Co-funded by the
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FOOD REGULATIONS GUIDELINE

"INCREASING FOOD LITERACY COMPETENCIES OF ADULTS"

2020-1-TR01-KA204-092828

2022

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ABBREVIATIONS

CAC: Codex Alimentarius Commission
DG-SANTE: Directorate General for Health and Food Safety
EC: European Commission
EFSA: European Food Safety Authority
EPPO: European and Mediterranean Plant Protection Organization
EU: European Union
EURL-FCM: European Reference Laboratory for Food Contact Materials
FAO: Food and Agriculture Organization of the United Nations
FCAs: Food Contact Articles
FCM: Food Contact Materials
FVO: The Food and Veterinary Office
GDFC: General Directorate of Food and Control
GHP: Good Hygiene Practices
GMOs: Genetically Modified Organisms
GMP: Good Manufacturing Practices
HACCP: Hazard analysis and critical control points
IPPC: International Plant Protection Convention
JECFA: Joint FAO/WHO Expert Committee on Food Additives (Food additives, contaminants, residues of veterinary drugs))
JEMNU: Joint FAO/WHO Meeting on Nutrition
JEMRA: Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment),
JMPR: Joint FAO/WHO Meeting on Pesticide Residues
3-MCPD: 3-monochloropropane-1,2-diol or · 3-chloropropane-1,2-diol
MRLs: Maximum Residue Limits
OIE: World Organization for Animal Health
OML: Overall Migration Limit
PCBs: Polychlorinated Biphenyls
PAH: Polycyclic Aromatic Hydrocarbons
PPPs: Plant protection products
RASFF: Rapid Alert System for Food and Feed
SPS Agreement: The Agreement on the Application of Sanitary and Phytosanitary Measures
TTB Agreement: The Agreement on Technical Barriers to Trade
WHO: World Health Organization
WTO: World Trade Organization

PREFACE

“Increasing Food Literacy Competencies of Adults” Project is coordinated by Central Research Institute of Food and Feed Control from Turkey and funded by the Erasmus+ Program of the European Union in the field of Strategic Partnership for Adult Education. Project partners are the General Directorate of Agricultural Research and Policies, Bursa Provincial Directorate of Agriculture and Forestry, Bursa Metropolitan Municipality (TARIMAS) and Bursa Technical University from Turkey. Overseas partners of the project are Food Canning National Technology Center (CTC) from Spain, Széchenyi István University (SZE) from Hungary and Food and Fermentation Technologies Center (TFTAK) from Estonia.

With the "Increasing Food Literacy Competencies of Adults" project, it is aimed to increase the food literacy skills of individuals, to ensure their access to healthy and reliable food, to understand the importance of food literacy within the society. Food regulations ensure that domestic and imported foods are safe, hygienic, nutritious, healthy and correctly labeled. Food regulations have a role in helping to perform inspections of food facilities, to conduct laboratory analyses of foods, and to take enforcement action where infractions result in an unacceptable risk to the public. The Food Regulation Guide contains necessary information on the importance of the food regulation, the scope of the regulations and how to reach the regulations for the target group of the project, which consists of retirees, housewives and even the unemployed who produce and sell food to contribute to the livelihood of the house.

1. THE IMPORTANCE OF FOOD REGULATIONS

Consumers have access to the world's safest and healthiest food supply. In recent years, significant federal regulatory initiatives have been successfully implemented to enhance all aspects of our complex food safety system, including food production and distribution, animal and plant husbandry, processing, transportation, and preparation. There has been a surge in interest in nutrition policy recently. Healthy and nutritious foods are widely acknowledged as essential for preventing cancer and other illnesses, lowering obesity and diabetes, and preserving general good health. Food regulations ensure that domestic and imported food is safe, hygienic, nutritious, healthy, and correctly labeled. Food regulations have a role in helping to perform inspections of food facilities, to conduct laboratory analyses of foods, and to take enforcement action where infractions result in an unacceptable risk to the public.

The target group of people who are retired people, housewives, and even unemployed people who are desperate to contribute house income by cooking and selling their products will benefit from food literacy education for adults. They will be aware of food regulations on production, labeling, storage, and so on. In this way, they can acquire self-efficacy and will be able to make healthier eating choices, or they will improve the economy by creating more job opportunities.

2. INTERNATIONAL FOOD REGULATIONS

2.1. Codex Alimentarius and Its Purpose

The Codex Alimentarius, or "Food Code," is a set of international food standards, guidelines, and codes of practice that contribute to the worldwide food trade's safety, quality, and fairness, presented in a uniform way (www.codexalimentarius.org). The Codex Alimentarius was published to help guide and support the development and implementation of food regulations in order to aid in their harmonization and, as a result, to facilitate international trade. Since it deals with food safety on a global scale, consumers can trust the safety and quality of the food goods they buy in this way, and importers can know that the food they will meet their requirements. Thus, it ensures that food products are not harmful to the consumer and can be traded safely between countries (1).

The Codex Alimentarius was established by FAO and WHO to protect consumer health and promote fair practices in food trade. It was adopted by CAC. Therefore, the Commission is the central part of the Joint FAO/WHO Food Standards Programme. CAC held its first meeting in

1963. It has become the single most significant international reference point for developments associated with food standards and, as a result, the global community's knowledge of food safety and associated concerns has reached new heights (1).

The objectives of Codex Alimentarius can be summarized as;

- To protect the health of consumers
- To ensure fair practices in the food trade
- To promote coordination of all food standard work undertaken by IGOs and INGOs
- To develop and maintain the Codex Alimentarius

Codex standards;

- Not obligatory, but recommendations
- Each country decides how to apply it
- Used by millions world-wide
- Codex Standards are referenced in the WTO SPS Agreement
- Encourages international harmonization of national food regulations
- Opens markets for new products
- The invisible link between producers and consumers and all actors in the food chain

2.1.1. Nature and Revision of Codex Standards

National legislation is neither a replacement for, nor an alternative to Codex standards and related texts. Every country's law and administrative procedures have provisions that must be followed. Codex standards and associated documents offer food criteria aimed at providing consumers with a safe, healthy food product that is free of adulteration and is properly labeled and presented. Any food should have a Codex standard prepared in line with the Format for Codex Commodity Standards (2).

The Codex Alimentarius Commission continues to produce worldwide standards, guidelines, and recommendations to decrease food safety hazards. Risk analysis, the integrated food chain approach, and HACCP were also established by the Codex Alimentarius. Codex standards and associated documents are revised as needed by the Codex Alimentarius Commission and its

subsidiary organizations to ensure that they are compatible with and represent current scientific knowledge and other relevant information. A standard or associated text must be amended or eliminated as necessary, according to the Procedures for the Elaboration of Codex Standards and Related Texts. Any new scientific or other relevant material that may require amendment of any existing Codex standards or associated texts must be identified and presented to the appropriate committee by each member of the Codex Alimentarius Commission (2).

The development of the Codex Alimentarius has sparked research in the domains of food chemistry, food technology, food microbiology, mycology, pesticide and veterinary drug residues. Many researches are conducted in collaboration with individual scientists, labs, institutions, and universities, as well as joint FAO/WHO expert committees and consultations. Therefore, Codex decisions are based on science and some committees such as JECFA, JMPR, JEMRA, and JEMNU strengthens the role of FAO and WHO in providing scientific advices to Member states and bodies such as Codex Alimentarius Commission and hence they are responsible from risk assessments. In scientific topics, one of the benefits of the Codex-FAO-WHO collaboration is its flexibility. FAO and WHO have convened expert scientific consultations on a variety of topics in recent years. Not all of them have resulted in the formation of new Codex standards, since it is occasionally concluded that alternative methods are the best approach to manage food safety risks. Thus, Codex is not only reliant on the FAO and WHO for scientific competence. Other scientifically based international organizations are encouraged to participate to the combined FAO/WHO scientific system (2).

Codex standards are published in different Codex documents. These can be found on the website http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/ , guidelines are available at http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/ and Codes of practice are available at http://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/ (Fig. 1).

Fig.1. Codex document websites; codex standards, guidelines, and codes of practice.

2.1.2. Codex and Consumers

The Codex Alimentarius Commission, together with its subsidiary committees, has prioritized consumer protection and interests in the setting of food standards and related activities from its founding. The required structure for commodity standards reflects Codex's emphasis on ensuring that customers obtain products of acceptable quality and that do not pose a health risk. The name of the standard, its scope, description, weights and measurements, and labeling regulations for commodity standards are meant to guarantee that the customer is not misled and that the food item purchased is what the label says it is. The need for fundamental composition and quality characteristics ensures that the consumer does not get a product which meets the minimum acceptable standard (1).

The Codex Alimentarius contains standards for all the principal foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the degree that they are required to satisfy the Codex Alimentarius' stated

goals. The regulations governing food additives, contaminants, and hygiene are designed to safeguard customers' health. More than 200 standards for individual foods or groups of foods are contained in the Codex Alimentarius. It also comprises the General Standard for the Labelling of Prepackaged Foods, the General Guidelines on Claims, and the Guidelines on Nutrition Labelling, all of which are intended at assuring the honest food sales practices while also guiding customers in their product selection. Other general food hygiene, food additives, contaminants and toxins in food, and irradiated foods standards are of prime concern in preserving customers' health, and they are highly regarded for this reason. MRLs for pesticides and veterinary drugs as well as maximum limits for food additives and contaminants, have been created to guarantee that consumers are not exposed to dangerous compounds at unsafe levels. Food hygiene, food additives, pesticide and veterinary drug residues, contaminants, labelling, methods of analysis and sampling, and import and export inspection and certification are all covered under the Codex Alimentarius. The Codex website (1), contains all of these materials, including working papers, information papers, and meeting reports (2).

2.1.3. Codex and The International Food Trade

Harmonization of food standards is typically regarded as helping to preserve consumer health and facilitate international trade to the greatest extent practicable, as mentioned above. Trade facilitation happens as a result of countries matching their domestic standards with Codex standards, despite the fact that the Codex Alimentarius Commission does not have a mandate to do so. A growing number of nations are aligning their national food standards, or parts of them (particularly those pertaining to food safety), with those of the Codex Alimentarius. The founders of Codex envisioned fewer trade barriers and freer movement of agricultural items across nations as a result of harmonization, which would benefit farmers and their families while also helping to eliminate hunger and poverty. As a result, importing nations' governments have enacted necessary rules and regulations to prevent or mitigate threats to the health of consumers or to the health and safety of the animal and plant populations. These measures might contribute to restrictions that are necessary for food trade between nations in the areas of food, animal, and plant control (1).

While there are other trade agreements that affect food, SPS Agreement and TTB Agreement are two that are particularly relevant to the Codex Alimentarius Commission's work. The SPS and

TBT Agreements were appended to the 1994 Marrakesh Agreement, which formed WTO, as Multilateral Agreements on Trade in Goods (Fig. 2).

Fig. 2. The relationship between WTO and CODEX.

The SPS Agreement contains provisions about potential solutions to preserve animal, plant, and human health. In terms of human health, it recognizes that governments have the right to take sanitary and phytosanitary measures that are required to protect their populations' health. The TBT Agreement, which is not specific to foods, aims to eliminate unnecessary trade barriers by ensuring that technical regulations and standards, such as packaging, marking, and labeling requirements, as well as analytical techniques for assessing conformity with technical regulations and standards, do not obstruct trade. WTO's Agreement on SPS agreement has specifically identified the Codex Alimentarius Commission's standards, guidelines, and recommendations for food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice in its pursuit of harmonization in the area of food safety. WTO recognize Codex as the reference body regarding Food Safety Issues. Codex standards, guidelines and codes of Practice are recognized by WTO as reference for settlement of disputes and international trade, as well (1).

2. 2. EU Food Legislation

A series of food-related occurrences such as Bovine Spongiform Encephalopathy and dioxin crisis in the late 1990s highlighted the need for the EU to create universal rules and criteria for food and feed regulation. EC issued a Green Paper (30 April 1997) which eventually led to the introduction of the White Paper (12 January 2000). The Green Paper consultation indicated widespread agreement that the Community should participate by collaborating with a variety of stakeholders at the national, regional, and local levels. However, a greater need for transparency at all levels of food safety policy led to the creation of the White Paper. EC formed an integrated strategy for food safety "from farm to fork" which was principally outlined in the White Paper on Food Safety. It includes feed production, primary production, food processing, storage, transport, and retail sales, among other aspects of the food chain. The White Paper has aided in the strengthening and harmonization of sanitary conditions and procedures throughout all EU Member States. An integrated EU Hygiene Package was produced, which included current hygiene standards. White Paper provides an official set of suggestions in certain policy areas and are used as vehicles for their development, whereas Green Paper gives a range of ideas for public discussion and debate (3).

In 2002, the European Parliament and Council approved Regulation (EC) No 178/2002, which established the main principles and standards of food legislation (General Food Law Regulation). It outlines general principles, requirements, and procedures that guide decision-making in food and feed safety, and it applies to all phases of food and feed production and delivery. Similar to Codex standards, the basic principle of the EU's food safety policy is to ensure a high level of protection for human life and consumer interests regarding food while guaranteeing the efficient functioning of the internal market, but European Food Legislation is stricter than Codex standards (4). All EU legislation and other related information can be found at website: https://eur-lex.europa.eu/homepage.html.

EFSA, which is focusing on risk assessment and scientific advice in the field of food safety questions, was established after the existence of Regulation (EC) No 178/2002. Thus, this regulation also defines EFSA as an independent body charged with scientific advice and assistance. It also creates the basic processes and tools for the management of emergencies and crises, as well as RASFF. The risk analysis paradigm, which includes risk assessment, risk

management, and risk communication, has been codified as general principles in EU legislation and serves as the legal foundation for Member States' food safety systems. (3).

EU has enacted legislation to standardize official control processes throughout its member states. It also governs the requirements that nations outside the EU must meet in looking to trade their food on EU markets. Despite the fact that control processes are mostly standardized, the structure and organization of control organizations varies greatly within EU. Throughout the EU, there are a wide range of food safety control systems. Food safety control is decentralized in some nations and delegated to regions or provinces, whilst in others, food safety management is in the hands of a single central institution. Many EU nations have formed a National Food Safety Authority in recent years. The main role of European Legislation is generally to enforce food safety standards, although risk assessment, scientific advice, and risk communication are frequently involved as well (5). Risk management is based on risk assessment and scientific data, but other factors of food production, such as environmental protection and animal welfare, may also be included. A successful food safety management system may include a mixture of direct government oversight based on legal food safety criteria and private food safety control methods. Accredited organizations' certification of manufacturing procedures may aid manufacturers in lowering risk levels and persuading governments and customers of the safety and quality of their products.

Raw materials, additives, and ingredients, intermediate, and finished foods; product composition, formulation, process, and packaging; labeling, claims, supporting papers, data, and communication; traceability, intellectual property, and so on are all covered by food regulations. Because of the considerable diversity of the foodstuffs sector, it is often important to examine whether a horizontal strategy, which establishes broad rules that apply to all foodstuffs, or a vertical approach, which establishes specific rules for specific foodstuffs, should be preferred (Fig. 3). Priority has been given to horizontal measures that apply to all kinds of foodstuffs within the context of the laws enacted under White Paper Program for processed foodstuffs (additives, flavours, extraction solvents, labelling, nutritional labelling, hygiene etc). Nonetheless, vertical regulations have been regarded required in some cases, particularly in the case of products for specific nutritional objectives and rapid frozen foodstuffs (Figs. 3 and 4).

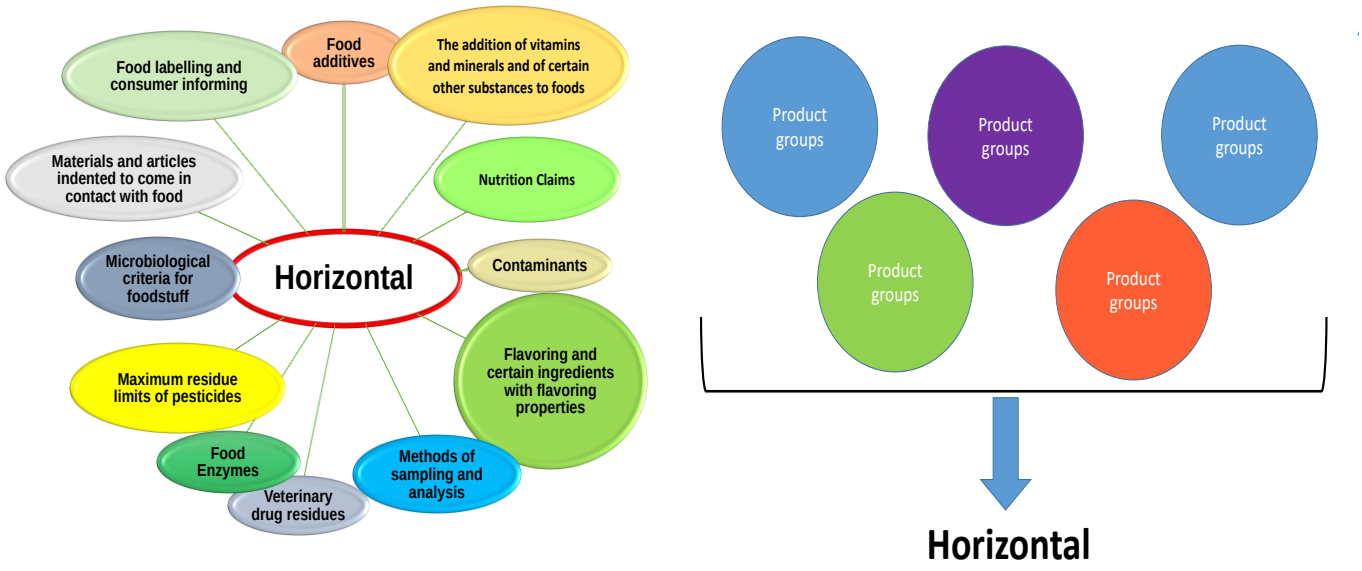

Fig. 3. Horizontal regulations

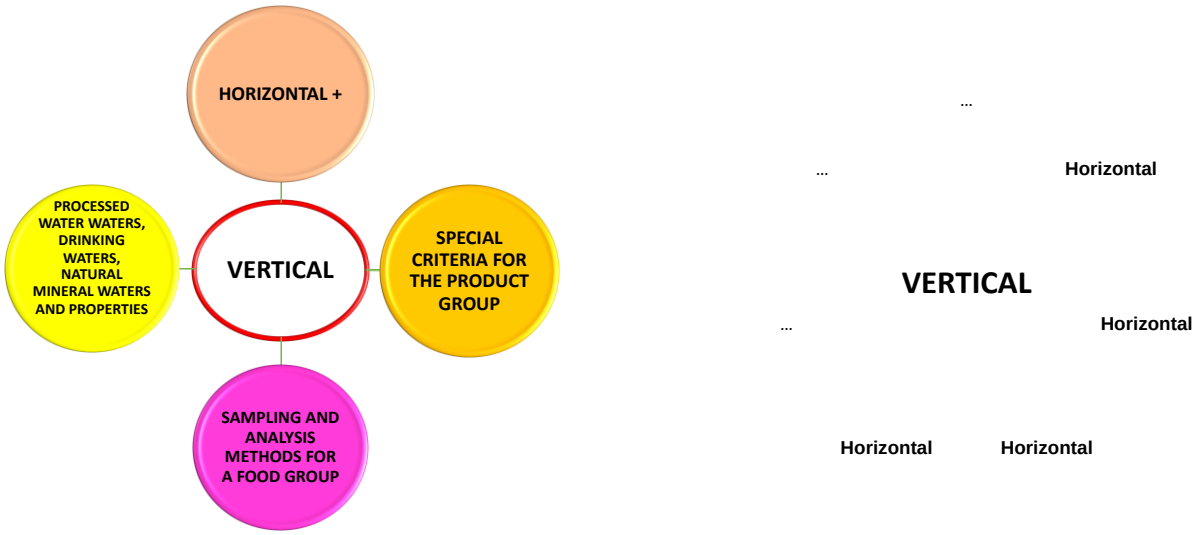

Fig. 4. Vertical regulations

Objectives of EU Food Legislation can be summarized as;

- To ensure a high level of safety in relation to public, animal and plant health in the EU
- To ensure that trade and imports in animals and their products can take place in safe conditions
- To define conditions relating to imports are equivalent to those for domestic producers
- To enable trade within the EU and with Third Countries
- To create a body of law that is effective, clear, easy to comprehend, and more user-friendly for those who are directly affected, such as producers, industry, food enterprises, enforcement authorities, and consumers

The following are some key aspects concerning EU food legislation;

- An extensive debate on participation and transparency in the European political system was stipulated and eventually inspired the White Paper on Governance (2001)
- The aim of harmonization of Food and Feed Safety Legislation is to ensure free trade in the internal market of the EU members, and assure a high level of protection of consumers in the community
- Legal framework of regulations, including contaminants in food and feed; developed by the Commission and the Member States
- It follows WTO rules and its SPS Agreement which follows OIE & CODEX standards
- DG-SANTE of EC is responsible from EU policy on food safety and health and for monitoring the implementation of related laws
- The responsibility for food safety was transferred from the Directorate-General Agriculture to the newly established DG Health and Consumers, thus separating the promotion of industrial interests (DG Agri) and consumer interests (DG Sanco).
- Food safety policy in the EU is based on the principle of risk analysis according to the Codex Alimentarius. This principle is copied in the EU legislation 178/2002
- Food safety as part of public health became a horizontal issue which has to be considered in all EU policies
- On the national level, responsibilities were equally rearranged and several independent agencies were founded

- In the European case and in many national cases, risk assessment as scientific process was separated from risk management as political process
- By Reg. (EC) 178/2002, EFSA was established which provides expertise and coordinates European risk assessments and it gives scientific advice to the Commission and to Member States
- Official control is supervised by the FVO

3. National Food Regulations

3.1. Turkish Food Codex Legislation

Turkey is a candidate country for membership in EU. The fundamental goal of Turkish Food and Agriculture Policy is to harmonize the related laws and regulations with those of EU (Fig. 5). The Ministry of Agriculture and Forestry is the agency in charge of developing and enforcing of food and agricultural policy and regulations, as well as serving as a point of contact for international organizations working on these problems.

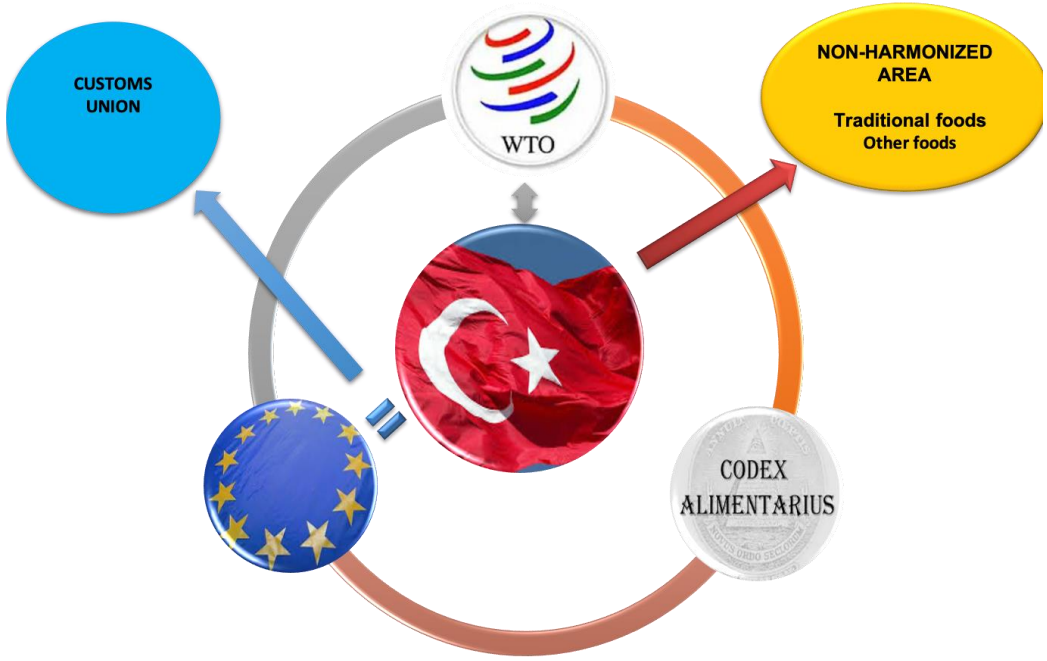

Fig. 5. The relationship between Turkish Food Legislation and EU Food Legislation

Food and feed safety, animal health and welfare, plant health, and agricultural biotechnology are all governed by two primary laws and over a hundred implementing regulations. The Turkish Government has been informing international organizations, such as WTO, about potential or actual regulatory changes more often in recent years than in the past, but not all regulatory changes affecting trade have been disclosed. Exporters should be aware that how laws are applied in different jurisdictions may differ. On June 13, 2010, the Turkish Government issued Law No. 5996 on Veterinary Services, Phytosanitary, Food, and Feed with the goal of protecting and ensuring public health, food and feed safety, animal health and welfare, plant health and consumer rights, while also taking environmental regulation into account, as part of the EU harmonization process (Fig. 6).

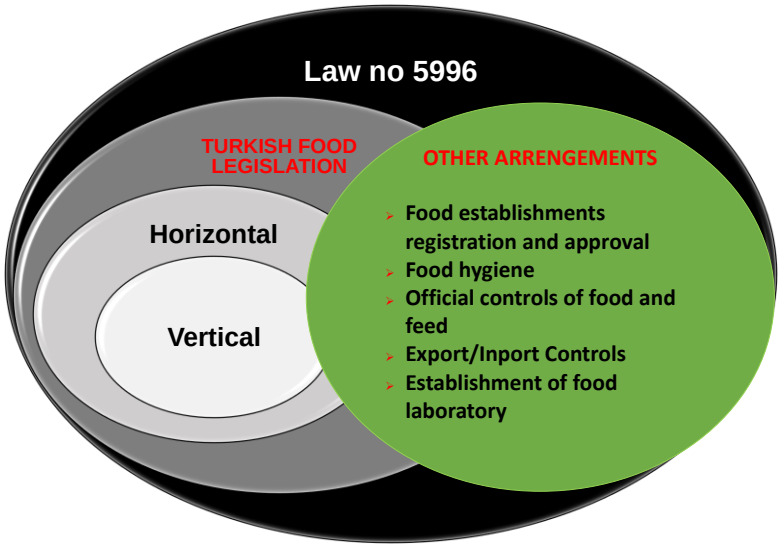

Fig. 6. The relationship between Law No. 5996 on Veterinary Services, Phytosanitary, Food, and Feed and Turkish Food Legislation.

The Ministry of Agriculture and Forestry is the competent authority in the fields of food safety, veterinary and phytosanitary. GDFC is the main central service unit of the Ministry in charge of controlling and regulating food safety, veterinary and phytosanitary sectors. GDFC is the contact

point for international organizations such as CAC, EFSA, EPPO, OIE, WTO and IPPC. Turkey also became a member of CAC on October 01, 1963. The Codex Contact Point of Turkey is also GDFC under Ministry of Agriculture and Forestry.

Another significant law is Law No. 5977 on Biosafety and the goal of this law is to create and implement a biosafety system to prevent potential risks from "GMOs" and their products obtained through modern biotechnological means in the context of scientific and technological developments; to protect human, animal, and plant health; and to protect and ensure the sustainable use of the environment and biological diversity and to determine the procedures and principles governing the control, regulation and monitoring of these activities. It governs all activities, including, but not limited to, the research, development, processing, placement on the market, monitoring, utilization, importation, exportation, transportation, preservation, packaging, labeling, and storage regarding genetically engineered products and products thereof. It regulates all aspects of genetically modified organisms and their products, including research, development, processing, marketing, monitoring, use, importation, exportation, transportation, preservation, packaging, labeling, and storage.

The aims of Turkish Food Codex Legislation can be summarized as;

- To protect the health of consumers
- To facilitate the production of safe food
- To ensure fair practices in the food trade
- To be simple, coherent, transparent
- To be based on risk assessment through the food chain
- To promote coordination of all food standard work undertaken by international governmental and non-governmental organizations.

3.2. Hungary Food Legislation

3.2.1. Key national food regulations and institutions of Hungary

In addition to the common **EU food regulations**, the following national provisions regulate the operation of the Hungarian food safety system:

The legal bases of food safety in Hungary are laid down in **Act XLVI. of 2008 on the Food Chain and Official Supervision**. "The law brings together the basic areas of food chain safety: animal health, feed safety, food production, production, distribution safety and plant health. **Government Decree 22/2012 (II. 29.)** has established the National Food Chain Safety Office (NFCSO/NÉBIH), which monitors compliance with food chain security rules with national competence, fights against food counterfeiting and the black economy" (6).

"Since its establishment, Hungary has been a member of the Codex Alimentarius Commission established by the World Food and Agriculture Organization (FAO) and the World Health Organization (WHO) in 1963, of which 188 countries are currently members and 1 Member Organisation (The European Union). The set of documents developed by the committee is the Codex, which serves as a basis for international and national food regulations. Based on this, the three-volume Hungarian food book (**Codex Alimentarius Hungaricus**) has been prepared and is being modified to constantly monitor the changes:

- Volume I: Specification and regulation: The application of which is mandatory. Regulations relating to food produced or distributed in Hungary. Harmonized with EU regulations
- Volume II: Guidelines: The application of which is not mandatory. Recommendations and guidelines concerning description, composition, and quality. Manufacture of foods produced by Hungarian manufacturers and consumed by Hungarian population.
- Volume III: Official methods of analysis and sampling

GHP = Good Hygiene Practice, GMP = Good Manufacturing Practice, GAP = Good Agricultural Practice, GLP = Good Laboratory Practice

Fig. 7. The place of the Hungarian Food Book in the Hungarian regulatory system. (Codex Alimentarius Hungaricus, 2018).

The Codex Alimentarius Hungaricus, which dates back four decades, "is a collection of regulations and guidelines for foodstuffs sold in Hungary. It includes regulations and guidelines for food quality, food labelling, food safety (food hygiene) and methods to be applied in the examination of food for individual foods, food groups or groups of food ingredients. Its main goal is to provide guidance to producers and to inform the public about the expected fair quality, fair products, their compositional characteristics and the technologies and test methods required for their production and control. Its aim and task is also to provide the opportunity to enforce national characteristics and preserve the good quality of traditional Hungarian products, while ensuring the smoothness of international trade and the purity of market competition (7).

The constantly updated list of food legislation in force in Hungary is available on the website of the National Food Chain Safety Office: https://portal.nebih.gov.hu/-/elelmiszer-jogszabalyok-jegyzeke

3.2.2. National Standardization

Act XXVIII of 1995 on National Standardization: This Act defines the organizational framework, principles of operation, requirements, relations and financial resources for management of national standardization. The national standards organization is the Hungarian Standards Body (MSZT) (8).

The Hungarian Standards Institution (MSZT), an independent non-profit public organization, is prepared for the certification of food-safety management systems of organizations participating in the food chain according to MSZ EN ISO 22000:2005 standard and certification of integrated management systems, and verification of HACCP systems developed according to the requirements of Codex Alimentarius Hungaricus.

National Standards can be found on https://ugyintezes.mszt.hu/search

3.3. Spain Food Legislation

3.3.1. Key National Food Regulations, Short List of Key Legislation (Food Chain, Safety, Etc.):

European Commission Provisions of Direct Application

• Decision 2008/721 / EC of the Commission, of August 5, 2008, creating a consultative structure of scientific committees and experts in the field of consumer safety, public health and the environment and repeals Decision 2004/210 / EC

• Regulation (EC) No. 178/2002 of January 28, 2002, which establishes the principles and general requirements of food legislation, creates the European Food Safety Authority and establishes procedures related to safety food

• Additives: Regulation (EC) No. 1331/2008 of the European Parliament and of the Council, of December 16, 2008, which establishes a common authorization procedure for additives, enzymes and food flavorings.

• Enriched Foods: Regulation (EC) No. 1925/2006 of the European Parliament and of the Council of December 20, 2006 on the addition of vitamins, minerals and certain other substances to food.

• Ultrafrozen Foods: Commission Regulation No. 37/2005 of January 12, 2005, regarding the control of temperatures in means of transport and warehousing and storage of deep-frozen foods intended for human consumption.
• Food Supplements: Regulation (CE) Nº 1170/2009 by which Directive 2002/46 / CE and Regulation 1925/2006 are modified regarding the lists of vitamins and minerals and their forms that can be added to food, including food supplements.
• Control of products of Animal Origin: Commission Delegated Regulation (EU) 2019/624, of February 8, 2019, regarding specific rules regarding the performance of official controls on meat production and regarding production areas and relaying of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council.

3.3.2. Institutional background in a nutshell - National food authorities, institutions, e.g. national food safety authority

• Spanish Agency for Food Safety and Nutrition (AESAN), belonging to the Ministry of Consumption: Food safety at the internal market level. Consumer protection by the General Directorate of Consumption.
• Ministry of Agriculture, Fisheries and Food (MAPA): Agriculture, livestock, fishing and aquaculture, commercial quality, ecological production and differentiated quality, plant health, Imports of live animals, products of animal origin not for human consumption and products intended for animal feeding.
• Ministry of Health (MS): Food imports, by the General Sub-Directorate of Foreign Health.
• Spanish Federation of Food and Beverage Industries (FIAB): its objective is to defend the interests of the sector with the Administration and the different national and international decision-making bodies, as well as anticipating future challenges that affect the development of its activity.
• Spanish Association of Juice Manufacturers (ASOZUMOS): is the business organization that integrates the Spanish juice producers and represents them in all areas, and before public administrations and private entities of all kinds.

3.3.3. Food safety management systems used in Spain:

IFS, BRC and ISO 22000

3.3.4. Important national websites - e.g. food safety and hygiene regulations in national language, list of food advisors (if relevant), food labelling, etc.:

Spanish Agency for Food Safety and Nutrition AESAN (9)

National Plan for Official Control of the Food Chain, PNCOCA (10)

Spanish Federation of Food and Beverage Industries (FIAB) (11)

National Food Centre (CNA) (12)

Network of Food Safety Laboratories – RELSA (13)

3.3.5. Special regulations for national/local food specialties (if any):

• General Hygiene of Food Products: Regulation (EC) nº 852/2004 of the European Parliament and of the Council, of May 29, 2003, relative to the hygiene of food products; Regulation (CE) nº 2073/2005 of the Commission, of November 15, 2005, relative to the microbiological criteria applicable to food products.

• Food Labelling and Information: Royal Decree 126/2015, of February 27, which approves the general rule regarding food information on foods that are presented unpackaged for sale to the final consumer and to communities, of the packaged at the points of sale at the request of the buyer, and packaged by the owners of the retail trade.

• Royal Decree 640/2006, of May 26, 2006, which regulates certain conditions for the application of community provisions on hygiene, production and marketing of food products. (B.O.E. 27.05.2006)

• Royal Decree 140/2003, of February 7, 2003, which establishes the sanitary criteria for the quality of water for human consumption (B.O.E. 02.21.2003)

• Royal Decree 135/2010, of February 12, with provisions relating to microbiological criteria of food products

• Royal Decree 3349/1983, of November 30, which approves Technical-Sanitary Regulations for the manufacture, commercialization and use of pesticides. (B.O.E. 01/24/1994) Amended by Royal Decree 162/1991, of February 8 (B.O.E. 02/15/1994) Amended by Royal Decree 443/1994, of March 11 (B.O.E. 03.30.1994)

• Law 17/2011, of July 5, on Food Safety and Nutrition (BOE 06.07.2011)

• Royal Decree 1801/2003, of December 26, 2003, on general product safety (B.O.E. 10.01.2004).

3.4. Estonian Food Legislation

Estonia is an EU country and therefore most of the food regulations are based on recommendations from European Commission, European Parliament, European Council and EFSA. Although, Estonia has a national food law, accepted by Estonian parliament in 1999. It has been updated yearly, the last update was done in April, 2021.

The national food law (Toiduseadus–Riigi Teataja) in Estonia gives legislation about food producing, self-control methods, food safety, novel foods, special foods, food additives, frozen foods, food fraud, hygiene, import, export, etc. More specifically, in the national food law it is given what is the definition of food, first production and first product, raw materials, how to handle food and who is the handler of food. In the food law, it is also regulated what are novel foods, genetically modified foods, special foods, food additives, etc. This law describes what are the hygiene requirements for food producers, self-control systems, certifying, etc. In addition to this, there are separate legislations governing the protected names of food groups. For example legislation for:

Coffee and chicory (https://www.riigiteataja.ee/akt/125112014014?leiaKehtiv)

Cocoa products and chocolate products (https://www.riigiteataja.ee/akt/111112014010?leiaKehtiv)

Sugar products (https://www.riigiteataja.ee/akt/125112014013?leiaKehtiv)

Honey (https://www.riigiteataja.ee/akt/125112014015?leiaKehtiv)

Jams (https://www.riigiteataja.ee/akt/112112014001?leiaKehtiv)

Juice products (https://www.riigiteataja.ee/akt/111112014009?leiaKehtiv)

4. GENERAL FOOD LAW REGULATION

While guaranteeing an effective internal market, EC strives to guarantee a high level of food safety and animal and plant health inside the EU through integrated farm to fork measures and sufficient monitoring (Figs. 8 and 9). Therefore, all EU legislation and standards in the agriculture, animal husbandry, and food production sectors seek to protect human health. The whole food production and processing chain within the EU, and also imported and exported commodities, is covered by a large body of EU-wide law.

Fig. 8. The EU's Food Safety Policy

As previously summarized in EU Food Legislation section, Regulation (EC) No 178/2002 on the general principles and requirements of food law, establishing EFSA and laying down procedures in matters of food safety lays the basis for guaranteeing a high degree of protection for human health and consumer interests in regard to food, taking into consideration, in particular, the diversity of food supply, including traditional goods, while maintaining the internal market's effectiveness. The fundamental principle of this regulation is to control food and feed. Thus, it establishes processes for matters that have a direct or indirect influence on the safety of food and feed. It also applies to all phases of food and feed production, processing, and distribution.

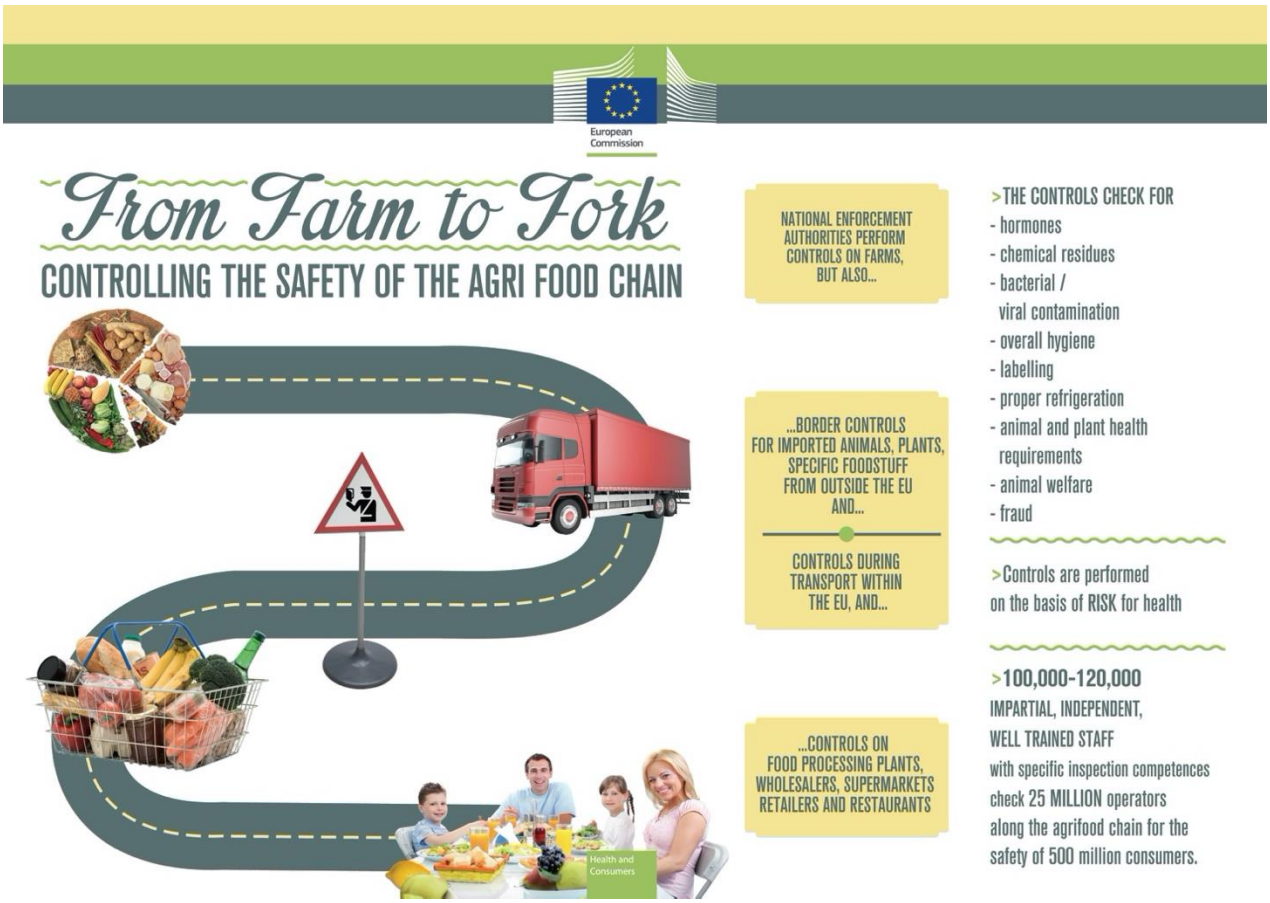

Fig. 9. Controlling the safety of the agri-food chain, integrated food safety strategy from farm to fork strategy (https://ec.europa.eu/food/system/files/2016-12/fs_infograph_from-farm-to-fork_en.pdf)

Regulation (EU) 2016/429 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') defines the prevention and control of animal diseases which are transmissible to animals or to humans.

Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products covers the rules for official controls.

The EU's execution of the integrated food safety (farm to fork) strategy entails a number of activities, including:

- To provide effective control systems and assess conformity with EU standards in the food safety and quality, animal health, animal welfare, animal nutrition, and plant health sectors in the EU and non-EU nations
- To handle international relations in the areas of food safety, animal health, animal welfare, animal nutrition, and plant health with non-EU nations and international organizations;
- To maintain good working relationships with EFSA and to guarantee science-based risk management

The EU's Food Safety Policy and actions are focused on four key protective areas:

1. Food hygiene: From farms to restaurants, all food enterprises, including those importing food into the EU, must follow EU food regulation.

2. Animal health: Sanitary controls and measures for pets, farm animals, and wildlife detect and manage illnesses, as well as track all farm animals' movements.

3. Plant health: Early identification and removal of pests minimizes the spread of disease and ensures the health of seeds.

4. Contaminants and residues: Contaminants are kept out of food and animal feed via monitoring. Food and feed products, both local and foreign, are subject to maximum acceptable limits.

Some Important Information Management System for Official Controls:

Some critical information management system for official controls to ensure compliance with food chain can be summarized as;

RASFF (the Rapid Alert System for Food and Feed): RASFF is a powerful resource for ensuring the flow of information and enabling rapid response when public health hazards are discovered in the food chain. RASFF, which was founded in 1979, allows for effective information sharing among its members. It provides a 24-hour service to guarantee that critical notifications are delivered, received, and reacted to collectively and promptly. Thanks to RASFF, many food safety hazards were prevented before they might damage European consumers

(https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts_en). Because of critical information supplied, RASFF can lead to product recalls.

RASFF is a strong system that has evolved through time and continues to demonstrate its usefulness in ensuring food safety in the EU and beyond (Fig. 10). The RASFF database was developed by EC in order to make its information as open as possible to consumers, businesses, and governments throughout the world. A searchable online database of RASFF can be found at https://webgate.ec.europa.eu/rasff-window/screen/search. It provides public access to summary information on the most recently sent RASFF notifications. It also includes the option to search for information on any previous notice. Since June 2014, customers have also chance to access to the RASFF consumer site (https://webgate.ec.europa.eu/rasff-window/screen/consumers). In all EU nations, the portal delivers the most up-to-date information on food recalls and public health warnings.

TRACES (Trade Control and Expert System): TRACES is EC's online platform for sanitary and phytosanitary certification, which is necessary for food, animals, feed, and plants imported outside from EU, or coming through the EU Member States. TRACES enables for the rapid detection of fraudulent certifications, which aids in the fight against food fraud and improves inter-agency communication and coordination. This allows to track animal illnesses and to combat fraud, as well as a to reduce administrative time.

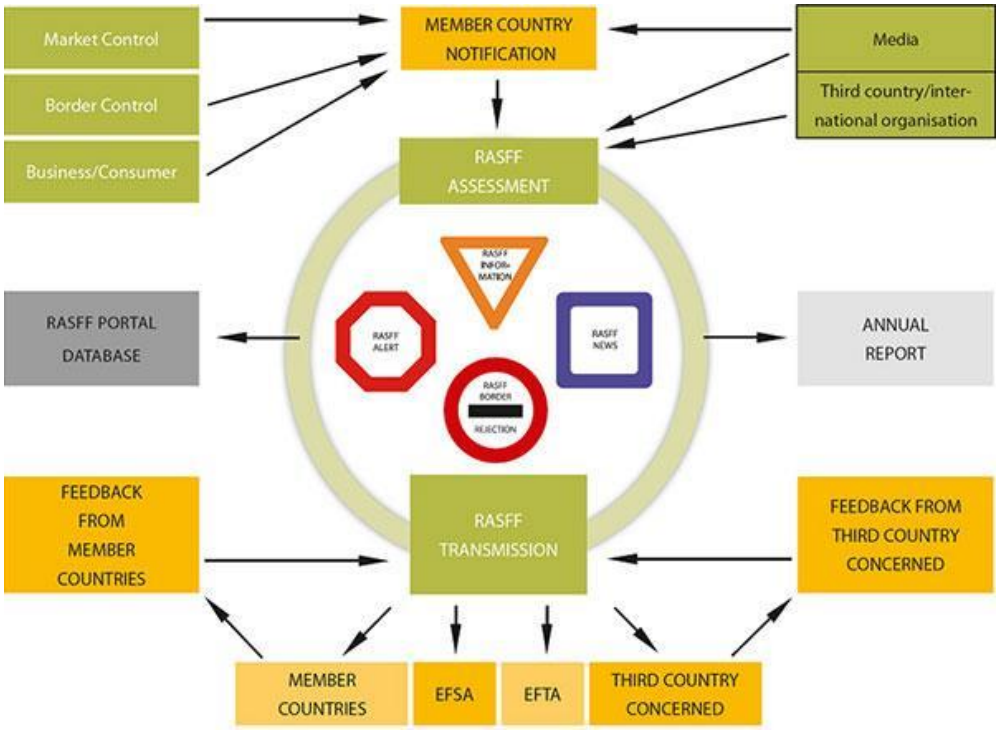

Fig. 10. How are RASFF notifications made? (https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts/how-does-rasff-work/how-are-notifications-made_en).

EUROPHYT: EUROPHYT is a web-based database and network, which make connections between the Plant Health Authorities of EU Member States and Switzerland, EFSA, and EC's Directorate General for Health and Food Safety. The main characteristics of EUROPHYT is to provide notification of interceptions (14)

5. SOME IMPORTANT EU FOOD REGULATIONS

5.1. Materials and Articles Intended to Come into Contact with Food

Food comes into contact with a variety of materials and articles during the manufacturing, processing, storage, preparation, and serving of food. Thus, FCMs are called as materials and articles that come into contact with food. These items are either intended to come into touch with food, are currently in touch with food, or may conceivably be brought into contact with food or transfer their components to food under normal or predictable conditions. This might be in the

form of direct or indirect touch such containers for carrying food, food processing equipment, packaging materials, and kitchenware and tableware (Fig. 11). On the other hand, fixed public or private water supply equipment is not included in this definition.

Fig. 11. Different kind of FCMs.

FCMs should be sufficiently inert such that their components have not any negative impact on consumer health as well as on food quality. EU legislation establishes obligatory regulations that company operators must follow in order to safeguard the safety of FCMs as well as to enable the free movement of commodities. EFSA assesses the safety of FCMs. Since chemicals can migrate from materials into food, the safety of food contact materials must be assessed. The materials must be created in accordance with EU laws, including good manufacturing practices, to ensure that any possible transfer to foods does not pose a safety risk, alter the food's composition in an undesirable way, or have a negative impact on the food's taste and/or odour. EFSA adopts and publishes scientific views on the safety of chemicals used or planned to be used in the manufacturing of materials that come into contact with food. EFSA also gives scientific opinions about the safety of related processes such as recycling of plastics. EFSA's opinions on substances to be used in food contact materials can be found at https://www.efsa.europa.eu/en/topics/topic/food-contact-materials.

Food Contact Materials are assessed for safety by the businesses that put them on the market, as well as by the Member States' competent authorities during official controls. EURL-FCM maintains scientific knowledge and technical expertise in testing procedures to the EU and the Member States. The information about EURL-FCM can be found at https://ec.europa.eu/jrc/en/eurl/food-contact-materials.

Regulation 1935/2004 on Materials and Articles Intended to Come into Contact with Food defines the general principles of safety and inertness for all FCMs. Regulation 1935/2004 has two main aims; to ensure the efficient functioning of the internal market in relation to the placing on the market in the Community of any materials and articles intended to come into direct or indirect contact with food, and to ensure a high level of consumers' health.

In addition to materials and articles intended to come into direct or indirect contact with food, it also sets out special rules on active and intelligent materials which are not inert by design. It also establishes further EU measures for specific materials such as plastics. It also ensures traceability and proof of compliance. Labeling requirements such as an indication for use (e.g., as a coffee machine, a wine bottle, or a soup spoon) or the reproduction of the relevant symbol are also defined in this Regulation (Fig. 12).

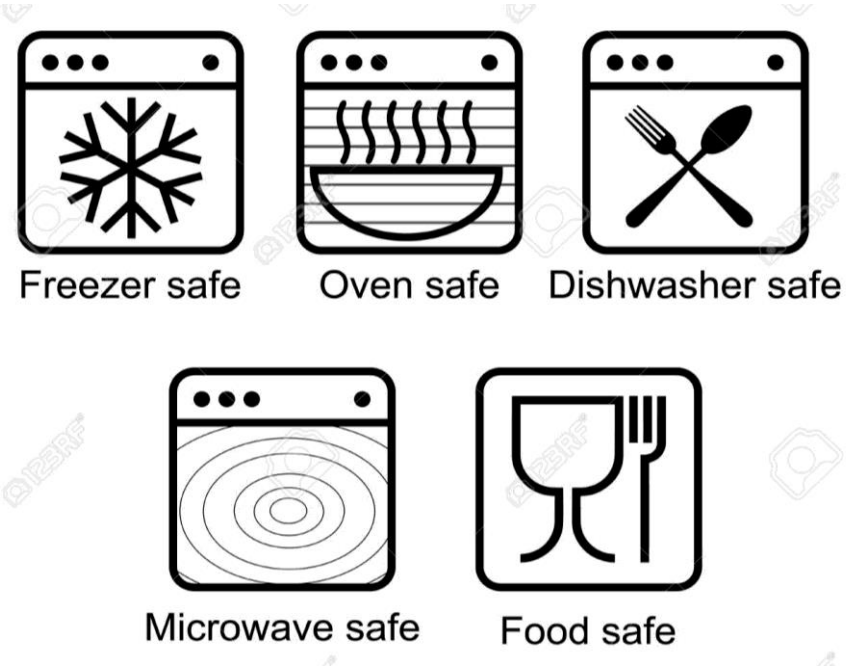

Fig. 12. Properties of food contact materials in order to ensure the food safety

On the other hand, this regulation does not cover the rules for materials and articles which are supplied as antiques, covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food and fixed public or private water supply equipment

Regulation 2023/2006/EC on good manufacturing practice for materials and articles intended to come into contact with food establishes GMP rules for the materials and articles intended to come into contact with food as well as combinations of those materials and articles and recycled materials and articles used in those materials and articles. Good manufacturing practices apply to not only starting materials but also to all stages of the manufacturing chain for food contact materials.

In addition to the general legislation (1935/2004/EC), Certain FCMs – ceramic materials (Directive 84/500/EC), regenerated cellulose film (Directive 2007/42/EC), plastics (including recycled plastic) (Regulation 10/2011/EC), as well as active and intelligent materials (Regulation

450/2009/EC) — are regulated by special EU regulations in which specific rules on some starting substances used to produce FCMs are defined. Thus, specific rules on some starting substances used to produce FCMs are defined in different regulations.

Among all these specific regulations, Regulation on plastic materials and articles (Regulation 10/2011/EC) is the most comprehensive specific EU legislation. The criteria on the composition of plastic FCMs and a Union List of substances that can be used in the production of plastic FCMs have been set out in this regulation. It also establishes the limitations on the use of certain chemicals and criteria for determining whether or not plastic materials and items are compliant. The application of migration limits is an essential technique for ensuring the safety of plastic materials and the maximum amount of chemicals that can migrate to food is specified by these limitations (Fig. 13). The Regulation establishes 'Specific Migration Limits' for the substances which are available in the Union list and these limits are determined by EFSA based on toxicity data for each chemical substance. To guarantee the plastic's overall quality, the total migration of all substances to food must not exceed OML of 60 mg/kg food or 10 mg/dm^2 of contact material. The same regulation gives also the detailed information about migration testing rules based on '***simulants***' (representative for a food category such as acetic acid 3 % (w/v) for acidic foods). Declaration of Compliance is required in order to provide the safety, quality and compliance of plastic materials, adequate data on the composition of (intermediate) materials must be transmitted along the manufacturing chain, up to but not including the retail stage.

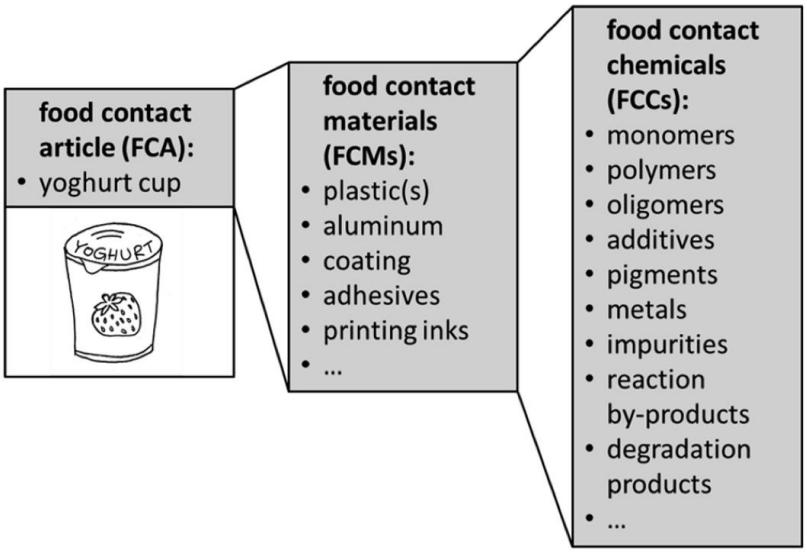

Fig. 13. FCAs are combinations of different FCMs, which consist of food contact chemicals (e.g., a yogurt cup made of polystyrene with printing inks and a coated aluminium cover glued on with adhesives) (Muncke et al (2017).

Active and intelligent materials are used to increase the shelf life of packaged foods by releasing or absorbing substances into or out of the product or its surroundings (Fig. 14). The rules for the use of active and intelligent materials are defined in Regulation 450/2009/EC on active and intelligent materials and articles intended to come into contact with food.

Fig. 14. An example of active and intelligent materials.

5.2. Food Contaminants

Contaminants are defined as any substance that not intentionally added to food but they are present in food as a result of production (including crop husbandry, animal husbandry, and veterinary drug), manufacture, processing, preparation, treatment, packaging, transport, holding, or environmental contamination. In addition to its detrimental effect on the quality of food, it may pose a danger to human health. Thus, the EU has taken measures to reduce contaminants in foodstuffs and Regulation 315/93/EEC establishes the fundamental principles of EU regulation on contaminants in food.

Food cannot be put on the market if it includes a contaminant in a level that is more than unacceptable from the standpoint of public health, and at a level that is toxicologically substantial. Contaminant levels must be kept as low as can be reasonably achieved by following good agricultural, fishery and manufacturing practices. Contaminants should be identified and controlled as part of a food safety management system based on HACCP.

The maximum levels are for the contaminants such as mycotoxins (aflatoxins, ochratoxin A, fusarium-toxins, patulin, citrinin), metals (cadmium, lead, mercury, inorganic tin, arsenic), dioxins and Polychlorinated Biphenyls (PCBs), Polycyclic Aromatic Hydrocarbons (PAH), 3-MCPD (3-monochloropropane-1,2-diol or · 3-chloropropane-1,2-diol), melamine, erucic acid and nitrates of the greatest concern to EU consumers, either due to their toxicity or their potential prevalence in the food chain. These levels are set in Regulation 1881/2006/EC on setting maximum levels for certain contaminants in foodstuffs. The levels are set out on the basis of scientific advice provided by EFSA. Similar to other regulations, Member State authorities are responsible for sampling food products to provide that they comply with the legislation. In case of imported food products, the country of origin is responsible for compliance with EU legislation. The compliance with EU legislation is controlled at EU borders and on the market.

Control and response processes in the EU are based on a system of random checks carried out by Member States. When a risk is recognized during the inspections, immediate action is done such as temporarily suspension or restriction of production or distribution of products. In addition, Member States and EC should be informed about the procedure. RASFF is a system that communicates information between national competent authorities, EC, and EFSA, enabling rapid

action. EC uses FVO to assess whether legislative rules and preventive measures are being applied correctly in Member States and third countries. It then issues and follows up on recommendations that must be implemented by national authorities.

Examples for contaminants:

Patulin: The EU's response to patulin in apple juice is a solid example of best practice. Patulin is a toxin generated by molds that may be detected in decaying apples and other moldy fruit. It has been proven to be a carcinogen, despite the fact that it is not a particularly powerful toxin. Therefore, EU regulations for apple juice and apple juice components in other drinks set maximum limits for patulin. The EU has also proposed a Code of Practice for the apple processing sector, because the handling and storage of fruit affects the likelihood of patulin contamination of juice. The regulation covers good manufacturing methods such as pruning of trees, fruit handling to avoid damage, and keeping fruit dry after harvested, among other things.

Fig. 15. Contamination of apples with patulin (Wright, 2015).

Fusarium Toxins: Fusarium fungi that produce toxins are widespread on grains cultivated in temperate parts of Europe, America, and Asia. Toxic effects have been observed in both experimental animals and livestock, and they are suspected of causing significant levels of toxicity in humans. In addition to defining maximum levels, the EU supports a variety of good agricultural practices in the handling, storage, processing, and distribution of cereals for human consumption and animal feed to prevent or reduce contamination by fusarium toxins. Crop rotation, timely harvesting, and dry storage can be given as examples for these techniques.

Fig. 16. Contamination of grains with fusarium.

Acrylamide: Acrylamide which is regarded as potential carcinogenic substance, often present in starchy foods such as potatoes and cereal goods as a result of cooking techniques such as deep-frying, roasting, or baking at high temperatures (over 120°C). Research have been focused on to analyze how it forms and to identify strategies to minimize its prevalence. It has been shown that a careful selection of raw materials, as well as using of certain cooking techniques are effective to reduce the production of acrylamide in potato and bread products. The food sector collaborated closely with EC and Member States to produce a toolbox and a series of brochures with practical recommendations.

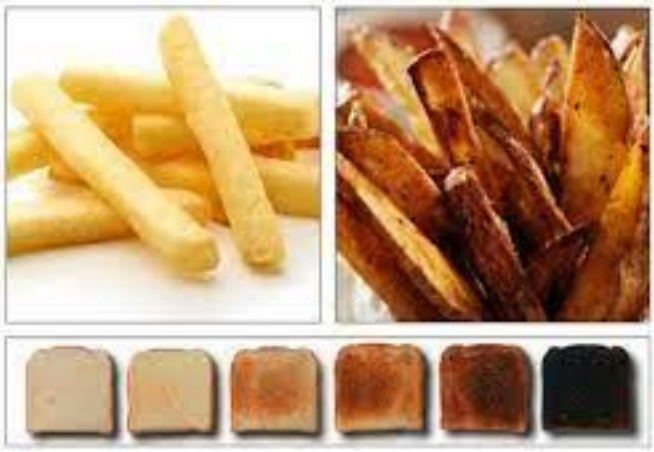

Fig. 17. Acrilamide in food (https://www.dangersalimentaires.com/en/2009/10/acrylamide/).

5.3. Microbiological Criteria

Microbiological criteria help identify if foods and their production procedures are acceptable based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume area or lot. Food safety may be achieved by preventative measures such as the use of GHP, GMO and HACCP principles. Although microbiological testing alone cannot ensure the safety of a product, these standards give objectives and reference points to aid food enterprises and competent authorities in their activities to manage and monitor food safety.

Microorganism of concern, analytical method, sampling plan, number of sample units, size of the analytical unit, microbiological limits, the foodstuff, the point of the food chain where the limit applies and actions to be taken when unsatisfactory results are regarded as components of a microbiological criteria. The main responsibilities of food business operators can be summarized as to demonstrate the compliance of their production with microbiological criteria, to establish a sampling and testing scheme based on risk (HACCP), to respond in case of non-compliance and to follow and assess trends.

Under General Food Law (Regulation (EC) No 178/2002), all food business operators have a legal obligation to produce safe food. In addition, Regulation (EC) No 852/2004 on the hygiene of

foodstuffs requires manufacturers/processors to adopt hygiene measures (this includes compliance with relevant microbiological criteria) and to put in place, implement and maintain a permanent procedure or procedures based on HACCP principles. Furthermore, this regulation lays down additional hygiene rules for foods of animal origin.

Regulation1441/2007/EC on microbiological criteria for foodstuffs (amending Regulation 2073/2005/EC) establishes the microbiological criteria for particular microorganisms, as well as the implementing regulations that food business operators must follow when executing the general and specialized hygienic measures. Food safety criteria for relevant foodborne bacteria, their toxins and metabolites, such as *Salmonella, Listeria monocytogenes, Enterobacter sakazakii, Staphylococcal enterotoxins*, and histamine in specific foods are laid out in this regulation. All microbiological criteria were created in line with internationally recognized norms, such as the Codex Alimentarius. EFSA provides scientific advice on issues pertaining to microbial hazards in food.

5.3.1. Process hygiene criteria

Process hygiene criteria indicates the correct functioning of the production process. It is applied during the process or at the end of the manufacturing process but not when product placed on the market. If unsatisfactory results are obtained, corrective actions such as improvement of production hygiene and selection of raw materials are defined in HACCP programme. It is established for microorganisms (usually indicator[2] microorganisms) in various food commodities, e.g. *E. coli* in minced meat, *Enterobacteriaceae* in egg products. More detailed information is given below;

Food hygiene criteria examples:

- *Salmonella* in Carcasses
- Aerobic colony count and *Enterobacteriaceae* in Carcasses
- *E. coli* in minced meat, meat preparations, butter and cream made from raw milk, precut fruit and vegetables
- Coagulase positive *Staphylococci* in certain dairy products
- *Enterobacteriaceae* in dried infant formulae

5.3.2. Food safety criteria

It is used to assess the acceptability of a product/batch of food stuffs. They usually apply for the whole shelf life of food that have been placed on the market. When unsatisfactory results are obtained, actions such as withdrawal or recall, further processing (not yet at retail level) or other corrective actions based on HACCP programme that need to be taken into consideration. They are established for microorganisms (usually pathogenic microorganisms), their toxins or metabolites in various food commodities, e.g. *Listeria monocytogenes* in ready-to-eat foods, *Staphylococcal* enterotoxin in certain cheeses, milk powder and whey powder. More detailed information is given below;

Table 1. An example of food hygiene criteria

Food Category	**Microorganisms**	**Sampling Plan**		**Limits[2]**		**Analytical reference method[3]**	**Stage where the criterion applies**	**Action in case of unsatisfactory results**
		n	c	m	M			
Cheese made from raw milk	Coagulase-positive staphylococci	5	2	10^4 cfu/g	10^5 cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values $>10^5$ cfu/g are detected, the cheese batch has to be tested for staphyloccal enterotoxins

Food safety criteria examples:

- *Listeria monocytogenes* in all ready-to-eat foods
- *Salmonella* in certain ready-to-eat foods, minced meat, meat preparations, meat products
- *Staphylococcal* enterotoxins in certain dairy products
- *E. sakazakii* in dried infant formulae

- *E. coli* in live bivalve molluscs
- *Histamine* in fishery products from certain fish species

Table 2. An example of food safety criteria

Food Category	**Microorganisms**	**Sampling Plan**		**Limits**[2]		**Analytical reference method**[3]	**Stage where the criterion applies**
		n	c	m	M		
Ready to eat foods intended for infants and ready to eat foods for special medical purposes	Listeria monocytogenes	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
Ready to eat foods able to support the growth of L. monocytogenes, other than those indented for infants and for special medical purposes	Listeria monocytogenes	5	0	100 cfu/g[5]		EN/ISO 11290-2[6]	Products placed on the market during their shelf-life
		5	0	Absence in 25 g[7]		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it

5.4. Pesticides

Pesticides is a term which is commonly used to describe to PPPs. On the other hand, it also includes items like biocides, which are meant for non-plant applications to control pests and disease carriers like insects, rats, and mice and do not fall within the EFSA's authority (18).

PPPs are pesticides including herbicides to control weeds before and during growth, fungicides to prevent mould forming on plants in the field and in store, insecticides to protect seeds and plants from damage by insects, nematicides and molluscicides to control attack on growing plants by worms and slugs, rodenticides to prevent damage and contamination by small mammals such as mice and rats during growth and storage, acaricides to kill ticks and mites. They are primarily used to keep crops healthy and prevent disease and infestation from destroying them.

At least one active ingredient is present in PPPs. Chemicals or microorganisms, including viruses, that enable the product to fulfil its function are examples of these substances. These active chemicals are a significant focus of EFSA's risk assessment work in the field of PPPs. Marketing and usage of PPPs, as well as residues in food, are governed by a broad set of EU regulation. Without prior approval, PPPs cannot be placed on the market or used. Member States evaluate and authorise the products at the national level. PPPs are principally regulated by framework Regulation (EC) No 1107/2009.

Regulation (EC) No 396/2005 governs all issues pertaining to pesticide residue limitations in food and feed. This regulation also includes necessities on official controls of pesticides residues in food of plant and animal origin that may result from their use in PPPs. EFSA provides risk managers with impartial scientific advice based on risk assessments, while EC and Member States take risk management decisions on regulatory matters including active substance authorisation and pesticide residue legal limits in food and feed (MRLs). EC must approve an active ingredient before it may be used in a PPP in the EU. Active chemicals must undergo a thorough a rigorous assessment procedure before a decision on approval may be made.

5.4.1. Maximum residue levels

5.4.1.1. Maximum levels of pesticide residues in food

Pesticide residues from the use of PPPs on food and feed crops may constitute a health concern. As a result, EU has developed a comprehensive legal framework that establishes regulations for the licensing of active chemicals, the use of PPPs, and pesticide residues in food. Food producers and importers must ensure that the food they manufacture or import complies with current regulations, including maximum residue levels.

MRLs are the highest amounts of pesticide residues that are legally permitted in or on food or animal feed, based on good agricultural practice (GAP) and the lowest exposure necessary to safeguard vulnerable consumers, according to Regulation (EC) No 396/2005. MRLs are defined following a thorough examination of the properties of the active substance and the intended applications of the pesticide. These regulatory restrictions also apply to imported food, which are referred to as "import tolerances" in order to accommodate international trade.

Any residue found in foods where a pesticide application is not permitted and there is no import tolerance (an MRL accepted for imported foods even if there is no approved use) is subject to a default MRL of 0.01 mg/kg, or higher if analytically impossible. Any food that does not meet MRLs must be removed from the market.

MRLs for active substances are reviewed in accordance with a method agreed upon by EC and Member States. EFSA’s application helpdesk receives applications for new or updated EU MRLs in line with Regulation (EC) No 396/2005. The results of EFSA's MRL evaluations are published in the EFSA Journal as reasoned opinions (19).

5.5. Additives

Additives are compounds used in the manufacture of food for a diversity of purposes, such as preservation, colouring, sweetening, and so on. According to European Union Regulation (EC) No 1333/2008, it is described as any material not typically consumed as a food in itself and not normally utilized as a distinctive element of food, whether or not it has nutritional value. They are added to food for technical purposes during its preparation, production, processing, treatment,

packaging, transportation, or storage. Additives are used for a variety of purposes, including colouring, preservatives, antioxidants, flour treatment agents etc.

Regulation (EC) No 1333/2008 establishes rules for food additives in order to ensure the effective functioning of the internal market while ensuring a high level of human health protection and consumer protection, including consumer interests and fair practices in the food trade, taking into account, where appropriate, environmental protection. It also lists all approved food additives, conditions of their used in foods (including in food additives and in food enzymes) as well as the rules on labelling of food additives sold as such. Furthermore, there is a database (20) showing that additives and foods in which they are allowed to be used, as well as the criteria that apply to their usage. Food additives on the European Community list are only allowed to be sold as such and used in foods under the restrictions set therein. The use of a food additive which is permitted for specific uses for certain authorised oenological practices and processes should comply with the regulations and with the specific provisions set out in the relevant EU legislation.

5.6. Food Supplements

Food supplements, which are concentrated forms of nutrients (minerals, vitamins or other substances) having a nutritional or physiological impact, are sold as a complement to a typical diet. Food supplements can be found in different forms such as “dose” form, such as pills, tablets, capsules, and liquids in defined dosages etc. Consumers purchase food supplements to complement their dietary consumption. For example, vitamins and minerals are mentioned on the label of food supplements, they should be present in a substantial amount in the product to guarantee that this goal is met.

The harmonised restrictions on such goods in Directive 2002/46/EC are designed to safeguard consumers from possible health hazards associated with those products while also ensuring that they are not given false information. In terms of the safety of food supplements, the Directive establishes a standardised list of vitamins and minerals that may be added to food supplements for nutritional purposes and this list may be found in Annex I to the Directive.

Vitamin D tablets, vitamin B12 powders, calcium pills and iron capsules can be given as examples for food supplements. Additional food rules, such as the General Food Law, the Food Additive

Regulation, and national EU member state legislations, may apply to other compounds included in supplements, such as amino acids, essential fatty acids, or herbal extracts. On the other hand, medicinal supplements fall under Directive 2001/83/EC and they are not covered by Directive 2002/46/EC.

A list of approved sources (vitamin and mineral compounds) from which such vitamins and minerals may be produced can be found in Annex II of the Directive. Therefore, only the vitamins and minerals specified in Annex I such as vitamin B, vitamin C, biotin, iron, calcium and zinc, in the forms stated in Annex II, may be used to make food supplements. There are such examples below;

Vitamin B1

- Thiamin hydrochloride
- Thiamin mononitrate
- Thiamine monophosphate chloride
- Thiamine pyrophosphate chloride

Vitamin C

- L-ascorbic acid
- Sodium-L-ascorbate
- Calcium-L-ascorbate
- Potassium-L-ascorbate
- L-ascorbyl 6-palmitate
- Magnesium L-ascorbate
- Zinc L-ascorbate

5.6.1. Labelling requirements

The regulation defines the following necessities for supplement labels:

a. The amounts of active substances having any nutritional or physiological effect must be listed on the label,

b. The amount of nutrients or substances in the product that have a nutritional or physiological impact must be indicated on the labelling in numerical form.
c. The names of the nutrient or substance categories that characterize the product, or a description of the nature of those nutrients or substances must be indicated on the labelling,
d. The label must not in any way mislead customers (e.g net quantity or other beneficial effects)
e. The amount of product that should be consumed on a daily basis must be indicated on the labelling,
f. A warning not to exceed the daily amount prescribed must be indicated on the labelling,
g. A statement showing that dietary supplements should not be used to replace a diverse diet must be indicated on the labelling,
h. There must be no statement or implication on the labelling, presentation, or advertising of food supplements that a balanced and varied diet cannot supply adequate amounts of nutrients in general.
i. A statement indicating that the items should be kept out of reach of small children must be showed on the labelling,
j. The label must provide information regarding the supplements' minimum durability/expiration date,
k. The labelling, packaging, and advertising of food supplements must not refer to the property of preventing, treating, or curing a human illness.

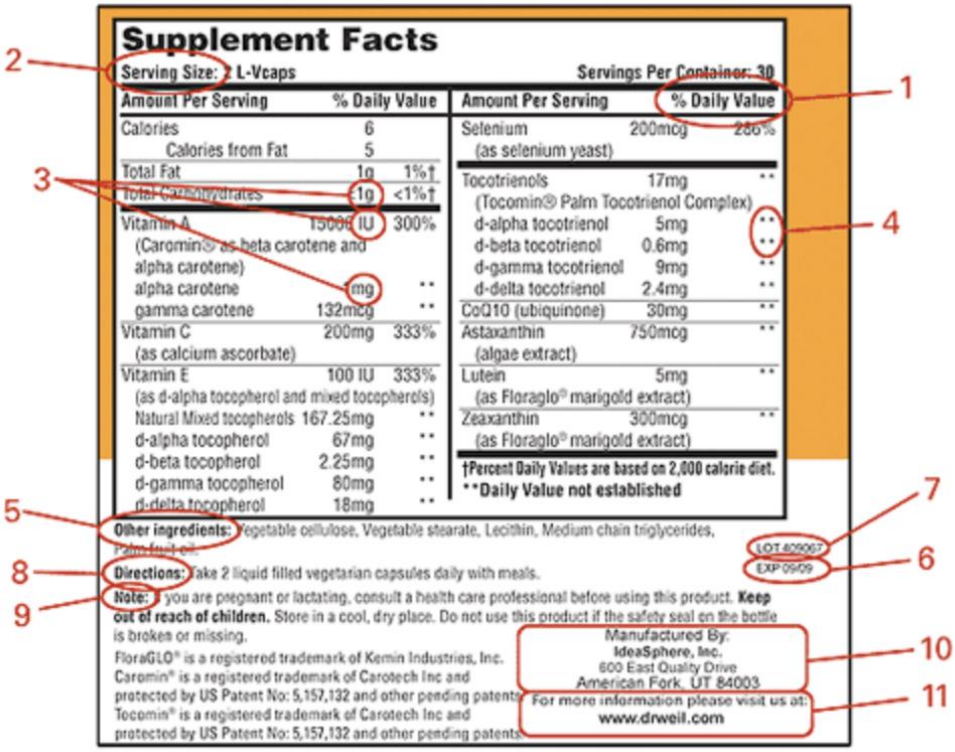

Fig. 18. An example for the labelling of food supplement

Figure 18 shows an example of food supplement labelling. Each number on this label represents a distinct type of information;

1. "% of Daily Value": The "Daily Value," or Daily Reference Values (DRVs), and Reference Daily Intakes (RDIs). For example, if the "% Daily Value" listed is "75%" that means one serving supplies 75 percent of the entire DV for that nutrient.

2. "Serving Size": This specifies how many units – tablets, softgels, capsules, and so on – must be consumed in a day to achieve the labelled percent of daily value.

3. Units of measure reflect the standard reference units for each kind of nutrient.

4. Asterisks in place of DV listings indicate that DVs for these nutrients have yet to be determined. Some dietary supplements contain these nutrients because they have scientifically verified health benefits and are safe to consume at the amounts contained in the supplement.

5.Other ingredients: This is a list of compounds that do not directly contribute to the nutrient DVs in the supplement. However, they provide tablet integrity, proper digestion or preservation of shelf life.

6. “EXP” indicates the expiration date. Consuming supplements that are past their expiration date is usually not harmful, but since the full nutritional value is not received by the consumer, it is recommended that supplements that have passed their expiration date be replaced with fresher ones. Consumption of supplements that are beyond their expiration date is typically not hazardous, but because the consumer does not obtain the full nutritional content, it is advised that expired supplements not be consumed.

7. LOT is a number that indicates the particular production lot in which this item was included. It is useful if there are any doubts regarding the integrity of the ingredients or manufacturing procedures utilized to make that lot.

8. Directions gives information to assist the consumer safely obtain maximum value from the product.

9. Note is a warning to customers about the supplement's possible negative effects on people like pregnant or breastfeeding women, those using certain prescription medicines, and people with allergies. This section also includes instructions for storing the supplements.

10. The manufacturer’s information reveals which company created the supplement and where its headquarters are located.

11. If customers or potential purchasers have queries about the product, “for more information” offers contact number

5.6.1.1 Nutrition Labelling

Major changes to food labelling regulation

Regulation (EU) No 1169/2011 on the provision of food information to consumers came into effect in 2011. It mandates a nutrition disclosure on the vast majority of pre-packaged goods as of December 2016. It must give the food's energy value as well as the fat, carbohydrate, sugars, protein, and salt content. On the packing, the statement must be provided in a readable tabular manner. If there isn't enough space, the information can be displayed in a linear format. This required nutrition statement is frequently found on the back of food packages.

The required nutrition declaration can be added voluntarily with the quantities of mono-unsaturated fats, polyunsaturated fats, polyols, carbohydrates, fiber, vitamins, and minerals. This optional information should not take up space that should be reserved for necessary information. All data must be given in terms of 100g or 100ml. In addition, it can also be stated per portion or per unit of consumption of the product.

Guidance document for competent authorities for the control of compliance of nutrient values declared on a label with EU legislation can be found at https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition-vitamins_minerals-guidance_tolerances_1212_en.pdf and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2018:196:FULL&from=EN

The following are some of the modifications on food labelling regulation;

a. In the EU, what was once known as "food labeling" is now termed as "food information to consumers."
b. The legislation came into effect on 13 December 2011, went into application on 13 December 2014. It became mandatory as of 13 December 2016.
c. Its goal is to provide a standard format for food and nutrition labeling. It also aims to offer consumers with clear information about what they're consuming so they may make better dietary choices.
d. It influences all food manufacturers producing or selling within EU member states' borders.

e. The provisions apply to all food items destined for end users, including foods supplied by mass caterers and foods destined for mass caterer supply.
f. Legibility, minimum font size, allergen presentation, and layout of necessary nutrition information are required.
g. The obligatory nutrition declaration comprises the following information: calorie value, fat, saturates, carbohydrate, sugars, protein, and salt content.
h. The regulation applies to all food information provided to the ultimate customer, whether on the product or through any distance selling method.
i. Food items that have already undergone a nutritional analysis may be needed to do so again if all of the details necessary by the legislation, such as engineered nanomaterials and additional proteins, are missing.
j. Some foodstuffs, such as unprocessed products with only one component, water, herbs, salt, and so on, are excluded from the obligatory nutrition disclosure. The list may be found in the Regulation's Annex V.

Figure 19 depicts some important changes to nutrition labelling that match current consumer behaviour and our expanding knowledge of nutrition research.

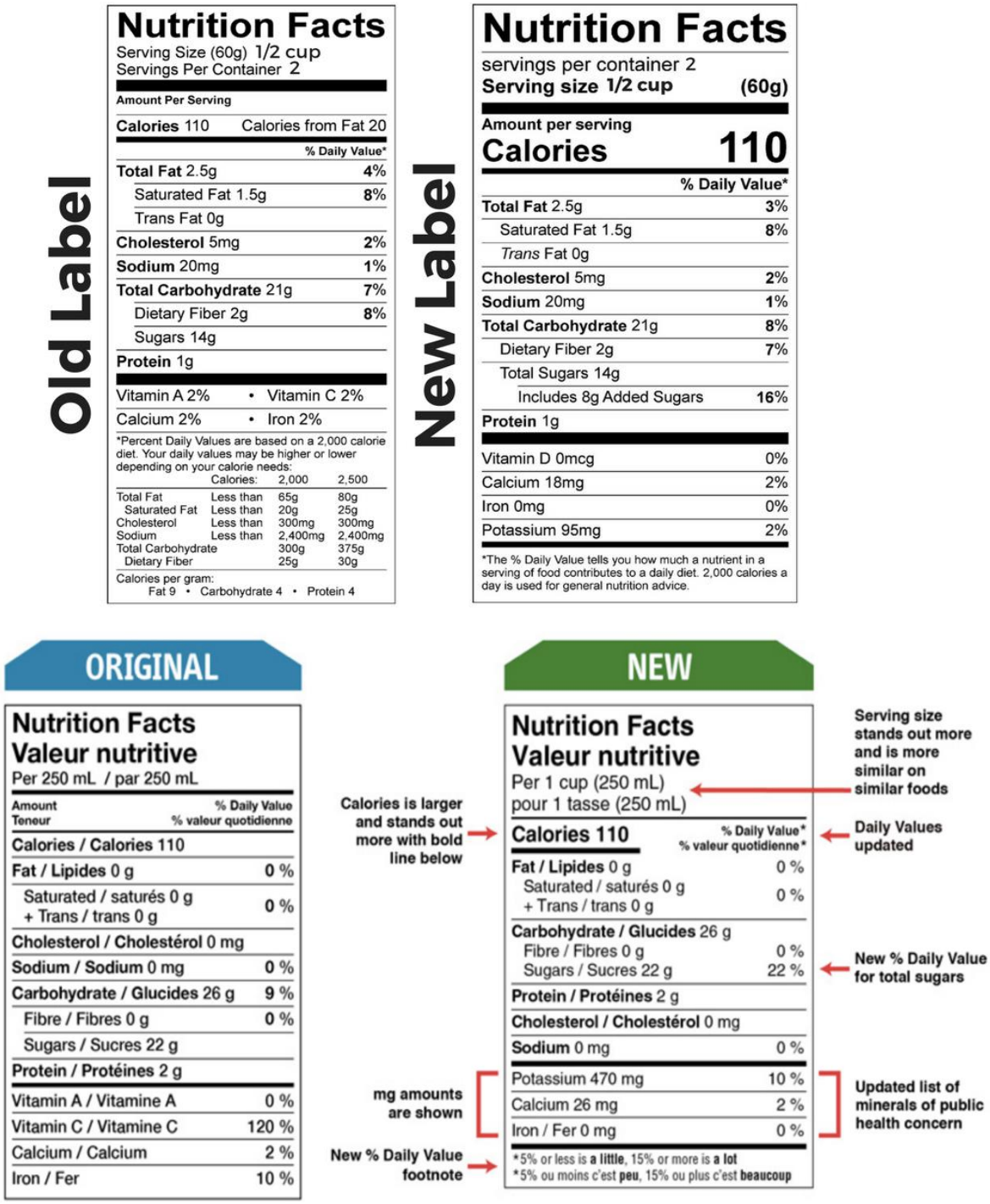

Fig. 19. An example of new and old nutrition label

5.7. Nutrition and Health Claims: The Role of Food Composition Data

Regulation (EC) No 1924/2006 covers nutrition and health claims made on all foods including food supplements, foods for particular nutritional uses (PARNUTS), natural mineral waters, water intended for human consumption and foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers marketed within EU.

This regulation also establishes the legal framework that food companies must follow when they want to promote the specific health and nutritional benefits of their goods on the product label or in advertising. It covers nutrition and health claims made in commercial communications, whether in the labelling, packaging, or advertising of foods to be given to the ultimate consumer, containing communications directed only at health professionals. It also establishes guidelines for nutrition claims ("low fat" and "high fiber") as well as health claims ("Vitamin D is required for optimal bone growth and development in youngsters"). It also ensures that clear, precise, and based on scientific evidence, claims should be made about a food's labelling, presentation, or advertising.

According to this regulation, food with claims that might mislead customers is forbidden and they must be clear and understandable by the average consumer. This protects consumers while simultaneously encouraging innovation and ensuring fair competition. The regulation ensures that food products with claims can circulate freely throughout the Union, as any food manufacturer can put the same claims on its products wherever in the EU. On the other hand, claims that overstate a food’s projected health advantages and/or are not properly substantiated by scientific data are not allowed. The guidance on the implementation of regulation 1924/2006 on nutrition and health claims made on foods can be found on the website (https://www.fsai.ie/uploadedFiles/EU_guidance_ClaimsRegulation.pdf).

5.7.1. Nutrition claim

Any claim states, suggests, or implies that a food has specific positive nutritional qualities because of the energy, nutrients, or other substances supplied, not supplied, or supplied in a reduced/increased amount is called as nutrition claim.

- the energy (calorific value) it

  - provides
  - provides at a reduced or increased rate; or
  - does not provide and/or

- the nutrients or other substances it

  - contains
  - contains in reduced or increased proportions; or
  - does not contain.

Fig. 20. An example of nutrition claim

5.7.2. Health claim

Any claim that states, indicates, or implies that there is a link between a food category, a food, or one of its contents and health (for example "aids digestion"). It can be classified as reduction of disease risk claim, health claims referring to children's development and health and other health claims is called as health claim.

Fig. 21. An example of health claim

If these claims are backed by well recognized scientific evidence and are widely understood by the majority of consumers, a comprehensive dossier is not required to get approval under the Regulation. A list of such claims is being compiled, and food business operators have had the opportunity to submit their claims, along with supporting scientific substantiation in the form of scientific papers, to their country's competent authority, which has then submitted a list of claims to EC for review by EFSA.

Before making any nutrition or health claim on a food, it is necessary to understand its nutritional composition in order to ensure that the constituent in issue is present in adequate amounts to support the claim. Because many food producers use food composition databases to determine composition, they must be precise, comprehensive, and up-to-date. It's also likely that health claims in the EU could extend in the future to include non-nutrient bioactive compounds like polyphenols from tea or lycopene from tomatoes, necessitating the collection of data on them.

5.7.3. General conditions for use of nutrition and health claims

The use of nutrition and health claims will be allowed only if the following requirement is met: The presence, absence, or reduced quantity of a nutrient or other substance in a food or category of food, as determined by generally accepted scientific data, has been proven to have a favourable nutritional or physiological impact.

The nutrient or other substance that is the subject of the claim:

- It is present in a considerable quantity in the finished product, as defined by Community legislation, or, in the absence of such regulations, in a quantity that would provide the nutritional or physiological impact stated, as established by generally recognized scientific data; or
- It is absent or present in in a reduced quantities to achieve the nutritional or physiological impact stated, as determined by well recognized scientific evidence;
- The nutrient or other component for which the claim is made is in a form that may be utilized by the body, if appropriate.
- A significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation, or, in the absence of such rules, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;
- Accordance with the specific requirements outlined in Chapter III or Chapter IV of the regulations, as applicable.
- The use of nutrition and health claims is only authorized if the average consumer can be anticipated to comprehend the claim's beneficial benefits.

- Nutrition claims must pertain to food that is ready to eat and has been prepared according to the manufacturer's instructions.

5.7.4. Specific conditions for nutrition claims

Nutrition claims will be allowed only if they are stated in the Annex and meet the requirements of this Regulation. Examples of nutrition claims listed in the Annex are given below;

- "low in fat" – a claim that a food is low in fat may only be made where the product contains no more than 3g of fat per 100g for solids or 1.5g of fat per 100ml for liquids.
- "sugar free" – a claim that a food is sugars-free may only be made where the product contains no more than 0.5g of sugars per 100g or 100ml.

5.7.5. Comparative claims

Only foods of the same category, considering a variety of foods of that category may be compared. The difference in nutritional content and/or energy value must be indicated, and the comparison must be made on the basis of the same amount of food. Comparative nutrition claims must compare the composition of the product in issue to a variety of similar foods that do not have a composition that permits them to carry a claim, including foods from other brands.

5.7.6. Specific conditions for health claims

Health claims are allowed if the following information is presented in the labelling, or in the presentation and advertising if there is no such labelling:

- A statement emphasizing the significance of a well-balanced diet and a healthy lifestyle;
- A statement showing the amount of food and the manner in which it is consumed in order to achieve the stated positive impact;
- A warning directed at those who should not consume the food, if applicable;
- A suitable warning for products that may pose a health risk if taken in large quantities.

5.7.7. Restrictions on the use of certain health claims

- statements that indicate that not consuming the food might harm one's health
- claims which relate to the rate or amount of weight loss;

- claims that refer to particular physicians' or health professionals' recommendations, as well as other associations not included in Article 11."

are not permitted

5.8. The Regulation on Food for Specific Groups

Regulation (EU) No 609/2013 covers food for infants and young children, food for specific medical purposes, and complete diet replacement for weight loss ('Food for Specific Groups'). The purpose of the regulation is to defend specific vulnerable groups of consumers such as infants and young children, people having specific medical conditions and people undertaking energy-restricted diets to lose weight by regulating the content and marketing of food products specifically produced for and marketed to them. In addition, this regulation attempts to improve legal transparency for businesses and make the laws easier to follow.

To guarantee the protection of vulnerable population groups, provisions on food are strengthened. The regulation sets broad compositional and labelling standards and requires the Commission to establish particular compositional and labelling rules through delegated acts for:

- Infant as well as follow-up formula
- Processed-cereal based food and other baby food
- Food for special medical purposes
- Total diet replacement for weight control

The regulation provides a single Union list of substances, containing minerals and vitamins, that can also be added to these food groups.

5.9. GMO Legislation

A genetically modified organism is one whose genetic material has been changed through genetic engineering to add genes it would not naturally have. EU has built a legislative framework to guarantee that contemporary biotechnology, and especially GMOs, is developed in a safe environment.

The legislative framework attempts to achieve the following goals;

- To protect human and animal health, as well as the environment, by requiring an EU-wide safety evaluation of the highest feasible standards prior to the release of any GMO.
- To put in place effective, time-limited, and transparent standardised processes for risk assessment and GMO licensing.
- To confirm that GMOs on the market are clearly labelled. Therefore, both consumers and experts such as farmers and food feed chain operators may make informed choices.
- To guarantee that GMOs on the market are traceable.

For these purposes, the following regulations define the basis of GMO. These major pieces of legislation are complemented by a variety of implementing rules, as well as recommendations and guidelines on more specific topics.

- Directive 2001/18/EC on the deliberate release of GMOs into the environment
- Regulation (EC) 1829/2003 on genetically modified food and feed
- Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory
- Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
- Directive 2009/41/EC on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs

Regulation (EC) 1829/2003 on genetically modified food and feed establishes guidelines for the approval and supervision of GMOs, as well as the labelling of genetically modified food and animal feed. It covers the rules related to GMOs in food or animal feed, GMO-containing food or animal feed, food or feed manufactured with or containing GMO-derived components. It aims to protect people's lives and health, as well as animal health and welfare, the environment, and consumer interests.

Risk management is done by EC. Based on EFSA's evaluation (EFSA panel on genetically modified organisms can be found at https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo), the Commission sends a proposal containing its recommendation to accept or

reject GMO application to the Standing Committee on the Food Chain and Animal Health. If the Standing Committee accepts the proposal, the Commission accepts it. If the proposal is not accepted by Standing Committee, the Council evaluates the draft decision, and agrees whether or not the Commission should adopt it.

In terms of labelling of food and feed containing GMOs, all products should be clearly labelled. However, as long as the GMO content is technically unavoidable, food or feed containing less than 0.9 % GMOs does not need to be labelled. The list of components for pre-packaged GM food/feed products must state "genetically modified" or "made from genetically modified [name of the organism]." These phrases must be prominently displayed in close proximity to the product even if the product does not have packaging (e.g a note on the supermarket shelf). There are "GMO-free labels" that state that, in addition to what is mandated by EU GMO regulation, special voluntary measures have been taken to rigorously prohibit the presence or use of GMOs in certain food and feed items. Such voluntary labelling is acceptable as long as it does not mislead consumers.

Fig. 22. An example of GMO and GMO-free labelling

5.9.1. Approval of GMOs

Applicants for GMO approval must submit a dossier containing experimental data. In addition, the dossier should also contain a risk assessment related to the use of GMO.

Authorisations are valid throughout the EU and can be used for a variety of purposes, including:

- Cultivation and marketing of food, feed, and derived products and
- It is sufficient to apply for food and feed uses, if the GMO is to be used in food or feed without cultivation. On the other hand, companies must apply for both cultivation and food/feed uses under Regulation if GMOs are to be used in food or feed in the EU. If the GMO is not be used in food or feed, in this case applying for authorisation for cultivation is enough.

5.10. How to Start a Food Business?

If someone wants to start a food business, they have to comply with a slew of regulations. For example, you must register your food business with the local authority not only for the establishment of a new food business but also for taking over an existing one. Some of these rules apply to all food enterprises, while others are specific to a single food product, such as low-acid canned food, fish, or juice. Food enterprises that manufacture, prepare, or handle meat, fish, eggs, or dairy products for the purpose of supplying other businesses may need the approval by a local authority rather than registration (22).

5.10.1. Who is Required to Register?

All sorts of food companies that serve customers directly will be required to register. Restaurants, cafes and takeaways, mobile catering and temporary businesses, food stalls, food vans, nurseries, schools, distance selling, mail order and food delivery including online can be included in food enterprises. Therefore, someone who wants to start a food company in order to sell food, cook food, store food, or prepare food for distribution will need to register it. Food distribution or supply companies that operate out of an office should also register as food enterprises.

Regulation (EC) No 853/2004 establishes the requirements for establishments handling products of animal origin, as well as the hygienic criteria that must be met, and it must be approved by each

Member State's competent body. Manufacturing, processing, distribution, and marketing are all covered.

The following principles are taken into consideration in the hygiene rules:

- The food business operator bears primary responsibility for food safety
- Starting with basic manufacturing, food safety is guaranteed throughout the food chain.
- The food business operator should be complied with general use of techniques based on the principles of HACCP.
- As a useful tool to assist food company operators at all levels of the food chain in accordance with appropriate requirements, food business operators should follow good practice guidelines for hygiene or HACCP principles.
- Basic hygiene standards should be applied by the food company operator, which can be further established for specific types of food.
- Certain food enterprises require registration or approval.
- Food produced in distant regions and traditional production and methods are given flexibility.

5.10.2. Registration of New Food Business Establishments

1. Applications for registration: The Council is obligated to create procedures for food business operators to follow when seeking for registration of their establishments under Article 31(1)(a) of Regulation 882/2004. These processes are outlined in the following paragraphs.

2. Time frame for registration: Food businesses should be registered with the relevant Food Authority (such as the District Council) at least 28 days prior to the start of food operations.

3. Registration form: When registering their businesses, food company owners must provide comprehensive details of their activities to the competent Food Authority.

4. When more than one food establishment may be found at the same location:

4.1. Establishments controlled by the same food service operator: On certain sites, there will be two or more food business establishments controlled by the same food company operator such as two or more food establishments at a shopping center. When it comes to businesses controlled by

the same food business operator, the operators must make sure that each one is registered individually (23).

4.2. Establishments controlled by various food business operators: There may also be two or more food business enterprises under the management of separate food business owners. A supermarket, for example, could have a coffee shop on premise that is run by a separate food business operator, such as a coffee shop chain. In this case, the coffee shop will not be covered by the supermarket's registration. It would need to be registered separately. Coffee shops, snack bars, and other establishments run by the supermarket would be covered as part of the registration (23).

5. Lists of food business establishments:

5.1 Use of existing lists: Article 31(1)(b) of Regulation 882/2004 allows the Council to compile a list of registered food businesses and allows the use of existing lists for this purpose. Food company owners will not be required to re-register food enterprises under their control that have previously been registered with a Food Authority (https://ec.europa.eu/food/safety/biological-safety/food-hygiene/approved-eu-food-establishments_en).

5.2. Separate list of registered food enterprises: At all reasonable times, Centralized Authorities and District Council Food Authorities will make a separate, up-to-date list of their registered food business enterprises accessible for public inspection. This list includes the information about each food establishments such as name of food business operator, name of the food business, address of the food business establishment and particulars and nature of the food business (24). Any individual who sends a request to get such information may receive a copy of their list or any entry on it from these authorities.

5.3. Food authorities of the county council: Requests from the general public for information on registered food business enterprises in their region will be sent to the appropriate District Council Food Authority by County Council Food Authorities.

6. Follow-up after receiving a completed registration form:

6.1. The application of the requirements: When the Council receives a completed registration form, the date of receipt will be recorded on the form. If any actions on the form are outside the Council's

enforcement remit, a copy of the form will be submitted to the appropriate responsible body as soon as possible. The required information from the registration form will be included into the database and lists of registered food industry enterprises by the Council. The registration form will subsequently be filed in a file for that particular food enterprises. The Council will preserve existing business application forms in a format that allows them to be used as evidence if necessary. If any information is missing from a food business operator's registration form, the Council will either contact the food business operator to collect the missing information. If a significant quantity of information is missing, in this case the Council will send the form again to the food company for correction. The Council will consider conducting an examination of the institution after receiving a completed application form.

6.2. Registration certificates/confirmation of receipt: Food business operators will not be granted Certificates of Registration because they have the ability to mislead consumers into assuming that a food business operation has "official approval". On request, the Council may certify that registration forms were received safely and that an establishment was added to the list of registered food industry enterprises. Any such confirmation shall serve as a reminder to the food company owner that, in line with Article 6(2) of Regulation 852/2004, any further changes to the business must be reported to the Council.

7. Modifications to activities following registration: Any changes to the details previously supplied e.g. a change of food business operator, a change to the activities carried out in relation to food, the closure of an establishment etc. must be notified to the Council. Such notifications should be made, preferably in writing and before the changes occur, and in any event no later than one month after the change has occurred.

According to Article 6(2) of Regulation 852/2004, food business operators must ensure that the appropriate responsible authority has up-to-date information on their food enterprises. They also must notify the relevant competent authority about if there are major changes in operations, closure, etc. The Council also be informed about any changes such as e.g. a change of food business operator, a change to the activities carried out in relation to food, the closure of an establishment etc. These notifications should be sent, preferably in writing and before to the occurrence of the changes, but no later than one month after the occurrence of the changes. The

new food business operator is responsible for notifying the previous food business operator of a change. The Council shall update the list of registered food business enterprises as necessary after receiving notification of a change of operations. The Council also put or record the data on the file related to that food business enterprises.

8. Relocatable businesses: Relocatable Businesses are also subjected by Regulation 852/2004. They should be registered by the food business operator with the Council in the area in which they are ordinarily kept.

9. Non-registered establishments thought to be engaged in activities subject to regulation 852/2004 (Other than Primary Production): In such cases, the Council will request that the food business operator complete a registration form and verify that the food business is functioning in accordance with the other conditions of Regulation 852/2004.

5.11. Home-Based Business and Legislation

There is no regulation in EU that defines the requirements for home-based food production. On the other hand, the regulations of FDA can be used as example for home-based business. Some of these regulations apply to all food enterprises, while others are specific to a single food product, such as low-acid canned food, fish, or juice.

Food service and retail enterprises are inspected by local and county health departments, who also give technical assistance to food facilities and educate customers about food safety. A private house is not a "facility" under federal laws, according to Title 21, Code of Federal Regulations (CFR), section 1.227 (21 CFR 1.227). As a result, it is not needed to register with FDA. A private residence must fulfil standard requirements for a private residence and does not include commercial facilities where a person also lives. As a result, a private house (domestic or foreign) that fulfils the standard for a private residence that also manufactures, processes, packs, or stores food does not need to be registered. Therefore, in order to understand how they apply to your unique set of circumstances, the regulations must be carefully reviewed (25).

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