1. GENERAL INTRODUCTION

1. The research

1.1 Problem Statement

In July 2017, a notification was sent through the Rapid Alert System for Food and Feed (RASFF). [5] Then several follow-ups (in terms of additional information, measures taken, outcome of investigations, etc.) were forwarded and are still being formulated now in November 2017.[6] The notification was an alert sent from Belgium following on from official controls on the market. Traces between 0.0031 and 1.2 mg/kg of Fipronil were found in eggs and egg products produced in the Netherlands.[7] Fipronil is an insecticide that impacts on the nervous system of the insect such as red mites, which are very bad for animals and which may cause their death.[8] Fipronil is generally authorized for use in dogs and cats, while it is banned for use in livestock (the maximum residue limit of Fipronil is 0.005 mg/kg).[9] When the traces of Fipronil are higher than 0.72 mg/kg, the active substance could be dangerous for kidneys, liver and thyroid.[10]

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[5] European Commission- RASFF Portal 'Notification details-2017 1065' <https://webgate.ec.europa.eu/rasff-window/portal/?event=notificationDetail&NOTIF_REFERENCE=2017.1065>.

[6] Ibid.

[7] Ibid.

[8] REPORT Rai 3 'Che polli!' Di Francesca Ronchin <http://www.report.rai.it/dl/Report/puntata/ContentItem-0fbbfb42-21fb-42a0-bf4a-001485ada6c6.html>.

[9] European Parliament and Council Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin [2005] OJ L70/1.
"*The maximum residue levels (MRLs) for fipronil* (sum of fipronil + sulfone metabolite expressed as fipronil) *is legally fixed by the EU at 0.005 mg/kg in both chicken eggs and chicken meat (0.005 mg/kg being the lower limit of analytical determination, as no residues are expected to be detected given the prohibition of fipronil in poultry farms)"*: European Commission- Health and Food Safety- SANTE Newsroom, 'Information note on EU measures concerning the illegal use of fipronil on some poultry farms' (10 August 2017)<http://ec.europa.eu/newsroom/sante/itemdetail.cfm?item_id=127463&utm_source=sante_newsroom&utm_medium=Website&utm_campaign=sante&utm_content=Information%20note%20on%20EU%20measures%20concerning%20the%20illegal%20use%20of%20fipronil%20on%20s&lang=en>.

[10] De Bac M, 'Com'è finita questa sostanza negli allevamenti. E' nociva per l'uomo' *Corriere della Sera* (Milan, 21 August 2017) 21.

The Fipronil case was clearly presented as a criminal activity.[11] Emphasis was placed more on the impact on consumer confidence than on human health.[12] The use of Fipronil was understood as a criminal fraud[13] since it consisted in the illegal use of a product in clear violation of the rules established on maximum residue levels. The Fipronil case involved the whole European Union ("EU"), since hundreds of farms were blocked for production and 26 Member States and 19 Third Countries were affected.[14] The EU reacted with the tools it had at its disposal (for example: messages put forward via RASFF especially on measures to be taken as regard to illegally treated farms and exchange of views with the Member States involved concerning the actions taken) and it pushed for a collection of data on the illegal use of acaricides.[15] Indeed, no control plans aimed at verifying the presence of Fipronil had had to be organized before.[16]

However, we should say that, although important tools exist (for example RASFF and AAC[17]), Member States where the Fipronil case sparked, did not react promptly.[18] Furthermore, since no official controls had been performed to monitor the illegal use of Fipronil, the commercialization of the illegal products containing Fipronil were not quickly detected. Not even Food Business Operators (especially farmers) were shown to be able to avoid the use of Fipronil. This either because they did not set an adequate monitoring system (or even simple "verification measures") or because they did not receive correct and clear information on the product they bought.

We do not deem it relevant, in relation to the scope of the present research, to further investigate *why* an illegal product was placed on the market, *who* was responsible and *which* were the possible advantages from the commercialization of the product. Instead, we consider it as very important to understand *what* was missing and the answer is: the enforcement of food fraud, to be intended (but not limited to) those behavioural infringements due to the "human factor" which affect consumer economic interests and,

[11] European Commission, 'Press remarks by Commissioner Andriukaitis following the Informal Agriculture Council' (5 September 2017) <http://europa.eu/rapid/press-release_SPEECH-17-3103_en.htm>.
[12] Ibid.
[13] Ibid.
[14] Ibid.
[15] European Commission- Health and Food Safety Directorate General, 'Summary Report of the Standing Committee on Plants, Animals, Food and Feed held in Brussels on 30 August 2017 (Section Novel Food and Toxicological Safety of the Food Chain)', < https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_toxic_20170830_sum.pdf> .
[16] De Bac, (n 10).
[17] Administrative Assistance and Cooperation. This tool will be presented further on in the thesis.
[18] REPORT Rai 3 'Che polli!' Di Francesca Ronchin (n 8).
From the investigations carried out, it appeared that Dutch Competent Authority was informed about the placing on the market of a product which contained Fipronil before the notification sent by Belgium.

only in some cases, consumer health. The design of EU Food (Enforcement) Law, and, therefore, the existing control system, seem to have overlooked the "human factor". Indeed, the rules articulated in the EU Food Law have mainly focused on ensuring that accidents (for example, due animal diseases) would not happen and/or would be managed. This legal framework therefore appears lacking in not having taken into consideration all the other numerous objectionable behaviours which may affect consumers. And to a certain extent the scope of impact of behavioural infringements due to the "human factor" can be even broader than risk. Violations may be committed both by the FBOs and also by businesses outside the food chain; similarly, these violations may be committed with the intent of misleading the consumer or with other intent (for example, competition obstruction). Broadly speaking this "objectionable behaviour" will always affect consumer economic interests and only in some cases can it disturb consumer health protection. In the present dissertation, we will concentrate on behavioural infringements due to the "human factor" and on the substance and on the ways of protecting consumer economic interests. Safe to say, consumer health is already being effectively managed thanks to food safety rules and tools. The attention will, thus, be placed on *infringements*, without encompassing specific cases of unclear/uncomplete labelling and advertising of food.

Famous "food cases" and routine enforcement practices show several difficulties and inconsistencies in dealing with certain types of violations which concern food (for example in the identification phase and in relation to suitable measures and/or sanctions to be applied). This may result in a possible improper use of food safety tools. Indeed, no control plans had been organized to detect the presence of Fipronil due to the fact that this was not a food safety issue. Maybe there might not be eggs contaminated with Fipronil but other cases of illegal use of substances which are banned could happen in the future. Therefore, the question which arises is: how could we avoid (and manage) the raising of cases of objectionable behaviour which in the Fipronil case have resulted in food fraud?

1.2 Research objectives and questions

The research is about enforcement of EU Food Law. Irrespective of the fact that some of the rules on enforcement have a broader scope of application (including, for example, also plant health), the research carried out in this thesis is limited to food. When referring to 'food' we generally do not refer to any specific food (for example unprocessed/processed food or meat/confectionery products); in addition, we mean to include also feed. This dissertation analyses in detail the discipline of food control

systems in the European Union ("EU") and its implementation on the part of Food Business Operators ("FBOs") as well in two Member States: Italy and The Netherlands. The objective of the research is to assess the functioning of control systems in the EU, the applicable rules and principles on which FBOs self-monitoring activities and National enforcement are based. The general approach and background issues which have inspired the recasting of the EU Regulation on Official Controls are described in order to understand whether the new rules and tools may be effective in managing any type of violation which may concern food. Throughout the research, criticalities are underlined regarding existing control procedures and milestone cases are presented which show several weaknesses in dealing with violations other than those where food is understood to be "at risk". In addition, possible cases which see an active involvement on the part of FBOs, are presented.

Therefore, the first question to be addressed is: are the existing rules and available tools suitable in handling any type of food violations?

The following questions are: can the ongoing public debate and initiatives taken (such as the recasting of the EU Regulation on Official Controls, the Italian Proposal on Agro-Food Crimes, the results of the Dutch Task Force on Food Fraud) serve to overcome possible weaknesses arising from the implementation of Official Controls? Also, how can we picture the outcome deriving from the implementation, in the Member States, of the "control system" elaborated in the EU Regulation on Official Controls as well as from FBOs compliance with the rules on controls on food?

The third question is: can a "composite system" of both public tools and private schemes be useful in effectively handling any types of food violations? Therefore, how could the role of FBOs be seen in the future framework of the food sector?

The present research encompasses both rules governing the food sector and rules on food. After having analysed which are the "actors" of the food sector, the focus is placed on the food itself and on how (thanks to rules and other possible measures) to ensure a smooth and safe circulation of foodstuffs.

Considerable attention is given to behavioural infringements due to the "human factor" in order to investigate whether the available instruments are suitable in dealing with those behavioural infringements or whether we may think of other possible solutions.

The research expressly looks at consumer protection, therefore, in the discussion of cases of violations and related rules and tools to be used, more emphasis will be placed on the impact on consumer health and/or economic interest than on the interests of other actors (for example: Companies).

EU Food Law: Food Safety Law	← Human factor →	New rules, new tools? Composite system (rules+ private schemes?)

2. Law on Food

2.1 What is "Food Law"

Before reflecting on the possible legal interpretations which explain what Food Law is, it is essential to focus on the pragmatic/social dimension of Food Law. Food Law is not a conventional field of Law but is characterized by a relevant social dimension. The object of Food Law is food, of course, which is a vital element shared amongst all people. Therefore, Food Law should not be framed as a formal sequence of rules, instead it should find its substantial nature in the rights related to food.

First and foremost, there is the Human Right to Food. The possibility of having food available to everyone is not a mere formal affirmation but it should be the goal of all societies. The right to food[19] is recognized as a Human Right in International sources, mainly in the Universal Declaration on Human Rights[20] and in the International Covenant on Economic, Social and Cultural Rights.[21] The legal concept of Human Right to Food has experienced an evolution towards the concept of food security.[22] In effect, in 1996, the World Food Summit took place and the Rome Declaration on World Food Security and the World Food Summit Plan Action were adopted. The concept of food security was defined by the World Food Summit as follows: food security is existing "*when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life*". During the Twentieth session of 1999 the Committee on Economic, Social and Cultural Rights issued the General Comment No 12 to the International Covenant on Economic, Social and Cultural Rights, with the objective of "*a better definition of the rights relating to food"* and with the purpose of "*monitoring the implementation of the specific measures provided for in article 11 of the Covenant",*

[19] This paragraph is based and adapted from: Corini A, 'Human Right to food: some reflections' in Escajedo San-Epifanio L, and De Renobales Scheifler M, *Envisioning a future without food waste and food poverty-Societal challenges* (Wageningen Academic Publishers: Wageningen, The Netherlands 2015) 317, 321.

[20] Article 25 of 'The Universal Declaration on Human Rights', (1948) <https://www.google.it/search?q=Universal+Declaration+on+Human+Rights&ie=utf-8&oe=utf-8&gws_rd=cr&ei=VXJkVfX0OeSxygOrq4K4Dw>.

[21] Committee on Economic, Social and Cultural Rights (26 April-14 May 1999, Twentieth session). Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment 12, The right to adequate food (Article 11). <http://www.unhchr.ch/tbs/doc.nsf/0/3d02758c707031d58025677f003b73b9>.

[22] Gualtieri D, 'Right to Food, Food Security and Food Aid Under International Law, or the Limits of a Right-Based Approach' (2013) 1 (2) Future of Food: Journal on Food, Agriculture and Society 18, 21.

as stated in the General Comment 12 to the Right to adequate food (Article 11). Three obligations are established on the part of State Parties of the International Covenant on Economic, Social and Cultural Rights: *"the obligations to respect, to protect and to fulfil the right to adequate food"*.[23] Nutritional value, safety and acceptability are some of the factors which govern the inner nature of the right to adequate food. Consequently, specific actions are required in order to respect the nutritional needs of the people, to protect food from possible risks and to ensure that food is available to each individual.
As to EU Legal System, the Human Right to Food is not expressly recognized in the EU Charter of Fundamental Rights,[24] but it can be derived from the fundamental right to dignity (title I Charter) that is one of the values on which the EU is founded.[25]
This proclamation of the fundamental value and right of dignity is extremely significant. The Treaties represent the primary source of Law in the EU and the rights recognized in the Charter guide the actions of the EU in the areas of its competence and of the Member States when they transpose EU Law.
Thus, we may ask ourselves: is Human Rights the basis of EU Food Law? Looking at EU rules on food, notable emphasis is placed on food safety and consumer health protection, all goals which can be achieved through preventive actions directed to protect the consumer. Conversely, rules on consumer (economic) interest protection may be the result of actions directed aimed at respecting people's nutritional needs. Nevertheless, it is hard to identify actions directed to ensure that food is available to all people. The recognition of the Human Right to Food (both literal, at International level and, also, as a logical consequence from the recognition of the right to dignity, in the EU) is a meaningful expression of the relevance of this right which, as all other Human Rights, shall represent an intangible sphere. However, we cannot consider the Human Right to Food as the basis of EU Food Law. Human Right to Food has to be safeguarded as an always present objective in the design of all EU Food rules and tools. The latter find their source in EU Primary Law and are envisaged to ensure the protection of other rights related to food, such as the good functioning of the EU Internal Market and the "governance" of the food sector.

Having discussed the link between the Human Right to Food and the EU Legal System, emphasis will be placed on the rules related to food and on their position within the Legal System.

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[23] Committee on Economic, Social and Cultural Rights (26 April-14 May 1999, Twentieth session), Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment 12, The right to adequate food, paragraph 15.
[24] EU Charter of Fundamental Rights (30 March 2010) OJ C83/389.
[25] Article 2 Consolidated version of the European Union [2012] OJ C326/12.

From an historical point of view, Food Law was understood, in the 1960s, as a "*new and constantly developing legal phenomenon"*.[26] Even if the notion which brought together Food and Law was considered as ambiguous, it appeared that a specific branch of Law existed, that is to say "Food Law": a set of rules applicable to all foodstuffs or substances which may be used to provide food for people.[27] Another positive definition of Food Law, can be found in Article 3(1) of Regulation (EC) 178/2002[28]: *"the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food- producing animals".* These two definitions embrace a notion which intend Food Law as a part of Positive Law that specifically addresses food and the food sector. To know what does "food" mean, we just have to look at Regulation (EC) 178/2002: Article 2 clearly defines what food is, that is to say "*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*". It is interesting to note that the word "ingested" has been translated differently in the various EU languages or in some cases with the corresponding word expressing a similar concept, for example in Dutch the word "ingested" is understood as "consumed". The notion of food does not include feed and other products (for example plants prior to harvesting). All these exceptions are indicated in Article 2 of Regulation (EC) 178/2002. Nonetheless, we should assign to Food Law not only the rules which govern the food sector but also the rules which regard food. The former set of rules identifies "who" and "where": *who* are the addresses of the rules (National Competent Authorities- "CAs" and FBOs) and *where* rules have to apply (for example: directly, on the part of FBOs throughout the EU, or "indirectly" on the basis of National enforcement). The latter set of rules describes '*what*' and "*which*". Rules on food introduce principles and tools (what) to be applied for a smooth and safe circulation of foodstuffs (which).

Food Law can be framed also as an academic discipline. Scholars have defined Food Law as a functional area of Law, that is to say a system of rules which have a *function* in relation to a societal phenomenon.[29] With this in mind, Food Law is an academic discipline studying Law from the perspective of food. This, by concentrating on aspects

[26] Bigwood E J & Gérard A, *Fundamental Principles and Objectives of a Comparative Food Law. Volume 1: General Introduction and Field of Application* (S. Karger AG: Switzerland 1967) 2.
[27] Ibid.
[28] European Parliament and Council Regulation (EC) 178/2002 [2002] OJ L31/1 (GFL).
[29] Van der Meulen B, van der Velde M, *Introduction to law,* in Van der Meulen B, *EU Food Law Handbook*, vol. 9 (Wageningen Academic Publishers: Wageningen, The Netherlands 2014) 74 <http://www.wageningenacademic.com/doi/book/10.3920/978-90-8686-246-7>.

such as the placing on the market of food, risk and science[30]and on their function in society. When we focus on the rules designed to deal with food, we intend these rules as a part of the general legal system. This lacking of the independence of Food Law does not mean that we should consider it as a "marginal" set of rules. On the contrary, this means that the concepts regarding food (for example "food safety") are extremely important objectives to be achieved both with food rules as well as with other effective/useful legal instruments (for example, the sanction system).
From a slightly different perspective Food Law may be understood as being an academic field of research since it aims at structuring the food sector. The more such Positive Law is in place, the more the scope of academic attention and Positive Food Law converge. Regulation (EC) 178/2002 which positively outlines definitions, rules and tools is always the basis for any academic analysis of Food Law in the EU.

2.2 Historical overview

Over the centuries, there has always been a certain interest in Food Law. However, the norms regulating the production and the marketing of foodstuffs have evolved over the centuries as well as the notion of Food Law.
The "ancient rules on food"[31] since the early regulation of foodstuffs have been a strong mixture of legal and cultural/anthropological/religious aspects.
In many cases, similar rules existed for medical products and for food. Foodstuffs and medical products were described as having similar characteristics and properties.
Much information and adequate rules on food content and permissible ingredients as well as their maximum limits were lacking and unclear. A considerable focus was placed on the human factor to be viewed as all the objectionable behaviours which had led to food related problems. This bad behaviour was often claimed as being food fraud and criminal sanctions were imposed. The falsification of food was a matter of grave concern to all. The famous "Treatise on Adulteration" was written by Frederick Accum, a very famous chemist, in 1822.[32] In this book, the author presented several serious cases of food fraud and caught (for the first time) the attention of the public on the need to cooperate in order to abolish food fraud and on the need to ensure food safety. This led

[30] On the link between Law and Science: *see* Van der Meulen B, 'Science Based Food Law' (2009) 4 European Food and Feed Law Review 58, 71.
[31] Some of the first rules on foodstuffs were adopted with the Hammurabi Code (1792-1750 BC). Also, religious texts deal with provisions on foodstuffs such as the Koran which establishes rules on "allowed"-HALAL foodstuff (prohibition, for example of eating pork meat) and the several Jewish dietary laws, mainly contained in the Torah, which stipulate rules on "fit for consumption" Kosher foodstuff (prohibition, for example, of mixtures of meat and milk).
[32] Accum F, *A Treatise on Adulteration of Food and Culinary Poisons* (1820).

to a growing interest in the use of science in detecting violations, determined by human fraudulent behaviour, which had an impact on food safety.

In the United States ("US") Federal Food Law dates back to the beginning of the Twentieth century.[33] In 1906, the Pure Food and Drug Act (the first of a series of Consumer Protection Laws enacted by the American Congress during the 20th Century) was adopted and the Food and Drug Administration came into being. Harvey Washington Wiley, an American chemist known as the "Father of the Food and Drug Administration", published a book, in 1929, entitled "*The History of a Crime Against the Food Law. The Amazing History of the National Food and Drugs Law Intended to Protect the Health of the People, Perverted to Protect Adulteration of Foods and Drugs*".[34] In this book, Wiley presented several cases which show the importance of bringing safer food onto the market, including the use of additives within a certain limit and through clear information to the consumer. With all this information, the efforts and serious investigations which led to the adoption of the Pure Food and Drug Act were described.

A set of rules on food were developed also in other Countries, including Europe. These regulations were mainly targeted with the criterion of commercial honesty and, to a certain extent, they also concerned rules aimed at preventing or punishing the production and sale of harmful foodstuffs.[35]

During the first half of the 20th-century the main cases of violations regarding food consisted in counterfeiting foods to consumers. In this period, many European Member States' responded by putting the proper composition of food products under legislation and by enforcing compliance with these legal standards.

This increasing interest in food was also at International level. In 1963, the Codex Alimentarius was adopted by the Codex Alimentarius Commission. The Codex Alimentarius is the main International collection of food standards applicable on a voluntary basis and, in many cases, grounds for the setting out of National legislation.

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[33] Van der Meulen B, 'Food Law', *Encyclopedia of Agriculture and Food Systems* (Elsevier 2014) <http://linkinghub.elsevier.com/retrieve/pii/B978044452512300053X>.
[34] Wiley H W, "*The History of a Crime Against the Food Law. The Amazing History of the National Food and Drugs Law Intended to Protect the Health of the People, Perverted to Protect Adulteration of Foods and Drugs*" (1929).
[35] *See* Bigwood & Gérard (n 26) 3.

Then, thanks to important progresses in several fields of science, such as toxicology, tools were provided for the identification of harmful effects of substances incorporated in food for human beings and for the elaboration of methods aimed at detecting and analysing foodstuffs.[36] All this made it possible to elaborate regulations aimed at increasingly protecting the health of consumers and, therefore, at establishing the need of industry's full co-operation in order to ensure consumer health protection.[37]

When in 1957 the Treaty of Rome was signed, the European Economic Community came into being. Linked to the economic character of this Community (as evidenced by its name), the objective of creating a common market was established. Key instruments in order to "build" the common market were the so-called four freedoms: the free movement of goods, the free movement of labour, the free movement of services and the free movement of people. The process of creating the EU Internal Market was not automatic and was completed in the 1990s. From this moment on the EU Internal Market has been functioning as a common market without borders, as would the market in a single country where goods can freely circulate.[38] When the Internal Market was completed, foodstuffs (as well as other goods) could freely circulate in all EU Countries. The free movement of goods[39] has been vital to the development of Food Law.[40]
The Internal Market and the several approaches towards Food Law will be discussed further in Section 3.

2.3 Food Law: National, International and EU levels

Over the years, the EU has adopted important rules which govern the selling and circulation of food in the EU and which are applicable in all European Member States. These rules often represent the "background rules" which have inspired the enforcing of several food legislations in many Countries in the world. These food rules set very important provisions which are applicable in the whole EU and also within each of the Member States. Also, at International level, significant principles on food are defined.

Therefore, we can say that rules on food are created in a multi-level dimension by Institutions at National, European and International level. Practically speaking, an increasing number of food related issues are regulated by European Law. In the EU, the

[36] Ibid.
[37] Ibid.
[38] Van der Meulen B, Corini A, 'Food Law Enforcement In the EU: Administrative and Private Systems" (2016) 87 issue 2 Revue Internationale de Droit Pénal (RIDP) 71, 95.
[39] Articles 14 and 28–37 of the Treaty on the Functioning of the European Union (TFEU).
[40] Van der Meulen B, 'The Structure of European Food Law' (2013) 2 Laws 69, 74.

reorganisation of food governance brought the food sector into one of the most heavily regulated sectors in the EU.[41] However, some matters are still regulated only at National level, for example the sanctions applicable in cases of infringements of EU Law. This, of course, leads to considerable differences in the enforcement phase.

3. EU Food Safety Law

3.1 Primary Law and Food Law in the Internal Market[42]

EU Treaties do not expressly mention Food Law. Still, Primary Law articulates several objectives which are essential in the design of Food Law such as human health protection, consumer protection and the smooth functioning of the Internal Market.

As to the protection of human health, Article 6 TFEU indicates the "protection and improvement of human health" among the objectives which the EU shall carry out in order to support, coordinate or supplement the actions of the Member States. In that light, the European Parliament has stressed that *"The Treaty of Lisbon has enhanced the importance of health policy, stipulating that 'a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities'. This objective is to be achieved through Community support to Member States and by fostering cooperation. Primary responsibility for health protection and, in particular, the healthcare systems continues to lie with the Member States. However, the EU has an important role to play in improving public health, preventing and managing diseases, mitigating sources of danger to human health, and harmonising health strategies between Member States".*[43]

Within the EU Legal framework, the EU can adopt legislation only if the Member States have attributed this power to the EU itself. Consequently, we have to investigate if Primary Law attributes to the EU any relevant power on the basis of which to adopt Food Law.

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[41] Ibid. 69, 71: *"food is the third most regulated sector in the EU. If we simply count hits in the EU database of official publications with 14,569 (out of 68,735 for the category Agri-Foodstuffs) foodstuffs is first in front of sectors such as chemistry with 8,330 (out of 38,465 for industry) (visited 10 March 2013)".*

[42] This Section is partially based and adapted from Van der Meulen B, Corini A, 'Food Law Enforcement In the EU: Administrative and Private Systems" (2016) 87 issue 2 Revue Internationale de Droit Pénal (RIDP) 71, 95.

[43] European Parliament- Fact Sheets on the European Union, 'Public Health' <http://www.europarl.europa.eu/atyourservice/en/displayFtu.html?ftuId=FTU_2.2.4.html>.

Member States and the EU enjoy shared competence in some areas including agriculture and fisheries, excluding the conservation of the marine biological resources (Article 4(2)(d) of Treaty on the Functioning of the European Union –"TFEU"[44]). Therefore, the European Parliament and the Council shall establish the common organization of agricultural markets provided for in Article 40(1) TFEU and the other provisions necessary for the pursuit of the objectives of the common agricultural policy and the common fisheries policy (Article 43(2) TFEU). Other relevant rules are represented by Article 168 TFEU which establishes the "complement" competence of the EU in relation to National policies directed to ensure a high level of human health protection.

A legal basis for the adoption of rules on consumer protection is represented by Article 169 TFEU which indicates that the EU shall contribute to consumer protection.

Stress is placed also on rules aimed at the smooth circulation of foodstuffs within the Internal Market. Article 114 TFEU provides for the adoption, on the part of the EU, of measures for the "*approximation of Member States rules in the framework of the establishment and functioning of the internal market"* (Article 114(1)). Therefore, the EU can adopt rules aimed at the approximation of provisions laid down by Law, regulation or administrative actions in Member States. This, with the objective to establish and to ensure the functioning of the Internal Market. Article 114 TFEU, to be read in combined disposition with Article 168 TFEU and with Article 169 TFEU, provides the necessary legal basis for a correct functioning of the Internal Market and for the adoption, at EU level, of rules on the circulation of foodstuffs with the purpose of ensuring the protection of consumer health and consumer interests. Indeed, Article 114(3) TFEU stipulates: *"concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts*".

Going in detail into the historical development of EU Food Law, the EU regulatory approach to the food sector has changed over the years. From the end of the 1950s onwards, the Countries that founded the EU, a Supra-National entity different from its Member States with sovereign powers conferred by the Member States themselves, have pursued the objective to establish a common market without borders where goods can freely circulate, as happens in the market of each single Country.[45] Since goods,

[44] Consolidated version of the Treaty on the Functioning of the European Union [2012] OJ C326/12.
[45] Article 28 TFEU states: *"1. The Union shall comprise a customs union which shall cover all trade in goods and which shall involve the prohibition between Member States of customs duties on imports and exports and of all charges having equivalent effect, and the adoption of a common customs tariff in their*

including foodstuff, freely circulate in the EU, more and more products can enter the various Member States and the number of potential consumers is increasingly higher. Therefore, the objective becomes even more compelling to ensure the highest level of safety for all these foodstuffs/food products.

Prior to the creation of this Supra-National organisation, the dominant approach, in the European Countries, to the food sector consisted in vertical legislation (i.e. product standards).[46] To deal with food-related problems such as safety and quality issues and deception of consumers due to the use of inferior ingredients, National legislators resorted to defining composition and properties on a product-by-product basis. With a view to creating a common market, the Countries members of what, at that time, was called the European Economic Community, tried to harmonise the mass of differing National standards. In this way, EU-wide standards were created for products such as marmalades, jams, chestnut paste and chocolate. However, it was quickly acknowledged that, due to the relevant differences among rules and food cultures and products which exist among the Member States in the EU, the harmonisation of all existing National product standards was an unachievable mission.

The Court of Justice of the European Union, in its case-law including the landmark judgement 'Cassis de Dijon'[47] recognised the 'principle of mutual recognition' as a principle underlying the rules on free movement of goods in the founding Treaties.

According to this principle, products conforming to the National standard in the Member State of origin, in principle have access to all EU Member States, even if the product under scrutiny does not comply with the National legal standard in the Member State of destination. With the principle of mutual recognition, the Court of Justice of the European Union solved the problem that food standards presented *de facto* barriers to trade. The down side was however due to the fact that all National food standards could apply simultaneously in all EU Member States and that more and more products could freely circulate in the EU, consequently National standards could no longer adequately be used to protect consumers and to prevent fraudulent practices. Therefore, actions were needed to provide additional protection to the consumers. Instead of complying to legal product definitions, businesses were required to disclose the composition of their

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relations with third countries. 2. The provisions of Article 30 and of Chapter 3 of this Title shall apply to products originating in Member States and to products coming from third countries which are in free circulation in Member States".

[46] This paragraph is partially based and adapted from: Van der Meulen B, Corini A, 'Food Law Enforcement In the EU: Administrative and Private Systems" (2016) 87 issue 2 Revue Internationale de Droit Pénal (RIDP) 71, 95.

[47] Case C-120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECLI:EU:C:1979:42.

products by declaring all the ingredients on the label of the product[48] enabling consumers to make informed choices.

3.2 General Food Law[49]

General Food Law	⟶	Rules and procedures aimed at ensuring *food safety*

Until the late 1990s, the EU approach was mainly focused on enabling the free circulation of goods and on consumer information. Then priorities dramatically shifted to food safety and consumer protection from harm. The series of food safety crises that broke out in the 1990s, and particularly the BSE crisis, showed the urgency to ensure food safety and to protect consumers' life and health. All this required a reorganization of EU Food Law with the purpose of preventing hazards and avoiding the occurrence of risks.[50]

In 2000, the White Paper on Food Safety was adopted. In this text, the need to adopt measures envisaged at protecting the consumer and the steps to be taken in order to achieve this objective were described. A strong focus was placed on the need to link regulatory aspects with scientific advice. Food safety measures had to be based on the best available science. Therefore, the importance was shown of instituting an organism responsible for providing the best scientific advice and for contributing to the development of food safety rules.

The reorganisation of the legal infrastructure began with Regulation (EC) 178/2002 "*laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety"*. This regulation acquired the popular name "General Food Law" or "General Food Law Regulation" ("GFL"). As evidenced from its official title, this Regulation addresses three main issues:

1. it provides general principles;
2. it creates the European Food Safety Authority ("EFSA");

[48] Council Regulation 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer [1979] OJ L33/1.

[49] This Section is partially based and adapted from: Van der Meulen B, Corini A, 'Food Law Enforcement In the EU: Administrative and Private Systems" (2016) 87 issue 2 Revue Internationale de Droit Pénal (RIDP) 71, 95.

[50] Van der Meulen B, 'Is current EU food safety law geared up for fighting food fraud?' (2015) 10 Journal of Consumer Protection and Food Safety S19 DOI 10.1007/s00003-015-0992-2.

3. it provides procedures for food safety incidents. (We will analyse in detail these procedures in Chapter 2, Section 2.2)

The rules set out in GFL respond to the need to provide rules and instruments in dealing with any food safety problems. Recital 10 GFL stipulates that these food safety rules are adopted in order to respond to food safety problems so as to ensure the proper functioning of the Internal Market and to protect human health. Recital 12, then, indicates that these rules on food safety cover all aspects of the food production chain and tools (risk analysis, precautionary principle, traceability) are established with the objective to deal with food safety issues. As we can see, both Recitals mean that food rules have been drafted mainly with the aim of managing food safety crisis.

Food safety is the central goal conceived by EU Food Law. The core provision of this Regulation, and indeed, of all EU Food Laws,[51] states that food shall not be placed on the market if it is unsafe (Article 14(1) GFL). Food is considered unsafe when it is injurious to health or when it is unfit for human consumption (Article 14(2) GFL). According to the CJEU a food can be unfit for human consumption and thus unsafe without being injurious to health.[52] We will return to the concept of food safety in the following Section.

When examining the main provisions of GFL, it is important to make a reference to the general principles of Food Law. One of these is the high level of protection of human life and health and, secondly, the protection of consumers' interests that have to be achieved through Food Laws, as stated in Article 5(1) GFL. This principle has to be balanced with the other one of the free movement of food and feed in the EU stated in the same Article 5(2) GFL.[53]Article 5 GFL is a very important provision since it defines the purpose of all Food Laws.

Another relevant principle is Risk analysis (Article 6 GFL) (which includes risk assessment, risk communication, risk management) which is established in order to achieve the general objective of high level of protection of human health and life and the Precautionary Principle. Article 7 GFL, on Precautionary Principle, states that in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures may be adopted. These measures, necessary in ensuring the high level of health protection, have to be proportioned and no more restrictive on trade

[51] Van der Meulen B, 'The Core of Food Law- A Critical Reflection on the Single Most Important Provision in All EU Food Law' (2012) 3 European Food and Feed Law Review 117.
[52] C-636/11 *Karl Berger v Freistaat Bayern* [2015] ECLI:EU:C:2013:227.
[53] On Article 5 GFL *see* Van der Meulen B, 'The Function of Food Law. On the objectives of food law, legitimate factors and interest taken into account' (2010) 2 EEFL 83, 90.

than what is required in order to achieve the high level of health protection that has to be ensured in the EU.

Finally, Article 8 expresses that one of the goals of Food Law is the protection of consumer interests and the possibility for them to make informed choices in relation to the food they consume. This can be achieved, among other things, through measures of prevention of fraudulent or deceptive practices.
Rules established in the GFL are applicable all across the food sector. With the GFL, an integrated approach to food safety "from farm to table" is implemented, covering the whole food chain and including all aspects, from animal feed production, primary production, food processing, storage and transport to retail. Tools introduced by the GFL are fundamental instruments in order to ensure the safety of the whole food chain: from the hygienic conditions to be respected during the production of food to the information to be provided to consumers; as well as from not processed food to functional foods (food given an additional function by adding new ingredients or more of existing ingredients). In order to ensure the compliance with Food Law requirements at each stage of the food chain, a system of *"traceability of food, feed, food-producing animals and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established".*[54] This is a fundamental tool able to rebuild/piece together the life of a product. According to the "one- step back"-"one-step forward" approach "*Food and feed business operators shall be able to identify any person from whom they have been supplied with a food*",[55] they also "*shall have in place systems and procedures to identify the other businesses to which their products have been supplied*". The traceability system may also serve to identify the responsible individuals in cases were violations have been committed. However, this function of the traceability system has not been expressly formulated in the GFL. Differently, in Regulation (EC) 1935/2004[56] on materials and articles intended to come into contact with food, a broad description of the traceability system is provided: "*The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility*" (Article 17(1)).

We have to note that the traceability system is not suitable in order to identify violations made with intent or violations not made along the typical phases of the food chain but made in the occasion of activities related to the selling of food products (for example:

[54] Article 18(1) GFL.
[55] Article 18(2) GFL.
[56] Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC [2004] OJ L388/4.

falsified invoices). In these cases, food cannot be considered at risk but the traceability system is in any case obstructed and other paths shall be followed in order to identify who is, actually, the person/company responsible for the violation.

As to the scientific support on Food Law, Chapter III of the GFL establishes EFSA, which is an independent Authority responsible for scientific risk assessment.[57] It is based in Parma (Italy).
EFSA provides advice in relation to possible risks associated with the whole food chain (this means that EFSA is committed to provide its support on several issues, such as feed, food, pesticides or plant protection products). It delivers scientific advice and scientific opinions.
It takes part in several procedures in order to provide an assessment on safety (for example, authorisation of novel foods) and in order to manage possible cases of risk (notified through the RASFF).[58]

Notwithstanding all the above-mentioned tools offered by the GFL and the fact that any food which complies with EU Food Law shall be deemed to be safe,[59] problems related to *conventional* food can, in any case, be raised.
Among the general principles, the GFL attributes responsibility[60] to FBOs for compliance with legal requirements on food and feed[61] at all stages of production, processing and distribution within the businesses under their control. In addition, it grants[62] Member States overall power in the enforcement of Food Law and on the performance of official controls aimed at monitoring and verifying the fulfilment of the relevant requirements of Food Law by FBOs.
More in detail, according to Article 17(1) GFL, FBOs, "*at all stages of production, processing and distribution within the businesses under their control*", shall ensure compliance with Food Law requirements. This responsibility arises in relation to several activities performed by FBOs who have to comply with hygiene rules, labelling rules and measures of prevention and management of possible food risks. When a product is

[57] Including a limited number of risk management tasks and quasi-regulatory powers. *See* Groenleer M.L.P., *The Autonomy of European Union Agencies: A Comparative Study of Institutional Development* (Doctoral Thesis, Eburon: Delft, The Netherlands 2009) 177, ff. <https://openaccess.leidenuniv.nl/bitstream/handle/1887/14519/Finale%20versie%20proefschrift%20Groenleer.pdf?sequence=3>.
This paragraph is based and adapted from Van der Meulen B, Corini A, 'Food Law Enforcement In the EU: Administrative and Private Systems" (2016) 87 issue 2 Revue Internationale de Droit Pénal (RIDP) 71, 95.
[58] We will come back to RASFF following on in this Section.
[59] Article 14(7) GFL.
[60] Article 17(1) GFL.
[61] Hereafter we make no separate reference to feed.
[62] Article 17(2) GFL.

likely not to be in compliance with the food safety requirements, FBOs shall adopt procedures of withdrawal and recall of products. Specifically, a withdrawal shall be initiated when FBOs "*believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements*"[63] and this food "*has left the immediate control of that initial food business*".[64] Instead, when the food may have reached the consumer and when other measures are not sufficient to achieve a high level of health protection, the FBOs shall recall the products already supplied to the consumer.[65] Article 19(3) GFL indicates the specific case where FBOs non-compliances may have an impact on human health; in this case the FBO *"shall take adequate measures and inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health"*.

Cases of risks which concern human heath must be adequately communicated. EFSA, among its competences of scientific advice and scientific and technical support, is the recipient of messages forwarded via RASFF.[66] RASFF is a network set up between the European Commission, the Member States and EFSA with the purpose of notifying direct or indirect risks that may arise to human health deriving from food.[67] When Member States take measures dealing with a risk they must immediately notify the European Commission and explain these measures. The notification must be followed up in good time by supplementary information, in particular where the measures are modified or withdrawn.[68] This is fundamental in order to protect company interest since companies may suffer reputation damage and financial losses in cases where the information is divulged that their products have been shown to be at risk.

European case-law provides an example where businesses tried to defend themselves against notification of an alert in RASFF. Specifically, Malagutti, a Company which exported fruits from France to the Netherlands and the United Kingdom, was named in a rapid alert notification as the supplier of apples which contained a higher content of pesticide residues than the maximum permitted level. Afterwards, Malagutti's responsibility has been excluded by the French CAs due to the negative results on

[63] Article 19(1) GFL.
[64] Article 19(1) GFL.
[65] An insight of the obligations to recall and withdraw products: European Commission 'Conclusions of the standing Committee on the food chain and animal health, Guidance on the implementation of articles 11, 12, 14, 17, 18, 19, 20 of Regulation (EC) No 178/2002 General Food Law' <https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf>.
[66] Article 35 GFL.
[67] Article 50 GFL.
[68] Interestingly, in the Bowland case discussed in Section 2.2, the supplementary RASFF notification from the FSA regarding its satisfaction with the marketing of Bowland's cheese was accompanied by the Commission's comment of disagreement.

samples of Malagutti taken at Malagutti's warehouse. Therefore, the Company brought an action before the CFI[69] where it sued the European Commission for extra-contractual liability because European Commission did not consult before circulating the alert.[70] The European Commission, on its part, considered the action as inadmissible since the RASFF is ultimately triggered on the initiative of, and according to an analysis made by, the National Authorities alone and cannot incur liability on the EU towards individuals.[71] The CFI recalling the case-law on EU extra-contractual liability dismissed the claim for damages because it upheld that under the RASFF it is only the National Authorities, and not the European Commission,[72] which are responsible for establishing whether there is a serious and immediate risk to the health and safety of consumers[73] and the European Commission, on its part, should perform a formal check on the notification but it does not have to enter into details concerning the accuracy of the findings.[74]

Non-conformities may emerge also *ex post.* Further to official controls (or self-controls performed by the FBOs) and the identifications of non-conformities it is very important to have an adequate evaluation of the possible risks arising from the product. This evaluation is aimed at "measuring" the "severity" of the risk and the high or low possibility of the verification of the risk itself, taking into account several issues such as the level of exposure to the risk itself. This serves as a parameter in order to opt for the more effective and suitable measures to be taken (for example withdrawal or recall of products, notification or simply information). Therefore, an alert should be started only when it is really needed and the consumer shall be adequately and clearly informed about the presence of risk. This parameter should be taken into account for the communication of food cases. According to Article 10 GFL, consumers shall be informed "*where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health*". It follows that consumers shall receive information which is transparent, true, understandable, non-alarmistic and based on the presence of an actual risk.

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[69] T -177/02 Malagutti-Vezinhet/Commission [2004] ECLI:EU:T:2004:72.
[70] Cf. T -177/02 point 35.
[71] Cf. T -177/02 point 27.
[72] Point 28: "*The applicant should therefore have referred the matter to the national court having jurisdiction. The question of compensation by a national agency for damage caused to private individuals by national agencies, either by reason of an infringement of Community law or by an act or omission contrary to national law, must be determined by the national courts (Case 101/78 Granaria [1979] ECR 623). The applicant has by no means demonstrated that a claim for compensation brought before the national courts of any of the States involved would not have enabled it to obtain fair compensation for the damage at issue*".
[73] Cf. T -177/02 point 51.
[74] Cf. T -177/02 Cf. point 52.

3.3 The concept of Food Safety

> Article 14(1) GFL: "*Food shall not be placed on the market if it is unsafe".*

Article 14 GFL, the core provision of all EU Food Law states, in its paragraph 1, that food shall not be placed on the market if it is unsafe.[75] Food is considered unsafe when it is injurious to health or when it is unfit for human consumption.[76] This is explained as a "negative concept": Article 14 GFL establishes a ban on the placing on the market of "unsafe food" and, in the following paragraphs, it indicates principles according to which food should be considered as unsafe. Differently, the Codex Alimentarius introduces a "positive concept" by defining the "requirement" on food safety and it indicates that a food shall be deemed as safe if it will not cause harm to the consumer when it is prepared and/or eaten according to its intended use. FBOs shall ensure that food that reaches the consumer is safe.

Article 14 GFL refers above all to "food" which definition has already been articulated in Section 2.1. Furthermore, another concept that Article 14 GFL refers to is the placing on the market. Placing on the market means any activity of selling, distribution and storage in order to market the product and it refers to any type of market, irrespective of its boundaries. Food safety has to be ensured also within the local market. However, Article 3(8) GFL on definitions refers to this concept as being strictly linked to the functioning of the EU Internal Market. The free circulation of foodstuffs in the EU Internal Market is possible only if safe food is placed on the market.

Even though Article 14(1) GFL formulates a very concise but substantial concept, the same Article 14 GFL but the paragraph 2 of Article 14 GFL articulates that "*Food shall be deemed to be unsafe if it is considered to be: "(a) injurious to health; (b) unfit for human consumption*". This provision helps us in what is the scope of application of "food safety" and, more specifically, which are the issues to be taken into consideration in the "assessment" of unsafety. Bearing this in mind, Article 14(3) GFL indicates that *"In determining whether any food is unsafe, regard shall be had: (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing*

[75] Article 14(1) GFL.
[76] Article 14(2) GFL.

and distribution, and (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods". As to the concept of "*the normal conditions of use of the food by the consumer",* we should refer to the common habits, praxis, ways of behaving (and of eating) of the consumers.[77] To explain this, we could take as reference the "average consumer test"[78] as defined by the Court of Justice of the European Union. Although this test has not been conceived expressly for food consumers, it lends itself to be taken into account since it concerns the evaluation of fairness or unfairness of a commercial practice by indicating that the "*average consumer, is 'reasonably well-informed and reasonably observant and circumspect', taking into account social, cultural and linguistic factors*". As to the information provided to the consumer, we should refer to the presumed knowledge of the consumer on the basis of the information that is generally available, including the information present on the label.[79] Information considered as "generally available", can be all the information such as "Institutional websites", labels such as "Nutritional facts" or other elements to be communicated with adequate instruments (such as notices, signboards placed next to the bulk products). As a result from all presented so far, we can understand that food which is injurious to health or unfit for human consumption shall not be placed on the market. This, in order to solely protect the consumer, given the fact that the criteria to be taken into account in the assessment of unsafety are of "*the normal conditions of use of the food by the consumer"* and "*the information provided to the consumer".*

To a certain extent, Article 14 GFL appears contradictory. Indeed, the core provision of EU Food Law,[80] states that food shall not be placed on the market if it is unsafe, which, according to Article 14(2) GFL, is when it is injurious to health or unfit for human consumption. However, according to the Court of Justice of the European Union, a food can be unfit for consumption – that is, unsafe – without being injurious to health.[81] This, for example, can occur in the case of contamination with non-pathogenic micro-organisms causing alterations in flavour and/or smell.

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[77] The consumer behaviour and purchasing decisions are the most varied and do not necessarily change following, for example, campaign on healthy food choices, *see* Holle M, 'Nutrition Policy in the European Union' in van der Meulen, B, *EU Food Law Handbook*, vol 9 (Wageningen Academic Publishers: Wagenigen, The Netherlands 2014) 519.

[78] European Commission- Justice, 'Is it unfair?' <http://ec.europa.eu/justice/consumer-marketing/unfair-trade/unfair-practices/is-it-fair/is-it-unfair/index_en.htm>.

[79] When dealing with Food Law, labelling is a very important issue: European Parliament and Council Regulation 1169/2011 on the provision of food information to consumers [2011] OJ L304/18. The scope of application of rules on consumer information is provided in a broad way, not limited to labelling.

[80] Van der Meulen (n 51).

[81] C-636/11 *Karl Berger v Freistaat Bayern* [2013] ECLI:EU:C:2013:227.

Then, Article 14(4) GFL explains the notion, recalled in Article 14(2)(a) GFL of "Food injurious to health": *"4. In determining whether any food is injurious to health, regard shall be had: (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations; (b) to the probable cumulative toxic effects; (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers*". Therefore, the concept of injuriousness is explained in a broad way since it refers to possible impacts which may be traced immediately after having consumed a food or after a short or long term and to possible damages which may be experienced not only by those who have consumed the food but also by people of the next generation. The injuriousness is not understood as something separate from any other activity or characteristics, such as cases where also other "injurious-borderline" food is consumed (and therefore possibilities of "*cumulative toxic effects*") and cases where only specific categories of consumers may experience problems. Article 14(4)(c) GFL, thus protects the several categories of consumers such as people who suffer from allergies (compulsory information on allergenic ingredients) and other specific consumers where the food is intended for that category of consumers (for example: infant formula).

Article 14(5) GFL provides the notion, recalled in Article 14(2)(b) GFL, of "Unfitness": "*In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay".*

When applying the notion of "unfitness" we will deem putrid food certainly as being unacceptable for human consumption but only *potentially* injurious to health. Or it may happen, since a food is unfit by reason of contamination or bad storage conditions, that "injuriousness is presumed".

In some cases, "unfitness" is a subjective concept, therefore, it is difficult to understand this concept and even more difficult to enforce it. Since the unacceptability may be subjective, there is a missing link between consumers and business where consumers complain/start an action following their purchase because they consider the food as unacceptable. Also, since Article 14(5) GFL makes reference to concepts that have to be interpreted, it is possible that Member States have a different understanding of these concepts, especially the one of "unacceptability for human consumption". However, Article 14(5) GFL recalls also concepts which are "measurable", such as contamination, putrefaction, deterioration and decay.

In addition, consumers may consider a food as unfit and therefore unacceptable to be consumed by them because this food has been placed on the market by a FBO who has committed intentional frauds and, therefore, the consumer no longer trusts this FBO. This, although the food could be in principle not injurious to health for the consumer.

Even more complex to be understood and interpreted is the wording of Article 14(7) GFL which states: "*Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned*". It follows that food shall be deemed as safe and therefore not injurious to health or unfit for human consumption in all cases where there is compliance with Food Law requirements. This provision, in contrast to the general approach followed by the GFL, appears, as has been highlighted, to "*turn unsafety into a legal fiction rather than a science based reality regarding effects on human health in terms of injuriousness*".[82] In addition, this provision does not encompass the several cases where potential unsafety (especially in the sense of "unfitness for human consumption") follows from violations of other rules provided by EU Law on Food Safety.

3.4 Macro-objectives

As stated in Article 1 GFL the principles set up in this Regulation, which are applicable to all stages of production, processing and distribution of food, are established in order to guarantee a high level of health protection and also to safeguard consumer interests.
Although life and health are clearly interests of consumers, in the thesis we will use the expression "consumer interests" (also when referring to the problems/shortcomings related to safeguarding them) with a more concise sense by meaning only consumer *economic* interests. The latter specification clearly expresses the core difference between all what concerns health and health related interests and also what concerns all the many consumer economic interests which may arise when selecting and consuming a food as a result of the action of buying.
However, we should point out that, even if the same set of rules are applicable in order to ensure that both consumer health and consumer economic interests are safeguarded, these two macro-objectives present relevant differences as will be explained throughout the thesis. Consequently, infringements may arise which affect only the objective of consumer economic interest protection without determining any negative impact on consumer health protection. This is often the result of infringements characterized by the

[82] Van der Meulen (n 51) 122.

"human factor", that is to say bad/objectionable behaviour (intentional or not) which do not cause any biological or chemical risk.

Consumer Health protection	Consumer economic interest protection

Food Law, thus, carries out two macro-objectives which, however different, are both important.

There may be adverse health effects when unsafe food is placed on the market for example cases such as: "mad cow disease", "dioxin crisis", "melamine in milk" and "red Sudan". The so-called "mad cow disease" was the consequence of using meat and bone meal made from carcasses of cattle infected by BSE. Since the meat was not safe (the neurodegenerative disease attacks the brain and spinal cord of cows and it may be transmitted to human beings by the eating of the contaminated food) it caused serious health problems to humans. Numerous people died after having eaten the diseased cow meat and millions of animals were destroyed. This was the milestone case that brought to the to the acknowledgement that rules were needed in order to avoid the raising of food risks in the future. Further to the adoption of the GFL several other measures have been taken, first of all the ban on feeding meat and bone meal to cattle. In 2001, the Regulation (EC) 999/2001 was adopted and rules were formulated for the prevention, control and eradication of certain transmissible spongiform encephalopathy and several prohibitions concerning animal (first of all, the prohibition to feeding to ruminants of proteins derived from mammals).[83] Another serious food safety scare was represented by the dioxin case. In 1999, dioxin, a highly toxic and carcinogenic substance was detected in eggs, chicken meat and pork meat. Similarly, to the "mad-cow disease" dioxin originated from contaminated fat used in animal meat.

Also, the Chinese case of melamine in milk is worth mentioning. In 2008 notifications were exchanged through the RASFF concerning milk and products containing milk contaminated by melamine and adequate assessments and measures were performed.[84] "Red Sudan case" was the consequence of the use, in a chili pepper coming from India, of an artificial colouring called "Sudan I". This is a cancerogenic substance, therefore, following the notification sent by France in May 2003, the European Commission took emergency measures.[85] All this was determined by the use of the cancerogenic substance and its *potential* impact on health.

[83] European Parliament and Council Regulation (EC) 999/2001 [2001] OJ L147/1.
[84] Capelli F, 'Il Regolamento (UE) n. 16/2011 della Commissione europea sul "sistema di allarme rapido" applicabile in materia di prodotti alimentari e di mangimi' (2012) 2 Diritto comunitario e degli scambi internazionali 367, 382.
[85] Ibid., 381.

All these cases have caused and potentially could have caused serious health problems to the consumers, therefore they highlighted the importance of having at CAs and FBOs disposal adequate rules and tools to be used in order to prevent and/or to manage these cases. EU Law provides special tools in order to ensure food safety (risk analysis, precautionary principle, traceability, food information, recall and withdrawal of products, RASFF); it also specifies some rules for consumer economic interest protection (true and complete label, loyalty in commerce, avoidance of fraudulent or deceptive practices, avoidance of adulteration of food and any other practices which may mislead consumers). However, not all food safety procedures are effective in order to deal with certain violations which may concern consumer economic interest.

In the design of EU Food Law, only a few provisions appear to be drafted in order to ensure consumer economic interest protection. In addition, Food Law does not weigh up all the possible and several issues which may involve consumer economic interest. Indeed, Food Law has mainly conceived provisions and measures which set up rules related to the inner composition and presentation of food. In reality, the relation between consumer and food comes to the fore not only when food is consumed (and consumers need to be adequately informed about the composition of the food) but also when food is bought. Consumer interests may be not suitably safeguarded when, for example, the label of the food is incomplete and, consequently, consumers are not adequately informed about the product quality/non-quality or when the label indicates that the product contains a certain amount of an ingredient, while the actual percentage is lower. This, irrespective of the fact that the product is perfectly safe. The same happens when consumers buy a product of a lower quality compared to the price they have paid or when on the label of the food there are false or misleading indications regarding the origin of the specific product.

Another factor which expresses the essential legal difference between the macro-objective of guaranteeing a high level of health protection and that of safeguarding consumer economic interest is represented by their different placing within the legal system.
The two stated macro-objectives belong to different legal sectors. Health protection is a matter of Public Law. [86] Health protection is recognized in Italian Constitution[87] in Article 32, as well as in others Constitutions, for example the Constitution of the

[86] "*In the field of Food Law public legislation is applicable, which aims at protecting a right which is worth to be safeguarded as health*": Costato L, 'Protezione del consumatore tra strumenti contrattuali e norme di carattere pubblicistico: il caso del diritto alimentare' 2010 (I) Rivista di diritto agrario 46.
[87] Italian Constitution [1947] OJ 298.

Kingdom of the Netherlands in Article 22(1) states that "*The authorities shall take steps to promote the health of the population"*. Instead, consumer economic interest is a matter of Private-Commercial Law (commercial violations may be a consequence of circulation of goods and if the food chain is too weak and excessively complex, this may facilitate certain violations).

Given the above-outlined legal system of Food Law, which shows that rules on food can be Public Law based or can be Private Law based, it does not however always appear so easy to categorize food rules as pertaining to one legal field or another. The same food rules can be labelled as a part of Commercial Law or of Penal Law. This depends on the object which is regulated and on and the scope of these rules. Therefore, rules which govern trade of foodstuffs are part of Commercial Law, while provisions which punish cases of fraud are part of Penal Law.[88] Instead, provisions which concern the protection of health may be considered as Social Regulations while rules affecting the production and sale of foodstuffs may be considered as Economic Law.[89]

It follows that the two macro-objectives of consumer health and consumer economic interest safeguarding shall not be confused and shall be analysed and developed separately. This, too, for the rules applicable to these objectives.

Therefore, it is interesting to study the "grey area" represented by all the cases where violations concerning food are committed although the food itself is not at risk. In effect the violations may consist in the infringement of rules of Hard or Soft Law other than those stated in the GFL, for example when FBOs deliberately do not conform with requirements on sustainable production and, in spite of that, put on the label indications related to their commitment on sustainability. Similar violations can be committed when rules on Intellectual Property are breached and, therefore, both consumer economic interests of buying a product with certain characteristics and commercial interests of competitive companies are simultaneously infringed.

3.5 Control systems: Food Business Operators and Competent Authorities (a brief introduction)

The only instrument which, at present, is suitable to detect when violations are committed is the control system. As already indicated above, the GFL set up a control system. Article 17 GFL requires an involvement both on the part of FBOs and on the part of Member States' CAs. Controls are performed in order to check food safety requirements (including some requirements related to labelling, i.e. presence of allergens) and to verify the conformity with labelling and food information rules. This

[88] Bigwood & Gérard (n 26) 4.
[89] Bigwood & Gérard (n 26) 4.

means that controls should be adapted to pursue both macro-objectives namely health and consumer economic interest protection. Since substantial EU Food Law was "generated" and created as a direct result of food safety incidents,[90] this indirectly affects the control system which is mainly framed to food safety and to the few hypothesis of consumer economic interest protection enumerated by EU Food Laws. Therefore, it is difficult to deal with infringements depending on the "human factor" which often have an impact on consumer economic interest protection.

Specific provisions and tools regulate the control system. This will be dealt with particularly in the following Chapter.

In this Section it is worth discussing the other aspect of the control system, namely self-controls performed by the FBOs. Food Law primarily addresses food businesses.[91] Indeed, FBOs are judged as "*best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe*".[92] FBOs legal responsibility is to ensure food safety.[93] Self-controls are planned and defined following the risk classification. This depends on several assessments including site inspections on plants/factories aimed at evaluating the machines and the production typology, the results of official controls and the required adjustments in order to avoid other non-conformities. All this shall be adapted according to each type of risk. An effective self-control system shall prevent the raising of non-conformities even through controls in addition to "routine controls", with the purpose of verifying possible contaminations according to the characteristics of each specific product and to the position of the FBOs along the food chain.[94] Self-controls are performed at various stages; for example, FBOs which deal with the production of foodstuffs shall carry-out controls on the raw materials, on the products (in order to detect specific risks, for example presence of insects or other external bodies) and on samples (for example: microbiological analysis on the product, quality-control on the product). As evidenced by the characteristics and requirements of the self-control system described above, these controls are directed at avoiding non-conformities to the rules on food safety. In this context cases where a product does not cause any health risk while

[90] Van der Meulen (n 50) S19.
[91] Van der Meulen (n 53) 83.
[92] Recital 30 GFL, *see* Capelli F, 'Responsabilità degli operatori del settore alimentare' (2006) 2 Diritto comunitario e degli scambi internazionali 391, 395.
[93] Instead, as to nutritional needs, consumers are considered as responsible for their choices: Holle, M., 'Nutrition Policy in the European Union' in *EU Food Law Handbook*, vol 9 (Wageningen Academic Publishers: Wageningen, The Netherlands 2014) 519.
[94] Corte di Cassazione civile Sezione II, 15824/2014.

causing commercial violations fall outside the scope of the control system.[95] However, an express statement of FBOs responsibility to be extended also to consumer economic interest safeguarding can be found in some provisions of EU Food Laws, for example in Article 8 (2) of Regulation (EU) 1169/2011 on the provision of food information to consumers: "*The food business operator responsible for the food information shall ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions*". Nevertheless, these provisions, mainly limited to labelling requirements, cover only few of the possible cases where consumer economic interest can be infringed.

[95] However, sanctions for cases of "commercial violations" can be applied when established by National law: C-315/05 Lidl Italia Srl v Comune di Arcole (VR) [2005] ECLI:EU:C:2006:736.