, *Triticum spelta*, wheat species (Poaceae family) grown for animal fodder and used in baked goods and cereals. It is also used in artisan bread and pasta and has a nutritional profile similar to conventional wheat. Then, it gained some modern popularity as an organic agricultural crop.

ATTACHMENT B

Data of the Ofelia Snc brewery production. Period 1st half-year 2018.

Table 50. Production in the interval 1 January 2018 - 30 June 2018.

PRODUCT NAME	DATE OF PRODUCTION	MUST Litres	BEER Litres	WASTE Litres	WASTE %	YEAST Variety	USED YEAST Grams
AMITABH	05/01/18	2207	2036	171	8	US-05	1000
DARK SIDE	15/01/18	1973	1769	204	10	US-05	1000
GLU	29/01/18	957	845	112	12	US-05	500
PIAZZA	09/02/18	2499	2317	182	7	BELLE SAISON	1000
UILL IU BAI	28/02/18	2271	1941	330	15	US-05	1000
CANCELLIERA	08/03/18	2338	2011	327	14	W 34/70	2000
BEERGAMOTTA	15/03/18	950	882	68	7	US-05	500
INFRADIPA	22/03/18	2292	1884	408	18	US-05	1000
NEVERMILD	29/03/18	1232	1202	30	2	US-05	500
SPELTINA	20/04/18	2322	2127	195	8	BELLE SAISON	1000
BITTERDUCK	03/05/18	950	910	40	4	US-05	500
SCARLET	04/05/18	1250	1014	236	19	US-05	500
AMITABH	10/05/18	2396	2203	193	8	US-05	1000

PRODUCT NAME	DATE OF PRODUCTION	MUST Litres	BEER Litres	WASTE Litres	WASTE %	YEAST Variety	USED YEAST Grams
PIAZZA	17/05/18	2364	2188	176	7	BELLE SAISON	1000
UILL IU BAI	28/05/18	2451	2138	313	13	US-05	1000
GLU	11/06/18	954	867	87	9	US-05	500
BEERGAMOTTA	19/06/18	2434	2279	155	6	US-05	1000
LALABLEND	29/06/18	951	900	51	5	S-33	500
Total amounts		32791	29513				

Table 51. Type of hops used in production in the 1st half of 2018.

HOPS Variety	**PLACE OF ORIGIN**	**QUANTITY Kilograms**
EAST KENT GOLDING	UK	6,5
FUGGLE	UK	5,5
STYRIAN GOLDING	CZ	7,5
STYRIAN WOLF	CZ	10,5
SAAZ	CZ	6,0
COLUMBUS	USA	12,0
CASCADE	USA	8,0
SIMCOE	USA	8,0
MOSAIC	USA	19,0
HERKULES	GER	1,5
TRADITION	GER	1,5
RAKAU	AUS	11,0
Total amount		97,0

Table 52. Temperature and pressure monitoring in the 1st half of 2018.

		TEMPERATURES (°C)							PRESSURES (bar)		
PRODUCT	**DATE OF PRODUCTION**	**MASHING**									
		PROTEASE	**BETA AMYLASE**	**ALFA AMYLASE**	**MASH OUT**	**REFINING WORT**	**FERMENTATION**	**LAGERING**	**FERMENTATION**	**LAGERING**	**CONDITIONING**
AMITABH	05/01/18	NO	66°	72°	78°	20°	18,5°	1°	0,2	0,2	1,5
DARK SIDE	15/01/18	NO	64°	72°	78°	20°	18,5°	1°	0,2	0,2	2,0
GLU	29/01/18	56°	63°	72°	78°	20°	18,5°	1°	0,2	0,4	2,0
PIAZZA	09/02/18	56°	63°	72°	78°	22°	20°	1°	0,2	0,4	2,5
UILL IU BAI	28/02/18	NO	64°	72°	78°	20°	18,5°	1°	0,2	0,5	2,0
CANCELLIERA	08/03/18	56°	64°	72°	78°	14°	12°	1°	0,2	0,4	2,0
BEERGAMOTTA	15/03/18	NO	63°	72°	78°	20°	18,5°	1°	0,2	0,4	2,0
INFRADIPA	22/03/18	56°	63°	72°	78°	20°	18,5°	1°	0,2	0,5	2,0
NEVERMILD	29/03/18	NO	66°	72°	78°	20°	18,5°	1°	0,2	0,2	1,5
SPELTINA	20/04/18	NO	63°	72°	78°	22°	20°	1°	0,2	0,4	2,5
BITTERDUCK	03/05/18	NO	65°	72°	78°	21°	19°	1°	0,2	0,2	1,5
SCARLET	04/05/18	NO	63°	72°	78°	20°	18,5°	1°	0,2	0,5	2,0
AMITABH	10/05/18	NO	66°	72°	78°	20°	18,5°	1°	0,2	0,2	1,5
PIAZZA	17/05/18	56°	63°	72°	78°	22°	20°	1°	0,2	0,2	2,5
UILL IU BAI	28/05/18	NO	64°	72°	78°	20°	18,5°	1°	0,2	0,5	2,0
GLU	11/06/18	56°	63°	72°	78°	20°	18,5°	1°	0,2	0,4	2,0
BEERGAMOTTA	19/06/18	NO	63°	72°	78°	20°	18,5°	1°	0,2	0,4	2,0
LALABLEND	29/06/18	56°	64°	72°	78°	21°	19,5°	1°	0,2	0,5	2,0

Table 53. Non-conformities recognized in the 1st half of 2018.

ISSUE	DATE OF THE EVENT	TYPE OF NON-CONFORMITY	PROBLEM SOLUTION	REMARKS
HOPS	13/03/18	EXPIRATION DATE EXCEEDED	WASTE DISPOSAL	12.3 KG OF HOPS WITH MINIMUM STORAGE PERIOD EXCEEDED
ENZYME	11/07/18	EXPIRATION DATE EXCEEDED	WASTE DISPOSAL	0,3 KG OF PROTEASIS TO DEGLUTINIZE WITH MINIMUM STORAGE PERIOD EXCEEDED
BEER NAMED BITTERDUCK	03/05/18	PRESENCE OF LACTIC BACTERIA	WITHDRAWAL OF PRODUCTION LOT	VERIFIED PRESENCE OF LACTIC BACTERIA IN THE BEER FOLLOWING A COMPLAINT BY A CUSTOMER

Table 54. Maintenance carried out during the 1st half of 2018.

TYPE OF TECHNICAL INTERVENTION	DATE OF THE EVENT	DESCRIPTION OF THE TECHNICAL INTERVENTION	REPAIR COMPANY	TYPE OF MAINTENANCE	PLANT SHUTDOWN
ON PLANT MACHINERY	07/02/18	DAMAGED PNEUMATIC VALVE REPLACEMENT	INTERNO	EXTRAORDINARY MAINTENANCE	2 HOURS
ON EXTINGUISHERS	16/05/18	PRESSURE CONTROL	APIS	ORDINARY MAINTENANCE	---
ON PLANT MACHINERY	21/05/18	REPLACEMENT OF PLANT BOILER TEMPERATURE PROBE	INTERNO	EXTRAORDINARY MAINTENANCE	48 HOURS
ON WASHING PUMP	14/06/18	IMPELLER BEARING REPLACEMENT	DEM	EXTRAORDINARY MAINTENANCE	24 HOURS
ON COMPRESSOR	20/07/18	STERILE FILTER REPLACEMENT	DGM COMPRESSORI	ORDINARY MAINTENANCE	---
CHILLER	23/07/18	CLEANING CIRCUIT WITH ANTI-ICE AND GLYCOL REPLACEMENT	REIFF	ORDINARY MAINTENANCE	---

Table 55. Financial report for the 1st half-year of 2018.

PRODUCT NAME	CATEGORIES OF BEERS	DATE OF PRODUCTION	BEER Litres	OUTFLOWS per Litre	OUTFLOWS half year period	EARNINGS per Litre	EARNINGS half year period	PROFITS € / Litre	PROFITS half year period
CANCELLIERA	ALL YEAR LONG	08/03/18	2011	€ 2,69	€ 5.409,59	€ 3,90	€ 7.842,90	1,21	€ 2.433,31
NEVERMILD	ALL YEAR LONG	29/03/18	1202	€ 2,63	€ 3.161,26	€ 3,90	€ 4.687,80	1,27	€ 1.526,54
AMITABH	ALL YEAR LONG	05/01/18	2036	€ 2,65	€ 5.395,40	€ 3,95	€ 8.042,20	1,30	€ 2.646,80
AMITABH	ALL YEAR LONG	10/05/18	2203	€ 2,65	€ 5.837,95	€ 3,95	€ 8.701,85	1,30	€ 2.863,90
LALABLEND	ALL YEAR LONG	29/06/18	900	€ 3,20	€ 2.880,00	€ 4,50	€ 4.050,00	1,30	€ 1.170,00
SPELTINA	ALL YEAR LONG	20/04/18	2127	€ 2,63	€ 5.594,01	€ 3,95	€ 8.401,65	1,32	€ 2.807,64
SCARLET	ALL YEAR LONG	04/05/18	1014	€ 3,15	€ 3.194,10	€ 4,50	€ 4.563,00	1,35	€ 1.368,90
PIAZZA	ALL YEAR LONG	09/02/18	2317	€ 2,58	€ 5.977,86	€ 3,95	€ 9.152,15	1,37	€ 3.174,29
PIAZZA	ALL YEAR LONG	17/05/18	2188	€ 2,58	€ 5.645,04	€ 3,95	€ 8.642,60	1,37	€ 2.997,56
UILL IU BAI	ALL YEAR LONG	28/02/18	1941	€ 2,78	€ 5.395,98	€ 4,20	€ 8.152,20	1,42	€ 2.756,22
UILL IU BAI	ALL YEAR LONG	28/05/18	2138	€ 2,78	€ 5.943,64	€ 4,20	€ 8.979,60	1,42	€ 3.035,96
INFRADIPA	ALL YEAR LONG	22/03/18	1884	€ 2,76	€ 5.199,84	€ 4,20	€ 7.912,80	1,44	€ 2.712,96
GLU	GLUTEN-FREE	29/01/18	845	€ 2,65	€ 2.239,25	€ 3,95	€ 3.337,75	1,30	€ 1.098,50
GLU	GLUTEN-FREE	11/06/18	867	€ 2,65	€ 2.297,55	€ 3,95	€ 3.424,65	1,30	€ 1.127,10
BITTERDUCK	SEASONAL	03/05/18	910	€ 2,50	€ 2.275,00	€ 3,50	€ 3.185,00	1,00	€ 910,00
DARK SIDE	SEASONAL	15/01/18	1769	€ 2,95	€ 5.218,55	€ 4,25	€ 7.518,25	1,30	€ 2.299,70
BEERGAMOTTA	SEASONAL	15/03/18	882	€ 2,60	€ 2.293,20	€ 3,95	€ 3.483,90	1,35	€ 1.190,70
BEERGAMOTTA	SEASONAL	19/06/18	2279	€ 2,60	€ 5.925,40	€ 3,95	€ 9.002,05	1,35	€ 3.076,65
TOTAL AMOUNTS					€ 79.883,62		€ 119.080,35		€ 39.196,73

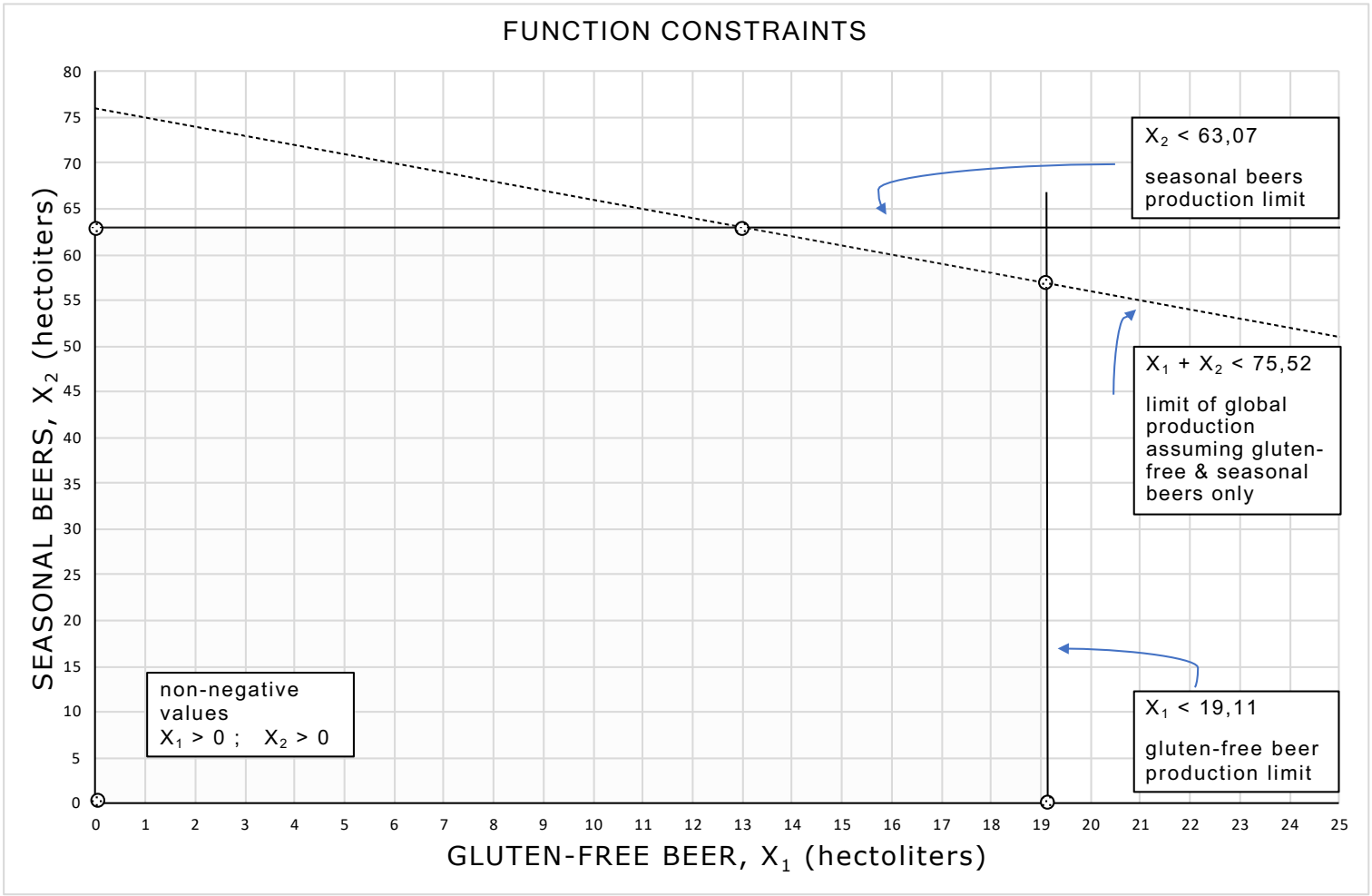
ATTACHMENT C - Linear programming step by step

Calculation and data analysis for this document were generated using the suggestions in the book Practical Optimization: A Gentle Introduction by John W. Chinneck, Systems and Computer Engineering, Carleton University, Ottawa, Ontario K1S 5B6 Canada. http://www.sce.carleton.ca/faculty/chinneck/po.html

OBJECTIVE FUNCTION	max $Z = 1.30 X_1 + 1.25 X_2 + 0 X_3 + 0 X_4 + 0 X_5$	$Z - 1.30 X_1 - 1.25 X_2 - 0 X_3 - 0 X_4 - 0 X_5 = 0$
VARIABLES NON-NEGATIVITY:	$X_1 > 0$	X_1 = GLUTEN-FREE BEER LINE
VARIABLES NON-NEGATIVITY:	$X_2 > 0$	X_2 = SEASONAL BEER LINE
CONSTRAINS:		
GLUTEN-FREE WORT PRODUCTION LIMIT	$X_1 \leq 1{,}911$ liters	$0 Z - 1 X_1 - 0 X_2 - 0 X_3 - 0 X_4 - 0 X_5 = 1{,}911$
SEASONAL WORT PRODUCTION LIMIT	$X_2 \leq 6{,}307$ liters	$0 Z - 0 X_1 - 1 X_2 - 0 X_3 - 0 X_4 - 0 X_5 = 6{,}307$
BEERS PRODUCTION LIMIT DUE TO WASTE	$X_1 + X_2 \leq 7{,}552$ liters	$0 Z - 1 X_1 - 1 X_2 - 0 X_3 - 0 X_4 - 0 X_5 = 7{,}552$

The variables X_3, X_4, X_5, defined as surplus or slack variables, represent the non-negative difference between the first and second member of the inequalities that represent the constraints of the problem.

Figure 33. Function constraints.



STEP 1

1) We build the simplex tableau by entering the coefficients of the inequalities transformed into equality using the surplus or slack variables for each constraint: three constraints and three slack variables, X_3, X_4, X_5.

2) The basic variable must be selected. The procedure to solve maximum problems starts by selecting the line of the objective function and the variable that has the coefficient with the minimum value. Here it has Z coordinates X_1 = -1.3.

3) The corresponding column becomes a PIVOT Column.

4) Now the MRT (minimum test ratio) is calculated for each line: the one with the minimum value corresponds to the PIVOT Line.

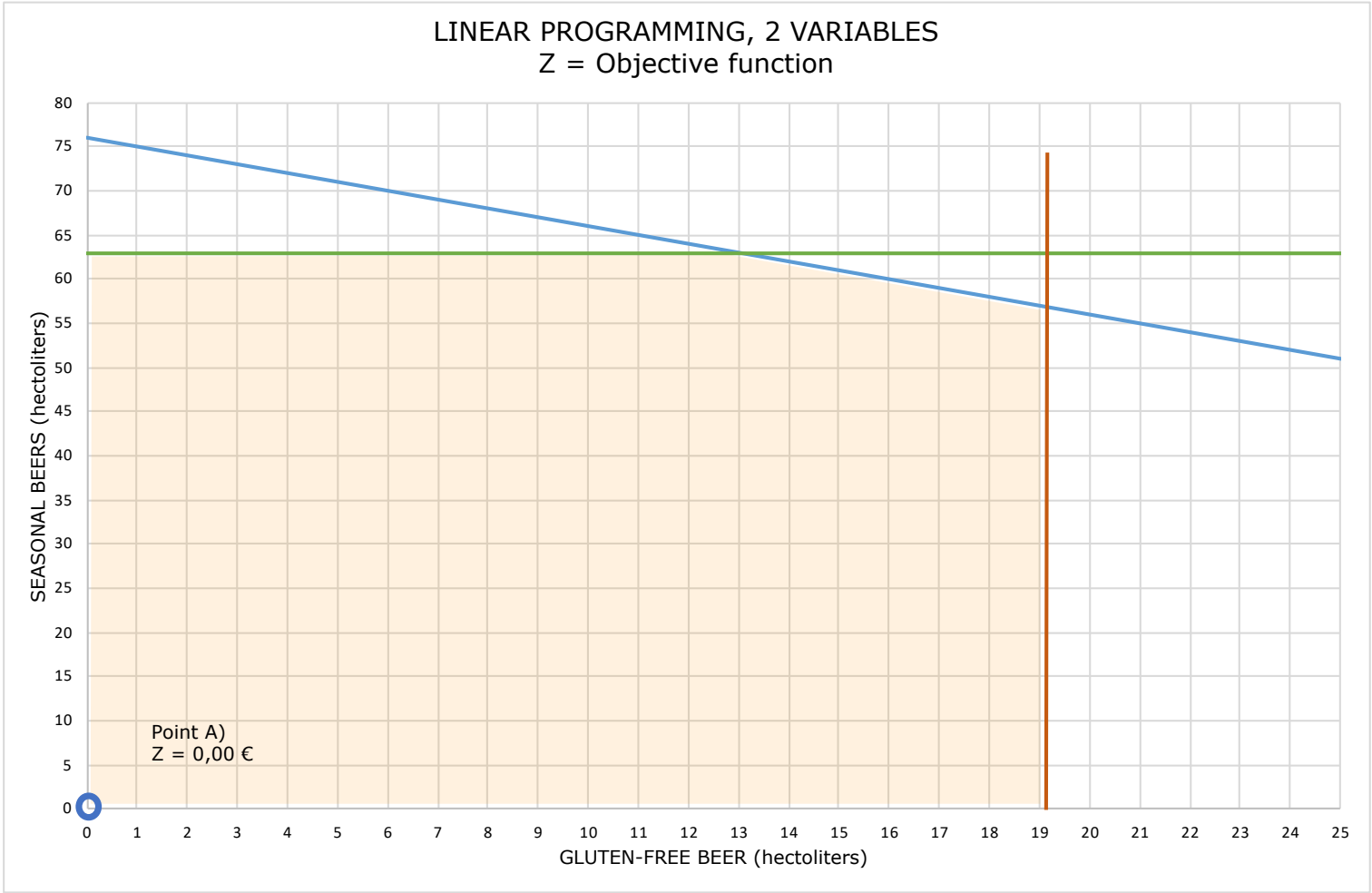
5) The intersection element is called the Pivot Element.

6) Graphically, the situation in which the objective variable Z = 0 corresponds to the intersection of the abscissa and ordinate axes with coordinates (0, 0).

STEP 1

	BASIC VARIABLE	EQUATION	COEFFICIENTI Z	COEFFICIENTI X1	COEFFICIENTI X2	COEFFICIENTI X3	COEFFICIENTI X4	COEFFICIENTI X5	right hand side RHS	minimum test ratio MRT	MRT = RHS / coefficient of entering basic variable (explicit MRT)	
	Z	0	1	**-1,3**	-1,25	0	0	0	0	---	0,00 €	← FORMAL OPTIMAL SOLUTION (value zero) IN X=0 AND Y=O COORDINATES
1^ PIVOT ROW →	X3	1	0	1	0	1	0	0	1911	1911	1911/1	← after the calculation this is the minimum ratio
	X4	2	0	0	1	0	1	0	6307	#DIV/0!	6307/0	#DIV/0! ← means no limits
	X5	3	0	1	1	0	0	1	7552	7552	7552/1	
				↑ 1^ PIVOT COLUMN								
PIVOT ELEMENT →		1										

STEP 1


LINEAR PROGRAMMING, 2 VARIABLES
Z = Objective function
SEASONAL BEERS (hectoliters)
GLUTEN-FREE BEER (hectoliters)
Point A)
Z = 0,00 €
0
5
10
15
20
25
30
35
40
45
50
55
60
65
70
75
80
0
1
2
3
4
5
6
7
8
9
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11
12
13
14
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16
17
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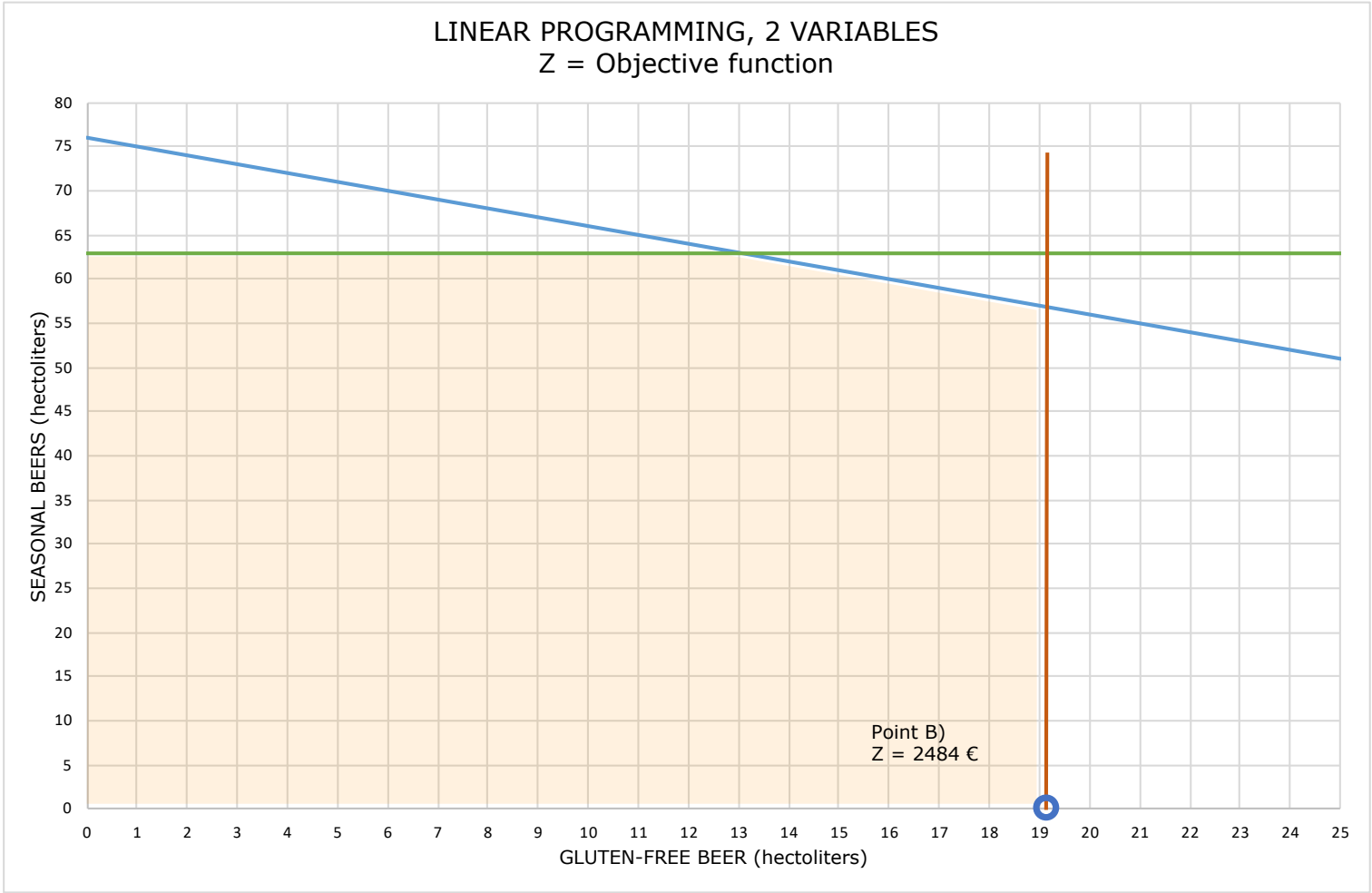
STEP 2

7) The name of the Basic Variable of the PIVOT Line is changed to X1 because it assumes the rank of a basic variable.
8) If the coefficient of the Pivot Element were not equal to +1, all the elements of the Pivot Line should be divided by the value of the Pivot Element. In this case, it is not necessary.
9) The next step involves cancelling the coefficients of the Pivot Column excluding the Pivot Element, using the following equation: new row k = (row k) - (pivot column coefficient in row k) * (pivot row)
10) However, this expression "new row k = (row k) - (pivot column coefficient in row k) * (pivot row)" does not apply to Pivot Row.
11) If you look at the underlying matrix, there is a new RHS (right hand side) value for the target variable = 24.843. This is an excellent solution.
12) In the line of the objective function there is still a coefficient with a negative value. Therefore, a definitive optimal solution was not reached.
13) We must continue with the pivot process (of lightening, streamlining) to improve the value of the objective function.

STEP 2

	BASIC VARIABLE	EQUATION	COEFFICIENTI Z	COEFFICIENTI X1	COEFFICIENTI X2	COEFFICIENTI X3	COEFFICIENTI X4	COEFFICIENTI X5	right hand side RHS	minimum test ratio MRT	
	Z	0	1	0	-1,25	**1,3**	0	0	2484,30	---	€ 2.484 ← OPTIMAL SOLUTION
	X1	1	0	1	0	1	0	0	1911	#DIV/0!	← means no limits
	X4	2	0	0	1	0	1	0	6307	6307	
2^ PIVOT ROW →	X5	3	0	0	1	-1	0	1	5641	5641	
					↑ 2^ PIVOT COLUMN						
new row k = (row k) - (pivot column coefficient in row k) * (pivot row)							1	←	PIVOT ELEMENT		

STEP 2

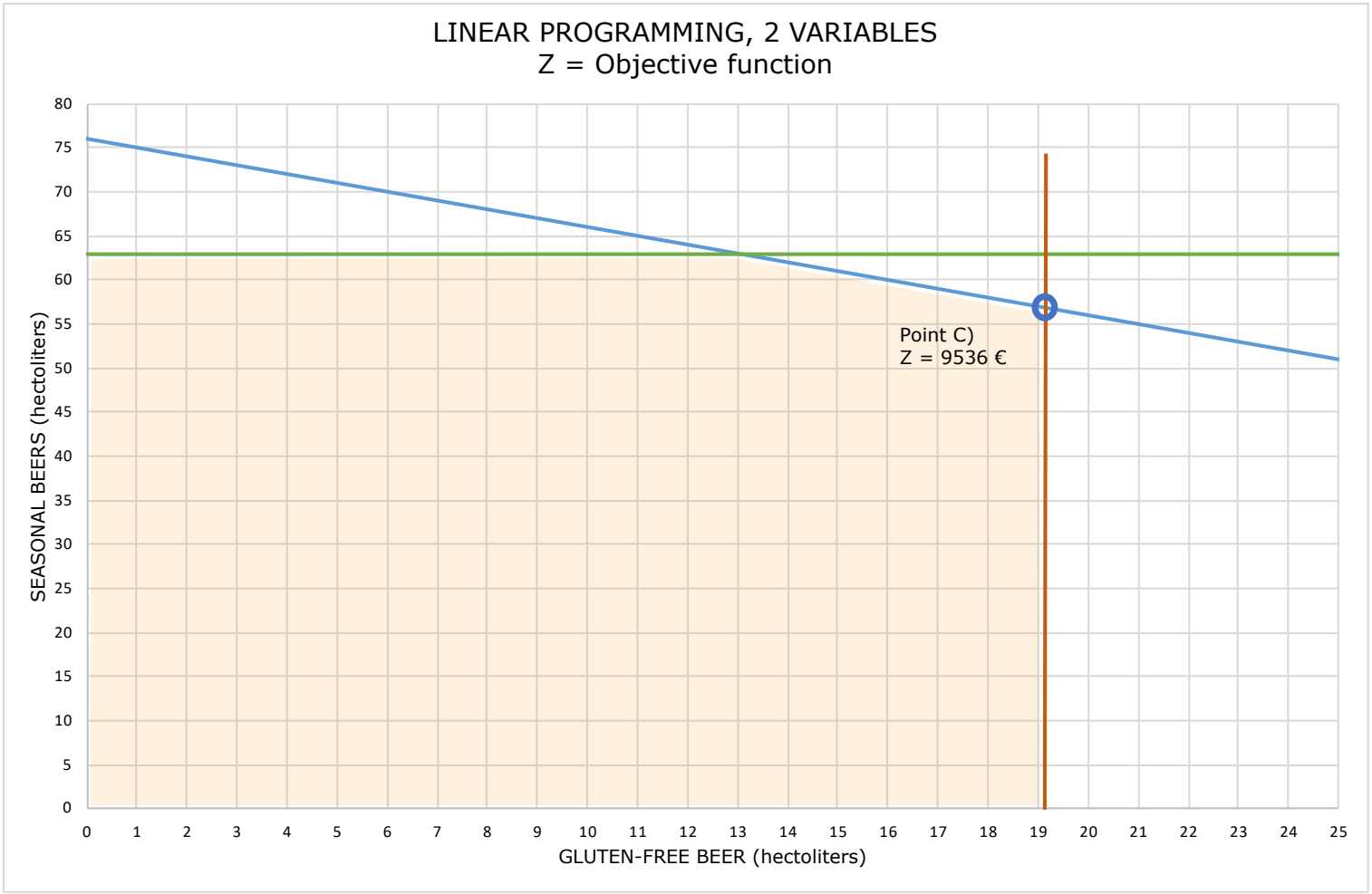

LINEAR PROGRAMMING, 2 VARIABLES
Z = Objective function
SEASONAL BEERS (hectoliters)
GLUTEN-FREE BEER (hectoliters)
Point B)
Z = 2484 €

STEP 3

14) Now the input variable is X_2 because it has the most negative coefficient (-1.25). This becomes the Pivot Column.
15) The MRT is recalculated. The lowest value is of the row corresponding to X_5 which becomes the Pivot Line.
16) The Pivot element is +1 and here in the matrix has coordinates X_5, X_2.
17) The Pivot Line takes the name X_2 because it becomes the second basic Variable.
18) The process of calculating the cancellation of coefficients in the Pivot Column is repeated with the following expression, but excluding the Pivot Row from the calculation:
new row k = (row k) - (pivot column coefficient in row k) * (pivot row)
19) Looking at the Target Line there are no more negative numbers, so the optimal point of the problem has been reached.

	BASIC VARIABLE	EQUATION	COEFFICIENTI Z	COEFFICIENTI X1	COEFFICIENTI X2	COEFFICIENTI X3	COEFFICIENTI X4	COEFFICIENTI X5	right hand side RHS	minimum test ratio MRT	
	Z	0	1	0	0	0,05	0	1,25	9535,55	---	← OPTIMAL € 9.536 SOLUTION
PIVOT ROW →	X1	1	0	1	0	1	0	0	1911	---	
	X4	2	0	0	0	1	1	-1	666	---	
	X2	3	0	0	1	-1	0	1	5641	---	

STEP 3


LINEAR PROGRAMMING, 2 VARIABLES
Z = Objective function
SEASONAL BEERS (hectoliters)
GLUTEN-FREE BEER (hectoliters)
Point C)
Z = 9536 €
0
5
10
15
20
25
30
35
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45
50
55
60
65
70
75
80
0
1
2
3
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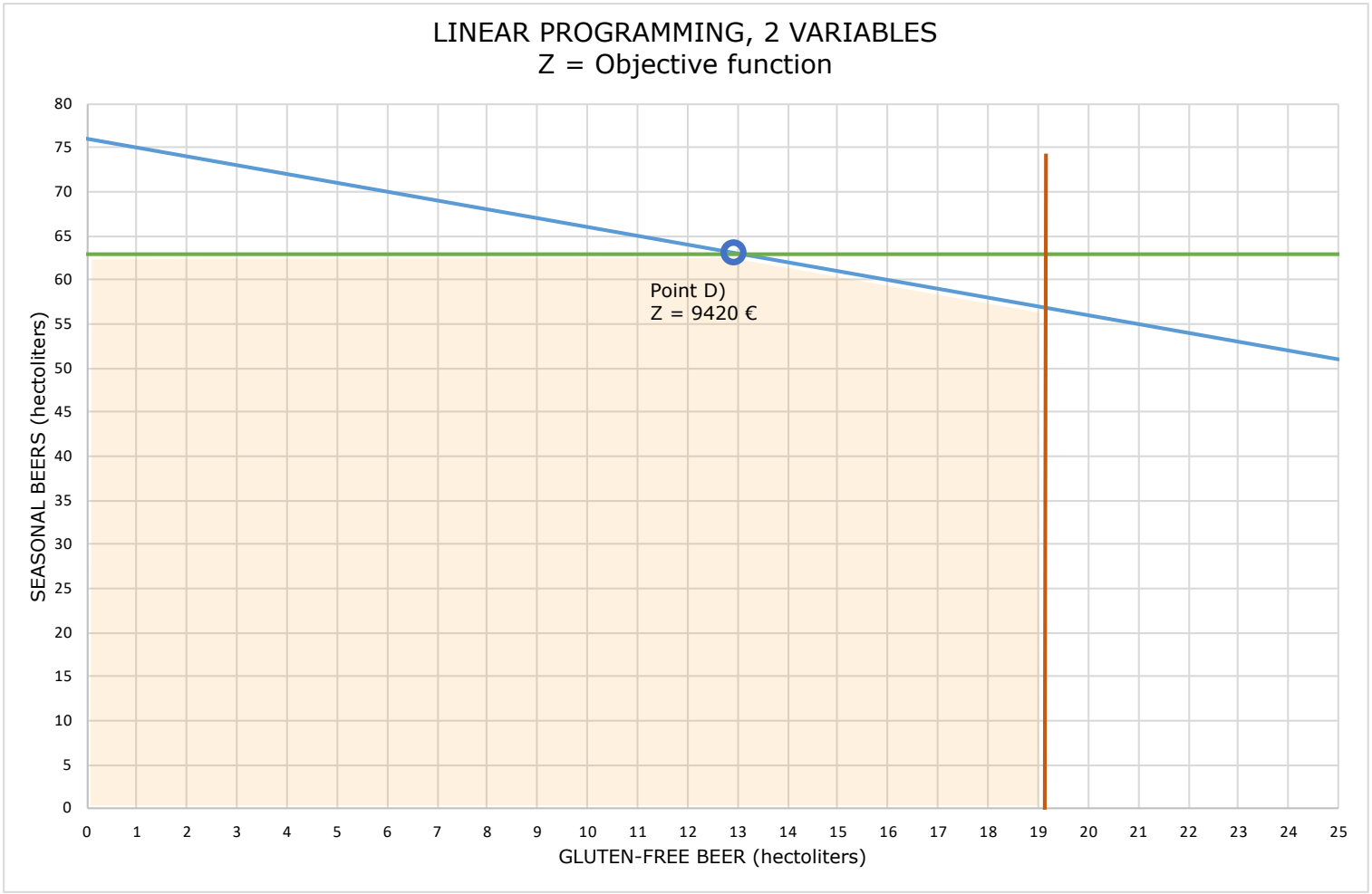
STEP 4

VERIFICATION Point D) Now, you calculate the values of the objective function at point D) in order to monitor. It is noteworthy that it does not exceed the optimum point.

STEP 4


LINEAR PROGRAMMING, 2 VARIABLES
Z = Objective function
Point D)
Z = 9420 €
SEASONAL BEERS (hectoliters)
GLUTEN-FREE BEER (hectoliters)
0
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55
60
65
70
75
80
0
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2
3
4
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6
7
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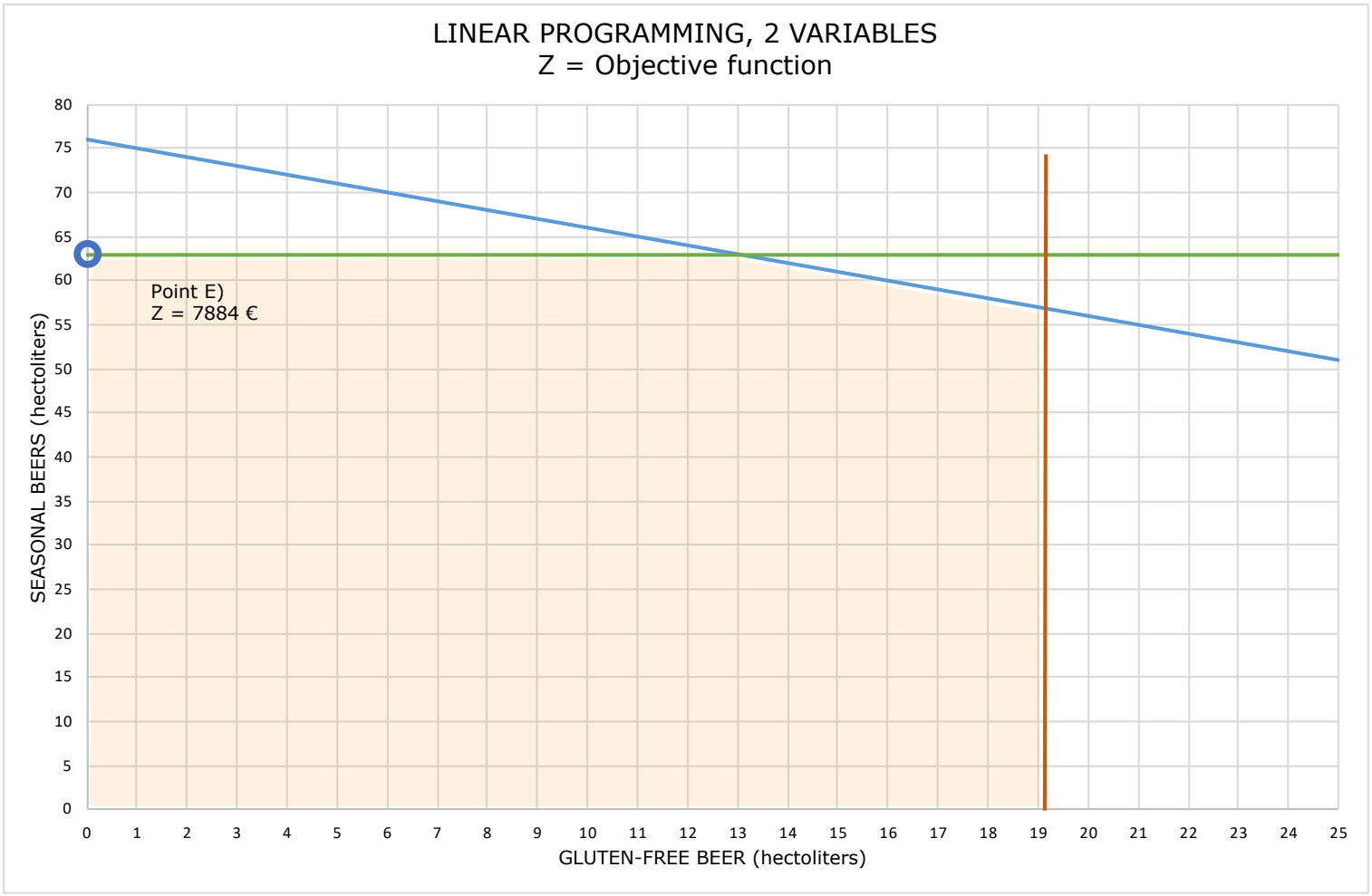
STEP 5

VERIFICATION Point E) Now, you calculate the values of the objective function at point E) in order to monitor. It is noteworthy that it does not exceed the optimum point.

STEP 5


LINEAR PROGRAMMING, 2 VARIABLES
Z = Objective function
Point E)
Z = 7884 €
SEASONAL BEERS (hectoliters)
GLUTEN-FREE BEER (hectoliters)
0
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10
15
20
25
30
35
40
45
50
55
60
65
70
75
80
0
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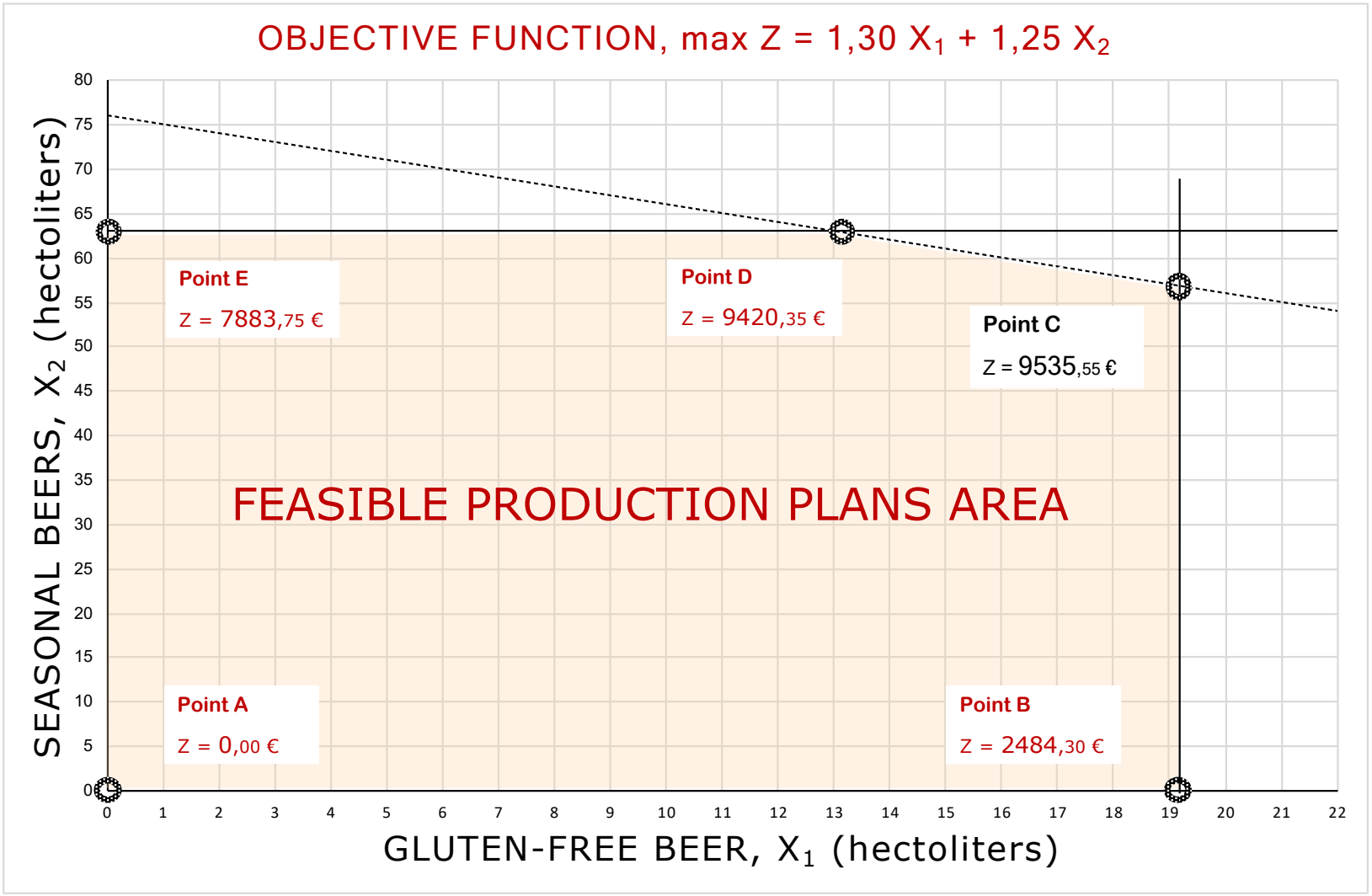
Figure 34. Production optimization of two manufacturing lines of beer in the half-yearly profit account.



ATTACHMENT D - GHP checklist

Table 56. Good Hygiene Practices checklist for Ofelia brewery in Italian for business use. Production from 1 January 2018 to 30 June 2018.

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Responsabilità della Direzione							
Impegno, responsabilità e politica di gestione							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	La Direzione (il management aziendale) ha messo in atto un sistema di sicurezza degli alimenti?	**x**					
	La Direzione è coinvolta fattivamente nella realizzazione e nello sviluppo di tale sistema?	**x**					
	L'ambito di applicazione del sistema HACCP è definito per tutte le categorie di prodotti?	**x**					
	Le attività esternalizzate (se ve ne sono) sono identificate e controllate?					**x**	Non c'è nulla di esterno

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Team leader HACCP: responsabilità, autorità e comunicazione							
	Il team leader HACCP ha responsabilità chiare e autorità adeguate?	**x**					
	La modalità di comunicazione sull'HACCP fatta dal team leader è adeguata?		**x**				Al bisogno, cioè quando ci sono problemi o modifiche di processo. Praticamente annualmente
	Le risorse rese disponibili dalla Direzione per il mantenimento del sistema di sicurezza degli alimenti sono adeguate?	**x**					

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Controllo di gestione							
	C'è una procedura documentata per il controllo di gestione? In altri termini, il sistema di gestione è operativo e documentato?		**x**				Parzialmente si perché è i file di implementazione ex gestione dei lotti, laboratorio. la stanno migliorando
	È disponibile il rapporto annuale del controllo di gestione?		**x**				Vengono scritte le singole anomalie ma non esiste un resoconto annuale. Sono tutte in un fascicolo
Gestione delle risorse							
Risorse umane							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Esiste una tabella organizzativa che identifichi gli obblighi e le responsabilità del personale?				x		No, sarà fatto
	Il personale è qualificato e addestrato per il proprio ruolo?			**x**			Il personale in produzione è qualificato (corso birraio) quello nel bar meno. Vengono formati in azienda alcuni atri sono già formati ma non sono previsti corsi

	Sono in corso, o programmati, corsi di formazione sulla sicurezza alimentare a favore del personale interessato? Sono documentati?				X, no		RSPP esterno non c'è il libretto certificativo ma ora Autocertificazione. Percorsi di informazione e formazione La Regione Veneto ha disposto che: - i titolari di nuova attività e l'operatore neoassunto all'atto dell'assunzione prendono visione di quanto riportato nel documento scaricabile "Norme di comportamento per una corretta preparazione/manipolazione sicura degli alimenti"; - il titolare di nuova attività per la produzione, preparazione, manipolazione e vendita di sostanze alimentari (soggette alla disciplina di cui all'art. 14 della L. 30.04.1962 n. 283 e agli artt. 37,39 e 40 del D.P.R. n. 327/1980), applica le indicazioni riportate nel documento scaricabile "Norme di comportamento per una corretta preparazione/manipolazione sicura degli alimenti". Il documento deve essere sottoscritto e conservato, a disposizione delle autorità di vigilanza; - il titolare di nuova attività (soggetta alla disciplina di cui al decreto legislativo n. 155/97), integra il piano di autocontrollo, previsto dal D.Lgs. n. 155/97, con le informazioni riportate nel documento scaricabile "Norme di comportamento per una corretta preparazione/manipolazione

							sicura degli alimenti". L'autodichiarazione di presa visione di tale documento è conservata all'interno della documentazione relativa all'espletamento delle procedure previste per l'applicazione del piano di autocontrollo. - In caso di assunzione di nuovo personale, il titolare dell'attività implementa il piano di autocontrollo e, laddove previsto, conserva l'attestazione del neoassunto inerente la consegna e la presa visione del documento scaricabile all'interno della documentazione relativa all'espletamento delle procedure previste per l'applicazione del piano di autocontrollo. Tale attestazione è sottoscritta congiuntamente dal neoassunto e dal titolare. Ho trovato questo nel sito dell'ULSS di Padova non capisco se con questo intendono dire che è sufficiente l'autocertificazione come mi è stato detto in azienda.
	Sono chiare le istruzioni fornite per non fumare, non mangiare e bere nella postazione di lavoro?	**x**					

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	I visitatori e gli esterni sono informati e rispettano le norme di igiene nelle aree visitate?	**x**					
Infrastruttura							
	Gli edifici, le strutture e le attrezzature sono progettate per evitare contaminazioni dirette, contaminazioni crociate o effetti negativi sulla sicurezza alimentare?	**x**					

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Le strutture igieniche esistenti per il personale sono idonee e mantenute in buono stato e ben pulite?	**x**					
	Sono disponibili spogliatoi e/o armadi personali?		**x**				Non c'è un armadio a testa.si sono separati
	L'illuminazione dei locali è adeguata?	**x**					
Manutenzione							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	È disponibile ed è attuato un piano di manutenzione che sia anche documentato?			**x**			È attuato un piano di manutenzione e sono documentati quasi tutti gli interventi ma sono raccolti in maniera sparsa, non riassunti in un unico documento.
	Se ne ricorre il caso, sono utilizzati lubrificanti ammessi per le lavorazioni di tipo alimentare? Ad esempio, nei nastri trasportatori.						Non avendo nastri trasportatori o altro non utilizzano lubrificanti. L'unico olio che usano è l'olio diatermico che serve per scaldare l'impianto di produzione. Un nastro trasportatore per etichettare e una macchina imbottigliatrice sono i prossimi acquisti.
Tracciabilità							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	I metodi e i procedimenti per identificare la fonte e l'origine di alimenti e ingredienti sono predisposti e documentati?	**x**					Si, ogni singolo lotto è nel programma di gestione
	I prodotti immessi sul mercato sono adeguatamente identificati ed etichettati?	**x**					

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Il piano di rintracciabilità include le procedure previste per il ritiro o il richiamo dei prodotti?		**x**				È tutto nel programma di gestione in modo tale da poter fare il controllo inverso. Non è stato tesato ma il programma di gestione mi dice lotto per lotto dove è stato venduto il prodotto. Stanno creando un foglio Excel per la tracciabilità delle materie prime ecc. ci sono vari tipi di filtri per data per lotto per fornitore per data di scadenza ecc.
Documentazione							
	Esiste una procedura documentata circa i monitoraggi e i controlli?		**x**				In alcuni casi si ad esempio per temperature frighi, lotta ai parassiti. sono fatti i monitoraggi tranne il monitoraggio chiller di raffreddamento fermentatori, e per i filtri dell'aria sono sterili quindi viene a controllare l'azienda che li ha montati

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	I documenti e i registri sono tenuti aggiornati, consultabili e facilmente identificabili?			**x**			Non sono facilmente consultabili, non ha schede tecniche, ci sono dei miglioramenti
Piano di monitoraggio della sicurezza alimentare							
	Il piano di monitoraggio individua, e documenta, i pericoli che possono influenzare la sicurezza dei prodotti nell'ambito dei processi definiti?			**x**			È da fare, ci sono documenti singoli ma non c'è un piano ben definito

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Il piano di campionamento e analisi è realizzato sulla base della valutazione dei rischi?	**x**					

	L'operatore ha definito e realizzato metodi di campionamento appropriati, riconosciuti e adottati dal settore merceologico di appartenenza?		**X**				Metodo personale perché non esiste un protocollo. Fa esami a campione per ogni lotto. I campioni vengono anche sottoposti ad uno stress test cioè vengono tenuti in condizioni pessime di temperatura ecc. per vedere come reagisce il prodotto. Vengono controllati nel piccolo laboratorio aziendale e mandati a laboratori esterni. I test chimico micro sono pH, temperatura, e grado Plato. Carica batterica aerobica complessiva sia sulla birra che ambientale. Batteri lattici birra e ambientali. Lieviti selvaggi solo birra. Glutine. Vitalità e conta numerica lieviti. Escherichia coli nell' acqua di rete. Esame di shelf life accelerata sui prodotti finito, cioè 100 ml di birra vengono inserite in 900 ml di reagente cioè si aumenta di 10 volte, è un moltiplicatore di vitalità di batteri. Si aumenta la velocita di deperimento della birra, se il colore è violaceo significa che la birra è ancora integra cioè non è deperita. Se cambia colore o si fa un ulteriore analisi sennò guardo a microscopio che c 'è dentro. Le analisi le fa il birraio e alcuni sono test rapidi fatti nel piccolo laboratorio interno altri non sono rapidi e alcool e elisa non vengono fatti in sede. L'alcool lo fa in loco in maniera deduttiva con delle formule che

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
							partendo dal grado Plato degli zuccheri del mosto posso ricavare l'alcol ma non è un valore preciso quindi mandano in laboratori esterni.
	Le eventuali prove e analisi esterne effettuate da laboratori accreditati, e gli eventuali test interni, sono eseguiti secondo metodi ufficiali?	**x**					Vengono mandati dei campioni a laboratori esterni. I lab sono accreditati da Accredia
	È presente in azienda un adeguato sistema di registrazione e documentazione degli eventuali test?				x		Come sempre sono conservati i risultati dei test ma non c'è una documentazione esaustiva. Cioè da un mese a questa parte viene registrato tutto ad ogni cotta prima si segnava solo se c'erano delle anomalie. Ora c'è un foglio Excel, conta di lieviti, batteri ecc.

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Prodotti non conformi							
	Esiste ed è operativa una procedura documentata per la gestione dei prodotti non conformi?		**x**				Esiste una procedura ma non è ben documentata
	È stata individuata la figura aziendale che ha la responsabilità della valutazione dei prodotti circa la loro non conformità e che ha l'autorità per predisporne lo smaltimento?	**x**					
Rilavorazione							

GHP	QUESITI	CLASSI DI NON CONFORMITÀ					NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	La rilavorazione, se è contemplata e prevista, è gestita in modo da garantire la sicurezza alimentare, la rintracciabilità e la conformità normativa?					**x**	Non c'è perché non è contemplata una rilavorazione
Rifiuti							
	I rifiuti sono smaltiti in modo da evitare contaminazioni?			**x**			Si tranne le trebbie che vengono buttate in un cesto di plastica che è difficile da lavare e viene portato dentro e fuori dall'azienda. È previsto l'acquisto di un contenitore in acciaio lavabile. La procedura viene fatta in sicurezza alimentare. Perché viene fatto alla fine del processo di produzione del mosto e poi viene lavato.

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	I materiali di scarto sono adeguatamente identificati e separati per prevenire la contaminazione di altri prodotti?	**x**					
Gestione delle crisi							
	Esiste ed è attuata una procedura di gestione delle crisi? Ovvero, la procedura di richiamo è definita?	**x**					Non viene testata ma esistono le procedure. Non sono mai state fatte simulazioni
	La validità di tale procedura viene verificata e documentata con cadenza annuale?				x		Non viene verificata con cadenza annuale

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Audit interni ed esterni							
	Il dipendente che effettua il controllo interno (auditor interno) è qualificato per questa attività grazie a formazione adeguata o a seguito di addestramento (esterno o interno) o a comprovata esperienza?		**x**				Il responsabile interno ha fatto dei corsi e ha molta esperienza. Seminari Unionbirrari: 1-difetti della birra e le cause 2- processo produttivo della sala cottura 3- tipologie modalità di utilizzo della luppolatura con analisi 4- haccp 5-analisi di laboratorio applicate alla birra 6- pulizia e sanificazione dei macchinari del laboratorio. Tutti questi corsi hanno rilasciato un attestato.

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	L'auditor interno documenta le sue risultanze, le possibili raccomandazioni, le conclusioni e comunque riferisce alla Direzione aziendale?			**x**			Non documenta
	Gli audit interni (controlli interni) sono svolti su tutte le attività rilevanti con periodicità annuale?	**X**					
Reclami							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	La procedura per la gestione dei reclami è adeguatamente documentata? In altri termini, esiste il modulo per i reclami da inviare ai clienti?					**x**	No, i reclami vengono fatti di persona, al telefono o via e mail. Ok
Gestione delle apparecchiature di monitoraggio e misurazione							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
In riferimento a termometri, manometri, ecc.:	Le apparecchiature di monitoraggio e misurazione sono registrate?			**x**			Alcune apparecchiature sono registrate altre no. pH, temperatura e atre si. Manometri no, tranne quello dei fermentatori. È necessario per ottenere la certificazione gluten-free? Perché la Azienda Sanitaria Locale non ha mai chiesto né le dogane le hanno chieste per i conta litri e neppure Il Responsabile del Servizio Prevenzione e Protezione antinfortunistica non le ha chieste per la sicurezza. L'azienda non la fa fare da un ente esterno perché sarebbe una spesa molto grande e non obbligatoria. Loro tarano le strumentazioni internamente senza aiuto esterno.

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Le registrazioni dei risultati delle calibrazioni e dei controlli sono archiviate?						I valori vengono scritti ogni tot quando vengono tarati. Non viene scritto ad ogni utilizzo
Non conformità ed azioni correttive							
	Esiste una procedura documentata che definisca i controlli e le relative responsabilità e competenze necessarie per affrontare le non conformità?		**x**				Non è ancora completata ma è in corso d' opera.

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Ad esempio, in caso di lavorazione non compatibile con precedenti lavorazioni, la linea produttiva - di norma - è seguita da pulizia appropriata. Questa procedura di pulizia è registrata?					**x**	Non sussiste il problema nemmeno per il gluten-free visto che si utilizza l'enzima. Il birraio dice che non è necessario perché anche se l'enzima in minima parte andasse a contatto con altre birre o altre fasi della produzione non crea alcun problema. Per legge bisognerebbe avere una procedura lo stesso?
	Le registrazioni sulla natura delle non conformità e le eventuali misure correttive adottate sono archiviate?				x		Non sono archiviate, in corso d'opera
Operazioni di ricevimento merce							
L'ambiente esterno							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Gli ambienti degli edifici sono sottoposti a manutenzione ordinaria e tenuti puliti dall'operatore?	**x**					
	Il drenaggio dell'acqua piovana e il deflusso sono stati progettati per evitare danni o deterioramento dei prodotti?	**x**					Il drenaggio è ok ma non sussiste il problema perché non ci sono prodotti all'esterno
	Il piano di controllo dei parassiti e dei roditori è adeguato, è implementato ossia realizzato, attuato, ed è documentato?	**x**					Viene fatta dall'azienda esterna che si occupa di tutto e lo documenta nel registro

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Ricevimento delle merci							
	Sono messe a disposizione dei fornitori adeguate e igieniche condizioni di accoglienza?			**x**			Non è presente il bagno esterno per far lavare le mani prima dello scarico merci. Si è previsto un accesso in sicurezza ai servizi igienici
In fase di ricevimento delle merci:	sono identificate (numero di lotto) e registrate le merci?	**x**					
In fase di ricevimento delle merci:	viene controllato e registrato lo stato effettivo del lotto di prodotto ricevuto?	**x**					

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
In fase di ricevimento delle merci:	sono stabiliti i criteri di classificazione e di sistemazione dei prodotti ricevuti?		**x**				Esiste un foglio Excel, compilato ecc.
In fase di ricevimento delle merci:	è presa in considerazione l'eventualità di uno sversamento di merce solida o liquida? Nel caso si dovesse verificare, è prevista ed attuata una adeguata pulizia?	**x**					
Operazioni di stoccaggio/magazzinaggio/deposito							
Locali di stoccaggio e movimentazione							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Gli edifici, i locali e le attrezzature sono progettati in modo da tenere sotto controllo i rischi di sicurezza igienico-sanitaria?	**x**					
	I locali e attrezzature vanno tenuti in buone condizioni. Il piano di manutenzione è attuato e documentato?			**x**			Attivato ma non documentato
	I locali e attrezzature devono essere in buon stato di igiene. Il programma delle pulizie è definito, applicato e registrato?		**x**				Viene applicato un piano di pulizie e i locali e le attrezzature sono in un buono stato di igiene. Il piano non è registrato.

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Nel piano delle pulizie sono elencati i prodotti chimici detergenti utilizzati?	**x**					No,, non viene scritto nulla. Bisogna scrivere il nome generico dei prodotti o proprio la marca?
	Le aree in cui sono stati rilevati e/o conservati lotti in qualche modo contaminati, vengono pulite prima di un ulteriore e diverso utilizzo?					**x**	Non è mai capitato di avere lotti contaminati
	I locali di movimentazione e stoccaggio sono trattati e puliti a fondo almeno una volta all'anno?	**x**					Molto più frequentemente

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Viene regolarmente controllata la presenza di parassiti e i roditori negli ambienti di stoccaggio e nelle aree circostanti?	**x**					Si l'azienda che fa la prevenzione, una volta al mese circa
	I parametri per il ricambio dell'aria nel magazzino, con riguardo anche alla conservazione dei prodotti, sono definiti e applicati?	**x**					Si, ci sono i portoni della grandezza giusta per il ricambio dell'aria e nella sala del malto c'è un sistema di ventilazione fatto apposta. È stato fatto dall'ingegnere che ha fatto l'impianto elettrico con relative conformità
Attrezzature per movimentazione e smistamento							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Gli impianti e le attrezzature di movimentazione, selezione e smistamento merci sono tenuti in buono stato di manutenzione?	**x**					Se si parla di muletti, si sono in buono stato. Si esiste un fascicolo per la manutenzione ma non è ancora stato fatto nulla perché è nuovo. Parlo al singolare perché hanno solo un muletto
	È definito, pianificato, effettuato e registrato un programma di manutenzione e pulizia di tali attrezzature?				x		Non viene registrato
Disposizione dei locali di stoccaggio e movimentazione							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
La disposizione del magazzino consente:	di prevenire la cross-contamination dovuta alle sostanze (velenose) utilizzate per il trattamento di lotta ai parassiti e roditori?	**x**					
La disposizione del magazzino consente:	la rilevazione, l'identificazione e la segregazione (separazione fisica) di sostanze considerate pericolose o non commestibili?	**x**					Si sono in degli scaffali appositi
La disposizione del magazzino consente:	di impedire l'ingresso di veicoli non ammessi nelle aree di stoccaggio?	**x**					

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Stoccaggio dei campioni (per eventuali analisi)							
	I campioni raccolti sono conservati in luoghi idonei per tutta la durata dello stoccaggio?				x		Non esiste un luogo apposta
	Le condizioni di conservazione impediscono il deterioramento o il danneggiamento dei campioni?						In alcuni casi vengono messe appositamente in condizioni ottimali per farle deteriorare, ma negli altri casi la conservazione non crea problemi al campione temperatura sopra i 40°C, esposizione alla luce diretta, congelamento, posizionamento errato della bottiglia (distesa anziché in piedi), superamento del TMC

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Tracciabilità							
	Le bolle di consegna contengono le previste informazioni di rintracciabilità?	**x**					

	Tutti i dati e i relativi documenti sono registrati e conservati per un periodo congruo? (*) Oppure sono dematerializzati? (**) (*) Leggere come semplice indicazione il paragrafo a pagina 11 del file Rintracciabilità prodotti alimentari, linee guida.pdf (**) Come avviene, ad esempio, nel settore vitivinicolo con la "dematerializzazione dei registri nel settore vitivinicolo ai sensi dell'articolo 1-bis, comma 5 del DL 91/2014"						Un po' e un po'. Ad esempio, le informazioni inerenti ai lotti sono in fogli, invece la direzione è nel programma gestionale. Ora è migliorato ed è tutto in Excel così posso fare i controlli incrociati è tutto computerizzato
Monitoraggio delle merci							
	Durante il processo di stoccaggio il responsabile incaricato			**x**			Non registra i dati ma vengono controllati.

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	controlla la temperatura e la condizione della merce immagazzinata. Ne registra i dati?						
Strumenti per le ispezioni, collaudi, misurazioni							
	Le apparecchiature utilizzate per le eventuali operazioni di ispezione o misurazione sono controllate e calibrate annualmente?						Si e ad esempio i termometri vengono calibrati più frequentemente. La calibrazione viene fatta dal birraio stesso
Consegna della merce							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	L'azienda ha il diritto di rifiutare il carico o lo scarico delle merci su o da un mezzo di trasporto in verosimili cattive condizioni igienico-sanitarie e strutturali. Viene verificato che il trasporto delle merci avvenga in conformità (*) alle linee guida di trasporto? (*) Leggere come semplice indicazione il file Manuale ditta autotrasporti.pdf	**x**					

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Controllo del magazzino							
	È documentato il controllo dello stato strutturale del magazzino e l'eventuale pulizia?				x		Viene controllato ma non documentato
Controllo dei nastri trasportatori							

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
	Viene presa in considerazione l'opportunità di pulire la linea di trasporto su nastro eventualmente presente nel ciclo produttivo?					**x**	Non è ancora presente in azienda
Packaging (imballaggio)							
	I materiali da imballaggio sono conformi agli utilizzi previsti?	**x**					
	I prodotti confezionati sono conservati in modo da preservare la qualità dei prodotti?	**x**					

GHP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	
Rifiuti							
	I materiali di scarto sono adeguatamente identificati e separati?	**x**					
	L'area di stoccaggio dei rifiuti è separata dalle strutture di stoccaggio dei prodotti?	**x**					
Varie ed eventuali ↓							

Ad esempio, e solo se ne ricorre il caso:	Il controllo degli organismi nocivi (*) (**) è stabilito e realizzato? (*) Così come definiti nell'articolo 2, lettera e, della Direttiva 2000/29/CE del Consiglio come qualsiasi specie, ceppo o biotipo di vegetali, agenti animali o patogeni nocivi per le piante o i prodotti vegetali. A tal proposito, leggi il file Harmful Organism in the European Union.pdf (**) Stabilire se è applicabile alle materie prime utilizzate.						Ci sono pochi patogeni nella birra ma viene fatto il controllo degli organismi nocivi. Controllo di escherichia coli nell'acqua viene fatto direttamente in azienda. per controllo micotossina nell'orzo ma sono i fornitori che fanno il controllo. Per quanto riguarda animali è detto sopra
…	…						…

Table 57. Results from the GHP checklist of the Ofelia Snc brewery in January 2018.

AUDIT SUMMARY ON GOOD HYGIENE PRACTICES	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY
TOTAL SUM OF CRITERIA	39	12	10	8
%	56.5%	17.4%	14.5%	11.6%

ATTACHMENT E - HACCP checklist

Table 58. HACCP checklist for Ofelia brewery in Italian for business use. Production from 1 January 2018 to 30 June 2018.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
Valutazione dei rischi							
	La valutazione dei rischi è eseguita effettuata secondo il metodo HACCP previsto dal Codex Alimentarius?	**X**					La valutazione dei rischi è stata fatta da un esterno, RSPP BEFOR ingegneria, Ing. Bertolaso Fabrizio.

HACCP	QUESITI	CLASSI DI NON CONFORMITÀ					NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Rientra nella valutazione dei rischi lo scopo di identificare e controllare i pericoli che potrebbero influire negativamente sulla sicurezza dei prodotti?	**X**					Si, il RSPP l'ha fatto, ma non è presente in azienda.
	Il programma HACCP copre tutti gli aspetti dell'attività produttiva aziendale?	**X**					
Prerequisiti							
	È stato realizzato un programma efficace di rispetto dei prerequisiti? È documentato?				**X**		Non è documentato, è integrabile ma all'AUSL va bene così. A voce perché non è stata fatta nessuna verbalizzazione durante i vari controlli

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
HACCP Team							
	L'operatore ha nominato un team HACCP con la missione di redigere e gestire un piano HACCP efficace?	**X**					Nel manuale c'è scritto come è formato il gruppo haccp, è sufficiente?
Il team HACCP costituito comprende:	personale proveniente dagli ambiti rilevanti esistenti all'interno dell'azienda?	**X**					
Il team HACCP costituito comprende:	almeno un membro che abbia ricevuto formazione specifica riguardo l'HACCP?	**X**					Libretto sanitario presso la camera di commercio ed ha partecipato ad un corso organizzato dall'associazione Birrai.

HACCP	QUESITI	CLASSI DI NON CONFORMITÀ					NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	La composizione del team HACCP e le singole competenze dei membri sono documentate?				**X**		No, ora si impegneranno a documentarle.
Specifiche del prodotto							
	Il prodotto venduto ha delle specifiche scritte?		**X**				Attendo una risposta più chiara.
Le specifiche scritte includono:	la denominazione precisa del prodotto fornito?	**X**					
Le specifiche scritte includono:	la tabella nutrizionale?					**X**	No, l'etichetta nutrizionale è diventata obbligatoria solo per le birre con contenuto alcolometrico inferiore all'1,2%. REGOLAMENTO (UE) N. 1169/2011, articolo 9 lettera l.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
Le specifiche scritte includono:	qualunque lavorazione o trattamento del cibo o degli ingredienti fatto a priori?					**X**	L'azienda non utilizza semilavorati utilizza solo materia prima cruda.
Le specifiche scritte includono:	eventuali caratteristiche speciali che possono influenzare o migliorare l'uso potenziale del prodotto?					**X**	Coadiuvanti? Se si, non ne utilizzano. Vengono usati anche altri cereali e vengono segnati in etichetta.
Le specifiche scritte includono:	l'indicazione di pericoli o limitazioni per l'uso previsto, ad esempio, la presenza di allergeni?	**X**					Vengono scritti in grassetto gli allergeni ad esempio l'orzo. citare la presenza di ingredienti considerati allergenici, introdotto con direttiva 2003/89/CE
Fase di acquisto							

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	In fase di acquisto delle materie prime, è fatta dall'azienda la valutazione dei rischi basata sui principi HACCP?	**X**	**X**				Cioè bisogna richiedere l'HACCP al fornitore prima dell'acquisto?
	L'operatore (l'azienda) stabilisce i criteri per la selezione, la valutazione e la rivalutazione dei fornitori?		**X**				Non c'è proprio un criterio di valutazione preciso ma va molto sulla fiducia e sull'esperienza.
Definizione delle fasi del processo produttivo							
	Il team HACCP ha identificato e registrato tutti i passaggi coinvolti nelle operazioni?	**X**					Si è documentato nel manuale di auto controllo ed è anche stato allegato all'AUSL nella SCIA di inizio attività.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Tutti i processi interni sono documentati nei diagrammi di flusso? In altri termini, esiste il diagramma di flusso?	**X**	**X**				Esiste ed è pronto e non sono mai stati fatti cambiamenti.
	Tutti i processi relativi alle attività esternalizzate sono documentati nei diagrammi di flusso?					**X**	Non esistono attività esternalizzate.
	I diagrammi di flusso rappresentano la situazione attuale?	**X**					Si, è presente.
	Eventuali modifiche di processo sono registrate ed archiviate?	**X**	**X**				Si, sempre.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Le eventuali modifiche di processo sono verificate, convalidate e approvate dal team HACCP ed inserite nel piano di autocontrollo?	**X**					
1° principio Individuazione e analisi dei pericoli							
	Sono stati identificati, classificati, valutati, registrati e documentati i pericoli chimici, fisici o microbiologici?	**X**					
	È stata condotta un'analisi dei rischi per ciascun prodotto?		**X**				Esiste un'analisi del rischio ma non è specifica per ogni prodotto ma è generica poiché non è necessario perché i rischi sono uguali per tutti i prodotti che sono tutte birre.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Sono state prese misure di controllo per ogni fase del processo per eliminare o ridurre a livelli accettabili tali pericoli e per garantire la produzione di alimenti sicuri?	**X**					Si, si trova l'elenco a pagina 18 del piano di autocontrollo aziendale.
2° principio Individuazione dei Punti Critici di Controllo							
	I CCP sono stati identificati?	**X**					Si, vedi punto 5.6.1, pagina 15 del piano di autocontrollo aziendale.
	I CCP sono registrati nel piano HACCP?	**X**					Si, vedi sopra.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
3° principio Definizione dei limiti critici							
	I limiti critici nei CCP sono stati identificati per tutti i pericoli?			**X**			No.
	I limiti critici sono stati fissati a livelli sufficienti per garantire la sicurezza degli alimenti prodotti?			**X**			No.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	È stato istituito in azienda un sistema permanente (*) che consenta di essere aggiornati sugli sviluppi normativi che potrebbero influire sulla conformità di questi limiti critici? (*) Può essere utile l'iscrizione alla newsletter dell'associazione di categoria.	**x**					Si, newsletter di Unionbirrari.
4° principio Definizione delle procedure di monitoraggio							
	I CCP sono monitorati per garantire che i pericoli identificati restino sotto controllo?			**x**			Protocollo di analisi shelf life battei lattici ecc.

HACCP	QUESITI	CLASSI DI NON CONFORMITÀ					NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Il monitoraggio è realizzato secondo un programma documentato?			**X**			Non molto documentato, ora stanno documentando.
	I risultati sono registrati?			**X**			A volte, ora viene fatto per ogni lotto di produzione.
5° principio Definizione e pianificazione delle azioni correttive							
	È previsto di intraprendere azioni correttive adeguate, tempestive ed efficaci nel momento in cui i dati raccolti dovessero indicare che i pericoli non rientrano nei limiti critici?		**X**	**X**			Alcune misure correttive sono scritte altre no, in corso.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Sono stabilite le azioni correttive volte ad affrontare la causa e le conseguenze del problema?	**X**	**X**				Ora sono in conformità.
	Le azioni correttive e le relative verifiche sono documentate e registrate?			**X**			A volte. L' AUSL ha consigliato di scrivere le misure correttive in modo più generico possibile per non incappare in problemi se non si dovessero rispettare in futuro. Sostanzialmente consigliano di non scrivere delle azioni correttive troppo specifiche perché poi nel caso in cui in un futuro non venissero rispettate perfettamente potrebbero avere problemi.
6° principio Definizione delle procedure di verifica							

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Viene effettuata ogni anno una revisione (verifica interna) completa dell'HACCP?		**X**	**X**			Perché non viene fatta con cadenza annuale ma quando capita.
	La revisione include anche tutti i prerequisiti stabiliti come parte del piano HACCP?		**X**	**X**			Non con cadenza annuale.
	La verifica annuale assicura che le precedenti non conformità siano state risolte con azioni correttive?	**X**		**X**			
	Il team HACCP ha effettuato ulteriori revisioni periodiche del sistema HACCP per verificare che i requisiti del piano HACCP siano soddisfatti?	**X**		**X**			Alcune parti vengono riviste ma non tuto il piano.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Le verifiche del piano HACCP sono debitamente registrate, documentate e attuate?		**X**	**X**			Temperature delle celle, ecc., si ma le altre verifiche non vengono documentate.
7° principio Definizione delle procedure di registrazione							
	Il management aziendale ha stabilito un sistema di gestione (cartaceo o informatico) della documentazione?		**X**		**X**		Lo stanno facendo.
Il sistema di documentazione contiene:	I documenti HACCP facendo riferimento a ciascuna delle fasi che formano il piano HACCP?		**X**	**X**			In via di completamento.

HACCP	QUESITI		CLASSI DI NON CONFORMITÀ				NOTE & COMMENTI
	↓	FULL CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY	NA	↓
	Le voci (i record per il report) citati nel piano HACCP?	**X**					
	Tutti i documenti e le registrazioni prodotti nel contesto del sistema HACCP sono archiviati e archiviati per un periodo di tempo appropriato?		**X**	**X**			Alcuni si alcuni no, il tempo appropriato è 5 anni (criterio fiscale).
Varie ed eventuali							
…	…						…

Table 59. Results from the HACCP checklist of the Ofelia Snc brewery in January 2018.

AUDIT SUMMARY ON HAZARD ANALYSIS AND CRITICAL CONTROL POINTS	CONFORMITY	MINOR NON-CONFORMITY	MAJOR NON-CONFORMITY	CRITICAL NON-CONFORMITY
TOTAL SUM OF CRITERIA	23	14	14	3
%	42.6%	25.9%	25.9%	5.6%

ATTACHMENT F - GMP checklist

Table 60. Good Manufacturing e Practices checklist for Ofelia brewery in Italian for business use. Production from 1 January 2018 to 30 June 2018.

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
GMP	STABILIMENTO			
01	I locali sono liberi da rifugi/tane e luoghi di riproduzione per roditori, insetti, ecc.?	X		
	Ci sono attrezzature o forniture immagazzinate in modo permanente entro il perimetro della struttura?		X	
	Le aree dello stabilimento sono libere da rifiuti?	X		
	C'è qualche attrezzatura esterna posizionata a meno di 50 cm dall'edificio? (in altri termini, il perimetro esterno dell'edificio ha un'area libera per almeno 50 cm intorno?)		X	
	Le erbacce e gli arbusti sono almeno a 50 cm dall'edificio?	X		
Totale		3	2	
%		60%	40%	
02	Il drenaggio è idoneo per evitare la contaminazione delle strutture e dei prodotti?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Le acque piovane defluiscono in modo da non entrare in contatto con la birra e/o i suoi ingredienti?	X		
	Il drenaggio all'interno dello stabilimento è tale da scongiurare l'accumulo di acqua o rifiuti?	X		
	Il sistema fognario è adeguato a gestire il volume delle acque reflue e piovane?	X		
Totale		4	0	
%		100%	0%	
03	È stato previsto spazio sufficiente per il posizionamento delle attrezzature, lo stoccaggio dei materiali e per i processi di produzione?	X		
	C'è un minimo di 50 cm tra le attrezzature all'interno dell'edificio e le pareti?	X		
	C'è spazio sufficiente per conservare i materiali di produzione?	X		
	C'è un adeguato deposito non umido ovvero senza tracce di umidità?	X		
	C'è un adeguato deposito refrigerato per i prodotti e le materie prime sensibili alla temperatura?	X		
Totale		5	0	
%		100%	0%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
04	I pavimenti, i muri ed i soffitti sono costruiti con materiali facilmente pulibili e sono conservati in buono stato?	X		
	Il pavimento è pulito, privo di crepe e con superficie integra?	X		
	In corrispondenza delle aree di produzione, il tetto è privo di perdite e infiltrazioni?	X		
	Il soffitto è intatto e non si sfalda o sbriciola?	X		
	Le pareti e i soffitti sono privi di muffa superficiale?	X		
	Le pareti ed il soffitto sono facilmente accessibili per essere puliti?	X		
Totale		6	0	
%		100%	0%	
05	Le superfici a contatto con gli alimenti sono protette dalla contaminazione da perdite da tubazioni sospese?	X		
	Il soffitto soprastante le aree di produzione, è libero da tubi che potrebbero gocciolare il loro contenuto o condensa nel mosto, nella birra o sugli ingredienti?	X		
Totale		2	0	
%		100%	0%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
06	Le aree di lavorazione del prodotto alimentare sono fisicamente separate da tutte le aree ove avvengono operazioni che potenzialmente possono causare contaminazione?	X		
	Le aree di produzione sono separate dalle zone preposte, ad esempio, allo smaltimento delle acque reflue, allo stoccaggio dei prodotti resi, ecc.?	X		
Totale		2	0	
%		100%	0%	
07	La linea di produzione ed il prodotto stesso sono protetti dal vetro derivante da rottura di lampadine o altra fonte di vetro?	X		
	Nelle aree di produzione, fermentazione e confezionamento, le lampadine del sistema di illuminazione sono opportunamente protette in plafoniere?	X		
Totale		2	0	
%		100%	0%	
08	C'è un adeguato ricambio d'aria che ne assicuri la qualità e ne prevenga la contaminazione da polvere ed altre eventuali sostanze?	X		
	Esiste un dispositivo di controllo delle polveri funzionante presso l'area di molitura (se è presente tale area)?		X	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Le aree di carico e scarico sono separate da quelle di lavorazione?	X		
Totale		2	1	
%		66%	33%	
09	Le porte, le finestre e le altre aperture sono protette in modo da impedire l'ingresso di insetti, roditori e altri parassiti?	X		
	Tutte le porte e le finestre sono intatte e in buono stato di manutenzione?	X		
	Ci sono zanzariere o simili su tutte le finestre e porte, comprese le porte basculanti?		X	Non in tutte.
	Tutte le porte esterne sono sufficientemente aderenti per impedire l'ingresso di parassiti?	X		
Totale		3	1	
%		75%	25%	
Totale del criterio		29	4	
%		88%	12%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
GMP	ATTREZZATURE			
10	Tutti gli utensili e le attrezzature del birrificio sono costruiti con materiali adatti agli usi previsti?	X		
	Sono in uso utensili non previsti quali, ad esempio, strumenti in legno o in materiale metallico non idoneo all'uso alimentare?		X	
	Le connessioni tra recipienti, contenitori, serbatoi e linee di collegamento sono ben isolate e sigillate con rivestimenti pulibili?	X		
Totale		2	1	
%		66%	33%	
11	Le attrezzature sono progettate e utilizzate in modo tale da impedire la contaminazione con lubrificanti, acqua contaminata, frammenti metallici, vetri, ecc.?	X		
	Le guarnizioni di contenimento del grasso e olio lubrificanti sono in buone condizioni?	X		
	Le boccole e le altre superfici di contatto metallo-metallo sono in buone condizioni?	X		
	Le valvole di intercettazione sono esenti da perdite?	X		
Totale		4	0	
%		100%	0%	
12	L'attrezzatura è installata e mantenuta in modo tale da facilitarne la pulizia nonché l'igiene delle aree adiacenti?	X		
	Ci sono almeno 50 cm di distanza reciproca tra serbatoi, recipienti, attrezzature e muri?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Ci sono adeguati spazi al di sotto delle attrezzature di processo al fine di accedere sia al pavimento che alla parte inferiore dei serbatoi con gli usuali strumenti di pulizia?	X		
	Motori, elettrovalvole e altri componenti elettrici sono classificati *per* e idonei *al* lavaggio?	X		
Totale		4	0	
%		100%	0%	
Totale del criterio		10	1	
%		91%	9%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
GMP	IGIENICITÀ			
13	L'approvvigionamento idrico è adeguato in quantità e qualità per l'uso previsto?	X		
	Esistono controlli per prevenire ed impedire il passaggio di sedimenti?		X	
	Viene effettuato giornalmente il monitoraggio della qualità dell'acqua utilizzata?		X	
	I parametri chimico-fisici dell'acqua sono controllati periodicamente?	X		
	La linea di approvvigionamento idrico è diretta ovvero priva di punti intermedi di connessione?	X		
	Ci sono dispositivi di protezione di retro-flusso su tutte le linee di acqua in entrata?	X		
	Se nel processo di produzione, l'acqua viene in contatto con le superfici di processo o con la birra stessa, si è certi che l'acqua possegga i previsti requisiti igienico-sanitari?	X		
Totale		5	2	
%		72%	28%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
14	La temperatura e la pressione dell'acqua sono mantenute a livelli adeguati agli usi previsti?	X		
	Il serbatoio dell'acqua calda dispone di un adeguato controllo della temperatura?	X		
	La pompa di alimentazione dell'acqua calda è adeguatamente dimensionata per l'erogazione a pressione costante?	X		
	La linea in entrata dell'acqua fredda è adeguatamente dimensionata per l'erogazione a pressione costante?	X		
Totale		4	0	
%		100%	0%	
15	Il sistema di smaltimento delle acque reflue è adeguato?	X		
	Se le acque reflue versano su una fogna municipale, le autorità locali sono consapevoli ed informate circa le portate massime dello stabilimento?	X		
	Se le acque reflue versano su una fossa settica, il sistema è adeguatamente dimensionato per sostenere il flusso massimo?	X		Fogna municipale
Totale		3	0	
%		100%	0%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
16	L'impianto idraulico è adeguatamente dimensionato, progettato, installato e mantenuto in modo da prevenirne la contaminazione?	X		
	I tubi di drenaggio sono abbastanza grandi da trasportare e defluire rapidamente gli effluenti dalla fabbrica di birra?	X		
	Tutti i tubi di scarico hanno valvole di intercettazione e sono collegati alla fogna?	X		
	Il drenaggio del pavimento è inclinato in modo tale da evitare l'acqua stagnante?	X		
	I pavimenti sono tenuti regolarmente puliti?	X		
	Gli scarichi a pavimento hanno dispositive o filtri per evitare a particelle od oggetti di grandi dimensioni di entrare nel flusso degli effluenti?	X		
	È impedita l'eventualità di contaminazione crociata tra approvvigionamento dei processi e flusso dei rifiuti?	X		
Totale		7	0	
%		100%	0%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
17	Sono presenti un adeguato numero di servizi igienici con WC opportunamente attrezzati e in buono stato di manutenzione?	X		
	I bagni sono tenuti puliti secondo un regolare programma di pulizie?	X		
	È presente un lavandino per lavare le mani con sapone igienizzante?	X		
	C'è un asciugamano monouso o altro idoneo dispositivo di asciugatura, ad esempio, ad aria?	X		
Totale		4	0	
%		100%	0%	
18	In area di lavoro sono presenti adeguati dispositivi per il lavaggio delle mani?	X		
	Nelle immediate vicinanze di ogni area di lavoro, ci sono lavandini per il lavaggio delle mani con sapone igienizzante e asciugamani di carta o ad aria?	X		
	I dipendenti sono consapevoli della necessità di lavarsi le mani dopo ogni allontanamento da un'area di lavoro, ad esempio, dopo una pausa e per una manutenzione?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	C'è un'illuminazione adeguata nelle aree di lavaggio mani?	X		
Totale		4	0	
%		100%	0%	
19	I rifiuti sono adeguatamente stoccati e protetti da insetti, roditori e altri parassiti e sono smaltiti in modo adeguato?	X		
	Tutti i cestini e i contenitori per rifiuti sono chiaramente contrassegnati per l'uso previsto?	X		
	Tutti i bidoni per l'immondizia sono dotati di adeguati coperchi?	X		
	I contenitori dei rifiuti sono svuotati con cadenza regolare?	X		
	Tutti i cassonetti dei rifiuti sono tenuti lontano dalle materie prime?	X		
Totale		5	0	
%		100%	0%	
Totale del criterio		32	2	
%		95%	5%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
GMP	PULIZIA			
20	La struttura è tenuta pulita e in buono stato?	X		
	Ci sono perdite osservabili sul tetto?		X	
	I pavimenti sono puliti e privi di residui nelle aree di stoccaggio, di produzione, di fermentazione, di etichettatura e di imballaggio?	X		
	I pavimenti sono privi di acqua stagnante?	X		
	Le fogne e le fosse sono pulite e senza odori?	X		
	Le aree in cui le apparecchiature entrano in contatto con il pavimento sono pulite e progettate per la pulizia?	X		
Totale		5	1	
%		84%	16%	
21	La pulizia degli impianti e delle attrezzature è effettuata in modo tale da evitare la contaminazione dei prodotti alimentari?	X		
	Le attrezzature di detersione sono esenti da microbi indesiderati?	X		
	Sono in atto procedure per assicurare la giusta concentrazione/diluizione dei detergenti?	X		
	Sono in atto procedure per garantire che i detergenti siano stati effettivamente risciacquati dalle apparecchiature?	X		
Totale		4	0	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
%		100%	0%	
22	Detergenti, disinfettanti, materiali pericolosi ed altre sostanze, sono utilizzati in modo sicuro ed efficace?	X		
	Il fornitore ha fornito una garanzia o una certificazione sulle sostanze chimiche? Ovvero sono state esaminate e classificate ai fini della contaminazione?	X		
	Ci sono SOPs (= standard operative procedures) per tutte le procedure di pulizia?	X		
	I dipendenti sono addestrati con cadenza annuale circa la gestione delle sostanze chimiche e le relative POS (= procedure operative standard)?	X		
	I prodotti per la pulizia utilizzati in produzione sono approvati per il contatto alimentare?	X		
	Nel birrificio, tra sostanze e materiali tossici sono utilizzati o conservati:	---	---	---
	esclusivamente quelli necessari per mantenere le condizioni di pulizia e igienico-sanitarie.		X	
	quelli necessari per l'uso in procedure di collaudo dell'impianto.		X	
	quelle necessarie per la manutenzione e il funzionamento di impianti e attrezzature.	X		
	quelli necessari per l'impiego nelle operazioni sugli impianti.	X		
Totale		7	2	
%		78%	22%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
23	Detergenti, disinfettanti e materiali pericolosi, sono conservati in contenitori originali e tenuti separati dalle materie prime?	X		
	I prodotti chimici sono tutti nei loro contenitori originali?	X		
	Tutti i contenitori e recipienti hanno la loro etichetta originale?	X		
	Le sostanze chimiche sono immagazzinate nell'area loro dedicata e lontano da materie prime?	X		
	Circa l'uso e la conservazione di queste sostanze chimiche, si opera in conformità ai regolamenti comunitari/nazionali/sanitari previsti?	X		
Totale		5	0	
%		100%	0%	
24	Le aree di lavorazione sono mantenute libere da insetti, roditori e altri parassiti?	X		
	Il birrificio ha un servizio di controllo dei parassiti?	X		
	Il servizio esterno di pest-control fornisce le denominazioni dei pesticidi, la posizione delle trappole, la disposizione delle esche, ecc.?	X		
	Il servizio esterno di pest-control ispeziona la struttura mensilmente/periodicamente e fornisce un rapporto scritto o elettronico di tale attività?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	L'applicazione di rodenticidi e insetticidi viene eseguita in modo tale da impedire la contaminazione della birra, delle superfici di contatto con la birra, degli ingredienti e dell'imballaggio?	X		
	È vietato l'ingresso e lo stazionamento di animali, come cani e gatti o altri animali, nelle zone di produzione?	X		
Totale		6	0	
%		100%	0%	
25	Gli insetticidi e i rodenticidi sono usati e conservati in modo da prevenire la contaminazione dei prodotti alimentari?	X		
	La società di controllo e gestione dei parassiti fornisce documentazione sui pesticidi utilizzati, quando sono stati utilizzati, e dove?	X		
	I pesticidi sono conservati in loco?		X	
	Se i pesticidi sono immagazzinati sul posto, l'accesso è limitato?			
Totale		2	1	
%		66%	33%	
26	Tutti gli utensili e le attrezzature sono puliti e igienizzati ad intervalli abbastanza frequenti, tali da evitare la contaminazione dei prodotti alimentari?	X		
	Sono disponibili adeguate misure di sanificazione degli utensili?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Sono previste ed effettuate adeguate pulizie dei recipienti?	X		
	Sono previste ed effettuate pulizie delle apparecchiature di filtraggio?	X		
	Sono previste ed effettuate pulizie di bottiglie, lattine, utensili riempitivi di fusti?	X		
Totale		5	0	
%		100%	0%	
27	Le minuterie* vengono conservate in contenitori appropriati e manipolate, dispensate, usate e smaltite in modo da prevenire la contaminazione della birra o del mosto? * Minuterie d'officina: l'assortimento di piccoli pezzi meccanici (bulloncini, viti, rondelle, rosette, ecc.), generalmente raccolti in apposite cassettiere.	X		
Totale		1	0	
%		100%	0%	
28	Gli utensili e le attrezzature portatili sono conservati in modo da proteggerli da schizzi, polvere e altre contaminazioni?	X		
	I mestoli, i cucchiai, le palette, ecc. vengono conservati in modo da non essere contaminati da schizzi durante la pulizia, da polvere di malto, ecc.?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Le attrezzature portatili per la pulizia sono immagazzinate in modo tale da non essere contaminate da acque reflue, materiali di scarto, ecc.?	X		
Totale		3	0	
%		3%	0%	
Totale del criterio		38	4	
%		90.5%	9.5%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
GMP	PROCESSI			
29	La responsabilità per l'igiene generale dell'impianto è specificamente assegnata a un dipendente o responsabile?	X		
	Questa persona ha una formazione adeguata riguardo le leggi e i regolamenti attinenti?	X		
	Questa persona ha una formazione adeguata riguardo gli impianti di lavorazione di birra / bevande / e industria alimentare?	X		
	Questa persona ha una formazione adeguata riguardo I processi di sanificazione di impianti di lavorazione di birra / bevande / e industria alimentare?	X		
Totale		4	0	
%		100%	0%	
30	La gestione della sicurezza alimentare di ingredienti e materie prime è assicurata?	X		
	Le materie prime da utilizzare nella produzione sono state chiaramente identificate e ispezionate?	X		
	Le materie prime sono state immagazzinate in aree controllate per evitarne possibili contaminazioni?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Le materie prime sono state manipolate o processate in modo da evitarne la contaminazione?	X		
	L'acqua utilizzata per il lavaggio, risciacquo, o il trasporto di alimenti è sicura e di qualità sanitaria adeguata?	X		
Totale		5	0	
%		100%	0%	
31	Il ghiaccio, se utilizzato, è prodotto con acqua potabile e immagazzinato e manipolato in modo igienico?			Non utilizzato
	L'acqua utilizzata per creare il ghiaccio è sicura e di adeguata qualità sanitaria?			
	Il ghiaccio viene manipolato e conservato in modo pulito e igienico fino al momento dell'uso?			
Totale				
%				
32	La lavorazione degli alimenti è condotta in modo da prevenire la contaminazione e minimizzare la crescita microbiologica indesiderata?	X		
	Viene eseguito un attento monitoraggio di fattori fisici come tempo, temperatura, pH, pressione e portata?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Esiste un piano per prevenire il deterioramento e la contaminazione di ingredienti, materiali di imballaggio e birra durante i periodi di guasto / fermo impianto?	X		
Totale		3	0	
%		100%	0%	
33	Sono fatti test analitici di controllo di tipo chimico, fisico o microbiologico per identificare problemi di contaminazione degli alimenti?	X		
	La struttura è dotata di strumenti o mezzi per effettuare test per individuare materiali estranei, sostanze chimiche o contaminazioni microbiologiche?	X		
	Sono impiegati strumenti come setacci, trappole, magneti, rilevatori di metalli o altri mezzi efficaci?	X		
Totale		3	0	
%		100%	0%	
34	I processi e i materiali di imballaggio sono adeguati a prevenire la contaminazione del prodotto?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Esiste un controllo di qualità documentato su tutti i punti critici di controllo del confezionamento per garantire la sicurezza del consumatore?	X		
	L'identificazione e la tracciabilità sono mantenute per tutti i materiali di imballaggio?	X		
	I materiali di imballaggio sono sicuri e adatti all'uso previsto?	X		
	I prodotti / materiali ricevono protezione fisica dalla contaminazione, in particolare dalla contaminazione per via aerea?	X		
	Le procedure igienico-sanitarie sono rispettate e i materiali sono conservati non a diretto contatto con il pavimento?	X		
Totale		6	0	
%		100%	0%	
35	Sono utilizzati solo alimenti e/o additivi e coloranti approvati?	X		
	Sono utilizzati solo ingredienti il cui uso è riconosciuto come sicuro dalle norme e dalla conoscenza scientifica attuale?	X		
	Sono utilizzati solo additivi e coloranti il cui uso è generalmente riconosciuto come sicuro?	X		
	Tutti i prodotti che contengono cibo e/o additivi colorati sono etichettati come tali?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
Totale		4	0	
%		100%	0%	
36	I prodotti sono codificati per consentire un'identificazione certa del lotto e le registrazioni sono mantenute oltre la vita commerciale prevista?	X		
	Tutte le etichette dei prodotti sono conformi alle norme per le bevande alcoliche?	X		
	Le identificazioni del lotto e le date sono leggibili e facili da identificare e interpretare?	X		
	Tutte le registrazioni dei lotti precedenti sono conservate in ordine cronologico e sono di facile accesso e interpretazione?	X		
Totale		4	0	
%		100%	0%	
37	Le pratiche di pesatura e misurazione sono adeguate a garantire la quantità dichiarata dei contenuti?	X		
	Esiste uno scostamento standard massimo consentito per un singolo lotto oltre il quale lo scostamento è considerato non accettabile?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	La quantità netta media di contenuto in un lotto (± le tolleranze previste) equivale almeno alla quantità netta di contenuto dichiarata in etichetta?	X		
	Le variazioni consentite sono limitate in modo che la media delle quantità nel pacco non sia inferiore alla quantità indicata in etichetta?	X		
Totale		4	0	
%		100%	0%	
38	I monitoraggi e le verifiche prendono in considerazione anche le etichette dei prodotti?	X		
	Tutte le etichette delle birre e dei keg / bariletti sono conformi alle norme per le bevande alcoliche?	X		
Totale		2	0	
%		100%	0%	
39	I prodotti finiti sono immagazzinati e spediti in condizioni tali da evitare contaminazioni e deterioramenti?	X		
	Qualora esistesse una possibilità di contaminazione crociata, i processi interessati sono adeguatamente separati in modo efficace?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Tutti i risultati sono registrati su un rapporto di spedizione o su un rapporto di servizio per documentare le eventuali carenze nella gestione?	X		
	Se utilizzati, tutti i mezzi di trasporto sono stati verificati come puliti prima del carico con ingredienti, materie prime o birra?	X		
	Il caricamento di veicoli o container viene effettuato in modo tale da evitare danni e proteggere i carichi per evitare spostamenti indesiderati durante il transito in fase di trasporto merce?	X		
	Il personale è stato informato e addestrato in merito ai prodotti che richiedono condizioni di trattamento speciali?	X		
Totale		6	0	
%		100%	0%	
Totale del criterio		41	0	
%		100%	0%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
GMP	PERSONALE			
40	Il personale con malattie, lesioni, infezioni, ecc. è limitato/esonerato/inibito nella manipolazione di prodotti alimentari?	X		
	Esiste una procedura operativa standard scritta (SOP) per prevenire la contaminazione del prodotto da parte di personale con malattie tali che impediscano loro di lavorare nella produzione, fermentazione e confezionamento e in qualsiasi altro luogo in cui potrebbero contaminare il prodotto?	X		
	La SOP copre malattie gastrointestinali e respiratorie, ferite aperte, bolle cutanee, ecc.?	X		
	Quanto sopra è spiegato anche ai visitatori e agli appaltatori?	X		
Totale		4	0	
%		100%	0%	
41	I dipendenti, quando trattano gli alimenti, indossano indumenti esterni puliti, usano adeguati contenimenti per i capelli e la barba e rimuovono i gioielli?	X		
	Il birrificio fornisce indumenti di lavoro per i dipendenti che lavorano in aree critiche, quali fermentazione, confezionamento, ecc.?		X	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Gli indumenti di lavoro sono lavati regolarmente?	X		
	I vestiti e gli oggetti personali sono conservati in un'area diversa dalla produzione?	X		
	Nelle aree di produzione i capelli e la barba sono trattenuti da reti, cuffie, mascherine, ecc.?	X		
	I dipendenti usano i guanti quando entrano in contatto con la birra, ad es. per accoppiare i tubi flessibili, maneggiare bottiglie e lattine, ecc.?	X		
	In aree laddove ingredienti, mosto, birra o contenitori sono aperti o esposti, sono indossati indumenti puliti e utilizzate cuffie per capelli e mascherine per barba?	X		
	Nell'area di imbottigliamento e imballaggio vengono vietati piercing, braccialetti e orologi?	X		
	Sempre nell'area packaging, sono ammessi soltanto anelli basici, collane all'interno di una maglietta e occhiali mantenuti da cordicella?	X		
	Nell'intero birrificio sono ammessi solo semplici anelli, collane sotto una camicia o maglietta e orecchini fermi?	X		
	Le tasche delle camicie sono cucite, chiuse da cerniere o tenute libere da oggetti che potrebbero cadere negli ingredienti, nel mosto o nella birra?	X		

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
	Viene adottata ogni prevenzione per evitare la contaminazione della birra da parte di traspirazione, cosmetici, prodotti chimici e farmaci topici?	X		
Totale		11	1	
%		92%	8%	
42	I dipendenti lavano e igienizzano accuratamente le loro mani quando e se è necessario?	X		
	Le postazioni di lavaggio sono disponibili negli spogliatoi affinché i dipendenti si lavino le mani prima di iniziare il lavoro?	X		
	Le postazioni di lavaggio sono disponibili in aree accessibili in modo che i dipendenti possano lavarsi le mani durante il turno o al ritorno al lavoro?	X		
	Sono disponibili sapone igienizzante e attrezzature o materiali di asciugatura adeguati?	X		
	Ai lavandini è disponibile l'acqua tiepida ad una temperatura di almeno 35 – 45°C?	X		
Totale		5	0	
%		100%	0%	

Item No.	Criteri di ispezione per argomenti	SI	NO	Note
43	I dipendenti si astengono dal mangiare, bere e fumare e osservano le buone tecniche/pratiche di manipolazione degli alimenti nelle aree di lavoro?	X		
	È chiaramente indicato che è vietato mangiare nelle aree di produzione?	X		
	È chiaramente indicato che è vietato bere bevande nelle aree di produzione?	X		
	È chiaramente indicato che è vietato masticare chewing gum e simili nelle aree di produzione?	X		
	È chiaramente indicato che il fumare è limitato alle apposite aree designate e lontane dalla produzione?	X		
Totale		5	0	
%		100%	0%	
Totale del criterio		25	1	
%		96%	4%	

Table 61. Results from the GMP checklist of the Ofelia Snc brewery in July 2018.

AUDIT SUMMARY ON GOOD MANUFACTURING PRACTICES	FULL CONFORMITY	NON-CONFORMITY
PLANT	29	4
EQUIPMENT	10	1
HYGIENE	32	2
CLEANING	38	4
PROCESSES	41	0
STAFF	25	1
TOTAL SUM OF CRITERIA	175	12
%	93.6%	6.4%

Appendix 1

Food product “Vitajam” and update of a HACCP plan

Introduction

The company “I Rodi” by Raemy Helen & C. simple agricultural company based in via Cimalotta 848/a 41021 Fanano (Modena), Ateco[79] code 01.25 - Cultivation of other fruit trees, berries and nuts, produces jams, compotes, syrup, fruit pulp, extracts, juices, nectar, muesli, and herbal teas. In addition, it deals with the collection and storage of cultivated or spontaneous fruit, fruit drying, and carries out work on behalf of third parties.

The company “I Rodi” asked our study group to provide an HACCP plan for their new product called Vitajam. This is a vitamin additive for jams, juices and food in general with nutritional purposes for the finished product.

[79] The Ateco code is an alphanumeric combination that identifies an economic activity. The letters identify the economic macro-sector while the numbers (from two to six digits) represent, with different degrees of detail, the specific articulations and sub-categories of the sectors themselves.

Background

In the “i Rodi” company, the HACCP plan concerns the analysis of food safety hazards, the determination of critical control points, preventive actions, control actions and corrective measures. Then, in accordance with European Regulations, the company implements good hygiene practices when receiving raw materials, storing, processing, packaging, labeling and shipping the final products. In addition, it implements good manufacturing practices in all production processes.

Methods

Elements of auditing

The Regulation (EC) No. 882/2004 defines an audit as a:

<< systematic and independent examination to establish whether the activities and the related results comply with the envisaged provisions and whether these methods are effectively implemented and are suitable for achieving the objectives >>.

Audits can be performed internally, externally or by third parties. The audit approach should be based on the internationally agreed standard format, as described in ISO 19011 on Guidelines for the review of quality and environmental management systems (UNI, 2019). Normally, the auditor follows the scheme in the table as a guideline by examining the main and secondary aspects of the documentation. The next step is to evaluate the HACCP plan in both practical and documentary aspects before drawing conclusions.

Table 62. Main phases of an HACCP audit

STAGE	PRACTICE
AUDIT START	Formal activation of the audit
RECOVERY OF DOCUMENTATION	Acquisition of available documentation
PREPARATION OF THE AUDIT	Auditing planning
AUDITING ACTIVITIES IN THE PRODUCTION SITE	Opening meeting with company representatives
	Documentation review
	Audit process: analysis of procedures and processes
	Registration of non-conformities
	Final meeting
REPORT PREPARATION	Issue of the report
	Resolution and end of non-conformities

The purpose of an audit of an HACCP system by the competent authority is to have evidence that the HACCP principles have been implemented, the prerequisites and the HACCP plan are correctly implemented and that the self-control system has been kept operational over time.

On the one hand, in a large and complex food company, the competent authorities carry out inspections of the premises, observe the production process focusing on the hygiene aspects, observe the premises, workers and practices. In particular, the prerequisites for food hygiene as compliance requirements are noted and recorded as significant elements. Therefore, the competent authority controls many different operations that present a different level of complexity, both in terms of process and documentation.

On the other hand, in a small food company fewer complex transaction procedure produce fewer documentary reports. In these cases, the competent authority may have more time to critically observe the operating practices inherent in the production processes and the personnel and, if necessary, to question the procedures.

In any case, regardless of the size of the company, the approach to auditing is the same because the final objective of an audit is to establish whether the food or feed business operator is able or not to produce safe products.

Results

Product description

Generic description

The Vitajam product is a gelatinous compound containing a dispersion of vitamins and flavouring.

Description of the ingredients

The compound contains: amidated pectin (E440b), vitamin C (ascorbic acid, E300), vitamin E (tocopherol, E307), flavouring (beet taste).

Microbiological safety of the product

Products must comply with European Union legislation implemented in Italian national legislation. In particular, all the microbiological safety parameters concerning the maximum admissible quantities of pesticide residues, the legal obligations regarding preservatives, colourings, flavourings, acidity regulators must be respected.

Legal references

Commission Regulation (EC) No. 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, whose latest updated version is dated 01/01/2018.

Commission Regulation (EU) No. 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives, whose latest updated version is dated 21/11/2013.

Table 63. Maximum permissible levels of pathogenic microorganisms in food products

MICROORGANISMS	MAXIMUM DESIDERABLE LEVELS (number of colonies per gram, presence on 25 grams)
Bacillus cereus	10^4/g
Campylobacter jejuni	Absent/25 g
Clostridium botulinicus	Absent/10 g
Escherichia coli o157: h 7 and other verotoxin-producing strains	Absent/25 g
Pseudomonas aeruginosa	10^3/g
Shigella spp.	Absent/25 g
Yersinia enterocolitica (enteropathogenic serotypes)	Absent/25 g
Listeria monocytogenes	Absent/25 g

Product declarations

At the time of writing, some items are still being examined by management. Missing declarations are indicated with the initials NS meaning *not stated* or NA meaning *not applicable* or *not available*.

Finished product packaging

Containers of ... (name of the material): NS

Nominal content of containers / cans… (grams) / (millilitres): NS

Capsules / lids in ... (material name): NS

Shelf life

Minimum shelf life or expiry date: NS

To be consumed by ... (shelf life or expiry date): NS

Approved and expected human use

Example: ... Adults, children aged > ... (years)

Instructions for the consumer / user

Example: ... Store away from light, away from heat sources, in a dry place.

Manufacturing use

Product suitable for adding and emulsifying hydro and liposoluble vitamins in foods such as jams, juices and food in general.

Average nutritional values

Table 64. Nutrient values of Pectin.

	Unit	Value per 100 g		Unit	Value per 100 g
Nutrients			Vitamins		
Water	g	8.70	Vitamin A	IU	3
Energy	kcal	325	Riboflavin	mg	0.060
Protein	g	0.30	Vitamin B6	mg	0.010
Total lipid	g	0.30	Thiamine	mg	0.008
Carbohydrate	g	90.40	Niacin	mg	0.005
Fibre	g	8.6			
Minerals					
Sodium	mg	200			
Calcium	mg	7			
Potassium	mg	7			
Iron	mg	2.71			
Phosphorus	mg	2			

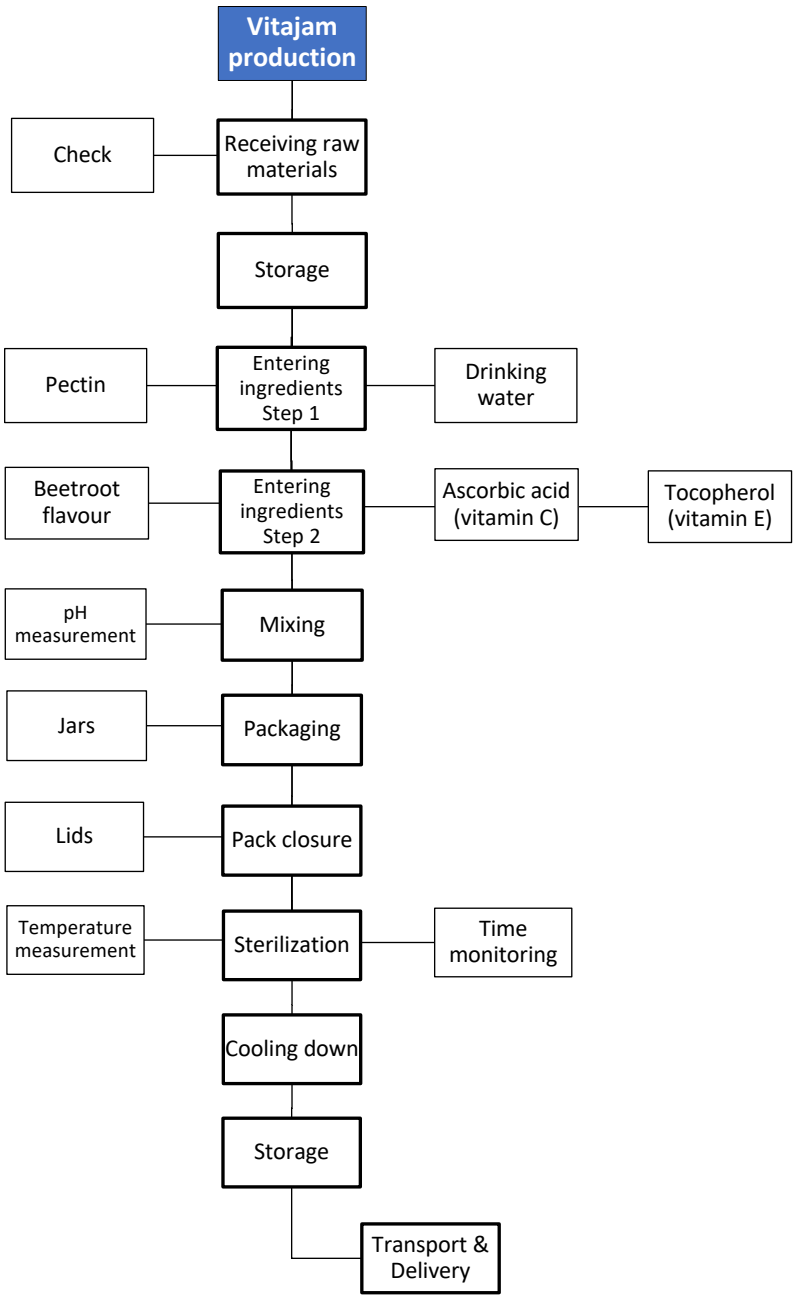
(Source: United States Department of Agriculture, Agricultural Research Service, National Nutrient Database for Standard Reference Legacy Release)

Discussion and conclusions

As for the pasteurization, labeling, raw material verification, product verification, work environments and equipment, prerequisites, good hygiene practices, good manufacturing practices, hazard identification, identification of critical control points, monitoring of points control critics, the corrective actions to be implemented to restore the smooth running of the production processes are confirmed. Furthermore, the provisions set out in the self-control plan regarding the monitoring, recording and storage of the documentation are confirmed. In particular, this document represents an addition to the HACCP plan of 29/01/2018 drawn up by the company “Progetto ambiente Srl”.

Production process

Figure 35. Vitajam product flow chart.



(Chart created by the author)

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Commission Regulation (EC) No. 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, whose latest updated version is dated 01/01/2018.

Commission Regulation (EU) No. 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives, whose latest updated version is dated 21/11/2013.

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Appendix 2

Designing a survey about certification

Note

This survey was conceived for educational purposes only and was planned in the last period of the study to create a future field of investigation.

Preface

Any company can adopt an internal investigation model that allows evaluating the actions taken to achieve certain results. In this context, the principles of the ISO 9001 series and those of the European Foundation for Quality Management (Sallis, 2002) may be useful.

On the one hand, to understand what the company does to achieve its objectives, it is necessary to analyze several aspects. The main ones are strategic policy, leadership, resource management, process implementation, staff motivation, and other complementary but no less important aspects such as, for example, the commitment of management.

On the other hand, to evaluate the actual achievement of the objectives, it is necessary to monitor aspects such as customer satisfaction, staff compliance, the social and environmental impact of the productions, and the economic and financial indicators regarding the profit obtained.

Methods

Given the assumption that agri-food companies meet legal requirements on time, the survey was designed to understand the companies' approach to the need to qualify their processes and products.

The survey was called "Quality perceived vs. Effective quality, a 5 x 5 survey on the level of customer satisfaction regarding the topic of quality".

In essence, this is a survey designed to offer only 5 questions to be answered in just 5 minutes. The questions have been structured to answer the following questions.

1) Which of the following requirements are adopted in your company?
   Purpose: the first question examines compliance with the prerequisites and requirements established by public regulations.
2) Which certifications have not expired in your company?
   Purpose: the second question investigates the certifications held by the company and intends to analyse the company's propensity to improve processes and products.
3) In your opinion, what are the factors that business partners consider enhanced by certifications?
   Purpose: the third is an indirect question and intends to evaluate the meaning that the company gives to certification. In other words, the benefits that the company perceives from having a certification program in place.
4) Thinking about the current economic situation and the evolution of the market, what do you think about the renewal of the certification?
   Purpose: the fourth question considers the post-certification phase. The aim is to assess the degree of satisfaction or disappointment of the company towards the possession of the certification.
5) How often do you visit the website of your business sector and what do you read?
   Purpose: the fifth question intends to study the culture of the company and the topics of interest that give the motivation for senior management decisions.

Results and discussion

The survey questionnaire was proposed to a sample of 110 agri-food companies operating in the Emilia-Romagna region and belonging to 25 product sectors.

The response rate was 3 out of 110 companies invited to respond to the survey. So, the response rate was 2.73%.

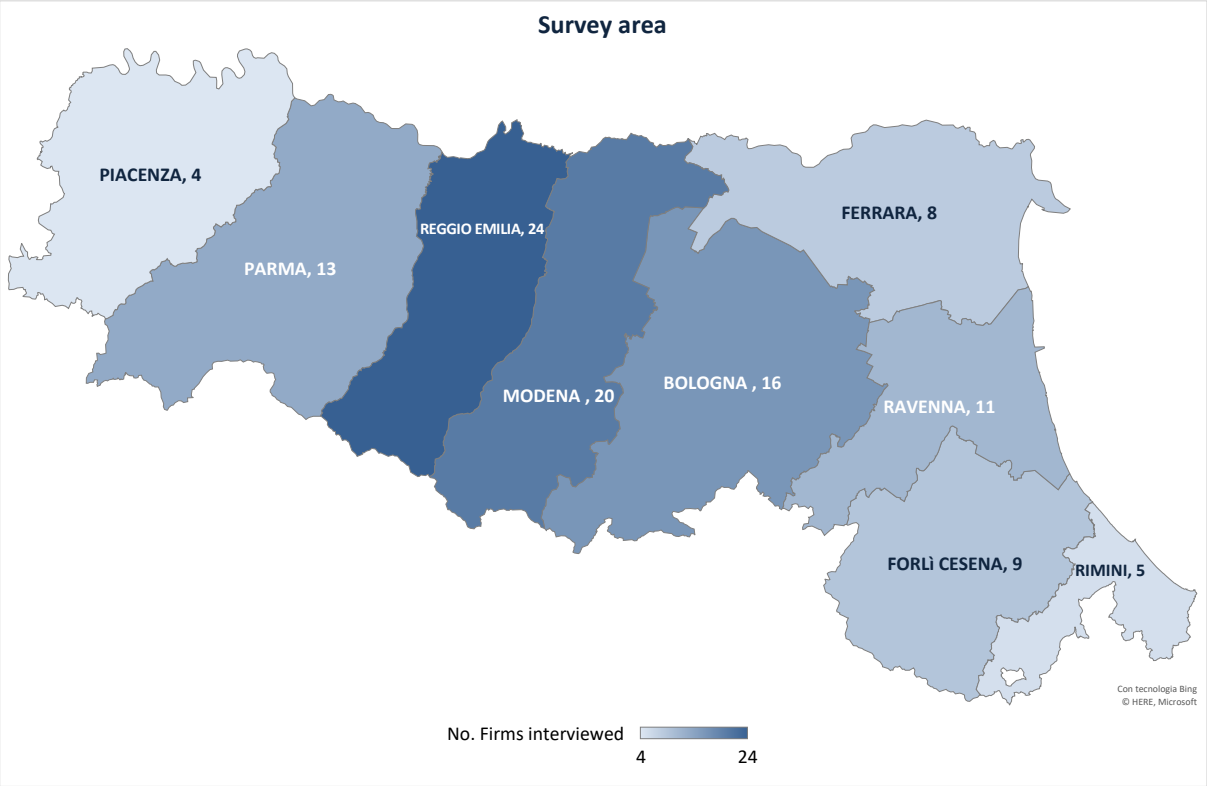
Limitation of study

Probably the number of answers does not make the survey significant because of the impossibility to verify the greater or lesser propensity to answer the questionnaire. Another trivial reason may have been the non-receipt or non-reading of the e-mail that sent the survey. This appears to be a problem common to many polls. However, such a fact-finding investigation may be the basis for future investigations.

Conclusions

Due to the limited number of answers it is not possible to draw definitive conclusions. However, for the future it would be interesting to carry out this type of study, for example, in collaboration with the local Chambers of Commerce and trade associations in order to obtain greater adhesion and therefore make the survey significant.

Figure 36. Geographical area covered by the survey.



(Key: the numbers indicate the number of companies interviewed)

Answer #1

Qualità percepita & Qualità effettiva

Le presento un'indagine conoscitiva 5 x 5 sul livello di soddisfazione dei clienti circa il tema della qualità.

Solo 5 domande in soli 5 minuti per esprimere l'opinione nell'ambito dello studio di ricerca Qualità percepita e Qualità effettiva nel settore agroalimentare.

Riferimenti
Ricercatore: De Giorgio Roberto, https://personale.unimore.it/rubrica/dettaglio/182704
Tutor: Prof. Pulvirenti Andrea, https://personale.unimore.it/rubrica/dettaglio/apulvirenti
Scuola di Dottorato dell'Università di Modena e Reggio Emilia: http://www.steba.unimore.it/site/home.html

L'indirizzo email è richiesto per inviarle una copia del modulo da Lei compilato.

Ringrazio per la cortese disponibilità e resto a disposizione per ogni informazione e futuri aggiornamenti.
Con i migliori saluti, Roberto De Giorgio.

Indirizzo email *

qualita@steriltom.com

Quali dei seguenti requisiti sono adottati presso la Sua azienda?
(Può indicare più di una voce)

- [x] GHP - Good Hygiene Practices / Buone Pratiche di Igiene
- [x] GMP - Good Manufacturing Practices / Buone Pratiche di Fabbricazione
- [ ] GAP - Good Agricultural Practices / Buone Pratiche Agricole
- [x] HACCP Hazard Analysis and Critical Control Points / Analisi dei Rischi e valutazione dei Punti Critici di Controllo
- [ ] Altro: .....

Quali sono le certificazioni non scadute presenti nella Sua azienda?
(Può segnare più voci)

- [x] BIOLOGICO / Organic
- [x] BRC Food
- [ ] BRC Packaging
- [ ] DOP Denominazione di Origine Protetta
- [ ] FAIRTRADE (commercio equo e solidale)
- [x] FDA Registration (per il commercio verso USA)
- [ ] FSSC 22000
- [ ] GLOBAL GAP
- [ ] GLUTEN FREE
- [ ] GMO FREE / NON OGM
- [x] HALAL
- [x] IFS Food
- [ ] IFS PACsecure (per imballaggi)
- [ ] IGP Indicazione Geografica Protetta
- [x] ISO 9001
- [x] ISO 14001
- [ ] ISO 22000
- [x] ISO 22005 (rintracciabilità)
- [x] KOSHER
- [ ] LACTOSE FREE

- [x] OHSAS 18001 (o ISO 45001)
- [ ] STG Specialità Tradizionale Garantita
- [ ] UTZ Rainforest Alliance (sostenibilità)
- [ ] VEGAN
- [x] Altro: Marchio QC

Secondo Lei, quali sono i fattori che i partner commerciali considerano tutelati dalle certificazioni?

	Significativo	Importante	Indifferente	Poco utile	Ininfluente
Le norme legali per la sicurezza agroalimentare	☑	☐	☐	☐	☐
Il sistema di gestione della qualità	☐	☑	☐	☐	☐
Il sistema di gestione della salute e sicurezza sul lavoro	☐	☑	☐	☐	☐
Il sistema di gestione della sicurezza alimentare	☐	☑	☐	☐	☐
La rintracciabilità delle merci nella filiera	☐	☑	☐	☐	☐
La produzione libera da organismi geneticamente modificati	☐	☑	☐	☐	☐
La produzione integrata nel biologico	☑	☐	☐	☐	☐
L'efficienza dei processi di produzione alimentare	☐	☑	☐	☐	☐

La qualità delle colture agricole, degli allevamenti e delle acquacolture	☐	☑	☐	☐	☐
La conformità degli imballaggi e delle etichette	☐	☐	☑	☐	☐
L'accesso al mercato internazionale	☐	☑	☐	☐	☐

Considerando l'attuale congiuntura economica e l'evoluzione del mercato, Lei pensa che rinnovare una certificazione o acquisirne una nuova:

	Molto	Abbastanza	Non sembra determinante	Non molto	Poco
Consenta di ampliare le opportunità del mercato?	☐	☑	☐	☐	☐
Incentivi il personale a sentirsi parte di un progetto di prestigio?	☐	☑	☐	☐	☐
Sostenga l'azienda verso la ricerca e lo sviluppo di nuovi obiettivi?	☐	☑	☐	☐	☐
Semplifichi il rispetto degli obblighi di legge circa la sicurezza alimentare?	☑	☐	☐	☐	☐

Quanto spesso visita e cosa legge sul sito web del Suo settore imprenditoriale?

	Spesso	Regolarmente	A volte	Occasionalmente	Quasi mai
Le Notizie Nazionali	☐	☑	☐	☐	☐
Le Notizie Globali	☐	☑	☐	☐	☐
La Sezione normativa	☐	☑	☐	☐	☐
La Sezione Economica	☐	☐	☑	☐	☐
La Sezione Ricerca & Sviluppo	☑	☐	☐	☐	☐

Questo è un Suo spazio per domande e commenti.

Answer #2

Qualità percepita & Qualità effettiva

Le presento un'indagine conoscitiva 5 x 5 sul livello di soddisfazione dei clienti circa il tema della qualità.

Solo 5 domande in soli 5 minuti per esprimere l'opinione nell'ambito dello studio di ricerca Qualità percepita e Qualità effettiva nel settore agroalimentare.

Riferimenti
Ricercatore: De Giorgio Roberto, https://personale.unimore.it/rubrica/dettaglio/182704
Tutor: Prof. Pulvirenti Andrea, https://personale.unimore.it/rubrica/dettaglio/apulvirenti
Scuola di Dottorato dell'Università di Modena e Reggio Emilia: http://www.steba.unimore.it/site/home.html

L'indirizzo email è richiesto per inviarle una copia del modulo da Lei compilato.

Ringrazio per la cortese disponibilità e resto a disposizione per ogni informazione e futuri aggiornamenti.
Con i migliori saluti, Roberto De Giorgio.

Indirizzo email *

ivano.fornaciari@premixsrl.it

Quali dei seguenti requisiti sono adottati presso la Sua azienda?
(Può indicare più di una voce)

- [ ] GHP - Good Hygiene Practices / Buone Pratiche di Igiene
- [x] GMP - Good Manufacturing Practices / Buone Pratiche di Fabbricazione
- [ ] GAP - Good Agricultural Practices / Buone Pratiche Agricole
- [ ] HACCP Hazard Analysis and Critical Control Points / Analisi dei Rischi e valutazione dei Punti Critici di Controllo
- [ ] Altro: .....

Quali sono le certificazioni non scadute presenti nella Sua azienda?
(Può segnare più voci)

- [x] BIOLOGICO / Organic
- [ ] BRC Food
- [ ] BRC Packaging
- [ ] DOP Denominazione di Origine Protetta
- [ ] FAIRTRADE (commercio equo e solidale)
- [ ] FDA Registration (per il commercio verso USA)
- [ ] FSSC 22000
- [ ] GLOBAL GAP
- [ ] GLUTEN FREE
- [x] GMO FREE / NON OGM
- [ ] HALAL
- [ ] IFS Food
- [ ] IFS PACsecure (per imballaggi)
- [ ] IGP Indicazione Geografica Protetta
- [ ] ISO 9001
- [ ] ISO 14001
- [ ] ISO 22000
- [ ] ISO 22005 (rintracciabilità)
- [ ] KOSHER
- [ ] LACTOSE FREE

- [ ] OHSAS 18001 (o ISO 45001)
- [ ] STG Specialità Tradizionale Garantita
- [ ] UTZ Rainforest Alliance (sostenibilità)
- [ ] VEGAN
- [x] Altro: GMP e FAMIQS

Secondo Lei, quali sono i fattori che i partner commerciali considerano tutelati dalle certificazioni?

	Significativo	Importante	Indifferente	Poco utile	Ininfluente
Le norme legali per la sicurezza agroalimentare	☐	☑	☐	☐	☐
Il sistema di gestione della qualità	☐	☑	☐	☐	☐
Il sistema di gestione della salute e sicurezza sul lavoro	☐	☑	☐	☐	☐
Il sistema di gestione della sicurezza alimentare	☑	☐	☐	☐	☐
La rintracciabilità delle merci nella filiera	☐	☑	☐	☐	☐
La produzione libera da organismi geneticamente modificati	☐	☐	☐	☑	☐
La produzione integrata nel biologico	☐	☑	☐	☐	☐
L'efficienza dei processi di produzione alimentare	☐	☑	☐	☐	☐

La qualità delle colture agricole, degli allevamenti e delle acquacolture	☐	☑	☐	☐	☐
La conformità degli imballaggi e delle etichette	☐	☐	☑	☐	☐
L'accesso al mercato internazionale	☐	☐	☑	☐	☐

Considerando l'attuale congiuntura economica e l'evoluzione del mercato, Lei pensa che rinnovare una certificazione o acquisirne una nuova:

	Molto	Abbastanza	Non sembra determinante	Non molto	Poco
Consenta di ampliare le opportunità del mercato?	☐	☑	☐	☐	☐
Incentivi il personale a sentirsi parte di un progetto di prestigio?	☐	☐	☑	☐	☐
Sostenga l'azienda verso la ricerca e lo sviluppo di nuovi obiettivi?	☐	☑	☐	☐	☐
Semplifichi il rispetto degli obblighi di legge circa la sicurezza alimentare?	☐	☐	☐	☑	☐

Quanto spesso visita e cosa legge sul sito web del Suo settore imprenditoriale?

	Spesso	Regolarmente	A volte	Occasionalmente	Quasi mai
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Le Notizie Globali	☐	☐	☑	☐	☐
La Sezione normativa	☐	☐	☑	☐	☐
La Sezione Economica	☐	☐	☑	☐	☐
La Sezione Ricerca & Sviluppo	☐	☐	☑	☐	☐

Questo è un Suo spazio per domande e commenti.

Answer #3

Qualità percepita & Qualità effettiva

Le presento un'indagine conoscitiva 5 x 5 sul livello di soddisfazione dei clienti circa il tema della qualità.

Solo 5 domande in soli 5 minuti per esprimere l'opinione nell'ambito dello studio di ricerca Qualità percepita e Qualità effettiva nel settore agroalimentare.

Riferimenti
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Indirizzo email *

graziella.montanari@italisrl.com

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Il sistema di gestione della salute e sicurezza sul lavoro	☑	☐	☐	☐	☐
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La produzione libera da organismi geneticamente modificati	☐	☐	☐	☐	☐
La produzione integrata nel biologico	☐	☐	☐	☐	☐
L'efficienza dei processi di produzione	☐	☐	☐	☐	☐

alimentare					
La qualità delle colture agricole, degli allevamenti e delle acquacolture	☑	☐	☐	☐	☐
La conformità degli imballaggi e delle etichette	☐	☑	☐	☐	☐
L'accesso al mercato internazionale	☑	☐	☐	☐	☐

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Sostenga l'azienda verso la ricerca e lo sviluppo di nuovi obiettivi?	☐	☐	☑	☐	☐
Semplifichi il rispetto degli obblighi di legge circa la sicurezza alimentare?	☑	☐	☐	☐	☐

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La Sezione Economica	☐	☐	☐	☑	☐
La Sezione Ricerca & Sviluppo	☑	☐	☐	☐	☐

Questo è un Suo spazio per domande e commenti.

Table 65. Interviewed companies.

ATECO Code[80]	**Business sectors**	**Firm name**	**County**
10.1	Processing and preservation of meat and production of meat products	CLAI	BOLOGNA
10.1	Processing and preservation of meat and production of meat products	LEM CARNI	BOLOGNA
10.1	Processing and preservation of meat and production of meat products	CASTELFRIGO	MODENA
10.1	Processing and preservation of meat and production of meat products	SUINCOM	MODENA
10.1	Processing and preservation of meat and production of meat products	GOLFERA IN LAVEZZOLA	RAVENNA
10.1	Processing and preservation of meat and production of meat products	BERVINI	REGGIO EMILIA
10.12	Production of poultry meat and products of their slaughter	RCA	REGGIO EMILIA
10.2	Processing and preservation of fish, crustaceans and molluscs by freezing, salting, etc.	FINITTICA	FERRARA
10.2	Processing and preservation of fish, crustaceans and molluscs by freezing, salting, etc.	FOODLAB	PARMA
10.2	Processing and preservation of fish, crustaceans and molluscs by freezing, salting, etc.	RIZZOLI EMANUELLI	PARMA
10.3	Processing and preservation of fruit and vegetables	CONSERVE ITALIA	BOLOGNA

[80] The Ateco code is an alphanumeric combination that identifies an economic activity. The letters identify the economic macro-sector while the numbers (from two to six digits) represent, with different degrees of detail, the specific articulations and sub-categories of the sectors themselves. In Italy from 1st January 2008 the new Ateco 2007 classification is in force, approved by ISTAT (National Statistical Institute) in close collaboration with the Revenue Agency, Chambers of Commerce and other interested Bodies, Ministries and associations.

10.3	Processing and preservation of fruit and vegetables	CAVICCHI	FERRARA
10.3	Processing and preservation of fruit and vegetables	SIPO	RIMINI
10.32	Production of fruit and vegetable juices	TOSCHI	MODENA
10.32	Production of fruit and vegetable juices	GEMMA	PIACENZA
10.32	Production of fruit and vegetable juices	FRUTTAGEL	RAVENNA
10.32	Production of fruit and vegetable juices	SUECO	RAVENNA
10.32	Production of fruit and vegetable juices	IL CANARINO	REGGIO EMILIA
10.39	Processing and preservation of fruit and vegetables (excluding fruit and vegetable juices)	AGRIMOLA	BOLOGNA
10.39	Processing and preservation of fruit and vegetables (excluding fruit and vegetable juices)	FABBRI 1905	BOLOGNA
10.39	Processing and preservation of fruit and vegetables (excluding fruit and vegetable juices)	LA CESENATE CONSERVE ALIMENTARI	FORLI'-CESENA
10.39	Processing and preservation of fruit and vegetables (excluding fruit and vegetable juices)	STERILTOM	PIACENZA
10.39	Processing and preservation of fruit and vegetables (excluding fruit and vegetable juices)	ITALFRUTTA	RAVENNA
10.4	Production of vegetable and animal oils and fats	FRANTOIO OLEARIO ORO VERDE	BOLOGNA
10.4	Production of vegetable and animal oils and fats	OLEIFICIO DEI CASTELLI	REGGIO EMILIA
10.41.1	Production of oils and fats	OLITALIA	FORLI'-CESENA
10.41.1	Production of oils and fats	GIGI IL SALUMIFICIO	MODENA
10.41.1	Production of oils and fats	OLEIFICIO PASQUINONI	RIMINI
10.42	Production of margarine and similar edible fats	EULIP	PARMA
10.42	Production of margarine and similar edible fats	UNIGRA'	RAVENNA
10.51.2	Dairy industry, hygienic treatment, milk conservation	VALCOLATTE	PIACENZA

10.51.2	Dairy industry, hygienic treatment, milk conservation	ALIVAL	REGGIO EMILIA
10.52	Production of ice cream without direct sale to the public	CASA DEL GELATO	MODENA
10.52	Production of ice cream without direct sale to the public	GELOSTAR	MODENA
10.52	Production of ice cream without direct sale to the public	INDIAN – GELATO D'ITALIA	REGGIO EMILIA
10.52	Production of ice cream without direct sale to the public	LABORATORIO MONTE DI BEBBIO	REGGIO EMILIA
10.6	Grain processing, starch production and starch products	GRUPPO GULINELLI	FERRARA
10.61	Grain processing	GRANDI RISO	FERRARA
10.61	Grain processing	MOLINI PIVETTI	FERRARA
10.61	Grain processing	ANSEME	FORLI'-CESENA
10.61	Grain processing	MOLINI INDUSTRIALI	MODENA
10.61	Grain processing	AGUGIARO & FIGNA	PARMA
10.61	Grain processing	MOLINO GRASSI	PARMA
10.61	Grain processing	MOLINO SPADONI	RAVENNA
10.61	Grain processing	INDUSTRIA MOLITORIA DENTI	REGGIO EMILIA
10.7	Production of bakery and flour products	MULTICEREALS	BOLOGNA
10.7	Production of bakery and flour products	DOLCIARIA VAL D'ENZA	REGGIO EMILIA
10.7	Production of bakery and flour products	I.T.ALI.	REGGIO EMILIA
10.7	Production of bakery and flour products	LIODRY FOODS	REGGIO EMILIA
10.7	Production of bakery and flour products	DOLCIARIA ROVELLI	RIMINI
10.71.1	Bread production; fresh pastry products	UNIPASTA	FERRARA
10.71.1	Bread production; fresh pastry products	C.R.M.	MODENA
10.72	Production of rusks and biscuits; production of preserved pastry products	RUGIADA	BOLOGNA

10.72	Production of rusks and biscuits; production of preserved pastry products	TATTINI	BOLOGNA
10.72	Production of rusks and biscuits; production of preserved pastry products	BABBI	FORLI'-CESENA
10.72	Production of rusks and biscuits; production of preserved pastry products	IPAM	PARMA
10.72	Production of rusks and biscuits; production of preserved pastry products	ARMONIE ALIMENTARI	REGGIO EMILIA
10.72	Production of rusks and biscuits; production of preserved pastry products	CABRIONI BISCOTTI	REGGIO EMILIA
10.72	Production of rusks and biscuits; production of preserved pastry products	GRISSIN BON	REGGIO EMILIA
10.72	Production of rusks and biscuits; production of preserved pastry products	LA MERENDERIA	RIMINI
10.73	Production of pasta, couscous and similar starchy products	PASTA FRESCA ROSSI	MODENA
10.73	Production of pasta, couscous and similar starchy products	GHIGI 1870	RAVENNA
10.73	Production of pasta, couscous and similar starchy products	SURGITAL	RAVENNA
10.73	Production of pasta, couscous and similar starchy products	GRANDI PASTAI ITALIANI	REGGIO EMILIA
10.81	Sugar production	COPROB	BOLOGNA
10.81	Sugar production	ERIDANIA	BOLOGNA
10.82	Production of cocoa, chocolate, candies and confectioneries	RIZZATI FERRARA	FERRARA
10.82	Production of cocoa, chocolate, candies and confectioneries	FLAMIGNI	FORLI'-CESENA
10.82	Production of cocoa, chocolate, candies and confectioneries	CIOCCOLAMI	MODENA
10.83.01	Tea and coffee processing	G.I.FI.ZE.	BOLOGNA
10.83.01	Tea and coffee processing	MOKADOR	RAVENNA
10.84	Production of condiments and spices	CABER	BOLOGNA
10.84	Production of condiments and spices	ACETAIA GIUSEPPE CREMONINI	MODENA

10.84	Production of condiments and spices	ACETIFICIO CARANDINI EMILIO	MODENA
10.84	Production of condiments and spices	ACETUM	MODENA
10.84	Production of condiments and spices	ALICO	MODENA
10.84	Production of condiments and spices	ANTICHI COLLI	MODENA
10.84	Production of condiments and spices	FATTORIE GIACOBAZZI	MODENA
10.84	Production of condiments and spices	MONARI FEDERZONI	MODENA
10.84	Production of condiments and spices	CERRETO	REGGIO EMILIA
10.85	Production of meals and ready meals	GI-GASTRONOMIA ITALIANA	BOLOGNA
10.85	Production of meals and ready meals	ITALPIZZA	MODENA
10.85	Production of meals and ready meals	PARMA IS	PARMA
10.85	Production of meals and ready meals	LA PIZZA + 1	PIACENZA
10.85	Production of meals and ready meals	REGGIANA GOURMET	REGGIO EMILIA
10.86	Production of homogenized preparations and diet foods	DIETOPACK	MODENA
10.86	Production of homogenized preparations and diet foods	EUDINAMIS	RAVENNA
10.89.09	Production of food products (not codified elsewhere)	APICOLTURA PIANA	BOLOGNA
10.89.09	Production of food products (not codified elsewhere)	VALPIZZA	BOLOGNA
10.89.09	Production of food products (not codified elsewhere)	LESAFFRE ITALIA	PARMA
10.89.09	Production of food products (not codified elsewhere)	PARMOVO	PARMA
10.89.09	Production of food products (not codified elsewhere)	MEC3 - OPTIMA	RIMINI
10.9	Production of animal feed products	ACME	REGGIO EMILIA
10.91	Production of feed for farm animals	M.B. MANGIMI	FORLI'-CESENA
10.91	Production of feed for farm animals	NEOFARMA	FORLI'-CESENA

10.91	Production of feed for farm animals	VALMORI MANGIMI	FORLI'-CESENA
10.91	Production of feed for farm animals	CARRA MANGIMI	PARMA
10.91	Production of feed for farm animals	SO.PR.E.D.	RAVENNA
10.91	Production of feed for farm animals	CASINI & MARANI	REGGIO EMILIA
10.91	Production of feed for farm animals	G.I.MA. GRUPPO ITALIANO MANGIMI	REGGIO EMILIA
10.91	Production of feed for farm animals	PREMIX	REGGIO EMILIA
10.91	Production of feed for farm animals	VETAGRO	REGGIO EMILIA
10.92	Production of pet feeding products	COFRIMAR	FERRARA
10.92	Production of pet feeding products	CONSORZIO GATTEO PROTEINE	FORLI'-CESENA
10.92	Production of pet feeding products	PAPPIFICIO PELITTA	MODENA
10.92	Production of pet feeding products	DOGGY MEAL	PARMA
10.92	Production of pet feeding products	IMPERIAL FOOD	PARMA
10.92	Production of pet feeding products	RACOF	PARMA
10.92	Production of pet feeding products	CHEMI–VIT	REGGIO EMILIA
46.21.22	Wholesale of seeds and livestock feed, medicinal plants, oilseeds, seed potatoes	NUTRISTAR	REGGIO EMILIA

Bibliography Appendix 2

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