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Article

The Structure of European Food Law

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Abstract: This contribution lays bare the structure of EU food law as it appears from scholarly analysis at Wageningen University in the Netherlands. The structure of EU food law can be used as a framework for teaching, application, further analysis and comparison to food law approaches in other parts of the world. From this analysis, food law emerges as a functional area of law. Core elements are: (1) the objectives of EU food law to protect consumers' interests; (2) the principles of risk analysis and precaution; (3) obligations on businesses regarding the products they place on the market, the processes they apply and their communication towards consumers; and (4) public powers of law enforcement and incident management.

Keywords: EU food law; functional area of law; Wageningen; system; structure

1. Introduction

1.1. In Search of Structure

The objective of this article is to provide the readers with the “big picture” of EU food law in the form of a structured representation. The structure aims to capture the essence and thus provide a tool for comparing EU food law to food law in other parts of the world, for studying EU food law in an organised manner, and providing the legal context for analysing and applying specific elements of EU food law.

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We² started to develop food law as a functional area of law—as an academic discipline in its own right—after I became the chair of Law and Governance at Wageningen University in September 2001. Our efforts have now resulted in a two-year MSc specialisation in Food Safety Law open to students with a background in food science, social science, or law.³

One of the first questions we confronted as a basis for both research and teaching was the question “what is the structure, what is the system of food law?”⁴ At first sight, food law in the European Union presents itself as an endless amount of provisions⁵ of a very technical and detailed nature impossible to comprehend without applying some form of organisation to them. At that time, some authors dealing with the subject matter resorted to treating subjects in alphabetic order. Our conviction that it would be possible to organise the subject matter in a more meaningful way was not met with disappointment.

While food-related provisions are countless, a closer analysis of the way they deal with food-related issues reveals a pattern of approaches. We organised the provisions on the basis of “what, who and how” questions. That is to say, which problem do the provisions take on, who do they address, and how do they deal with the problem in terms of rights and obligations they assign to the addressees? We have taken the pattern emerging from this analysis to design a framework that enables researchers, students and practitioners to *understand* EU food law. Understanding here means to comprehend EU food law in its totality at an aggregate level. This framework can be used for research and teaching but also to acquire understanding of EU food law with a view for application in legal practice.⁶

² Where reference is made to “we” this means the Law and Governance Group at Wageningen University. “I” is the author.

³ The programme offers a choice of courses such as: Food Law; International and American Food Law; Food Law, Management and Economics; Food Quality Management; Basics in Food Technology; Food Safety Economics; Chinese Law on Food and Agriculture; Food Toxicology; Food Safety Management; Risks Associated with Foods; Intellectual Property Rights; Food, Nutrition and Human Rights and Risk Communication. For details see [1].

⁴ In asking this question, we showed a civil law background. In an American booklet on comparative law [2], I found the following remark: “one of the greatest differences between legal education in common law and civil law systems appears in the manner in which the student is initiated into the study of law. While an American law student typically spends the first days of law school reading cases and having his or her attention directed over and over again to their precise facts, a student of the civil law is provided at the outset with a systematic overview of the framework of the entire legal system. The introductory text (a treatise, not a casebook) may even include a diagram depicting ‘The Law’ as a tree, with its two great divisions, public and private, branching off into all their many subdivisions and categories—each of which will become, in turn, the subject of later study.” Systematisation is not limited to education: “all other actors in the legal system receive their training from the scholars who transmit to them a comprehensive and highly-ordered model of the system that to a great extent controls how they organise their knowledge, pose their questions and communicate with each other. This model is not only taught in the universities but constitutes the latent framework of the treatises and articles produced by the professors. Furthermore, legal periodicals, which in civil law countries are run by professors rather than students, play a much more important role there than in common law countries in bringing new legislation and court opinions to the attention of the profession” ([2], p. 91). Such a diagram can indeed be found in ([3], pp. 50–51).

⁵ Between 1 January 1997 and 10 November 2006, the Official Journal published 1,359 measures addressing the food industry in whole or in part ([4], p. 64) (based on the website of the University of Reading [5]).

⁶ In our experience, food regulatory affairs managers in particular feel more confident for better understanding the context of the rules they work with on a daily basis.

We presented our view on food law in books that we initially prepared as teaching materials: *Food Safety Law in the European Union* (2004) [6] and *European Food Law Handbook* (2008) [3]. Our current understanding of the structure of EU food law is presented in graphic form in the next section and is further elaborated in the remainder of this article.

1.2. Structure

The structure of European food law presented in this contribution does not—at least not entirely—relate to a blueprint that has consciously been applied in creating the legislation, but is analytically superimposed on a situation that has grown organically, to help make sense of it. It consists of the common features and typical characteristics identified through scholarly analysis in a host of legislation and other sources of law.

The quantity of European legislation regarding food is overwhelming, and, as described below, most of what is currently in place followed the bovine spongiform encephalopathy (BSE) crisis of the mid-1990s. The food sector has become one of the most heavily regulated sectors in the EU.⁷ On a closer look, however, this legislation can be structured in a rather straightforward manner, into public powers of implementing the law, law enforcement and incident management on the one hand, and legislation addressing food businesses on the other. The latter legislation can mostly be grouped in one of three categories: legislation on the *product*, legislation on the *process*,⁸ and legislation on the *presentation* of food products. The whole structure is embedded in general *principles*, and is represented in Figure 1.

Figure 1 shows at the top the principles of European food law with, on the left-hand side, the provisions addressing public authorities and, on the right-hand side, the provisions addressing businesses. An important aspect of EU food law not represented in this figure consists of institutional provisions e.g. the creation of specialised authorities to deal with food related issues.

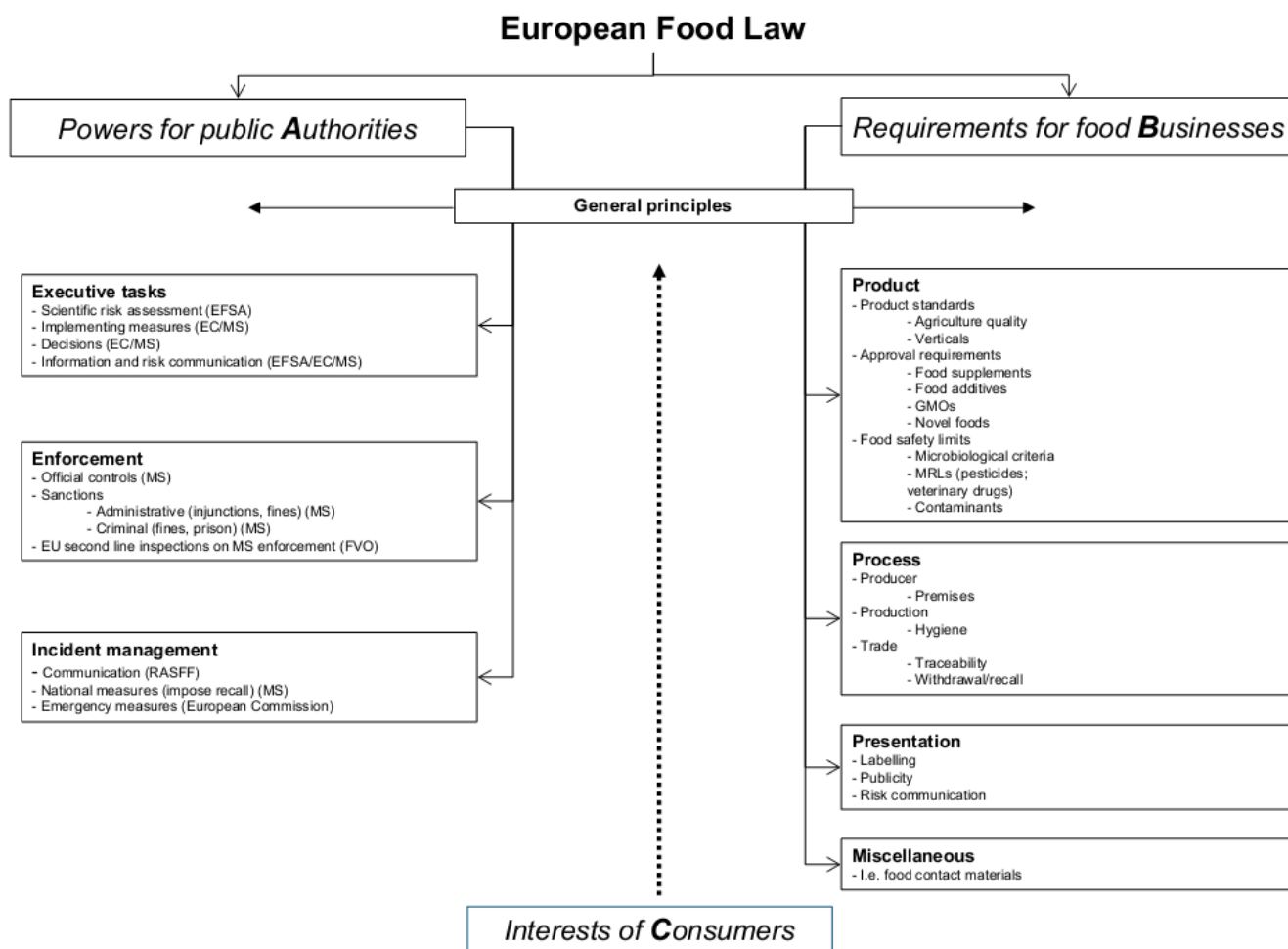
1.3. The ABC of EU Food Law

The “ABC” of EU food law is its focus on **A**uthorities, **B**usinesses, and **C**onsumers. The three are addressed in very different ways, however. While the protection of the life and health and other interests of consumers is the main objective of food law (see hereafter), EU *food* legislation does not provide consumers with any specific rights or remedies. Consumers that want to take legal action must rely on general consumer protection law such as product liability legislation (see section 9). The key to food safety is in the hands of the businesses handling the food. The most important requirements regarding food have the businesses as addressees. Obligations of public authorities—both at Union and at Member State level—are secondary to the obligations of businesses. Authorities have to ensure businesses’ compliance and they have to deal with situations of non-compliance.

⁷ How does one establish the measure of regulation of a sector? According to [7], food is the third most regulated sector in the EU. If we simply count hits in the EU database of official publications [8], 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 10-3-2013).

⁸ We include legislation on the premises under this heading. In the future this may develop into a separate category. This topic is not addressed in this contribution.

Figure 1. Structure of EU food law.



1.4. Overview

The structure in Figure 1 represents the framework for the analysis of EU food law in this contribution. The text follows this framework roughly clockwise. Section 2 addresses the historical background of EU food law. Section 3 starts from the top of Figure 1 discussing general principles and concepts. Sections 4, 5 and 6 follow the right hand side of Figure 1 downwards. Section 4 is about legislation addressing the product, subdivided into vertical product standards (4.1), market access requirements (4.2) and food safety targets (4.3). Section 5 deals with process-focussed provisions, specifically hygiene in 5.1 and traceability in 5.2. Section 6 is about presentation of food products in labelling. Sections 7 and 8 deal with public powers represented at the left-hand side of Figure 1: enforcement in section 7 and incident management in section 8. Section 9 targets consumers, depicted at the bottom of Figure 1. Consumers' remedies to enforce food law mainly lie in product liability law. Section 10 returns to the general principles of EU food law at the top of Figure 1 by discussing its fundament in risk analysis. Section 11 concludes this contribution. For the benefit of readers who are not familiar with European law, Annex 1 sets out the basics in so far as needed to be able to understand this article. Annex 2 suggests some further sources.

2. Development of EU Food Law

2.1. Introduction

From its beginning, the European Economic Community (now the EU) devoted much of its attention to agriculture. Motivators were the desire to gain self-sufficiency and to support the rural areas and their agricultural populations. Almost immediately legislation started to develop addressing food as a commodity in its own right.⁹ At first, this legislation originated from the directorate general (DG) responsible for agriculture, but eventually emphasis shifted to the DGs responsible for industry, enterprises and the internal market.¹⁰

From the early 1960s until the eruption of the BSE crisis in the mid-1990s, European food law was principally directed at the creation of an internal market¹¹ for food products in the EU.

This market-oriented phase can be divided into two stages. During the first, emphasis was on harmonisation of national product standards through vertical directives. This stage ended with the “Cassis de Dijon” case law. During the second stage, emphasis shifted to harmonisation through horizontal directives.¹²

The BSE crisis and other food scares in the 1990s brought to light many serious shortcomings in the existing body of European food law. It became evident that fundamental reforms would be needed. In January 2000, the European Commission announced its vision for the future development of European food law in a “White Paper on Food Safety” [12].¹³ It emphasised the Commission’s intent to change its focus in the area of food law from the development of a common market to assuring high levels of food safety. In the years since its publication, a complete overhaul of European food legislation has taken place.

2.2. Creating an Internal Market for Food in Europe

When the six original members of what is today the European Union signed the Treaty of Rome in 1957, they created a community with an economic character. This was reflected not only in its original name—the European Economic Community—but also in the original objective to create a common market.

At the heart of the instruments to achieve this objective are the so-called four freedoms of the European Union: the free movement of labour, the free movement of services, the free movement of

⁹ It took some decades, however, before food law developed as an academic specialisation. The European Association for Agricultural Law (CEDR: Comité Européen de Droit Rurale), for example, was established in 1957 [9]. The European Food Law Association (EFLA) was founded only in 1973 [10].

¹⁰ On the history of EU food law, see also [11].

¹¹ In different stages of its development, it is also referred to as the “common market” or the “single market.” The expressions are used interchangeably in this article.

¹² The distinction between horizontal and vertical directives will be discussed hereafter.

¹³ Commission White Papers traditionally contain proposals for Community action in specific areas, and are developed in order to launch consultation processes at the European level. If White Papers are favourably received by the Council, they often form the basis of later “Action Programs” to implement their recommendations.

capital and the free movement of goods. The free movement of goods¹⁴ has been vital to the development of food law.

During the first years of implementing the ambitious idea of trade without frontiers, Community legislation aimed primarily at facilitating the internal market through the harmonisation of national product standards. Agreement about the quality and identity of food products was considered necessary. To reach such an agreement, directives were issued on the composition of certain specific food products. This is called vertical (recipe, compositional or technical standards) legislation.¹⁵

Early attempts to establish a common market for food products in Europe by prescribing harmonised product compositions faced two substantial obstacles. Firstly, at that time, all legislation required unanimity in the Council, which gave each Member State a virtual right of veto over new legislation. Secondly, there was the sheer scale of the task. There are, as the European institutions soon realised, simply too many food products to deal with. Nevertheless, quite a few products remain subject to European rules on compositional standards.¹⁶ These compositional standards form the legacy of the first phase of EU food law. They are being updated or replaced when necessary, but no new products are being added.

2.3. *Advancement through Case Law*

It was the Court of Justice that showed the way out of the deadlock through new, broad interpretations of the key provision on the free movement of goods in the common market: the prohibition of quantitative restrictions on imports and all measures having equivalent effect (now in Article 34 of the Treaty on the Functioning of the European Union¹⁷ (TFEU)).¹⁸ It should be read in connection with the exceptions to the free movement of goods, such as the protection of health and life of humans, animals or plants.¹⁹

The landmark decision in this context was *Cassis de Dijon* [16]. A German chain of supermarkets sought to import *Cassis de Dijon*, a fruit liqueur, from France. The German authorities, however, refused to authorise the import because the alcohol content was lower than allowed by German national standards, which stipulated that such liqueurs should contain at least 25% alcohol. *Cassis de Dijon* contained just 20% alcohol.

The German authorities acknowledged that this was a restriction on trade, but sought to justify it on the basis that beverages with too little alcohol pose several risks. The German authorities argued that alcoholic beverages with low alcohol content could induce people to develop tolerances for alcohol more quickly than beverages with higher alcohol content, and that consumers trusting the (German) law might feel cheated if they purchased such products with the expectation of higher alcohol content.

¹⁴ Now Articles 14 and 28–37 of the Treaty on the Functioning of the European Union (TFEU) [13], previously Articles 3 (1) (c) and Article 23–31 EC Treaty [14].

¹⁵ Vertical legislation resembles the product standards of the *Codex Alimentarius* and standards of identity in US food law.

¹⁶ E.g. sugar, honey, fruit juices, milk, spreadable fats, jams, jellies, marmalade, chestnut puree, coffee, chocolate, natural mineral waters, minced meat, eggs, fish. Wine legislation is a body of law in itself.

¹⁷ Previously Article 28 of the EC Treaty [14], at that time numbered Article 30.

¹⁸ On the relevance of the ban on customs duties and charges having equivalent effect (Article 30 TFEU [13], previously Article 25 EC Treaty [14]), see [15].

¹⁹ Now in Article 36 TFEU [13]. Previously in Article 30 of the EC Treaty [14].

Finally, Germany submitted that in the absence of such a law, beverages with low alcohol content would benefit from an unfair competitive advantage because taxes on alcohol are high, and beverages with lower alcoholic content would be saleable at significantly lower prices than products produced in Germany according to German law.

The Court held that the *type* of arguments presented by the German authorities would be relevant, even where they did not come under the specific exceptions contained in the Treaty, provided that those arguments met an urgent need. This is known as the rule of reason.

The Court found that Germany's public health argument did not meet this standard of urgency. The Court specifically cited the availability of a wide range of alcoholic beverages on the German market with alcohol content of less than 25%. As to the risk of consumers feeling cheated by lower than expected alcohol content, the Court suggested that such a risk could be eliminated with less effect on the common market by requiring the display of the alcohol content on the beverage label.

For cases such as this one, in which there are no specific justifications for restrictions on the trade between Member States, the Court extracted a general rule underlying the Treaty provisions: products that have been lawfully produced and marketed in one of the Member States may not be kept out of other Member States on the grounds that they do not comply with the national rules. This is called the *principle of mutual recognition*.

With its ruling, the Court in Luxemburg laid the legal foundation for a well-functioning common market.

Several commentators expressed concern that the principle of mutual recognition would lead to product quality standards based on the lowest common denominator. It is clear that manufacturers established in Member States with the most lenient safety or technical requirements or legal procedures do gain a competitive advantage.

The limitations and drawbacks of the principle of mutual recognition highlighted the need for further harmonisation of food requirements at the European level. For Member States with more stringent national standards, European-level legislation became the best hope for raising neighbours' standards to achieve a level playing field without compromising consumer protection.²⁰ The Cassis de Dijon ruling marked a significant change in the perception of the benefits of harmonisation. Before the Cassis case, harmonisation was seen merely as a *condition* for the functioning of the internal market. Afterwards, emphasis shifted to the need to alleviate the *consequences* of the internal market. In legal terms, too, the wave of harmonisation that followed the Cassis case differed from earlier efforts. Emphasis shifted from product-specific legislation to horizontal legislation, meaning general rules addressing common aspects for a broad range of foodstuffs.

2.4. Breakdown

The heyday of market-oriented food law based on mutual recognition ended in tears. The food and agricultural sectors in the European Union emerged deeply traumatised from the 1990s. A series of crises resulted in a breakdown of consumer confidence in public authorities, industry and science. The

²⁰ This will be shown later on in this article. In the meantime, the protection of consumer safety has been concentrated at EU level.

current third phase of EU food law can only be truly fathomed if the trauma to which it responds is understood.

Although the bovine spongiform encephalopathy (BSE) crisis was not the first and, in terms of death toll, not the worst²¹ food safety crisis in the EU, it caused a landslide in the legal and regulatory landscape of Europe. Subsequent food safety scares,²² outbreaks of animal diseases²³ and scandals over fraudulent practices²⁴ added to a sense of urgency to take protective measures.

Public awareness of the BSE epidemic, and the time it had taken British and European authorities to address it, presented a major challenge to European cooperation in the area of food safety. When the extent of the crisis became public, the European Union issued a blanket ban on British beef exports. In response, Britain adopted a policy of non-cooperation with the European institutions, and sought to deny the extent and seriousness of the BSE problem.²⁵

The European Parliament played a crucial role in defusing this crisis. A temporary Enquiry Committee chaired by Manuel Medina Ortega was instituted to investigate the actions of the national and European agencies involved in the crisis [22]. The Enquiry Committee presented its report in early 1997 [23]. The Medina Ortega report strongly criticised the British government, as well as the European Commission. The Commission was accused of wrongly putting industry interests ahead of public health and consumer safety, science had been biased and transparency had been lacking.

Paradoxically, this reproachful report followed by a motion of censure proposed to the European Parliament provided the Commission with the impetus it had hitherto lacked, indeed with a window of opportunity, to take the initiative in restructuring European food law in a way that considerably strengthened its own powers. The Commission undertook far-reaching commitments to implement the Committee's recommendations.

As early as May 1997, a few months after the Medina Ortega report, the Commission published a Green Paper on the general principles of food law in the EU [24].²⁶ It sketched the outlines of a legal system capable of getting a firm grip on food production. Consumer protection was made the main priority. The Commission committed to strengthening its food safety control function. This led directly to placing responsibility with the DG for health and consumers (DG Sanco) and to the establishment

²¹ See [17,18] on finding that the toxic oil syndrome (TOS) epidemic that occurred in Spain in the spring of 1981 caused approximately 20,000 cases of a new illness. Researchers identified 1,663 deaths between 1 May 1981 and 31 December 1994 among 19,754 TOS cohort members. Mortality was highest during 1981. The poisoning was caused by fraud consisting of mixing vehicle oil with consumption oil.

²² One example is the Belgian dioxin crises. It was caused by industry oil that had found its way into animal feed and subsequently into the food chain [19]. Another example is the introduction of medroxyprogesterone acetate (MPA) into pig feed in 2002 [20]. Sugar discharges from the production of MPA, a hormone used in contraceptive and hormone replacement pills, were used in pigs feed and, by that route, MPA entered the food chain. In 2004, a dioxin crisis broke out in the Netherlands.

²³ Including foot-and-mouth disease, SARS, pig plague and avian influenza.

²⁴ Such as the melamine crisis.

²⁵ Symbolic became the TV footage where the responsible Secretary of State, John Gummer is shown feeding his little daughter a hamburger, to convince the public that nothing was wrong with British beef [21].

²⁶ The Green Paper in turn referred to the Sutherland Report of October 1992: "The Internal Market after 1992; Meeting the Challenge." It is, however, beyond the scope of this article to trace the history of EU food law in all its rich detail.

within DG Sanco of the Food and Veterinary Office (FVO) in Dublin in 1997. Furthermore, the Commission announced the establishment of an independent food safety authority [24,25].

The Commission kept the pressure on beyond 1997, eventually gaining the support of the European Court of Justice for the measures—the export ban on cattle and beef in particular—that had been taken against Great Britain at the climax of the crisis [26–28].

On 12 January 2000, the Commission published its famous “White Paper on Food Safety” [12].²⁷

2.5. *The White Paper: A New Vision on Food Law*

The Commission’s vision of the future shape of EU food law was laid down in the White Paper on Food Safety. Before the BSE crisis, European food safety law was subordinated to the development of the internal market. The shortcomings in the handling of the crisis clearly revealed a need for a new, integrated approach to food safety.

The Commission aimed to restore and maintain consumer confidence. The White Paper focused on a review of food legislation in order to make it more coherent, comprehensive and up-to-date, and to strengthen enforcement.²⁸

Part of the package was the envisaged establishment of a new European Food Safety²⁹ Authority, to serve as the scientific point of reference for the whole Union, and thereby contribute to a high level of consumer health protection.

The Annex to the White Paper is the Action Plan on Food Safety, a list of 84 legislative steps that the Commission deemed necessary to create a regulatory framework capable of ensuring a high level of protection of consumers and public health.

The turn of the millennium saw the beginning of the planned overhaul of European food law and, within a decade, most of the 84 steps were taken. The new regulatory framework is based on regulations rather than directives.

2.6. *EU Food Law in the 21st Century*

Only two years after the White Paper was published, the cornerstone of new European food law was laid: Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and enacting procedures in matters of food safety [30]. This regulation is often referred to in English as the “General Food Law” (GFL). The Germans speak of it as a “*Basisverordnung*”—perhaps a more precise phrase given that the regulation is in fact the basis upon

²⁷ Unlike a Green Paper that is intended mostly as a basis for public discussion, a White Paper contains concrete policy intentions.

²⁸ This heralded in food an emphasis on regulatory involvement in the market that contrasts with the so-called “new approach” that was generally followed with regard to product standards. In this new approach, EU legislation limited itself to setting the safety requirements, leaving elaboration in technical standards to the private sector. For more on this topic, see [29].

²⁹ In the White Paper, the Commission speaks of a European Food Authority. The word “safety” was inserted later.

which European and national food laws are now re-constructed.³⁰ The main objective of the General Food Law is to secure a high level of protection of public health and consumer interests with regard to food products. It does so by stating general principles, establishing the European Food Safety Authority, and giving procedures to deal with emergencies.

After the creation of the General Food Law, whole packages of new legislation followed (Figure 2).

Figure 2. Highlights in the overhaul of EU food law.

2002	Regulation 178/2002 (GFL [30])
2003	Regulations 1829/2003 and 1830/2003: GMO package
2004	Regulations 852–854/2004 Hygiene package
	Regulation 882/2004 Official controls
	Regulation 1935/2004 Food contact materials
2005	Allergen labelling requirements included in Directive 2000/13.
2006	Regulation 1924/2006 Nutrition and health claims
2007	White Paper A Strategy for Europe on Nutrition, Overweight and Obesity related health issues
2008	Regulations 1331–1334/2008: Food Improvement Agents Package (FIAP); additives, flavourings and enzymes
2011	Regulation 1169/2011 Food information to consumers

The most pressing issue on the agenda for the years to come is probably overweight and obesity. Thus far, the EU legislator has not found suitable instruments to deal with this problem. Measures are currently limited to providing consumers with information directly and on food product labels.³¹ Some reformulation is done by the industry on a voluntary basis.

3. General Concepts and Principles

3.1. Scope

The General Food Law defines the scope of food law. Its approach is holistic in the sense that food law applies to all businesses in the food chain, “from farm to fork,” including feed for food producing animals. In principle, food law applies to the primary sector, but some exemptions are in place, particularly in regards to hygiene requirements.

The General Food Law provides a definition of “food” (Article 2).³² Its fulfilment is a precondition for the applicability of the GFL [30]. If a product meets this definition it is a food in the sense of the

³⁰ Contemporary European food law displays several characteristics in which it is different from its predecessor: more emphasis on horizontal regulations (than on vertical legislation); more emphasis on regulations that formulate the goals that have to be achieved, the so-called “objective regulations,” than on means regulations; increased use of regulations (rather than directives) and thus increasing centralisation.

³¹ Unlike in food safety law where responsibility rests with food business operators, according to the White Paper on A Strategy for Europe on Nutrition, Overweight and Obesity related health issues [31], ultimate responsibility for one’s lifestyle and that of one’s children is on the individual.

³² Surprisingly, although the European legislature had been very active in the field of food law, the term “food” was for the first time defined in the 2002 General Food Law. The GFL does not distinguish between food and food ingredients

GFL and the GFL applies to it. The same holds true for all the other laws and regulations that use this definition. In due course, that should be the whole body of food law in the European Union and its Member States.

‘Food’ (or ‘foodstuff’) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. ‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. (...) ‘Food’ shall not include: (a) feed; (b) live animals unless they are prepared for placing on the market for human consumption³³; (c) plants prior to harvesting; (d) medicinal products (...) (e) cosmetics (...) (f) tobacco and tobacco products (...) (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971; (h) residues and contaminants.

Unlike US food law, the concept of “food” does not include animal feed. The definition of humans as animals (by referring to “articles used for food or drink for man or other animals” [32]) would go against European culture. The animal feed chain is brought within the ambit of EU food law by separate provisions and definitions in the General Food Law.

3.2. Objectives

The General Food Law expresses the objectives of EU food law in Article 5: “1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers’ interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment. 2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this chapter.”

Thus far, this provision has provoked little discussion.³⁴ Taken literally, it could be interpreted to mean that other interests such as those of (individual) food businesses and of the food sector as a whole may not be taken into account. Subsequent legislation does not indicate, however, that such limitation has been taken into account. The main message, therefore, does not seem to be about excluding certain interests, but about focussing on the protection of consumers.

3.3. Principles

The General Food Law explicitly labels as “principles” that food law protecting human health should be based on risk analysis (GFL [30], Article 6), and thus on science. Undoubtedly, discussions within the World Trade Organization (WTO) regarding the EU approach to growth-promoting hormones and genetically modified foods have contributed to the decision to make food law (more) science based. For situations of scientific uncertainty, the precautionary principle applies (GFL [30],

as some older legislation does. Ingredients fulfil the definition of food and are (therefore) subject to the same safety rules. Only in labelling legislation does the distinction still have significance.

³³ Such as oysters (footnote added).

³⁴ However, we do address this issue in some detail in our book *Reconciling food law to competitiveness* [33] and in “The Function of Food Law. On the objectives of food law, legitimate factors and interests taken into account” [34].

Article 7). That is to say that, when risk assessment is inconclusive but gives scientific reasons to suspect a food safety risk, public authorities are legitimised to base protective measures on a “worst-case scenario” [35].

The question of what science based means in practice is discussed in section 10.

Another principle is that “[w]here international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community” (GFL [30], Article 5(3)). This principle is reflected, for example, in the definition of food which is based on the food definition in the *Codex Alimentarius*.³⁵

4. Product-Focused Provisions

Regarding food products, the EU legislature follows two different approaches. German scholars label these the “abuse principle” and the “prohibition principle,” respectively [44].

It is a basic provision in EU food law that food may not be brought to the market if it is unsafe (Article 14 GFL) [45]. It is the responsibility of food businesses (Article 17(1) GFL) to judge on a case-by-case basis if this requirement is met. Infringements may set off enforcement activities. If no other requirement applies, this is the abuse principle. The business is free to place a product on the market but may suffer consequences if it abuses this liberty. For some hazards, the legislator defines acceptable levels (food safety targets), thus distinguishing safe foods from unsafe foods. See section 4.3.

For some food categories, it is required that the safety is proven to the satisfaction of the authorities before they may be brought to the market. Before authorisation is obtained, a prohibition applies. To these foods, the prohibition principle applies. See section 4.2.

Some older legislation goes beyond safety requirements and defines all kinds of properties and quality aspects that a food must fulfil. See section 4.1.

4.1. Product Standards

In the early stages of development of EU food law and of the EU common agricultural policy, emphasis was on product-specific legislation.

The common agricultural policy initially set out to ensure self-sufficiency of the European Community and decent living conditions for the rural population. An important instrument in this context was price guarantees. The EC would buy all products that were not sold in the market at a set price. To ensure the quality of the produce bought under this regime, quality requirements were set for fresh fruit and vegetables brought to the EU market.³⁶

³⁵ For an overview of international food law, see: Bernd van der Meulen “The Global Arena of Food Law: Emerging Contours of a Meta-Framework” [36]. On international food law and related topics see also: Marsha A. Echols [37], A. Alemanno [38], Marco Bronckers and Ravi Soopremanien [39], Marielle D. Masson-Mathee [40], Joan Scott [41], D. John Shaw [42] and G. Faber, *Unilateral Measures Addressing non-Trade Concerns* [43].

³⁶ These quality requirements are increasingly abolished.

As described above, to create a common market for food products among countries where different product standards applied, attempts were made to agree on common definitions of requirements for food products in European directives. The success of this approach was limited and further attempts were abandoned after the European Court of Justice developed an alternative way to come to a common market: the principle of mutual recognition.

The EU Court of Justice is reluctant to accept product standards set by Member States if they are applied to keep products originating in other Member States from the market. The Court checks such requirements for proportionality: e.g., have they been made for a legitimate objective and are they the least restrictive measures to achieve that objective? The litmus test is if the same objective cannot be achieved by labelling e.g., by informing the consumer. In this way, we witness a shift from product-focussed requirements to labelling requirements.

In so far as product-specific provisions still exist, the legally defined names must be used on the label when they apply and may not be used if the legal standard has not been met.³⁷

4.2. Market Access Requirements

Conventional foods may freely be brought to the EU market. Since the early 1960s, systems of premarket approval requirements have been introduced for synthetic substances added to food for technological reasons. These are the so-called food additives. An additive is *any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods* [46].³⁸

The concept of additives includes sweeteners and colours. The system is based on so-called positive lists. That is to say, additives that have been approved for use in food are included in a list. Only those additives that are mentioned on the list and comply with the list's requirements may be used in food. All other substances that fulfil the definition of additive are forbidden. Additives are included in the list under an "E-number." This number may be used to declare the additive in the list of ingredients on the food product concerned.

The system of positive lists has gradually been expanded to include other categories of foods considered potentially hazardous. Among these are novel foods—foods that were not consumed in the EU before 1997. Initially, the concept of novel food included genetically modified foods. As from 2004, these form a separate category with separate legislation.

Approval schemes vary. A common aspect is that a food subject to approval may only be brought to the market after it has been approved on the basis of a scientific risk assessment. Other criteria for approval are that the food may not mislead the consumer and may not be nutritionally disadvantageous

³⁷ While I am writing this line, a radio commercial makes fun of this legislation by stating that it would be illegal to call their product a "jam" because it has less than 60% sugar. The hope is expressed that they will not be prosecuted for being too healthy.

³⁸ Article 3(2) (a) Regulation 1333/2008 on food additives. Note that this concept of food additives is much less wide than the one applied in the USA. See Federal Food, Drug and Cosmetics Act § 201 (21 USC § 321).

compared to a conventional food it will replace. For additives, there is the additional criterion that they must fulfil a technological need.

With regard to genetically modified organisms, American scholars sometimes maintain that the American approach focuses on the product, while the European approach focusses on the process [47]. It is true that the process of genetic modification brings a food within the ambit of the approval requirements, but it is the product that results from the process, not the process as such whose safety is assessed in the approval procedure.

The approval of food additives is generic. If an additive is included in the list, every business is entitled (from a food law point of view, intellectual property rights may decree otherwise) to bring it to the European market. For other foods such as GMOs, the approval is specific. This means that the approval authorises the *applicant* exclusively to bring the product to the market. If other businesses want to bring the same product, they need an approval, as well. This is in particular burdensome for the so-called exotic foods. These are foods that have no history in the EU and are thus considered novel, but that do have a history of safe use in other parts of the world, such as noni, stevia and baobab.

4.3. Food Safety Targets

Finally there is legislation setting limits to the presence of undesirable substances (contaminants, toxins, residues of pesticides or veterinary drugs) or organisms in food.³⁹ The limits are set on the basis of scientific risk assessment. To residues of products that have not been approved and to substances for which no lowest safety level can be established, a zero tolerance may apply.

5. Process-Focused Provisions

It has been realised that in order to ensure food safety, processes must be under control in production, as well as in trade. Practices aimed at the prevention of food safety risks are known as “hygiene” [48]. At the heart of EU legislation on food hygiene is the so-called HACCP system: Hazard Analysis and Critical Control Points. This system requires food businesses to make such an analysis of their processes that they know where hazards may occur, how to recognise them, and how to deal with them in order to maintain food safety. Application of the system must be well documented.

In trade, a requirement of traceability applies (GFL [30], Article 18). Food businesses must record where their inputs come from and where their products go. If a food safety incident occurs, this information must enable the authorities to swiftly identify the origin of the problem and its dispersal in order to eliminate the cause and take care of the consequences.

Finally, businesses that have reason to believe that a food they have brought to the market may not be in conformity with food safety requirements are under obligation to withdraw it from the food chain and recall it from consumers (GFL [30], Article 19).

³⁹ See, for example, Framework regulation 315/93; Regulation 1881/2006 on mycotoxins and chemicals; Regulation 2073/2005 on microbiological criteria; Regulation 396/2005 on pesticide residues; Regulation 470/2009 and Regulation 37/2010 on veterinary drugs, Directive 96/22 on hormones, Regulation (EURATOM) 3954/87 and Regulation (EURATOM) 944/89 on radioactive contamination.

5.1. Processing

The HACCP system was developed by the American space agency NASA to ensure that astronauts would not be plagued by diarrhoea, vomiting, food poisoning or other food-borne hazards during their stay in outer space. It has been adopted by the Codex Alimentarius Commission as a system suitable to ensure food safety worldwide. Parts of the system were previously in place in the EU, but as of 1 January 2006, the entire system applies to all food businesses in the EU with the exception of the primary sector⁴⁰ and some traditional producers.

5.2. Trade

From all food businesses in the EU, traceability is required. The concept of traceability is defined as “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution” (GFL [30], Article 3(15)). The aim of traceability is to be able to quickly identify the source of a food safety problem and to conduct well-aimed withdrawals to remove affected products from the market. If no other, more specific requirements apply based on Article 18 GFL, businesses must be able to trace their inputs and outputs one step up and one step down. The onus to reconstruct the entire chain from this information in cases of food safety incidents is on the authorities.

For some product groups such as GMOs [49] and beef [50] an obligation applies to have available an intact paper trail.

6. Presentation

6.1. Labelling

A major part of food legislation addresses the information food businesses provide to consumers regarding their product through advertising and—mainly—labelling. The most important codification of these rules is to be found in Regulation 1169/2011 on the provision of food information to consumers [51].⁴¹ Labelling means “any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food” (Regulation 1169/2011 [51], Article 2(2)(i)). Labelling and other food information may not be misleading (GFL [30], Article 16, Regulation 1169/2011 [51], Article 7(1)).

All pre-packaged food products must be labelled in a language that is easily understood. Usually this means in the national language of the Member State. Information addressed in the legislation is mandatory, restricted, or forbidden.

There are twelve required (mandatory) pieces of information listed in Article 9 of the Regulation, the most important of which are: the name of the food; the list of ingredients; the presence of allergens;

⁴⁰ At least in public law an exception applies. Primary producers following private standards such as GlobalGAP have to implement HACCP.

⁴¹ This regulation replaces the General Labelling Directive 2000/13 and some other horizontal pieces of legislation on labelling. The idea is to streamline food labelling law in the EU. For an eBook commenting on and explaining this regulation, see *The Food Label* [52].

the quantity of certain ingredients or categories of ingredients; the net quantity; the date of minimum durability or, in the case of foods which, from the microbiological point of view, are highly perishable, the “use by” date; the name or business name of the food business operator responsible for the food information, that is, the operator under whose name the food is marketed, or the importer into the Union market or the manufacturer or packager, or a seller established within the European Union.

The most important change that Regulation 1169/2011 has brought compared to the previous situation is mandatory instead of voluntary nutrition labelling, e.g., mentioning the nutrients and energy present in the food product.⁴²

Specific labelling requirements outside Regulation 1169/2011 demand that the presence of additives, novel ingredients and GMOs be mentioned on the label.

6.2. Nutrition and Health Claims

In 2006, a Regulation on nutrition and health claims was published [53]. Nutrition claims must conform to the annex to this regulation. The annex states among other things that the expression “light”⁴³ may be only used in case of a reduction of at least 30% of certain nutrients or energy. Health claims, e.g. claims about the effects of a certain food on health, must be science based and approved. Foods bearing health claims are sometimes⁴⁴ called “functional foods.”

6.3. Protected Designations

The origin of a product must be labelled if omitting this information would mislead the consumer. In most other situations, this is voluntary.

Some designations of origin are protected. Regulation 510/2006 on agricultural indications establishes rules for the protection of certain designations of origin (PDO) and geographical indications (PGI) on agricultural products. The Regulation provides opportunities for small-scale producers to use these quality symbols as a means of promoting their products, without the long and costly process of obtaining a trademark for their product. To a certain extent, they are comparable to collective trademarks in the sense that they can be used by a group of producers to distinguish their product. Member States may not introduce additional schemes.⁴⁵

Regulation 509/2006 [55] has introduced a register of recognised traditional specialties. To obtain the TSG designation (Traditional Speciality Guaranteed), a product must possess features that distinguish it from other products, and it must be traditional.

Regulation 834/2007 [56] and Regulation 889/2008 establish conditions for the use of terms referring to the “organic” production method (such as “eco” and “bio”). Such terms may only be used in labelling, advertisement or in trademarks with regard to products which satisfy the requirements set

⁴² This is the most concrete achievement to date in translating nutrition and health policy to legislation.

⁴³ In the EU, for products with reduced energy, the expression “light” is preferred over the expression “diet” because the latter is associated with illness.

⁴⁴ This is the case in literature and common speech, not in legislation.

⁴⁵ European Court of Justice. Case C-6/02. *Commission vs. France* [49]: protected designations of origin may not be introduced by national legislation but may only be afforded within the framework of Regulation (EC) 2081/92 (now Regulation (EC) 510/2006).

out under or pursuant to that regulation. In the case of processed food, at least 95% of the ingredients (by weight) must be organic. Additional information has to be supplied as well, such as the number of the control authority.

7. Enforcement

7.1. Member States

It is the responsibility of the Member States to enforce food law, and to monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, they have to maintain a system of official controls and other activities appropriate to the circumstances, including public communication on food and feed safety and risks (GFL [30], Article 10), food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution (GFL [30], Article 17(2)). Generally speaking, enforcement encompasses both verification of compliance with legal obligations and application of sanctions in case of infringements. Although Article 17 of the General Food Law holds the Member States responsible for the enforcement of food law, European food law increasingly sets standards for national enforcement and provides for supervision. *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules* includes obligations for verification by the Member States, measures to be taken in case of infringements, a framework for co-operation between national authorities and the Commission, and for the Commission to monitor the performance of national authorities in the Member States and in third countries.

Infringements on food law may cause food safety incidents. Such incidents can, however, also occur for other reasons (accidents). Incident management and enforcement can be closely related, but they are not necessarily the same thing. Incident management is discussed in the next section.

If a Member State establishes the non-compliance of a food business operator, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the operator's past record with regard to non-compliance (Regulation 882/2004 [57], Article 54).

Such action can include the imposition of sanitation procedures or the recall of a food product, the restriction or prohibition of placing foods on the market, or a closure of all or a part of the business concerned. In case of imported products these measures may include: destruction, special treatment to solve the irregularity, and re-dispatch of the product to the country of origin. For the latter action, a timeframe of no more than 60 days applies.

7.2. Food and Veterinary Office

In 1997, the Food and Veterinary Office (FVO) was instituted. It is not an independent agency similar to the European Food Safety Authority (EFSA), but a part of DG Sanco. It has its headquarters in Ireland, however, at a distance from the other parts of DG Sanco in Brussels. This indicates that at least a certain degree of independence is intended.

The FVO has two main tasks. It audits the performance of national agencies in the Member States and it inspects the performance of industry and public authorities in third countries that wish to export food products to the European Union. Although the FVO is not mentioned by name, Regulation 882/2004 provides a basis for its activities. The Member States must give all necessary assistance and provide all documentation that the Commission experts—the FVO—request.

Controls in third countries may only be executed if the authorities in those countries agree to them. However, as such controls may be a condition for export to the EU, these authorities often have little alternative. The inverse situation also exists; third countries carry out inspections in the EU, and the Regulation requires the European Commission (*i.e.*, the FVO) to assist Member States in dealing with such situations (Regulation 882/2004 [57], Article 52).

8. Incident Management

EU food legislation provides instruments to deal with food safety incidents and emergencies. Information is shared among authorities (section 8.1), businesses have their responsibilities (section 8.2), and—in addition to the enforcement powers discussed above—public authorities are given specific instruments (section 8.3).

8.1. Communication

A system for rapid alert has existed in the field of food safety since 1979. However, the scope of the former system initially did not include feed. The Rapid Alert System for Food and Feed (RASFF) introduced by the General Food Law ([30], Article 50), covers food and feed, in line with the “farm to fork” approach.

The RASFF is a network for exchanging information about direct or indirect risks to human health deriving from food or feed. The system involves the Member States, EFSA and the European Commission. Participation in the RASFF may be extended to third countries or international organisations, on the basis of agreements with the EU. RASFF is the EU contact point participating in the International Food Safety Authorities Network (INFOSAN) operated by the World Health Organization.

Where a member of the RASFF network has information about the existence of a serious direct or indirect risk relating to food or feed, it has to notify the European Commission. The Commission is responsible for managing the network. The Commission assesses the information received and categorises the notification under one of three categories (alert, information, border rejection) before it is passed on. The information can also be rejected from transmission through the RASFF by the Commission, if the criteria for notification are not satisfied or if the information is insufficient. The notifying country is informed of this decision.

The notification is transmitted to RASFF contact points designated by all members of the network and to EFSA. Additionally, when the notification concerns an attempt to import banned products (border rejection), the information is sent to the EU Border Inspections Posts in order to increase the vigilance and to ensure that the rejected product does not re-enter the EU through another border post. Moreover, when it is known that a product subject to a notification has been exported to a third

country or when a notification concerns a product originating from a third country, the Commission also sends information to that third country.

EFSA's role is to analyse the content of the notification and to supply scientific and technical information that will be helpful to Member States.

8.2. *Role Businesses*

The primary responsibility for ensuring that foods or feeds satisfy the requirements of food law rests with the food business operators (GFL [30], Article 17(1)). If the operators have reason to believe that their food or feed is unsafe, they shall immediately inform the competent authorities and withdraw the food or feed from the market and—if need be—recall it from the consumers. During these procedures, the operators are obliged to collaborate closely with the enforcement authorities (GFL [30], Article 19).

8.3. *Role Authorities*

8.3.1. National Authorities

National authorities in the Member States enforce food law, and monitor and verify whether food and feed business operators comply with the requirements of food law. In some cases, problems will be notified to the national authorities by food or feed business operators, who will also initiate withdrawals and recalls. There will be other instances where a problem is identified by the authorities, through inspection, outbreaks of disease, the testing of food samples or complaints by either consumers or competitors. A food alert may also result from information received through the RASFF. The national food safety authorities are the contact point for information and communication about the food or feed incident, and they coordinate investigations relating to withdrawals and recalls on a larger scale.

When the national authority adopts measures aimed at restricting the placing on the market or forcing the withdrawal or recall of food or feed, it shall immediately notify the Commission under the RASFF. It shall also inform the Commission of rejections of consignments at its Border Inspection Post, and of recommendations or agreements with food/feed business operators preventing, limiting or imposing special conditions on the placing on the market or the use of food or feed on account of a serious risk to human health requiring rapid action.

8.3.2. European Commission

Before the General Food Law entered into force, the mechanisms for adopting emergency measures by the Commission were different in various areas of legislation. The scope of the emergency measure introduced in Article 53 GFL [30] covers all types of food and feed, whether originating in one of the Member States or in a third country, and therefore the emergency measure ensures consistency and adequate coordination of the risks applying to different categories of foods or feeds. Where a food or feed is likely to constitute a serious risk to human health, animal health or the environment, and that—

given the gravity of the situation—the risk cannot be contained satisfactorily by means of measures taken by the Member State(s)⁴⁶ concerned, the Commission shall:

- suspend the placing on the market of the food/feed in question;
- lay down special conditions for the food/feed in question;
- adopt any other appropriate interim measure.

The European Commission can initiate such action at the request of a Member State, but also on its own initiative. If the Commission, following information from a Member State on the need to take emergency measures, does *not* initiate the procedure for the adoption of emergency measures at Union level, Article 54 GFL empowers the Member State in question to adopt interim protective measures. The Member State may maintain its national interim protective measures until a Union decision has been adopted concerning the extension, amendment, or abrogation of the said measures.

9. Liability and Consumers Rights

Even though the first and foremost objectives of EU food law are to protect consumers' health and other consumers' interests, no provision can be found in EU food law actually granting the individual consumer a remedy s/he can invoke in a court of law.

Nevertheless, EU food law increasingly mentions “consumers' rights.”⁴⁷ If we take a closer look at the way food law protects these rights, they turn out to be about empowerment in the marketplace, not in the courts of law. Actual legal rights for consumers have to be found outside the scope of food law.

While food law does not directly provide consumers with remedies, it does influence the rights they have on other bases. By defining the legal requirements for food, it gives substance to the *contracts* consumers conclude with food businesses. In general, it can be considered fair to interpret consumer contracts as being about food in compliance with the law. If the food is not in compliance, it should not be too difficult for the consumer to get a refund. Infringements of food safety requirements may also easily constitute a basis for non-contractual (tort) liability.

Consumer law has created an instrument meant to support the consumer in tort cases in their dealings with producers of defective products, called product liability law. The rules on product liability have been harmonised in the European Union by Directive 85/374 [57].⁴⁸ Directive 85/374 lays down the principle of strict liability of the producer, which means that a producer may be held responsible for a damage caused by a defective product s/he has put on the market even in the absence of fault.

10. Science-Based Food Law

The European legislature has pronounced the principle that EU food law is based on risk analysis [59]. Risk analysis is a science-based decision procedure that consists of risk assessment, risk communication, and risk management. To ensure the science basis of risk analysis in the EU, the

⁴⁶ The so-called subsidiarity principle applies. If action by the Member State(s) can solve the problem, the European Commission should not become involved.

⁴⁷ For the latest example (at the time of writing), see Regulation 1169/2011 on food information to consumers.

⁴⁸ As amended by Directive 1999/34.

General Food Law instituted the European Food Safety Authority (EFSA). In contrast to what its name suggests, EFSA is not an *authority* in the legal sense of the word, as EFSA has not been granted the competence to make decisions that are binding on other stakeholders. EFSA's responsibility is to provide the science, *i.e.*, risk assessment, that forms the basis for decisions, *i.e.*, risk management, to be made by others, namely, the European Commission.

At first sight, however, the statement that EU food law is to be based on risk analysis raises high expectations. These do, however, meet with some disappointment. An innocent bystander might have expected that, as from the entry into force of the General Food Law, DG Sanco would ask EFSA's opinion on each proposal for new food safety legislation (like the big packages on GM, hygiene and Food Improvement Agents). If Article 6 GFL is to be understood to require the legislature to ask scientific advice in preparing food safety legislation, it may well be the single most infringed upon provision of EU food law. Never does DG Sanco ask EFSA for an opinion on general provisions on food legislation.

If we take a closer look at the opinions available on EFSA's website [60], they virtually all refer to specific substances or food products or to claims made with regard to such substances or food products. Technically speaking, decisions regarding such substances, products and claims [61] are laid down in the *form* of legislation. By substance, however, they are case-specific *decisions* rather than general norms.

Reconciling the interpretation of Article 6 GFL with practices as they are found in the workings of DG Sanco and EFSA, the core of the "general principle" of food law is the rule that scientific advice must be part of the procedure preparing decisions on the marketability of specific substances or products. Considered against the background of EU's obligations in the global arena, this makes sense. Members of the WTO are beholden to avoid unnecessary barriers to trade. Ultimately, trade barriers will always have their effect on specific products.

In EU food safety law, two different types of questions are asked of science, depending on the type of decision under consideration. Decisions may entail restrictive measures, *e.g.*, measures limiting market access of products or measures lifting restrictions, *e.g.*, granting access. In the first situation, scientific substantiation justifying the measure answers the question if the product is *unsafe*. In the second situation, the question is if the product is *safe*. Or, to put it differently, in the first situation, science is asked to identify hazards and risks; in the second situation, it is asked to exclude them. Obviously, differences in questions asked lead to differences in burden of proof, standard of proof, and consequences if risk assessment fails to produce satisfactory answers.

Where science is asked to identify hazards, the burden of proof is usually on the authorities. In procedures where science is asked to exclude hazards, the burden of proof—or at least the burden to provide scientific data—is on businesses that want to bring a product to the market.⁴⁹

⁴⁹ This distinction runs parallel to the distinction between the abuse principle and the prohibition principle discussed in Section 4. On this topic see: "Structural Precaution: The Application of Premarket Approval Schemes in EU Food Legislation" [62].

11. Conclusions and Discussion

In this contribution, I have attempted to present the essence of food law in the EU in civil law style. That is to say that I have been looking for the system behind the law and have taken this system as a structure for presenting the subject matter. However, structure alone will not be sufficient to provide understanding. For this reason, I have devoted attention to history, as well. In its history, EU food law has developed from being single-mindedly market oriented, to encompassing consumer protection.

For the purpose of legal comparison at macro-level approaches to food law, I call upon my colleagues in other parts of the world to provide structures for the presentation of their legal systems of food law. Once we have acquired clarity on the extent to which the rules of game of food law are similar or different in various regions of the world, it would be very interesting to invest in comparative empirical research on how the game is actually being played.

To label “food law” a functional area of law is a choice to focus scholarly attention on the basis of societal phenomena rather than dogmatic distinction. This is in itself nothing new. In environmental law—for example—the same has been done. Several considerations argue in favour of giving special attention to the regulatory embedding of the food sector. The sector is worldwide and of primal importance to all people. Furthermore, it is fun. Everything relevant in law is happening in the food sector: different approaches to regulation; economic regulation and science-based risk regulation; politics and independent authorities. Food law develops at all levels of law: global (WTO, *Codex Alimentarius*, regional, national—in all the countries of the world—and even at the private sector level [63]). Finally, it can be done. I hope that this contribution shows that it is possible to approach food law as a well-structured package.

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Annex 1

Basics of EU law

1. Introduction

For the benefit of readers who are not familiar with the legal infrastructure of the European Union, this annex provides the background knowledge necessary to understand the information provided in the article.

2. Constitutional Framework

The European Union as we know it today developed out of the European Economic Community⁵⁰ which was founded by the Treaty of Rome in 1957 (entering into force on 1 January 1958). It is a supranational international organisation. The Member States have transferred a certain limited amount of their sovereignty to the Institutions with a view to achieving certain enumerated common goals.⁵¹ Over the years the Treaties have been amended and expanded repeatedly. The current treaty framework for the European Union results from a recast by the Lisbon Treaty (2007). It consists of three documents: The Treaty on European Union (TEU) that provides for the Institutions of the EU, the Treaty on the Functioning of the European Union (TFEU [13]) that grants the Institutions their tasks and legal powers, and the Charter of Fundamental Rights of the European Union that recognises the rights and liberties of people and businesses when they are confronted with the exercise of EU authority.

First among the goals of the European Union is the creation of an internal market like the market within one state.

Interestingly the founding treaties do not as such provide a basis for food law. By consequence EU food policy has based its legislation on a combination of Treaty provisions, such as the provisions on agriculture⁵² and on the internal market⁵³ in combination with the obligation to ensure in its policies a high level of protection of public health⁵⁴ and to contribute to a high level of protection of consumers.⁵⁵

3. EU Legislation

EU legislation is a common product of the European Commission acting as a day-to-day administrator, the Council representing the Member States (as it consists of national ministers) and the European Parliament representing the people in the EU. Within the European Commission the

⁵⁰ Intermediately it was labelled: European Communities and European Community. Each new name designated a further step in the integration process.

⁵¹ For a very accessible introduction to the system of EU law freely available on the Internet, see: *The ABC of European Union law* [64].

⁵² Previously Article 3(1)(e) and Article 33 EC Treaty [14]; now Article 43 TFEU [13].

⁵³ Article 114 TFEU [13] (previously Article 95 EC Treaty [14]).

⁵⁴ Article 168 TFEU [13] (previously Article 152 EC Treaty [14]).

⁵⁵ Article 169 TFEU [13] (previously Article 153 EC Treaty [14]).

Directorate-General (DG) Sanco (Health and Consumers) is responsible for the domain of food law. It initiates legislation and it acts as the executive.

EC legislation comes in two major forms: regulations and directives.⁵⁶ Regulations are comparable to legislation like that known in virtually all countries that address their citizens directly in conferring rights and obligations to them. Directives address the legislatures of the Member States; directives serve the purpose of harmonising Member States' national legislation. Regulations are immediately applicable in all the Member States and, therefore, result in uniform law. Directives result in harmonised national legislation.

4. *Comitology*

The European Commission is the executive power in the EU. It is the closest thing the EU has to a government. In the exercise of its powers, executive as well as legislative (delegated or implementing), to compensate the Member States for the absence of the Council in the procedure, the Commission cooperates with committees representing the Member States.⁵⁷ In food law, this is the Standing Committee on the Food Chain and Animal Health (SCFCAH). In the wording of the law, the Commission is 'assisted' by the SCFCAH.⁵⁸ This euphemism means that the Commission needs the SCFCAH's approval for its decisions.

5. *Agencies*

Part of DG Sanco is the Food and Veterinary Office (FVO). FVO is an inspection service that oversees if national inspections within the EU and in third countries wishing to export to the EU perform up to EU standards.⁵⁹

The European Food Safety Authority (EFSA) is responsible for scientific risk assessment.⁶⁰ It operates independently from the European Commission that is responsible for risk management.⁶¹ It is independent in the sense that the Commission cannot give it instructions.

6. *Court of Justice*

The Court of Justice of the European Union protects the uniform interpretation of EU law. It exercises several functions. It supports national courts in the Member States by providing preliminary rulings on matters regarding the interpretation of EU law; it hears actions for annulment of decisions taken by the EU institutions, and it judges behaviour of Member States brought before it by the European Commission in so-called infringement proceedings (alleged cases of non-compliance by Member States with EU law obligations).⁶²

⁵⁶ See Article 288 TFEU [13] (previously Article 249 EC Treaty [14]).

⁵⁷ See Articles 289, 290 and 291 TFEU [13] and Regulation 182/2011.

⁵⁸ Article 58 Regulation 178/2002 (GFL [30]).

⁵⁹ See 7.2 above.

⁶⁰ See chapter 10 above.

⁶¹ Depending on the type of risk management measure the responsibility may also rest with the Member States or with the Council and the European Parliament jointly with the Commission.

⁶² See Article 19(3) TEU.

7. Member States

All powers (and the related responsibilities) that have not been expressly transferred to the EU Institutions remain with the Member States, who are sovereign. There is no European police force. Member States are responsible for the enforcement of European law in general⁶³ and European food law in particular.

The sovereignty of the Member States is recognised among others in the so-called principle of institutional autonomy. EU law has little to say about the organisation of the public sector in the Member States. Usually, obligations in regulations or directives are conferred to the national “competent authority”. It is for the national legislature to decide which state organ will be the competent authority in any given matter and to endow it with the powers necessary to fulfil its obligations under EU law. In most Member States food law is in the domain of either the Minister of Agriculture or the Minister of Public Health, or both. Most Member States also have a more or less independent food safety authority.

8. Human Rights Dimension

All EU Member States are also among the members of the Council of Europe⁶⁴ and as such state parties to the European Convention on Human Rights and Fundamental Freedoms and to the European Social Charter. They are also state parties to the UN human rights treaties: the International Convention on Civil and Political Rights and—from a food perspective most important—the International Covenant on Economic, Social and Cultural Rights [66]. The EU has its own Charter of Fundamental Rights.

Despite the emphasis the EU lays on respect for human rights by its Member States, in EU food law human rights consciousness is virtually absent.⁶⁵ Nowhere does the EU legislature express the opinion that in ensuring the safety of food, it is living up to human rights’ obligations.⁶⁶ Nor does it give account of the fact that its labelling legislation limits the freedom of expression and should thus conform to the applicable limitation clauses in the human rights treaties.⁶⁷

⁶³ With the notable exception of competition law (anti-trust law).

⁶⁴ This is an international organisation distinct from the EU. It should in particular not be confused with the Council which is an Institution of the European Union. On the Council of Europe, see: [65].

⁶⁵ In a ruling of 6 September 2012 (Case C-544/10 Weintor) [67] the European Court of Justice for the first time judged a provision of food law against the Charter of fundamental rights of the European Union. It upheld the ban on health claims on alcoholic beverages. On this ruling, see: “Through the Wine Gate: Case note on tentative first steps in ECJ 6 September 2012 C-544/10 towards Human Rights awareness in EU food (labelling) law” [68].

⁶⁶ For a discussion of a similar lack in human rights consciousness in one of the EU Member States, see: *Fed up with the right to food? The Netherlands’ policies and practices regarding the human right to adequate food* [69].

⁶⁷ Unlike US food law, where labelling legislation is scrutinised in the context of the First Amendment. See for example: “The First Amendment and Federal Court Deference to the Food and Drug Administration: The Times They Are A-Changin’” [70].

Annex 2

Instruments that may help the reader to gain further access to EU food law.

- All EU legislation and case law is available at: <http://eur-lex.europa.eu/en/index.htm>;
- Information on EU food law is available at: <http://ec.europa.eu/food/>;
- For an elaborated account on EU food law see: Bernd van der Meulen and Menno van der Velde, *European Food Law Handbook*, Wageningen Academic Publishers, 2008: <http://www.wageningenacademic.com/foodlaw> or Luigi Costato and Ferdinando Albisinni (eds.), *European Food Law*, Wolters Kluwer Italia, 2012;
- The law journal specialised in EU food law is the European Food & Feed Law Review (EFFL): <http://www.lexxion.eu/effl/>. Every year EFFL organises a scientific conference;
- Expertise on EU food law is available at the European Institute for Food Law: www.food-law.nl;
- The association dealing with European Food Law, is the European Food Law Association (EFLA) <http://www.efla-aeda.org/>. Every second year EFLA organises a scientific conference.

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