



**FunTomP**

D4.5 Roadmap for FunTomP technology certification (M40)

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## EXECUTIVE SUMMARY

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The objective of FunTomP is to reestablish the Mediterranean Diet (MedD) in nowadays Mediterranean and European society through four functional products: tomato sauce, tomato juice, tomato leather and tomato bars. The goal of this deliverable is to identify regulations and certifications potentially applicable to FunTomP value chain, recommending the most suitable ones for a rapid market uptake.

Firstly, a systematic review of the current regulations, standards, and certifications in the European Union (EU) and world-wide was conducted to understand the mandatory requirements for functional food products. Secondly, essential regulations to be complied were identified, ensuring FunTomP products meet the baseline legal requirements. Thirdly, relevant standards and certifications were evaluated and selected for recommendation based on their significance and potential market impact. Finally, a structured roadmap was developed to outline the steps and timelines for achieving the recommended certifications, facilitating an organised and efficient implementation process.

The European regulatory landscape for functional products is extensive and varied, encompassing all aspects from formulation and microbiological testing to labelling. However, it is noteworthy that there is no formal definition for functional foods within the EU. The review and analysis led to the identification of ISO 22 000 as the primary standard to be implemented for the Food Management System, ensuring comprehensive food safety management. Additionally, the Foods for Specified Health Uses (FOSHU) certification was identified as critical for the international certification of functional foods, providing credibility and trust in global markets. Complementary recommendations include pursuing Kosher, Halal, and Organic Label certifications. These certifications, while not mandatory, offer significant commercial benefits by broadening the market appeal and catering to diverse consumer preferences. Additionally, actions such as Life Cycle Assessment (LCA) activities, updating management systems and best practices, and fostering international cooperation are recommended to ensure comprehensive compliance and market success. This roadmap provides a clear and actionable plan for FunTomP technology certification, positioning the products for successful market entry and sustained growth.

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# ABBREVIATIONS

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**CCPs:** Critical Control Points

**EC:** European Commission

**EFSA:** European Food Safety Authority

**EU:** European Union

**FAO:** Food and Agricultural Organization

**FIA:** Food Industry Association

**FOSHU:** Food for Specialized Health Uses

**GMPs:** Good Manufacturing Practices

**HACCP:** Hazard on Critical Control Points

**HPH:** High Pressure Homogenisation

**ISO:** International Standardization Organization

**LCA:** Life Cycle Assessment

**MedD:** Mediterranean Diet

**MHLW:** Ministry of Health Labour and Welfare of Japan

**OIE:** World Organization for Animal Health

**R&D:** Research and Development

**SDGs:** Sustainable Development Goals

**SQF:** Food Safety Code: Food Manufacturing

**TCs:** Technical committees

**WHO:** World Health Organization



# 1. INTRODUCTION

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Modern and developed societies have evolved their food concept and diet preferences beyond just obtaining necessary nutrients to also consider the relationship between diet and human health. Consequently, consumers choose certain food products over others to achieve health outcomes [1]. One of the well-recognised healthy diet preferences is the **MedD**. The MedD is a plant-based dietary pattern, full of vegetables, fruits, cereals, legumes, and nuts, complemented by moderate but beneficial fats such as olive oil, fish and shellfish, white meat, eggs, and dairy products. As a result of the abundance of resources available in such a region and over the course of history, the MedD was unique and associated with a healthy lifestyle [2]. Therefore, in November 2010, the MedD was recognized as part of the Intangible Cultural Heritage of Humanity by the United Nations Educational, Scientific, and Cultural Organization (UNESCO).

Along with this healthy diet demand, a particular and innovative food concept has emerged: **functional food products**. In the 1980s, the concept of functional food was introduced in Japan by a systematic regulatory system for functional foods. This concept was classified as “Food for Specified Health Uses” (FOSHU) and aims at *promoting health or reducing risks of diseases and controlling health conditions* [3].

In the EU context, the interest for functional foods started in the 1990s, establishing the European Commission (EC) Action called Functional Food Science in Europe (FUFOSE). The FUFOSE studies functional foods as the *potential to maintain or optimise physical and mental well-being, which may also reduce heart and gastrointestinal illnesses same as enhancing the immune systems* [4]. Worldwide recognition of functional foods and their nutritional values from both institutional and consumer perspectives has expanded **scientific research and developed promising technologies**. This has contributed to further advances in food products that support optimum healthcare. In such a context, the R&D case study for the FunTomP project is framed.

In the EU, 33 million people cannot afford a quality meal every day, and food assistance is essential for a part of the population in many Member States. Food insecurity and affordability risks have grown larger during recent economic crisis. Therefore, actions to change consumption patterns and curb food waste are needed. According to statistics, 20% of the food produced is wasted. Therefore, FunTomP products will help to reduce the gap between the food waste and the increasingly demand for cheap and nutritive food. [5]

Obesity is also rising inside the EU. Over half of the adult population are now overweight, contributing to a high prevalence of diet-related diseases (including various types of cancer) and related healthcare costs. Current European diets are not in line with national dietary recommendations. Furthermore, the food industry does not ensure healthy, ready-to-consume and affordable options. If European diets were in line with dietary recommendations, the environmental footprint of food systems would be significantly reduced [5]. So, certification for, healthy, zero waste product, and related claims should be aimed by FunTomP products in order to fill the gap between the concept of the product and the success of its commercialization.

As a matter of fact, the European Commission has conducted a survey in 2021 where a total of 26 570 entities participated (77% of the participants were citizens). A large majority of respondents (92%) agreed that the EU food systems should become more sustainable and believe that for this to happen is required a firm action mainly from public authorities (90%). When faced with the hypothesis of **an EU sustainability label being established, 77% of respondents considered that such a label should be mandatory.** Similarly, 83% of contributions underscored the necessity of setting food composition targets for added sugars, salt and saturated fat for processed and ultra-processed foods and meals. Therefore, it is expected that products that attend these needs of the public will be successful in their commercialization. [6]

The **objective** of the work accomplished within this task is to deliver valuable inputs for FunTomP products certification to positively impact on their potential marketability beyond the project. It is expected this roadmap will pave the way towards the commercialization of the products, being specific to several niche markets.

Regarding this deliverable, several legislations, certification, and regulatory frameworks have been assessed throughout the full project value chain. Transport, production of the foodstuff and storage are within the selected approach. Packaging and package related schemes have been excluded from the study as are out of the scope of the scientific and technological objectives of the project. Nevertheless, we refer to the reader to the public deliverable D2.6:” *Standardisation roadmap, and up-dated report of Legal, regulatory framework, REACH, and policies for plastic products and processes at M26*”, where a thorough analysis has been conducted in the topic in the frame of the NENU2PHAR (N2P) project [7].

## 1.1. Context and objectives of the work

The FunTomP project aims to **reformulate traditional Mediterranean** tomato products (i.e., juice and sauces) as functional foods. The project is investigating both tomato and olive, considered as the main ingredients of the MedD. Additionally, their nutritional value is being enhanced by using leaves from sugar beet plants (*Beta vulgaris L.*), by-products rich in protein source content.

In essence, FunTomP products offer extra health benefits to satisfy consumer's demand while keeping a sustainable product and process cycle with the **valorisation of agricultural waste**. Even though the proposed value chain is fully aligned with the EC **Farm to Fork Strategy**, at the heart of the European Green Deal, it is necessary to ensure an optimal environmental profile and preserve affordability for a competitive and sustainable deployment.

The present work is framed within WP4 on "*Formulation and quality evaluation of functional liquid tomato products*", having the following objectives:

1. Produce liquid functional tomato products (juices and sauces) using different technologies.
2. Determine the quality characteristics of the formulated products.
3. Test the effect of bio emulsifiers on the juices.
4. Determine the shelf life of the products, address a full sustainability analysis of FunTomP approach.
5. **Draw up a roadmap for FunTomP technology certification.**
6. Conduct an economic analysis for a large-scale production.

In particular, the present deliverable deals with the 5<sup>th</sup> objective, implementing a certification roadmap in order to gain knowledge to pave the way towards FunTomP products marketability. Indeed, from the regulations assessed, recommended standards will be highlighted and a proposal for the best fit certification (also including voluntary aspects) will be recommended.

The main purpose of this deliverable *D4.5 Roadmap for FunTomP technology certification* is to conduct a regulatory, standards and certification analysis, especially with the focus on food products compliance. The most relevant international and EU legal acts will be reviewed, including the identification on the standards and eco-label possibilities for the final products to evaluate the FunTomP market uptake and acceptability.

## 1.2. FunTomP products: Specifications

**Table 1** compiles the products developed within the project and assessed in this deliverable from a certification and standardisation point of view.

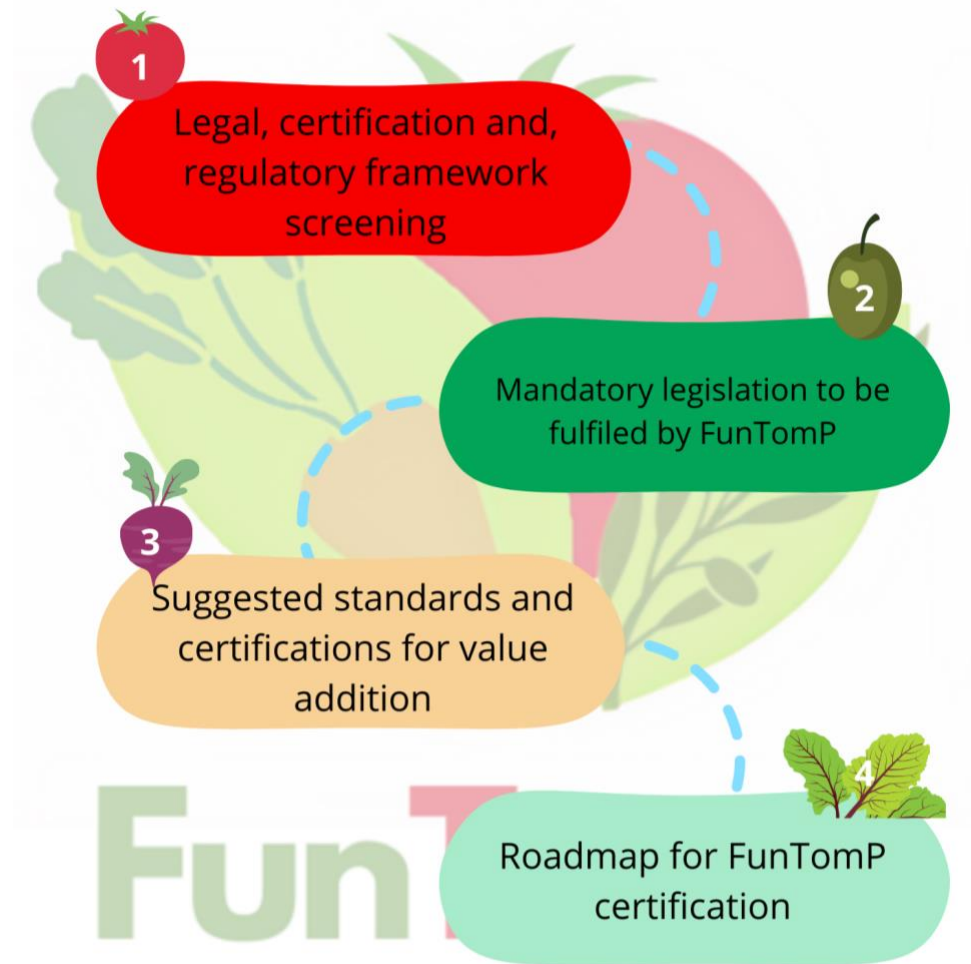
*Table 1. Specification of the FunTomP products.*

No.	Product	Responsible partner	Material	Processing Route
1	Dried tomato snack bar	METU	Tomato powder and juice, pectin, pea protein, olive powder, thyme, mint and red pepper	Drying, Grinding, Blending
2	Dried tomato leather	METU	Tomato juice, pea protein, olive powder, salt	Drying, High Pressure Homogenizer (HPH), Blending
3	Tomato juice	UAlg	Tomato, plant protein, olive powder	Cold Break Tomatoes, Centrifugation, hand Blending, High Pressure Homogenization, Pasteurization
4	Tomato sauce	UAlg	Tomato, plant protein, olive powder	Hot break of tomatoes, hand blending, high pressure homogenization, pasteurization

## 2. Methodology

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For the development of the FunTomP certification roadmap a four-step approach was formulated (as depicted in **Figure 1**). This approach includes: (1) a thorough screening of applicable legal framework review regarding certification available in the marketplace and regulatory framework; (2) identify certifications and standards that facilitates the accomplishment of the legal framework assessed; (3) identify on mandatory standards with high value on FunTomP's value chain; (4) kraft a roadmap synthesizing the mandatory regulation to follow and the procedure to obtain the selected certifications.



**Figure 1.** Road map step approach for FunTomP certification.

The search engines used were Google Scholar for scientific publications, Eur-Lex website for regulation and legal framework and Co-Pilot™ as a fast track for certifications and standards recommendation. The keywords used in these search engines were: **“sustainable food products”**, **“functional food certification”**, **“food regulations”**, **“claim regulations”**, and **“food standardization”**.

The result of the searching concluded in a review of the previous project documents, other research actions' outputs covering the same topic, legal literature, and other trustable sources such as specialised websites.

Collaboration of partners was also required regarding legal framework, certification, and standardization. Through interviews with partners, standards were recommended to assess, which was translated in time and effort saving for Lomartov staff. Furthermore, when the technical review was completed the opinion of partners was required for a more specialized outlook.

With this approach efforts were done to identify gaps and weakness of FunTomP technologies and the trends of the market by a SWOT analysis. This will enable to understand which of the certification would be easier to get once the project is done. A road map of action was traced defining which certification should be obtained in different moments after the project releases the product to the market.

## 3. Results

### 3.1. International Umbrella: Policy, regulatory and standardisation bodies

Food industry is one of the most demanded all over the world. Its importance is such that both national and international organizations developed tools to standardize, control and unify the production of the foodstuff. This phenomenon is part of the globalized world humans are living, and the incapability of certain countries to produce all the food products that a bigger and more informed demand has. Several standards are developed throughout the world but since the FunTomP project is focused on avoiding food waste and producing functional products the standards and certifications herein studied are related to two pillars: sustainability and functionalized food.

#### 3.1.1 United Nations (UN)



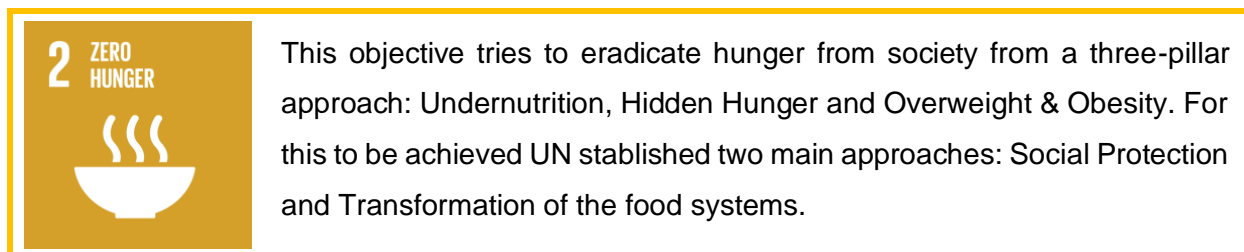
UNITED NATIONS

In 2015, all 193 United Nations member countries signed the [17 Sustainable Development Goals \(SDGs\)](#) – see **Figure 2** – to “*create the future we want in 2030*”, fostering a good climate for governments with financing opportunities to invest in sustainable projects. The aim is to ensure people that, as the development continues, it will be performed in a sustainable way, protecting environment, society and human health from negative impacts and risks. Furthermore, food security is highly related to food & environmental sustainability [19].

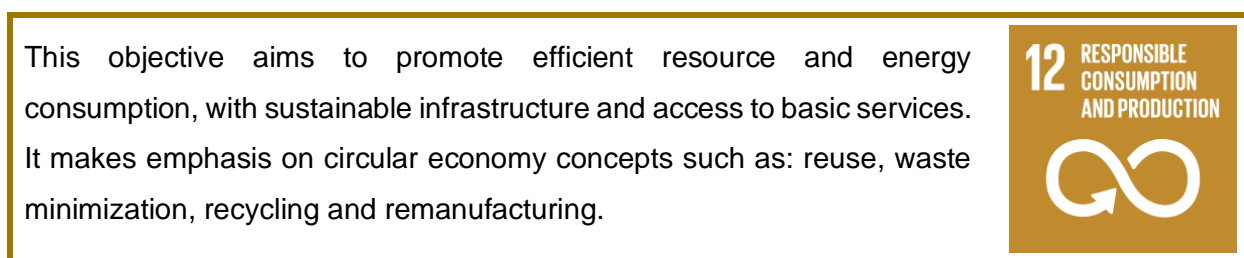


**Figure 2.** SDGs detail at the Paris agreement.

All the SDGs have a transversal concept, which is sustainability, being two of them directly interlocking the food value chain, namely: “Zero Hunger” (SDG2, **Figure 3**) and “Responsible Consumption and Production” (SDG12, **Figure 4**).



*Figure 3. SDG 2 description and approach.*



*Figure 4. SDG 12 description and approach.*

A sustainable food system is a system that delivers food security and nutrition for all in such a way that the economic, social and environmental basis to generate food security and nutrition for future generations are not compromised (FAO, 2018)

The transformation of food systems is at the heart of the 2030 Agenda for Sustainable Development, with sustainable food systems and nutrition patterns highlighted as one of the six entry points for successful transformation towards sustainable development (Independent Group of Scientists appointed by the Secretary-General, 2019). This will support many goals, including the achievement of SDG 2 to: **“end hunger, achieve food security and improved nutrition and promote sustainable agriculture.”** In addition, ensuring adequate, nutritious foods in a sustainable manner will support progress towards achieving SDG Target 3.4 of reducing premature mortality from non-communicable diseases caused by poor diets high in unhealthy fats, salt, sugar, excess energy and low fruit and vegetable consumption, an important risk factor.



### 3.1.2 Food and Agricultural Organization of the United Nations (FAO)

The importance for access to food and agriculture in order to finish hunger, food insecurity and malnutrition all over the world is such that the UN created the **Food and Agriculture Organization (FAO)** in 1945. This organization has several key priorities of action towards the accomplishment of such a defiant goal:



- Elimination of hunger, food insecurity and malnutrition.
- More productive and sustainable agriculture.
- Reduce rural poverty.
- Ensure inclusive and efficient agricultural food system.
- Protect livelihood from disasters.

FAO has identified critical gaps on implementing the SDGs. Overweight, undernourishment and chronic food deprivation has affected 820 million people in 2019. The most affected sector worldwide are the poor and extreme poor sectors, largely concentrated in rural areas. FAO also has highlighted a link between poverty and lack to food access to overweight. [20]

Furthermore, unsafe food infects 600 million people and kills 420 thousand every year from consuming food contaminated by bacteria, viruses and other pathogens. In economic terms, money losses due the unsafe food had a cost of 85 billion euros in 2019. [20]

From a sustainability point of view, there are several gaps to be overcome. Biodiversity for food and agriculture (BFA) is indispensable to food security, sustainable development, and the supply of many vital ecosystem's services. Furthermore, Agriculture, Forestry, and Land use sector are responsible for 23% of the GHG emissions due deforestation, agricultural production and a bad management of soil and nutrients. [20]

FAO has identified the following priority measures to accelerate the implementation of agenda 2030:

- Increase political commitments and support the implementation of the international agreements.
- Improve integration across sectors.
- Enhance innovation and technology.
- Market transparency and accessibility to market information

- Mobilize investments for food and agricultural sectors.

### 3.1.3 World Health Organization (WHO)

The World Health Organization (WHO) is the worldwide authority for public health following the UN system. Among its responsibilities, it is the detection and response to health emergencies (e.g., pandemics, disease outbreaks, natural disasters, and humanitarian crises). The WHO also manages strategies on the environmental risks and climate change which might arise human health and well-being issues, for instance, the loss of biodiversity, intensity of heatwaves, droughts, rainfalls, scarcity of water, etc. According to the WHO, global environmental changes are emerging due to the management of electronic waste, nanoparticles, microplastics, and endocrine-disrupting chemicals and pharmaceuticals that persist in the environment. To assist in addressing such issues across sectors, the WHO and other UN organisations developed a compendium of interventions. This compendium contains a list, or a classification, of the sectors principally involved in the plan (e.g., health, agriculture, transportation, food, waste, energy, etc), the level of implementation (e.g., national, schools, health care, workplace, etc), and the type of instrument (e.g., regulations, governance, taxes and subsidies, technology, education, etc.). The final goal of this compendium is to assist worldwide policymakers and other stakeholders on how health and environmental issues can be tackled.



Regarding food related issues, WHO is implementing **two lines of action: strengthening national food control systems and promoting safe food handling**. WHO and FAO have worked together and created a tool that allows government get easier the control on stakeholder within their productive fabric.

### 3.1.4 International Standardisation Organisation (ISO)

The International Standards Organization (ISO) is an independent, non-governmental international organization with 167 national standards bodies willing to develop and agree market-relevant international standards that support global trade, advance in innovation, and ensure health and safety for a sustainable future. Toward this goal, the organisation aligns with the UN's Agenda for 2030 and the 17 SDGs by integrating cross-sector collaboration, in which standardization is vital to transform society, economy, and environment.



ISO plays a key role in the food industry, an industry with a fast-growing pace throughout all over the world. For this, ISO created technical committees (TCs) with representatives from industry,

non-governmental organizations, governments and other relevant stakeholder. There are several TCs within the food industry regarding each subject (e.g., food safety, food quality, etc) or each food product (e.g., meat, teas, etc). Furthermore, the TCs are coordinated with the **Codex Alimentarius** and the **World Organization for Animal Health (OIE)**. All this coordination work and technical human resources are translated into more than 1 600 norms. [21]

Particularly, “**ISO/TC 34/ SC 3 - Fruits and vegetables and their derived products**” is the TC dedicated to the development of standards related to the fruit and vegetable value chain. The TC assess terminology, sampling, product specification, requirements for packaging, storage, transportation, methods of tests and analysis. The committee contributes with 123 standards to the SDGs as compiled in **Table 2**.

**Table 2.** SDGs interlocked through ISO TC 34/SC 3.




<p><b>2</b> ZERO HUNGER</p> 	<p><b>Hunger Zero related standards</b></p> <ul style="list-style-type: none"> <li>• ISO 22000 family - Food safety</li> <li>• ISO 26000 - Social Responsibility</li> <li>• ISO 20400 - Sustainable Procurement</li> </ul>
<p><b>Good Health and Well-Being</b></p> <ul style="list-style-type: none"> <li>• ISO 45001-Occupational Health &amp; Safety</li> </ul>	
<p><b>9</b> INDUSTRY, INNOVATION AND INFRASTRUCTURE</p> 	<p><b>Industry, Innovation and Infrastructure</b></p> <ul style="list-style-type: none"> <li>• ISO 44001- Collaborative bussiness relationships management systems</li> <li>• ISO 56002- On innovation management system</li> <li>• ISO 56003-On tools and methods for collaborative innovation partnership.</li> </ul>
<p><b>Responsible Consumption and Production</b></p> <ul style="list-style-type: none"> <li>• ISO 20400-Sustainable procurament</li> <li>• ISO 14020-Environmental labeling and self-declarations</li> </ul>	
<p><b>13</b> CLIMATE ACTION</p> 	<p><b>Climate Action</b></p> <ul style="list-style-type: none"> <li>• ISO 14001 - Environmental managment systems</li> <li>• ISO 14064 - Quantification,monitoring and validation/verification of greenhouse gases (GHG)</li> <li>• ISO 14067 - Carbon footprint of products</li> <li>• ISO 14080 - Methodologies in the figh against climate change</li> <li>• ISO Guide 84 - Guidelines for addressin climate change in standards</li> </ul>
<p><b>Life on Land</b></p> <ul style="list-style-type: none"> <li>• 14055-Environmental management – Guidelines for establishing good practices for combatting land degradation and desertification</li> </ul>	

Table 3 highlights the spectrum of action within the food sector that the ISO can achieve with the different TCs, apart from the already mentioned ISO/TC 34/ SC 3 on Fruits and vegetables and their derived products.

**Table 3.** Brief description of every ISO/TC activity field standard.<sup>1</sup>

ISO Technical Committee	Description
<b>ISO/TC34-Food Products</b>	Over 830 published standards. Covers every food product: coffee, meat, milk, species, cocoa, vitamins, animal welfare, microbiology and more.
<b>ISO/TC/SC5-Milk and Milk Products</b>	Over 180 standards. Evaluates and asses the entire product chain of the milk industry.
<b>ISO/TC 34/SC 4-Cereal and Pulses</b>	Over 60 different standards related to cereals' value chain.
<b>ISO/TC 34/SC9 - Microbiology</b>	Several standards related to microbiology within food products. There are standards for specific microorganism y defined frameworks. (e.g., ISO 6579-1: Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of Salmonella – Part 1: Detection of Salmonella spp.)
<b>ISO/TC 234-Fisheries and aquaculture</b>	Related to sustainable development in the sector and has published standards related to traceability and environmental monitoring of impacts.
<b>ISO/TC 54-Essential Oils</b>	More than 130 standards for essential oil used in food products, perfumes cosmetics and other fields.
<b>ISO/TC93-Starch (Including derivatives and byproducts)</b>	26 standards published related to analysis methods of sampling and examination.

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<sup>1</sup> For other food field related TC is recomendable to consult the bibliography recommended.

### 3.1.5 FOOD INDUSTRY ASSOCIATION (FIA)

















The food industry association is an organization founded in 1977 through the merge of the national Association of Food Chains and the Super Market Institute and is based in USA.

The FIA is an organization that works on behalf of the entire industry to provide the best conditions for food crafting. Safer, healthier, and more efficient food supply chain are the main pillars of this organization. Several stakeholders' joint efforts in FIA, such as: retailers, producers, food suppliers and more related-to-the-field companies. Within this fabric of stakeholders, the pursuit goal is to add value to the entire value chain of the food market. With this approach, FIA has impacted in 100 million households only in the USA. [22]

Furthermore, the FMI has a side branch organization called the Safe Quality Food Institute (SQFI) which aims to guarantee safety food products across the entire value chain of the food industry at a global scale. Particularly, these goals are pursued by the benchmarking of their stakeholders for food safety management systems.

The Safe Quality Food (SQF) is a standard recognized by the Global Food Safety Initiative (GFSI). Alongside with this recognition, clients using the SQF can be recognized as consistency, credibility, compliance towards international standards and continuously improving their food processes & practices. Therefore, new markets are expected to be open for stakeholders who holds the SQF certification. [23] There are several guidelines that have step-by-step procedures in order to achieve it. SQFI has several codes, within them the Food Safety Code: Food Manufacturing, which assesses several manufacturing from a broad spectrum of sectors within the food industry. Particularly, **Figure 5** highlights the module 11 of the Food Safety Code; where GMPs are defined for the different food industry sectors.

FOOD SECTOR CATEGORY	APPLICABLE GMP MODULES
 10 Dairy Food Processing	Module 11: GMP for Processing of Food Products
 11 Honey Processing	Module 11: GMP for Processing of Food Products
 12 Egg Processing	Module 11: GMP for Processing of Food Products
 13 Bakery and Snack Food Processing	Module 11: GMP for Processing of Food Products
 14 Fruit, Vegetable, and Nut Processing, and Fruit Juices	Module 11: GMP for Processing of Food Products
 15 Canning, UHT, and Aseptic Operations	Module 11: GMP for Processing of Food Products
 16 Ice, Drink, and Beverage Processing	Module 11: GMP for Processing of Food Products
 17 Confectionery Manufacturing	Module 11: GMP for Processing of Food Products
 18 Preserved Foods Manufacturing	Module 11: GMP for Processing of Food Products
 19 Food Ingredient Manufacturing	Module 11: GMP for Processing of Food Products
 20 Recipe Meals Manufacturing	Module 11: GMP for Processing of Food Products
 21 Oils, Fats, and the Manufacturing of Oil or Fat-based Spreads	Module 11: GMP for Processing of Food Products
 22 Processing of Cereal Grains	Module 11: GMP for Processing of Food Products
 25 Repackaging of Products Not Manufactured On Site	Module 11: GMP for Processing of Food Products
 33 Food Processing Aids Manufacturing	Module 11: GMP for Processing of Food Products

**Figure 5.** GMPs defined by the SQF within food industry. [24]

According to the SFQI website, SQF certification has reached over 14.000 companies around 40 different countries. [23]

### 3.1.6 EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

The European Food Safety Authority (EFSA) is a European agency that provides impartial scientific background and advice towards the minimization of food risks. EFSA develops guidelines related to management and communication within the food field and food value chain. Nevertheless, EFSA does not possess a self-created standard or certification. Instead, it collaborates with other international organizations such as ISO and SQF to develop better and updated standards and certifications.



Therefore, EFSA has international presence in relevant environments, working at high ranked level within the EU Member States. Furthermore, EFSA has a valuable insight which is share through its Scientific Panels (SP) and Scientific Committees (SC).

### 3.1.7 MINISTRY OF HEALTH, LABOUR, AND WELFARE OF JAPAN. (MHLW)

The MHLW is the national and public organism of Japan to develop and grant policies for the welfare of Japanese citizens.



Among the broad agenda within the MHLW, the organization has a pushing leadership on food safety and functional food products. Since 1990 MHLW has introduced the concept of FOSHU, which basically determined the bases for the correct identification, standardization, certification and labelling of functional products.

Furthermore, within the food certification field, the MHLW grants Health claims (Nutritional and Specified Health uses), for special dietary uses and also has a hard policy on misleading claims.

### 3.1.8 V-LABEL INTERNATIONAL



The V-Label International is a company that certifies the authenticity of the vegan and vegetarian products. It is supported by the European Union, through the European Vegetarian Union (EVU) which is an umbrella initiative that grants visibility and promotes several vegetarian and vegan enterprises. [26]

V-Label International has presence worldwide in 50.000 products scattered in 4.300 companies. This label is granted to products made 100% with vegetable raw materials. The label action is present in four different markets: **Food, Catering, Cosmetics and Non-Food related** products, such fashion. [26] Particularly, for food products V-Label International is in:

- Beef Alternatives.
- Fish Alternatives.
- Dairy Alternatives.
- Prepared meals.
- Desserts.
- Beverages.

Furthermore, V-Label International has a wide network of associated companies scattered throughout the world. Specifically, for the mediterranean zone, where FunTomP partners are

located, associated companies might be found in Spain (Union Vegetariana Española), Portugal (Associação Vegetariana Portuguesa) & Türkiye (Vegan Derneği Türkiye).

### 3.2. EU Food Law

The EU has faced the challenge of food certification with several measures, where the objective is to deliver safe, healthy, certified, and traceable food to the 27 members states population. The European Food Safety Authority (EFSA), explained above, was created by **Regulation 178/2002** [8]. EFAS' mission is **ensuring safety in the food chain from farm to fork**:

***“We contribute to protecting human life and health, taking account of animal health and welfare, plant health and the environment. We deliver independent and transparent scientific advice to policy makers, through cooperation with our partners, and in an open dialogue with society.”*** [9]

Furthermore, the establishment of an exhaustive legal framework of regulations, certifications and labelling have been adopted throughout the years in the EU, based on techniques which pursuit safety, high hygiene standards, traceability, and processing of the food. Next, **key legal acts applicable to FunTomP products** are summarised:

**Regulation 825/2004 on the hygiene of foodstuffs** establishes the general rules of food business operators related to the hygiene of food concerning affairs. In this document the main responsibilities are awarded to the primary food operator. Certain principles are based regarding cold chain maintenance, Hazard Analysis and Critical Control Points (HACCP) methodology, good practices of food management, sampling & analysing, microbiological criteria and temperature control. Furthermore, it establishes the obligations that primary food producer has towards national and European authorities. [10].

Despite HACCP system is not a forced to be included in the food value chain, it is recommended by the **5<sup>th</sup> article** of the **regulation 825/2004** [10]. The HACCP system has as a scope to control biological, chemical, and physical hazards for raw material production, procurement and handling, manufacturing, distribution, and consumption of the final product.

HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption.



**BOX 1 - HACCP implementation has 7 steps principles that are mandatory to fulfil [11].**

- 1.** Conduct a hazard analysis by identifying and listing the hazards and by evaluating the hazard on security and likelihood of the event.
- 2.** Determine the Control Critical Points (CCPs) by a tree decision opportunity to prevent mitigate and/or eliminate risks.
- 3.** Establish critical limits for each CCP minimum (m) or maximum (M).
- 4.** Monitoring procedures by defining **what** should be measured (Temperature, pH, etc), **how** it should be measured, **how frequently** should be measured and **who** will measure.
- 5.** Establish corrective actions when monitoring indicates that critical control point is not under control.
- 6.** Establish procedures, which shall be carried out regularly to verify that the measures outlined are effectively applied.
- 7.** Establish documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined.

Furthermore, the **regulation 825/2004** recommends the implementation of **Good Manufacturing Practice systems** (GMPs). The synergy between GMPs and HACCP leads to a better management of hazard and risks related to food processing.

The GMPs are guidelines and principles aimed to ensure food safety and quality. GMPs covers from raw materials to the final shipped product. GMPs' most remarkable benefits are assurance of safe products for human consumption and productive facility cleanliness. In addition, this might lead to minimisation of contamination events, enhance productivity, minimize wastes, and errors.

**Figure 6** and **BOX 2** present the ten guidelines for a GMP system.



**Figure 6.** GMPs' guidelines. Source: adapted from GMP practices. [12]

## BOX 2 - GMPs in food industry

- 1. Quality Assurance:** This implies that food quality verification with the required quality parameters needed. This includes raw materials, production processes monitoring and final inspections.
- 2. Sanitation and Hygiene:** Clean and disinfection are key parameters to prevent contamination. Clean and disinfection activities should be practiced in surfaces, equipment, and utensils.
- 3. Pest Control:** Prevention of plagues as bugs, birds and rodents in the food production is a key parameter.
- 4. Suitable Location:** Ideal location for the facility should be free from contamination and pollution. The facilities should be designed for minimal risk in food manufacturing, and the same time they should be easy and convenient for cleaning and maintenance.
- 5. Equipment:** Equipment maintenance done with periodicity guarantees an efficient and safe development. Duties such as cleaning and calibration are also suggested.
- 6. Raw Materials:** The raw materials must meet quality standards while they are stored handled and utilized to prevent the risk of contamination of the final product.

- 7. Transports and Storage:** Storing and transporting are key point regarding the safety and quality of the food chain. Temperature control, preventing contamination and safeguarding against physical, chemical, and biological threats are key features for a safe and high-quality production system.
- 8. Labelling:** A correct information labelling in crucial for GMPs. Information related to ingredient lists, shelf-life, storage instructions and warnings towards clients are considered good practices.
- 9. Personnel:** Personnel formation is a central in GMP practices is crucial. When all the employees are aligned with the same understanding and dynamics of work the safety and quality of the food products can be assured.
- 10. Verification and Validation:** Validation, traceability and validation are crucial techniques to guarantee a safety food process. These processes should be applied from raw materials till the dispatch of the final product with continuous and frequent monitoring of all the stages within the value chain.

*Microbiological control* is one of the key parameters regarding hygiene and security of foodstuff products, and specific criteria have been established by the European Commission through [Regulation 2073/2005](#) [13] for a variety of foodstuff products, alongside sampling guidelines, testing standards and recall strategies. For vegetable foodstuff mainly three microorganisms have been identified as potential hazards: *Salmonella*, *Listeria Monocytogenes* and *E. coli*. Since there is a wide range of criteria developed, only vegetable products related criteria have been selected for this deliverable. **Table 8** in Appendix can be consulted for further information regarding the limits established by the act.

Another potential issue is the contamination of food with non-microbiological material. For this case the EU also has a clear framework. [Council Regulation 315/93](#) determines the *contamination in foodstuff*, being defined as the: “**presence of any substance not intentionally added to food which is present in such food as a result of the production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food as a result of environmental contamination**” [14].

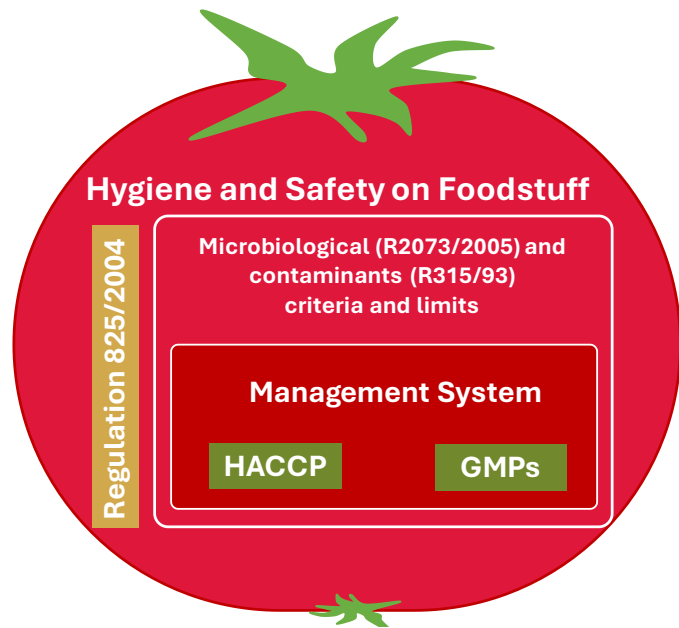
**Figure 7** highlights the dynamic in a layer scheme of the **Regulation 825/2005**, being the HACCP and the GMPs the foundational bricks of the implementation of the norm.

The **Regulation 825/2004** also establishes general hygiene provisions for primary production, where transport, storage, and handling are within the scope. Plant origin foodstuffs should not be transported or stored in conditions that might affect the product. Hygienic conditions, effective cleaning, and pest control measures must be implemented alongside with a control system of recording and updating.

All the transport measures are highlighted in Chapter IV of the regulation, being the most remarkable the following:

- Conveyances and containers used for food transporting shall be kept clean and in good conditions for possible hazards related to foodstuff contamination.
- Means of transport related to foodstuff only will carry foodstuff and nothing else in order to avoid contamination.
- When mixing during transportation is unavoidable, then physical separation inside the mean of transport is mandatory. This is applicable for different foodstuff products or a foodstuff and a merchandise of another kind.
- Bulk foodstuffs in liquid, granulated or powder form are to be transported in receptacles or tank-containers reserved for this purpose. Clear labelling is mandatory.
- If a container is to change its load from a non-food related product to a foodstuff, effective cleaning between loads must be applied.
- Foodstuff should be organized inside the mean of transport to reduce to a minimum the possible contamination of the load.
- Foodstuff containers are to be capable of maintaining foodstuff at appropriate temperatures and allow those temperatures to be monitored.

**Regulation 37/2005** provides guidelines regarding *monitoring of the temperature in transport and storage*. In a nutshell, the following considerations are enunciated:



**Figure 7.** Layers scheme according to the Regulation 825/2005

- Means of transport and storage of quick-frozen foodstuff shall be fitted with suitable recording instruments to monitor at frequent and regular intervals.
- All measuring instruments shall comply with EN 12 830, EN 13 485, EN 13 468 standards.
- Temperature recording shall be dated and stored by the food operator for a period of at least one year, or for longer periods considering the nature and the shelf life of the quick-frozen foodstuffs.

Going back to [Regulation 178/2002](#), it also provides the basis for the *assurance of a high level of protection of human health and consumers' interest in relation to food*, considering the diversity in the supply of food including traditional products. It establishes common principles and responsibilities to provide scientific base, organizational effectiveness and common procedures for decision making in matter of food and food safety, both for a national and European level. Furthermore, the regulation of food safety will be applied throughout the entire life cycle of the product. [8]

The law, in its section 4, from article 14 to 20, specify the general requirements of the food law, to be known:

- **Article 14<sup>th</sup> - Food safety requirements** establishes when a foodstuff is not able for human consumption or be placed on the market.
- **Article 15<sup>th</sup> - Feed safety requirements** establishes when a feedstuff is not able for animal consumption or to be placed on the market.
- **Article 16<sup>th</sup> - Presentation**: focuses on the presentation of the package, that should not mislead consumers regarding the nature of the product.
- **Article 17<sup>th</sup> - Responsibilities**: sets the responsibilities of all the actors throughout the value chain of the food product, like food testing, food surveillance and food control. It also qualifies the penalties to be sanctioned when a violation of the law is committed, being these: effective, proportionate and dissuasive.
- **Article 18<sup>th</sup> - Traceability**: establishes requirements towards traceability of foodstuff and feedstuff, the scope of the traceability systems and the responsibilities of the value chain's actor. Furthermore, the information must be accessible to all the public competent authorities. Article 58<sup>th</sup> lays down provisions to apply the requirements of the article 18<sup>th</sup>.

- **Article 19<sup>th</sup> - Responsibilities for food business operator** establishes communication guidelines of possible food contamination in the value chain. Therefore, the responsibility of controlling, detecting, communicating, and retailing possible threats is on food business operator.
- **Article 20<sup>th</sup> - Responsibilities for feed business operator** establishes in deep guidelines communication of possible feed contamination in the value chain. Therefore, the responsibility of controlling, detecting, communicating, retailing .and destruction of possible threats is on feed business operator.

**Figure 8** highlights the articles within the **Regulation 178/2002** marked as relevant to the FunTomP scope's project.



**Figure 8.** Regulation 178/2002 relevant articles towards FunTomP project.

Another important aspect in food industry is the use of additives, which is regulated by [Regulation 1333/2008](#). According to **it**, additives are defined as:

Substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for technological purpose in the manufacture processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result in it or its by-products becoming directly or indirectly a component of such food stuff.

**Regulation 1333/2008** makes especial focus on the final consumer protection and the implementation of fair practices in food trade. The regulation lists the approved additives allowed by the EU in its Annexes II and III (Community Lists of Approved Food Additives). At the same time, it establishes rules on additives for the products sold as such [15].

The scope of this regulation is clearly limited, highlighting which substances are **not additives**:

- Processing aids.
- Products for protection of plants and plant products in accordance with the Community rules.
- Substances added as food nutrients.
- Substances used for the treatment of water for human consumption falling within the scope of [Directive 2020/2184](#) on the quality of water intended for human consumption.

Nevertheless, if some of these substances are intentionally used as food additives, they must fulfil the alignments declared.

The regulation clearly specifies in its **Chapter II** which compounds are considered approved food additives. Since the development of functional products is the main goal of FunTomP project, the definition of functional additives should be consulted in Annex I. Regarding use of additives, **article 11** determines that the minimal dose must be used to obtain the desired effect on the product, following the principle of *quantum satis*<sup>2</sup>.

**Chapter III** establishes certain rules regarding the usage of the food additives. The regulation establishes through the **18<sup>th</sup> article** when the presence of the food additive shall be permitted:

- When a mixed food contains an additive allowed in one of its ingredients, excluding those listed in Annex II.

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<sup>2</sup> *Quantum satis* means the minimum amount of substance to achieve a desired effect.

- The norm specifies that if a raw material with a certain unexpected additive is used for food manufacturing, the presence of the additive must be demonstrated to come from the raw materials and not from the formulation itself.
- Food which is going to be developed as an ingredient for other foodstuff and complies with the regulation established.

**Labelling** is also a key factor to be assessed since it provides fast and clear information to clients. Hence, the regulation also establishes criteria for labelled products containing additives and additives itself. Since FunTomP will produce products which are not necessarily consumed only by end consumer, Table 9 in the Appendix 7.2 highlights the differences between the labels for each market niche.

Within this aspect, [Regulation 1169/2011](#) aims to assure a high level of protection towards the final consumer through information related on food matters. It establishes clear rules towards labelling and dissemination of relevant information. This legal framework shall apply to food business operators at all stages of the food chain and food intended for final consumer. [16].

In **Chapter II - article 4<sup>th</sup>** the mandatory information to be communicated is established, namely:

- Identity and composition, properties, or other characteristics of food.
- Protection of health and the safe use of food
  - Compositional attributes that may be harmful to the health of certain groups of consumers.
  - Durability: Storage and safe use.
  - The health impact, including risks and consequences related to harmful and hazardous consumption of foodstuff.
- Nutritional characteristics to enable consumers to make informed choices.

Furthermore, **Chapter III** establishes how the information should be granted to consumers and who is responsible of a good communication of this information. First, information should not be misleading regarding the characteristics of the food (nature, identity, properties, composition, etc). Second, it cannot attribute the food to certain effects which does not possess. Third, it cannot suggest that food has special characteristics, when in fact similar foods possess the same characteristics. Fourth, it cannot include any kind of description or pictorial representation for the presence of a determined food or ingredient when is not. In addition, all the information must be accurate, clear, and easy to understand for the consumer. These alignments must be applied to advertising and, particularly, in shape, appearance, packaging, and packaging materials used.



**Article 8<sup>th</sup>** establishes the responsibilities for each actor within the value chains of the foodstuff.

On the other hand, **article 9<sup>th</sup>** indicates the list of mandatory particulars that must be informed. For further consultation of these particulars, **Table 10** has been created in the Appendix.

Following, [Regulation 1924/2006](#) applies to procedure and administrative management of *nutritional and health claims* in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. Advertisement and claims such as labelling, product presentations or other ways of advertisement directly aimed to the final consumer are controlled by this regulation. It also affects hospitals, restaurants, schools, canteens, and similar establishments. At the same time, it clearly establishes that any kind of health or functionality of a product can be advertised as long as it does not undergo the legislative procedure [17].

**Article 3<sup>rd</sup>** of the **Regulation 1924/2006** clearly establishes the general principles for all claims. Claims cannot be false or ambiguous. They cannot give rise to doubt about the safety and/or adequacy to other foods. Furthermore, the claims should avoid the encouragement or condemnation of food consumption. In addition, any kind of suggestion or implying that a balanced diet cannot provide the enough amount of nutritional need for a healthy lifestyle is forbidden. Moreover, claims should not refer to changes in body functions which could rise or generate fear in the consumer, nor textually, pictorial, graphically nor symbolic representation.

Regarding the use of health claims, in **article 4<sup>th</sup>** it establishes the conditions of usage for nutritional and health claims. In January 2009 the Commission set specific nutrient profiles which the foodstuff or certain foodstuff should comply to achieve the health or nutritional claim. The nutritional profiles should be supported by scientific data and background information.

**Article 5<sup>th</sup>** establishes the general conditions of when the claims might be incorporate in the packaging of the product. Presence, absence, or reduced content in a food which leads to a beneficial nutritional or physiological effect must be established by scientific evidence, depending on the nature of the claim it is pursued.

Furthermore, the claim pursued in line with the nutrient presence must be contained in the final product under the legislation limits or, when is no further legislation, in quantities that allows to reach the physiological benefit which the claim states. On the other hand, when the claim stands to diminish the adverse effects of the regular product, is enough to demonstrate it scientifically according to each case.

In relation to communication of the claims, the communication of these benefits and nutritional profiles must be understandable for average clients and strictly related to the final product, ready for consumption.

**Article 7<sup>th</sup>** establishes the ground rules for the nutritional information to be shown to achieve the claim aimed. This article quotes the **Regulation 1169/2011**, which establishes that **articles 30, 31, 32 and 33** define the information required, its calculation, and its expression of results per 100 grams or 100 mL of product, respectively. In the Appendix **Table 9 & Table 11** has been included to sum-up the alignments regarding the mandatory and desired information for labelling. Furthermore, articles related to calculations and presentation are mentioned in the Appendix.

**Regulation 1924/2006** also defines the nutritional claims. Through **Chapter III - article 8<sup>th</sup>** specific conditions are highlighted. Nutrition claims shall only be permitted if they are listed in the regulation Annex in conformity with the conditions set out in the regulation.

Furthermore, several claims had been identified of interest, such as the ones compiled in **Table 4**. Since the nutritional information is not available at the moment this report is being wrote, these recommendations should be checked when nutritional information is available.

**Table 4** .Recommended claims for FunTomP products.

Claim	Fat			Protein	Sodium
	Monosaturated	Saturated	-		
Free			✓		
Very Low					✓
Low		✓	✓		✓
Source				✓	
High	✓			✓	

**Article 9<sup>th</sup>** establishes alignments regarding the comparative claims. Only products of a certain category can be compared. The expression of the energy and nutritional values must be in the same amount of food, normally 100 g or 100 mL.

**Chapter IV** defines the **health claims**. The **10<sup>th</sup> article** clearly states that health claims must comply with the requirements in Chapter II and the specific requirements established in Chapter IV. Health claims should only be permitted for:

- A statement indicating the importance of a varied and healthy lifestyle.
- The quantity of the food and patterns of consumption required to obtain the claimed benefit.
- If the situation requires so, a statement addressed to persons who should avoid using the food.
- An appropriate warning for the products that are likely to present a health risk if consumed to excess.

Restriction on the usage of health claims is stated on **12<sup>th</sup> article**. The next claims are not allowed:

- Claims that suggest that health could be affected by not consuming food.
- Claims which refer to the rate or amount of weight loss.
- Claims which refer to recommendations of individual doctors or health professionals not recognised by **Regulation 1924/2006**.

Furthermore, **articles 13 and 14** provide guidance related to reduction of disease risk & child health, which remain out from the scope of FunTomP project.

Finally, a special section has been created in the Appendix, in order to mention different standards and procedures to estimate relevant information required by the legal framework assessed. Shelf-life estimation, microbiological control and claim-related-analysis are defined in **Section 1.1**.

The **organic production** is established by the [Regulation 848/2018](#), which is vast and has several applications on the food system. It can be applied for the agriculture, aquaculture or even apiculture.

The idea of the regulation is to generate a tool that enables certification of products that:

- Contribute to the protection of the environment and climate.
- Contribute a high level of biodiversity.
- Contribute to a non-toxic environment.
- Contribute the animal welfare.
- Encourage short distribution channels and local production.
- Encourage preservation of rare and native breeds in danger of extinction

- Contribute to the development of the supply of plant genetic material adapted to specific needs and objectives of organic agriculture.
- Contributing to a high level of biodiversity, by using diverse plant genetic material, such as organic heterogeneous material and organic varieties suitable for organic production
- Fostering the development of organic plant breeding activities in order to contribute to favourable economic perspectives of the organic sector.
- Live or unprocessed agricultural products, including seeds and other plant reproductive material.
- Processed agricultural products for use as food.

Other aspects related to farming of food are considered within this regulation such as: environmental issues, health of plants and animals and the respect and balance of the trophic chain. Therefore, a broad scope is certified with this norm, taking into account the technical procedures, the ecological & environmental impact, the balance between species and the management of the farming and production of food goods.

Specifically, for **agricultural activities** there are certain principles that must be applied.

- Maintenance and enhancement of soil dedicated to agriculture activity. Limitation to non-renewable sources and external inputs to a minimum.
- Recycling of waste and by-products of plants.
- Maintenance of plant health.
- Use of seeds with high degree of genetic diversity, disease resistance and longevity.
- Choosing of plant varieties, having regard to the particularities of the specific organic production system. Agronomic performance, disease resistance, adaptation to local soil and climate and respect for natural crossing barriers are factors to be taken into consideration.
- Production of organic varieties

Additionally, in the **article 7** of the norm related to the processing of the organic food, five clear pillars are highlighted:

1. Organic food from organic agriculture ingredients
2. Restriction in the usage of food additives and non-organic ingredients.

3. The execution of substances and misleading processes that might mislead the nature of the product.
4. Careful processing of the food, prioritising physical, mechanical and biological methods
5. Inexistence of nanomaterials in the food product.

Furthermore, the norm provides guidelines towards organic production (Article 7), conversion (Article 8) and limits of usage of GMOs (Article 11) and plant production rules (Article 12). It is recommended to consult these articles for further and broader details. Further characteristics of the process is also established by the norm such as collection, packaging transport and storage (Article 24). [18].

### **3.2.1 European policy and regulatory positioning on Functional Food Products**

According to the report “**Functional Food in the European Union**” published in 2008 by the Joint Research Centre (JRC). Back then the European markets related to Functional Food were not fully developed. Inconsistencies within national scope legal frameworks and lack of constitutive data and information regarding the food and labelling topic difficulted a unique European legal framework. Despite these challenges functional food was a significant share of the European food market by that time. [34]

Until the last amendment of the EU Regulation 1924/2006 (2014), functional foods and nutraceuticals do not have neither a specific regulatory framework, nor a statutory definition in Europe, being the specific claims mixed within a broader regulatory framework [35]. Hence, there are not labels nor specific certifications to be reported towards the FunTomP products, only claims established through the limits proposed under Regulation 1924/2006.

#### **Relevant Milestones within the European Functional Food Sector**

The European Commission Concerted Action on Functional Food Science in Europe (FUFOSE) is an initiative with the commitment to research on functional food products. Three pillars have been the promoting agents within this work group:

1. To critically assess the science base required to provide evidence that specific nutrients and food components positively affect target functions in the body.
2. To examine the available science from a function-driven perspective rather than a product-driven one.
3. To reach consensus on targeted modifications of food and food constituents, and options for their application.

The first meeting was held on Nice, France in April 1996. The outcome of the meeting was the definition of six Individual Theme Groups (ITGs). These ITGs were in charge with the responsibility to review the criticality of functional food science in six major areas:

1. Growth, development and differentiation: a functional food science approach.
2. Functional food science and substrate metabolism.
3. Functional food science and defense against reactive oxidative species.
4. Functional food science and the cardiovascular system.
5. Functional food science and gastrointestinal physiology and function.
6. Functional food science and behaviour and psychological functions.

Once all the related documentation had been reviewed a second meeting was held on Helsinki, Finland in 1997. After these reviews the six ITGs reports were published in the British Journal of Nutrition in 1998 [25].

### **3.3. International certifications and standards for Food Management Systems**

In this section, international certifications and standards for Food Management Systems are assessed. These certifications herein informed had been carefully revised and summarised in order to provide a set of **minimum considerations**. If further information is needed, it is recommended to consult the original sources.

#### **3.3.1 ISO 22000 - Requirements for any organization in the food chain**

ISO 22000 is a certifiable standard related to food safety and food-borne hazards. The main aim of the ISO 22000 norm is to provide guidelines and best practices **for managing risks in all food production related areas**.

In 2020, more than **39.000 companies with presence in 157 countries** certified their processes with ISO 22000. [27]

A multiple approach is recommended in the ISO 22000 norm, including the following issues:

1. Interactive communication

Communication is essential to avoid relevant food safety hazards, to identify and control steps within the value chain that might be compromised by any kind of hazard.

2. System management

ISO 22000 is aligned with the ISO 90001 standard [29] on quality management systems. This way, establishment, operation and updating within the food system value chain are in a framework of a structured management system and incorporated to the management activities from each organization.

3. Prerequisite programmes (PRPs)

Its implementation can be isolated, aligned or integrated with existing related management system requirements, while organizations may utilize existing management system(s) to establish a food safety management system that complies with the requirements of this international standard [28].

4. HACCP principles

The ISO 22000 is based on principles from the HACCP system, and the above-mentioned steps within the HACCP are considered. Furthermore, it combines the HACCP planification with the prerequisite programmes. Within the HACCP principles, the risk analysis must be developed, where the PRP, operational PRPs and the HACCP plan are established

The scope of the ISO 22000 is clearly established, providing guidelines to demonstrate the ability to control the food hazards among the value chain, thus assuring the food is safe for human consumption. The requirements to be aligned with this scope can be summarised as follows:

- a) To plan, implement, operate, maintain and update a food safety management system oriented towards product intended to be safe for user.
- b) To demonstrate compliance with applicable authority and regulatory requirements.
- c) To evaluate and study the requirements of the costumers, demonstrating conformity with those mutually agreed.
- d) To communicate in an effective way food safety issues to suppliers, customers and interested parties on food safety issues.
- e) To ensure that the organization conforms to its stated food safety policy.
- f) To demonstrate such conformity to relevant stakeholders.
- g) To seek certifications or registration of its food safety management system by a third party or a self-assessment or self-declaration in conformity with the International Standard.

Regarding guidelines, the norm enters in detail for every single aspect on requirements, going from general to particular. **Figure 9** remarks the 4 pillars from which the general requirements are built.





**Figure 9.** General requirements for ISO 22000 implementation.

### 3.3.2 Food safety code: food manufacturing (SQF)

The food safety code form SQF is based on the HACCP methodology and GMPs. SQF certification assesses and assures the implementation of a site's food safety and quality plan, and confirms the site has the necessary tools and training to manage food safety and quality.

Three conditions must be accomplished by the organization to aspire to an SQF.

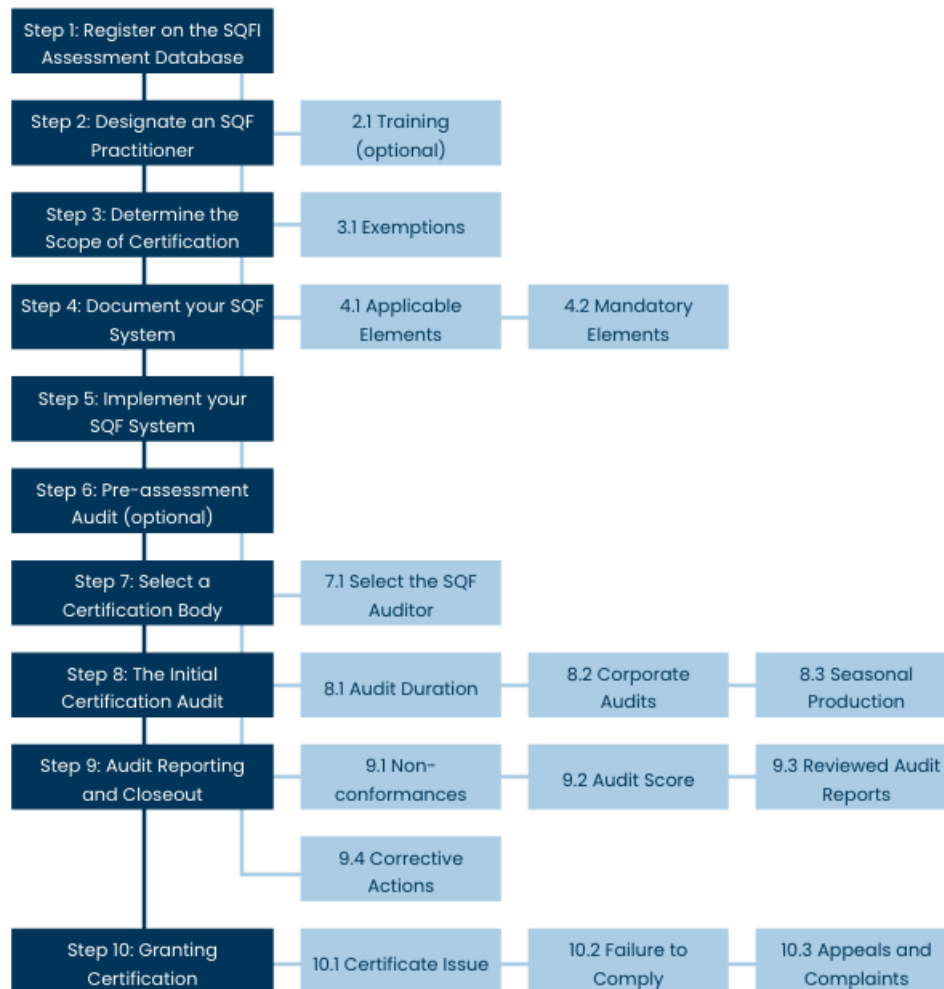
1. Produce safe & quality food.
2. Comply with the requirements of the SQF Code.
3. Comply with applicable food legislation.

By implementing an SQF Food Safety Management System (SQF-FSMS), sites become equipped to address buyer's food safety and quality requirements. The SQF Code provides a solution for businesses supplying local and global food markets. Products produced and manufactured via the SQF Code certification process retain a high degree of acceptance in global markets, benefiting both certified sites and their customers.

For the implementation of the SQF Food Safety Code the code has two sections:

- Part A: Which details the requisites to implement and maintain the SQF Certification
- Part B: Is the auditable standard where it is highlighted the requirements related to GMP and the manufacturing requirements.

Furthermore, for the implementation procedure, there are digital resources in order to practice the required procedure of the SQF Food safety code. Resources, such as training courses, bibliography and use cases are shared online. There are 10 steps to follow for the implementation of the SQF certification, highlighted in Figure 10.



**Figure 10.** Flow Diagram of the audit process for SQF certification. [24]

**Step 1: Sign up on DB and pay fees.**

It is required to register the site on the SQFI assessment database and pay the corresponding fees.

**Step 2: Select a SQF practitioner.**

To designate a SQF practitioner to audit the development, implementation, review, and maintenance of the SQF System (GMPS & Food Safety Plans)

**Step 3: Determine the scope of certification.**

Clearly identify which scope the certification will handle. Relevant features such as: sector categories, products, and processes are to be included in the SQF system. Scope needs to be agreed between the manufacturer site and the certification body before the beginning of the certification process. To reach a clear understanding of the scope, it must be determined:

1. **Site:** location, premises, and facility
2. **Food Sector Categories (FSCs):** Determine which specific category the company belongs so a SQF practitioner with required knowledge can be selected. **Figure 11** highlights the different FSCs.

FSC 10:	Dairy Food Processing	FSC 18:	Preserved Foods Manufacture
FSC 11:	Honey Processing	FSC 19:	Food Ingredients Manufacture
FSC 12:	Egg Processing	FSC 20:	Recipe Meals Manufacture
FSC 13:	Bakery and Snack Food Processing	FSC 21:	Oils, Fats, and the Manufacture of Oil or Fat-Based Spreads
FSC 14:	Fruit, Vegetable, and Nut Processing and Fruit Juices	FSC 22:	Processing of Cereal Grains
FSC 15:	Canning, UHT, and Aseptic Operations	FSC 25:	Repackaging of Product Not Manufactured On-site
FSC 16:	Ice, Drink, and Beverage Processing	FSC 33:	Manufacture of Food Processing Aides
FSC 17:	Confectionery Manufacture		

**Figure 11.** List of FCS related to manufacturing of foodstuff. [24]

3. **Products under certification:** Since SQF is product specific, the targeted products must be clearly identified.

#### **Step 4: Document your SQF System**

It is required to keep record and implement the system elements specified in module 2 and the relevant GMP requirements established in module 11 of the SQF-FSC. This is a two-stage process where the stages are: Applicable Elements & Mandatory Clauses. To face this two-stage process, it is recommended that policies, work instructions and specifications meet the system elements and GMP modules of SQF. For further information, it is recommended to consult the points 4.1 & 4.2 of the reference [30].

#### **Step 5: Implement according to the guidelines the SQF System**

Track on all the documents that ensure procedures are aligned with the norm are being followed. A minimum of 90 days track record is necessary for the SQF code.

#### **Step 6: Pre-assessment Audit (Optional)**

It is basically a rehearsal for the real audit. Despite is not mandatory; it is highly recommended by the norm.

#### **Step 7: Select a Certification Body**

It is mandatory to have a certification body which is licensed by SQFI audits and issue SQF certificates. These bodies are accredited by **ISO/IEC standard 17065:2012**. [31]

Within the commercial agreement, services to be provided at a minimum should be:

- Fulfil the scope certification.
- The expected audit duration and reporting requirements.
- Fee from body certification with a fully detailed budget.
- The conditions under which the SQF certificated is issued, withdrawn or suspended.
- Certification of body's appeals and complain process.
- Availability of the author for the site's FSC.

For further details that exceeds this document it is recommended to consult the selected bibliography Part A Section 1 Step 7. [30]

#### **Step 8: The initial certification audits.**

Is the process of audit by the SQF expert. In this step, all documentation will be reviewed to check the fulfilments of code's requirement (Step 4). In the consulted bibliography there is an Annex where detailed audit process can be checked [30]. The audit can be held online and on-site. As highlighted points in the audit it can be mentioned:

Online audit mode: Review of qualifications of the SQF practitioner(s) and the food safety (HACCP) team; review of policies, procedures, food safety plans, work instructions, and registers/listings; interviews with key personnel; food safety plans, HACCP programs, and food safety management personnel; review of internal audits, corrective actions, complaints, recalls; traceability and mock recall exercise; threat and vulnerability assessments for food defence and food fraud programs.

On-site audit mode: Follow-up on disputed documents and records from the remote activities; follow-up on interviews and observation of work procedures; implementation of the food safety plan(s) and GMPs; verification that the food safety management system, including HACCP, addresses all products, processes, and facilities included within the certification scope.

In the consulted bibliography there is also specific details and guidelines that establishes the audit duration, the approach to corporate audits, and seasonal production. For further information regarding these matters, it is recommended to consult the selected bibliography. [30]

#### **Step 9: Audit Reporting and Close-out**

Non-conformances are precisely informed (number, description, and extent) and then are categorized in three different categories.

- Minor non-conformance: random or infrequent failure to maintain accordance of requirements.
- Major non-conformance: failure of a system element, breakdown on the system management or a big deviation from the requirements of the code, or even de complete absence of evidence of that the norm is being followed respect of an asset.
- Critical non-conformance: the critical control points fail, and thus the HACCP method and GMPs has failed. This is immediately translated into a health threat.

Corrective actions should be taken to reverse non-conformances, and is required to be informed about this correction in a in a time frame of 30 days after the site audit has been held.

If evidence provide that the information received by SQF is enough to allege the fulfilments of the alignment with the norm the SQF will grant the certification within a time lapse of 45 days. For further information on the certification issue and the paperwork to be done it is recommended to consult the selected bibliography [30].

#### **Step 10: Granting Certification.**

## 3.4. International certifications and standards for Functional Food Products

### 3.4.1 Standards for Food for Specified Health Uses (FOSHU)

FOSHU refers to food which contains ingredients with functional benefits towards health. These functional benefits are previously demonstrated through physiological tests on the human body. The main objective of this certification is to enable the easy identification of these products, to provide specific information to the end user and to promote the consumption of highly specific food products related to the human welfare.



Since this was the first of the certifications in the world, the FOSHU seal of approval has been a reference in the functional food field from decades.

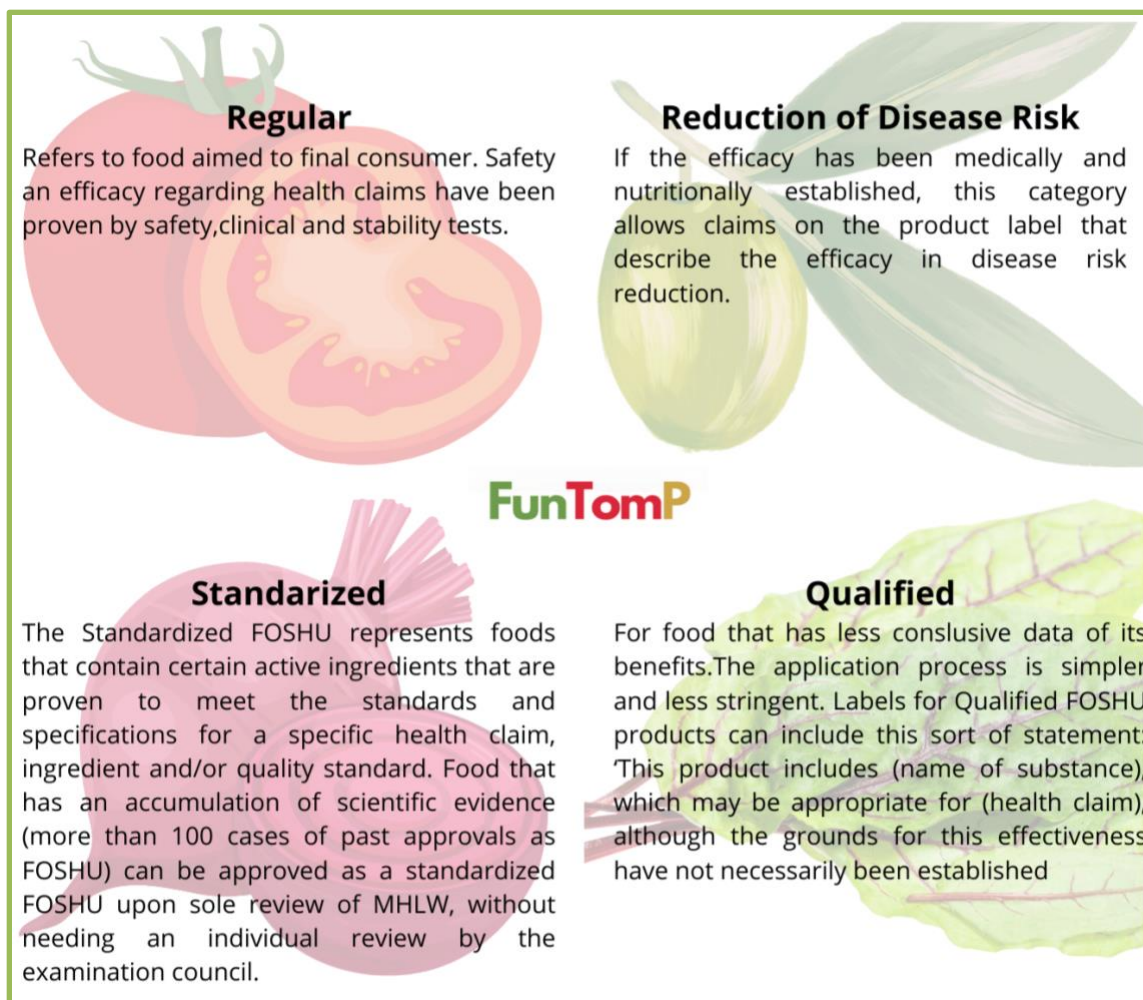
In order to be able to sell food as FOSHU, the following points are required as established by the MHLW.

1. Accomplish safety assessments of the food.
2. Check the effectiveness of the functions for health.
3. Use of nutritionally appropriated ingredients.
4. Guarantee of compatibility with product specifications by the time of consumption.
5. Establish quality control methods such as specifications of products, ingredients, process, and methods of analysis.

The FOSHU certification has four different types of qualifications, depending on the pursuit claim.

**Figure 12** highlights the difference between these four grades of the FOSHU certification.

Applications can be made directly to the MHLW. The information must be provided in Japanese and some of the data must come from specific organizations (i.e. laboratories) approved by Japanese authorities. Furthermore, the application must contain proposed claims, with samples and proposed labels. For more specific requirements further information can be consulted in the **Appendix** of this document.



*Figure 12. Categories within the FOSHU certification. [32]*

### 3.5. Other standards, certification and labels

#### 3.5.1 Halal<sup>3</sup> certification

The Europe Halal Food and Beverage Market size is estimated at 14.20 billion euros in 2024, and is expected to reach USD 17.40 billion by 2029, growing at a Compound Annual Growth Rate (CAGR) of 5.61% during the forecasted period (2024-2029), according to the consulted bibliography [36].

This is in line with Muslim population, that has considerably grown in the last years since several social phenomenon like immigration, and tourism. For example, countries like




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<sup>3</sup> Arabic word that translates to “permissible” in English. Within food field, is any food whatsoever permitted for Muslims to be consumed.

Unite Kingdom or France have a large population of Muslim within their borders. Muslims are in need of Halal certified food. Mayor food producer have already identified this niche market and had conducted Halal certification processes. Companies like Nestle, Ferrero International or SFK foods have gone Halal with several of their products. [36]

Since FunTomP is based on vegetables, which are Halal by the definition of Quran, it is highly recommended to have this certification. [37]

The process of Halal certification is granted by several bodies throughout the world and there are different standards that define the procedure of certification such as: Organization of Islamic Countries (OIC), United Arab Emirates (UAE), Gulf Region and Middle East, Malaysia and Indonesia. The consulted bibliography informs the procedure to fulfil the requirements of all these organizations. [38]

There are three types of certifications for Halal goods and services:

- **Factory Halal Certificate:** This certificate must include an appendix mentioning all approved products and describing their details. These types of certificates are usually valid for 1 up to 3 years.
- **Halal Shipment Certificate:** This certificate is specific to a shipment from an approved manufacturer or facility.
- **Halal Suitability Declaration or Halal Statement:** This certificate asserts that a process, product, or facility is Halal-compliant.

The application process is composed by 8 steps, to be known:

- Application process.
- Contractual Arrangements.
- Assessments.
- Corrective Actions.
- Reporting.
- Certification Decision.
- Surveillance.
- Re-Certification.

### 3.5.2 Kosher <sup>4</sup>certification

The Kosher foods market size is projected to be valued at 9.12 billion euros in 2023 and is expected to rise to 72.06 billion euros by 2033. The sales of Kosher foods are expected to grow at a significant CAGR of 6.3% during the forecasted period. [39]

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<sup>4</sup> Set of rules regarding food preparation in alignment with the Jewish Law..



An important factor is the sudden surge in popularity of the professional cuisine sector. Chefs have been creating new menus that rejoice in their heritage and create a connection with the past through flavour. These trends are slowly arriving to Europe and several major cities are experiencing this, like British or European cities [39]. There are numerous benefits associated with Kosher certification, including quality assurance, trustworthiness, and peace of mind for those adhering to dietary regulations. [40]

There are several Kosher certification bodies that enables the label in accordance with the interpretation of the Jew religion.

Kosher's certification process involves careful examination of all ingredients used in the production process & inspection of the manufacturing facility. Evidence must be provided that all ingredients used in their products are certified as being fit for consumption under Jewish dietary laws. Furthermore, machinery or equipment that is in contact with the food products must be formally certified as being suitable for use in producing kosher foods.

There are three types of Kosher certification paths:

1. **Rabbinical Certification:** Rabbi or Rabbinical organization is the organisation who grants the seal. Seen as the most stringent certification type.
2. **Government Certification:** Granted by governments. Is seen as less stringent than Rabbinical Certification
3. **Self-Certification:** Companies who are attached to government guidelines for Kosher food, but they have not gone through an audit from a rabbi or related organization whatsoever.

### 3.5.3 Organic label from EU

The EU has developed a label to easily identify organic products by the final users and helps farmers to market them across the entire EU.



The EU organic logo can only be used on products that have been certified organic by an authorised control agency or body following the **Regulation**

**848/2018**. The logo can only be used on products that content at least 95% of organic ingredients. The rest 5% is also controlled under strict conditions. Next to the EU organic logo, a code number of the control body must be displayed, as well as the place where the agricultural raw materials composing the product have been farmed. [41]

The logo must be used by all pre-packaged EU food products, produced, and sold as organic within the EU. Additionally, the logo can optionally be used by:

- Imported products where the product conforms to the EU rules on the import of organic goods.
- Non-pre-packaged organic products.
- EU organic products placed on third country markets.
- As part of information campaigns intended to educate the public about the organics scheme (if it is not misleading or false statement regarding authenticity of the product's organic statement).

It is important to point out that there are some restraints regarding its usage. The logo cannot be used for:

- Products containing less than 95% organic ingredients.
- Mass catering operations such as restaurants or hospitals.
- Products not in the scope of organic rules, such as cosmetics or products from hunting and fishing.
- Products in “conversion” (where organic methods have only just been introduced and there may still be non-organic substances in the soil or animal chain).

### 3.5.4 Vegan Label (V-Label)

According to Euromonitor International, plant-based food is having a growing trend within the Western world. This is not just promoted by the vegan or vegetarian oriented people, but also to flexitarian consumers, which understand the need of a plant-rich diet due the nutritional benefits and the environmental unsustainability of a meat-based diet. According to a survey conducted by Euromonitor in 2020, 42% of global food consumers consider themselves to follow a not strict vegan or vegetarian diet, while vegan and vegetarian account for 4% and 6%, respectively. When this number is cracked in generations, 54% of the “**generation Z**” prefers a plant-based diet, while in the case of the “**baby boomers**” this cipher reaches 34%. [42]



Besides, the plant-based ingredients have reached a sales record in the recent past years. With a CAGR of 8.94% in the period 2019-2025, it is expected this sector keeps growing, passing from 9 350 million euros to 25 901 million euros. [26]

The certification procedure is straightforward. First the company must sign-up as a new customer on the web site. This way, V-Label send a quotation for the service selected once the interested party fulfils a form and submit it to V-Label International. With the quotation duly accepted and the contract signed, a technical form and specifications product information is submitted to the certification body, which starts the procedure of cross checking. Once the viability study is accomplished, the V-Label is granted.

### **3.6. Summary of findings towards FunTomP market uptake**

The EC is developing several initiatives within the food field from a hygienic, safe, sustainable and functional point of view. These strategies are framed within a European and worldwide scenario of inequality for high quality food products. With the COVID pandemic, this gap has done nothing else but grow. Naturally, this scenario impacts more at lower society levels, pushing children and entire families to health-related problems as malnutrition and food poisoning, disabling them from a good physical development which will impact them the rest of their lives.

Secondly, the food industry sector is an environmental hotspot itself, due to the depletion of resources, land and sea in order to have the required food to feed the population. These unsustainable methods of food production may feed a wealthier part of the population in the short term but is also contributing significantly to climate change and global warming. Activities like intensive cattle raising and agriculture impact directly on the environment. Therefore, the European Union is working on programs and alongside organizations to promote a plant-based diet, where the mediterranean diet is placed. Here, initiatives as [Farm2Fork](#) and the [SDGs](#) are clear steps towards food goals aimed by the EU.

Despite of having a strong and bast regulatory framework, EC has not fulfilled a clear definition and standardization criteria for the promotion of functional food products. Instead, the European Union identifies such products with specifical claims, identifying the beneficial proven features of the food.

#### **3.6.1 Barriers/accelerators for FunTomP commercialisation**

The complete absence of a European Label for functional food products is a fact to be highlighted. This issue forces food producers to get a claim regarding the benefits of their product, or to certify themselves in other countries. In the latter case, the only world-wide recognized seal for functional food is the FOSHU seal, provided by the Japanese authorities, based on Japanese food code

and rules. This is not a minor fact, since the certification and labelling are subordinated to the decision of a foreign country, which constitutes another barrier.

Secondly, a tightening of regulations might occur to foreign products that might compete with the European agricultural sector, since the uprising of the agricultural sector protest across the EU last February. This is also a possible barrier and there are actions to be taken to by governments in relevant countries like Spain, France, Italy and Belgium<sup>5</sup>. [43]

Furthermore, the food sector day-by-day needs to fulfil the new demands of the consumers. As identified accelerators, the certification of FunTomP to vegan, vegetarian, and religious related diets is a market opportunity, since these diets are growing larger at a European and worldwide scenario. Furthermore, traceability and transparency behind the production of food are also an accelerator. Therefore, if it is desired for companies to reach more markets, these certifications are mandatory. Moreover, being FunTomP products functional food, the market intake in specific niches related to health might be accelerated.





**Table 5** highlights the recommendations in terms of standards, certifications and labels that FunTomP should achieve. The recommendations are made to achieve the market impact as much as possible within such specific niche, like functional products. For this, a step-by-step procedure has to be taken from mandatory frameworks established by the EU to selectable strategies of management (ISO, SQF) finishing in certifiable standards to get a desired label (FOSHU, HALAL, KOSHER).

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<sup>5</sup> In the French case, there is a ban non imported fruits and vegetables that were treated with pesticides.

**Table 6** also depicts possible ecolabels that might be useful for FunTomP products market differentiation.

**Table 5.** Standardization recommendations for FunTomP

Standard	Name	Summary	Application	Product Label
<a href="#">ISO 22 000</a>	Requirements for an organization in the food chain	Establishes a management system, towards the food management throughout the entire food chain value chain, based on GMP and HACCP among other.	<ul style="list-style-type: none"> <li>Traceability</li> <li>Identification of critical control points</li> <li>Health and safety food assurance</li> <li>Accessibility to international markets</li> </ul>	-
<a href="#">FOSHU</a>	Food for Specified Health Uses	Standard and label that recognize beneficial properties of food stuff related to health.	<ul style="list-style-type: none"> <li>Traceability</li> <li>Added value</li> </ul>	
HALAL	HALAL	Foodstuff certification that grants the availability to be consumed by Muslim orthodox.	<ul style="list-style-type: none"> <li>Market intake</li> </ul>	
Kosher	Kosher	Foodstuff certification that grants the availability to be consumed by orthodox jew.	<ul style="list-style-type: none"> <li>Market intake</li> </ul>	
<a href="#">V-Label</a>	Vega/Vegetarian	Certificates that the product is 100% done with vegetable base raw material.	<ul style="list-style-type: none"> <li>Market intake</li> </ul>	

**Table 6. Eco-labels recommended for FunTomP products**

Label	Field	Name	Summary
	Sustainability/Environment	<a href="#">AENOR environment</a>	Ecolabel system aimed to recognize environmentally friendly products or services. Specifically oriented to final consumer products.
	Sustainability/Environment	<a href="#">European Organic label</a>	Ecolabel aid to highlight, certify and recognize products craft by organic and sustainable pathways
	Sustainability/Environment	<a href="#">Carbon trust</a>	It is a certification that highlights the commitment of a company toward the emissions of CO <sub>2</sub> , within a specific product. Principal aim of this label is to calculate the carbon footprint and highlight the reduction of CO <sub>2</sub> emissions achieves since the first measure. It is based on ISO 14 067 norm.
	Sustainability/Environment	<a href="#">Rainforest Alliance</a>	Focus on sustainable agricultural production from a triple pillar approach: Environmental, Economic and Social.
	Waste Management	<a href="#">AENOR environment</a>	Recognises organisations that recover food waste fractions they generate, within the defined scope, thereby avoiding the landfill as their ultimate destination.

## 4. FunTomP ROADMAP

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From the different documents assessed, a roadmap for FunTomP project has been crafted. This roadmap has the purpose of summing up stages towards a successful market access for the developed products. This can be understood as “stops” within the traced roadmap:

- **Stop 1: Regulation Framework**

The step here is oriented to the full accomplishment and understanding of the European legal framework in order to be aligned with expected policies of health and safety towards food production. This is the first stop in the roadmap since the FunTomP products would not be able to be commercialized if this step is not fulfilled.

- **Stop 2: Management Systems**

The implementation of management systems based on different methodologies such as HACCP & GMPs are highly recommended. Despite not being a mandatory asset to determine, the implementation of this systems has demonstrated to be efficient way to align production with standards, certifications and labelling. From a practical point of view this system provide traceability, transparency and hotspots' identification within the production.

- **Stop 3: Standardization and Certification**

This step is related to the selection of standards that FunTomP should be interested in fulfilling to get certifications as a two-approach asset: To show transparency and alignment to public and private entities and also to differentiate the process or product within FunTomP in order to get more clients or tax benefits.

- **Stop 4: Labelling**

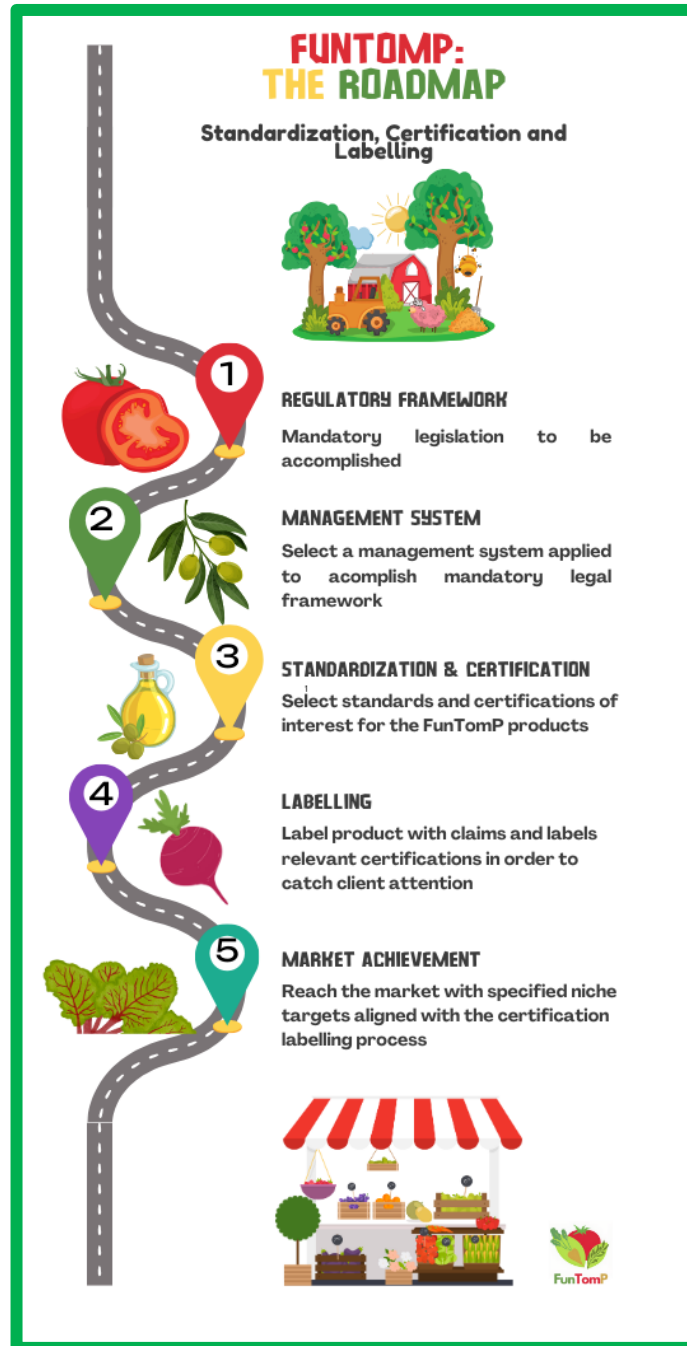
Once the standards are certified, selected labels and ecolabels can be chosen in order to resemble in the final product to achieve a direct communication for a bigger uptake in more markets (i.e: vegan, kosher, low CO<sub>2</sub>, zero food waste, etc).



- **Step 5: Market Achievement**

Once all the process and product are standardized, certified and labelled, FunTomP is ready to achieve the desired market to be developed in the short and midterm.

The **Figure 13** highlights in a scheme the explained roadmap.



**Figure 13.** Standardization, certification and labelling FunTomP's roadmap.

## 5. CONCLUSIONS

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Functional food products have the potential to be a safe, healthy, ecofriendly and cheap source of food for the world population. Nowadays, after several international misfortunes such as COVID 19 pandemic, the invasion of Ukraine from Russia, climate change or even the different strikes that agricultures have led around Europe makes more difficult the access to secure, cheap and healthy food. This is felt not just by the European population, but worldwide since an increment on international prices of foodstuff has been produced. Therefore, functional and sustainable food products generally, and Mediterranean diet particularly, have a gigantic gap to cover in order to deliver high quality food. Moreover, the environmental variable is also important to reframe under one of the most polluting production schemes: agriculture. FunTomP is presented as a potential response to this inconvenient scenario. Therefore, to prove and communicate properly the benefits and alignment with European legal framework of FunTomP product towards such problems, the present roadmap has been crafted.

This *D4.6: Roadmap for FunTomP technology certification at M40* is aimed to provide guidelines and recommendations towards the premature alignment with the legal framework, standards, certifications and labels plausible to be respected and achieved by FunTomP. With this input, it is expected that market and societal acceptance is achieved. Therefore, with the information assessed herein, several outcomes can be highlighted:

- Regulatory framework within the European Union is extensive and precise regarding crucial aspects within food industry. Hygiene, safety, labelling, communication, transport and procedures such as production, sampling and testing are clearly defined and thoroughly controlled by the competent authorities.
- Specifically, towards functional food products there is not a formal definition provided by the EU, which hardens the labelling and certification process, forcing to depend on foreign certifications.
- Several ecolabels have also been identified in the present report. The selection of one or several of these ecolabels will position FunTomP as an enterprise with environmental consciousness and transparency towards its clients. Furthermore, strictly commercial labels have been assessed, to exploit alignment between the fundamentals of FunTomP

and the consumption trends of the recent past years: veganism, vegetarianism. Religious based labels have also been identified.

Recommendations aligned with policy makers and tasks within the project can be highlighted to add value to the products:

- Regarding sustainability aspects, it is recommendable to keep on LCA activities periodically and trace improvements within production steps that will impact positively the environmental footprint.
- Management systems have been proved to be the core of a good productive, traceable and transparent scheme. Therefore, systems as HACCP and GMP should be employed with a continuous enhancement perspective.
- Scientific cooperation is also crucial within the FunTomP project. Being part of scientific activities towards research, development and innovation is highly recommendable. Therefore, association with partners like FUFOSÉ and FIA is highly recommendable. This would provide a synergy between academia's breakthroughs and market trends noticed by FunTomP.

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## 7. APPENDIX

### 7.1. Regulation 2073/235 on microbiological criteria for food stuff.

Table 7 and Table 8 highlight the different criteria related to the vegetable foodstuff security.

**Table 7.** Microbiological limits, sampling plan, reference methods, and action to take for vegetable products in their shelf life.

Food Category	Microorganisms/Toxins or metabolites	Sampling plan		Limits <sup>6</sup>		Analytical reference method	Stage where the criterion applies
		n <sup>7</sup>	C <sup>8</sup>	m <sup>9</sup>	M <sup>10</sup>		
Ready to eat foods intended for infants and ready to eat food for special medical purposes	<i>Listeria monocytogenes</i>	10	0	Not detected in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
Ready-to-eat foods unable to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes		5	0	100 CFU/g		EN/ISO 11290-2	Products placed on the market during their shelf-life
Precut fruit and vegetables (ready-to-eat)	<i>Salmonella</i>	5	0	Not detected in 25 g			Products placed on the market during their shelf-life

<sup>6</sup> In this case there is no range of acceptable concentration.

<sup>7</sup> Number of units comprising the sample

<sup>8</sup> Number of simple units giving values between m and M

<sup>9</sup> Minimal concentration

<sup>10</sup> Maximum concentration

**Table 8.** Microbiological limits, sampling plan, reference methods, and action to take during the manufacture process.

Food Category	Micro-Organism	Sampling plan		Limits <sup>11</sup>		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
Precut fruit and vegetables (ready to cut)	<i>E Coli</i>	5	2	100 CFU/g	1 000 CFU/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

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<sup>11</sup> Satisfactory: If all the observed values are  $\leq m$ ; Acceptable: If a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $\leq m$ ; Unsatisfactory: if one or more of the values are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$

## 7.2. Regulation 1333/2008 on food additives

**Table 9** highlights the different criteria related to the food additive labelling according of the costumer.

**Table 9.** Labelling sums up characteristics for the FunTomP products according to article 21,22 & 23.

Not intended for sale to the final consumer (Article 21)	General labelling requirements for food (Article 22)	Labelling of food additives intended for sale to the final consumer <sup>12</sup> (Article 23)
<ul style="list-style-type: none"> <li>• Name or E-Number</li> <li>• Statement “for food” or “restricted use food”</li> <li>• If necessary, special conditions of storage and handling</li> <li>• Batch ID or Lot</li> <li>• Instructions for use</li> <li>• Name and address of manufacturer, packager or seller.</li> <li>• Clear information about limits on the in food in accordance with the regulation 1333/2008</li> <li>• Net quantity</li> <li>• Date of expire.</li> <li>• Relevant information regarding the Annex IIIa of the 1333/2008 directive</li> <li>• Component description in descendent order of composition</li> </ul>	<ul style="list-style-type: none"> <li>• Name or E-Number</li> <li>• Statement “for food” or “restricted use food”</li> <li>• If necessary, special conditions of storage and handling</li> <li>• Batch ID or Lot</li> <li>• Instructions for use</li> <li>• Name and address of manufacturer, packager or seller.</li> <li>• Clear information about limits on the in food in accordance with the regulation 1333/2008</li> <li>• Net quantity</li> <li>• Date of expire.</li> <li>• Relevant information regarding the Annex IIIa of the 1333/2008 directive</li> <li>• Component description in descendent order of composition</li> </ul>	<ul style="list-style-type: none"> <li>• Name or E-Number</li> <li>• Statement “for food” or “restricted use food”</li> <li>• Labelling of containing sweeteners shall bearthe warning according to its nature                             <ul style="list-style-type: none"> <li>○ Polyols:”Excessive consumption may induce laxactive effects”</li> <li>○ Aspartame/ascesulfame-salts:”contains a source of phenylalanine”</li> </ul> </li> </ul>

<sup>12</sup> Sweeteners are specially highlighted in the norm with a specific labelling. Since FunTomP products are not expected to have sweeteners, these guidelines are excluded in this sum-up.

### 7.3. Regulation on 1169/2011 on food information

**Table 10** highlights the criteria related to the mandatory particulars on food information to be informed by all foodstuff responsible organizations.

*Table 10. List of mandatory particulars on food information according the a9th article of the regulation 1669/2008*

List of mandatory particulars on food information (Article 9)
<ul style="list-style-type: none"><li>• The list of ingredients</li><li>• Any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still presents in the finished product even in altered form.</li><li>• Quantity of the food</li><li>• The date of minimum durability or the “use by date”.</li><li>• Special storage conditions</li><li>• Name or business and address of the food business operator.</li><li>• Country of origin or place of provenance were provided for in Article 26</li><li>• Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions.</li><li>• A nutrition declaration</li><li>• Beverages containing more than 1.2% by volume of alcohol must inform the actual alcoholic strength</li></ul>

In the 31<sup>st</sup> article from the 1169/2011 establishes that the calculation of energy value shall be calculate according to the conversion factors informed in Annex XIV. Declared values shall be according:

- Manufacturer’s analysis of the food
- Calculation from the known or actual average values of the ingredients used.

- Calculation from generally established and accepted data.

**Table 11** enumerates the information required to be reported in labelling according to the regulation 1169/2011.

**Table 11.** *Nutritional information to be reported in labelling according to 1169/2011.*

<b>Content of nutritional information to be reported in labelling in Reg. 1169/2011 (article 30)</b>	
Mandatory nutrition information required	<ul style="list-style-type: none"> <li>• The amount of energy</li> <li>• The amount of fat saturates, carbohydrates, sugars, protein and salts.</li> </ul>
Supplementary information feasible to supply	<ul style="list-style-type: none"> <li>• Mono-unsaturated</li> <li>• Polyunsaturated</li> <li>• Polyols</li> <li>• Starch</li> <li>• Fibre</li> <li>• Vitamins of minerals listed on points A of Annex XIII and present in significant amounts as defined in point 2 of part 2 of part A of Annex XIII.</li> </ul>

**Table 12.** Claim specification according to regulation 1169/2011.

Claims specification regarding law.	
1. Low energy	A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.
2. Energy Reduced	A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.
3. Energy Free	A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0,4 kcal (1,7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.
4. Low fat	A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100 ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).
5. Fat Free	A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of fat per 100 g or 100 ml. However, claims expressed as 'X % fat-free' shall be prohibited.
6. Low Saturated Fat	A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1,5 g per 100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.
7. Saturated Fat Free	A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.
8. Low Sugars	A claim that a food is low in sugars, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5 g of sugars per 100 g for solids or 2,5 g of sugars per 100 ml for liquids.
9. Sugar Free	A claim that a food is sugars-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of sugars per 100 g or 100 ml.

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10. With No Added Sugars	A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.
11. Low Sodium Salt	A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.
12. Very Low Salt/Sodium	A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters
13. Sodium/Salt Free	A claim that a food is sodium-free or salt-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,005 g of sodium, or the equivalent value for salt, per 100 g
14. No added sodium	A claim stating that sodium/salt has not been added to a food and any claim likely to have the same meaning for the consumer may only be made where the product does not contain any added sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0,12 g sodium, or the equivalent value for salt, per 100 g or 100 ml.
15. Source of Fibre	A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.
16. High Fiber	A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 (kcal).
17. Source of protein	A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12 % of the energy value of the food is provided by protein.
18. High Protein	A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12 % of the energy value of the food is provided by protein.



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19. Source of Vitamins or Minerals	A claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (1)
20. High on vitamins or minerals	A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of 'source of [NAME OF VITAMIN/S] and/or [NAME OF MINERAL/S]'.
21. Contains vitamin or minerals	A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim 'source of' shall apply.
22. Increased in..	A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim 'source of' and the increase in content is at least 30 % compared to a similar product.
23. Reduced in..	A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30 % compared to a similar product, except for micronutrients, where a 10 % difference in the reference values as set in Directive 90/496/EEC shall be acceptable, and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.
24. Light/Lite	A claim stating that a product is 'light' or 'lite', and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term 'reduced'; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'.
25. Naturally/Natural	Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term 'naturally/natural' may be used as a prefix to the claim.
26. Source of omega-3 and fatty acid	A claim that a food is a source of omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,3 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.

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27. High of Omega-3 and Fatty Acid	A claim that a food is high in omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,6 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.
28. High Monosaturated Fat	A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45 % of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 20 % of energy of the product.
29. High Polyunsaturated Fat	A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45 % of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20 % of energy of the product.
30. High Unsaturated Fat	A claim that a food is high in unsaturated fat, and any claim likely to have the same meaning for the consumer may only be made where at least 70 % of the fatty acids present in the product derive from unsaturated fat under the condition that unsaturated fat provides more than 20 % of energy of the product.

## 7.4. Standards and measurements practices

### Shelf-life estimation:

Shelf-life of food stuff is a concept that is transversal to all the regulations developed in Section 3.2. Its correct communication and estimation may impact directly on the marketability of FunTomP products. Since regulations regarding communication of relevant parameters has been already mentioned, it is also useful to know how it shelf life should be estimated.

First, there are two approaches to determine de shelf life of a food product: Direct and Indirect methods [44].

Direct methods involve full length storage under normal forms of manufacturing, consumption and storage. The product will be analysed which certain periodicity in order to check the quality properties. The main idea of the method is to approach as much as possible to the real conditions the foodstuff will be expose to. This method needs long times of analysis being time consuming and costly.

Hence, there is Indirect methods, which include: accelerated shelf-life tests, challenges tests, predictive microbiology, or a combination of them.

ISO 16779:2015 [45] standard certifies the sensory analysis for the determination and verification of the shelf-life foodstuff by means of sensory tests. Under this approach several characteristics are evaluated. To be known.

- Changes in Appearance
- Odour
- Flavour
- Taste
- Trigeminal Sensation
- Texture

## Microbiological Measurement:

Microbiological measurement plays a key factor on the shelf life and safe consumption of the foodstuff. Therefore, clear, and standardized measurement techniques of the different pathogens present in food is a key factor within the sector. **Table 13** enumerates the different standardized techniques in line with the **Regulation 2073/2005** [46].

**Table 13.** ISO standards according to different microorganisms' detection, count and estimations.

Kind of analysis	Standard
Detection and count of <i>Coagulase-Positive Staphylococci</i>	ISO 6888
Detection and enumeration of <i>Shigella spp</i>	ISO 21567:2004
Detection and enumeration of <i>Escherichia Coli</i>	ISO 7251:2005 ISO 16649:2015
Total Coliform Count	ISO 4832:2006
Detection of <i>Escherichia Coli O157</i>	ISO 16 654:2001
Detection of <i>Vibrio spp</i>	ISO 21 872:2007
Detection and enumeration of other microorganisms in the food industry	ISO 15213:2003 ISO1 3720:2010 ISO 6611:2004 ISO 15214:1998
Mold and yeast count	ISO 21527:2008
Presumptive <i>Bacillus Cereus</i> count	ISO 7932:2004
Detection and enumeration of <i>Enterobacteria</i>	ISO 21528:2017
Count of <i>Clostridium Perfringens</i>	ISO 7937:2004

## Claim scientific background

In the current report, two claims are being highlighted for FunTomP products: Health Claims and Nutritional Claims. The acceptance or denial of these claims is conducted by a scientific committee from EFSA. Hence scientific information must be provided alongside the solicitation of the claim.

**Regulation 353/2008** clearly establishes that for Health Claims the information provided must consist primarily in human studies and children, if that is the case. Furthermore, a hierarchy of study designs shall be presented “**reflecting the relative strength of evidence which may be obtained from different types of study**” [47]. As mentioned in this report, for nutrition claims stakeholder must provide scientific information assuring that the claimed pursued in fact is reached.

Despite the vast information regarding regulation, no information regarding the most used techniques for claim verification has been found.

## 7.5. FOSHU's requirements

According to the consulted bibliography the requested information which must be supplied for the FOSHU label accreditation is:

- Name of applicant (representative) and the address
- Name and address of head office and factory.
- Product name
- Shelf life
- Content amount
- Reason for seeking approval and how the intake contributes to the improvement of one's diet and the maintenance/enhancement of health of the entire population.
- Health claims the applicant wishes to seek approval for
- List of ingredients and composition percentage
- Considerations and precautions at intake
- Instructions for preparation, storage, or intake of the product
- Product sample
- Sample of the entire package with labels and health claims
- Documentation that shows clinical and nutritional proof of the product's functional effects for the maintenance of health
- Documentation that shows clinical and nutritional proof of the intake amount of the product or its functional components
- Documentation concerning the safety of the product and its functional components, including additional human studies regarding the eating experience.
- Documentation concerning the stability of the product and its functional components.
- Documentation of physicochemical properties and the test methods for the product's functional components
- Results of the quantitative and qualitative tests of components of the functional component, and their testing method
- A report describing the analysis of the designated nutrient constituents and the product's energy content.
- Description of the production method, factory equipment, and an explanation of the quality control system y  
Reasons for not attaching any of the above
- Other information to support the application.